



# **ANSI Essential Requirements: Due process requirements for American National Standards**

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## **ANSI Essential Requirements: Due process requirements for American National Standards**

### **1.0 Essential requirements for due process**

These requirements apply to activities related to the development of consensus for approval, revision, reaffirmation, and withdrawal of American National Standards (ANS).

Due process means that any party (organization, company, government agency, individual, etc.) 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. Due process allows for equity and fair play. The following constitute the minimum acceptable due process requirements for the development of consensus.

#### **1.1 Openness**

Participation shall be open to all parties who are directly and materially interested in the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

#### **1.2 Lack of dominance**

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

#### **1.3 Balance**

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

#### **1.4 Coordination and harmonization**

Good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.

#### **1.5 Notification of standards development**

Timely and adequate notice of standards development activity shall be announced in media suitable to demonstrate that a meaningful opportunity for participation, debate and deliberation by all directly and materially interested parties in a fair and equitable manner was provided.

#### **1.6 Consideration of views and objections**

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *Standards Action*.

#### **1.7 Consensus vote**

Evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer shall be documented.

#### **1.8 Appeals**

Written procedures of an ANSI-Accredited Standards Developer (ASD) shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include whether a technical issue was afforded due process.

## **1.9 Written procedures**

Written procedures shall govern the methods used for standards development and shall be available to any directly and materially interested party.

## **1.10 Compliance with normative American National Standards policies and administrative procedures**

All ANSI-Accredited Standards Developers (ASDs) are required to comply with the normative policies and administrative procedures established by the ANSI Executive Standards Council.

## **2.0 Benchmarks**

This section contains information relative to the implementation of the *Essential Requirements* set forth in Section 1.0 of this document and articulates the normative policies and administrative procedures associated with the ANS process.

### **2.1 Openness**

Timely and adequate notice of any action to create, revise, reaffirm, or withdraw a standard, and the establishment of a new consensus body shall be provided to all known directly and materially interested parties. Notice should include a clear and meaningful description of the purpose of the proposed activity and shall identify a readily available source for further information. In addition, the member's name (or if membership is by organization, the name of the organization with a point of contact), affiliation and interest category of each member of the consensus body shall be made available to interested parties upon request. The affiliation of a consensus body member refers to the entity that the consensus body member represents, which may or may not be that person's employer. If the consensus body member is serving in an individual capacity, then the name of the individual, their sponsors<sup>1</sup> (if any) and interest category shall be made available upon request. Contact information is not required.

### **2.2 Lack of dominance**

Unless it is claimed in writing (including electronic communications) by a directly and materially interested party that a single interest category, individual or organization dominated the standards development process, no test for dominance is required.

### **2.3 Balance**

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

The interest categories appropriate to the development of consensus in any given standards activity are a function of the nature of the standards being developed. Interest categories shall be discretely defined, cover directly and materially interested parties and differentiate each category from the other categories. Such definitions shall be available upon request.

Consensus body members, including consultants<sup>2</sup>, typically are classified in accordance with the business or other interests of their employers or the sponsors they represent in connection with the standards development activity. In cases where a consensus body member receives funding from the sponsoring ANSI-Accredited Standards Developer (ASD) or other entities, that information shall be disclosed to determine if it will impact the member's interest classification.

In determining the interest categories appropriate to a standards development activity, an ASD shall give consideration to at least the following three categories:

- a) producer;

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<sup>1</sup> A sponsor is defined as an organization that provides funds specifically to support the individual's participation in the standards activities of the consensus body.

<sup>2</sup> For purposes of this section, a "consultant" is someone who agrees to provide professional service in exchange for compensation, financial or otherwise.

- b) user;
- c) general interest.

If, after consideration, a “General Interest” category is deemed appropriate, that interest category should include only those whose business or other interests are not covered by another discretely defined interest category.

Where appropriate, additional interest categories should be considered.<sup>3</sup> However, interest categories shall not be created for the purpose of avoiding balance requirements.

Appropriate, representative user views shall be actively sought and fully considered in standards activities. Whenever possible, user participants shall be those with the requisite technical knowledge, but other users may also participate. User participation should come from both individuals and representatives of organized groups. There are several user categories:

1. User-consumer: Where the standards activity in question deals with a consumer product, such as lawn mowers or aerosol sprays, an appropriate consumer participant’s view is considered to be synonymous with that of the individual user – a person using goods and services rather than producing or selling them.
2. User-industrial: Where the standards activity in question deals with an industrial product, such as steel or insulation used in transformers, an appropriate user participant is the industrial user of the product.
3. User-government: Where the standards activity in question is likely to result in a standard that may become the basis for government agency procurement, an appropriate user participant is the representative of that government agency.
4. User-labor: Where the standards activity in question deals with subjects of special interest to the American worker, such as products used in the workplace, an appropriate user participant is a representative of labor.

## 2.4 Coordination and harmonization

Good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.

### 2.4.1 Definition of Conflict

Conflict within the ANS process refers to a situation where, viewed from the perspective of a future implementer, the terms of one standard are inconsistent or incompatible with the terms of the other standard such that implementation of one standard under terms allowable under that standard would preclude proper implementation of the other standard in accordance with its terms.

### 2.4.2 Coordination/Harmonization

ANSI-Accredited Standards Developers shall make a good-faith effort to resolve potential conflicts and to coordinate standardization activities intended to result in harmonized American National Standards<sup>4</sup>. A “good faith” effort shall require substantial, thorough and comprehensive efforts to harmonize a candidate ANS and existing ANSs. Such efforts shall include, at minimum, compliance with all relevant sections of these procedures<sup>5</sup>. Developers shall retain evidence of such efforts in order to demonstrate compliance with this requirement to the satisfaction of the appropriate ANSI body.

## 2.5 Notification of standards development and coordination

Timely and adequate notice of standards development activity, including formation of a consensus body or consensus body meeting, shall be announced in media suitable to demonstrate that a meaningful opportunity for participation by all directly and materially interested parties in a fair and equitable manner was provided.

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<sup>3</sup> Further interest categories that may be used to categorize directly and materially interested parties consist of, but are not limited to, the following: a) Consumer; b) Directly affected public; c) Distributor and retailer; d) Industrial/commercial; e) Insurance; f) Labor; g) Manufacturer; h) Regulatory agency; i) Testing laboratory.

<sup>4</sup> Note that clause 4.2.1.3.4 *Withdrawal for Cause* provides a mechanism by which a directly and materially interested party who has been or will be adversely affected by the ANS may at any time request the withdrawal of an existing ANS.

<sup>5</sup> See, for example, clauses 2.1, 2.4. 2.5, 2.6 and 4.3.

Developers are encouraged to consult any relevant international or regional guides that may impact the proposed standard and shall advise the relevant ANSI-Accredited U.S. TAG(s) if the standard is intended to be submitted for consideration as an ISO, IEC or ISO/IEC JTC-1 standard.

### **2.5.1 Project Initiation Notification System (PINS)**

At the initiation of a project to develop or revise an American National Standard<sup>6</sup>, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*. Comments received in connection with a PINS announcement shall be handled in accordance with these procedures.

A statement shall be submitted and published as part of the PINS announcement that shall include:

- (a) an explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard; and
- (b) identification of the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard; and
- (c) the interest categories that will or are expected to comprise the consensus body.

If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published.

If a developer receives a written request for additional information or for the opportunity to discuss the proposal from a directly and materially interested outside party or current consensus body member, during the 30-day PINS comment period, the ASD shall respond in writing within 30 days of the comment deadline.

#### **2.5.1.1 PINS Exceptions**

A PINS is not required for revisions of an American National Standard that is maintained under continuous maintenance and (1) is registered as such on the ANSI website, (2) has a notice in the standard that the standard is always open for comment and how to submit comments, and (3) has information on the developer's website that the standard is under continuous maintenance and how to submit comments. A PINS is also not required in connection with the decision to maintain an ANS under the stabilized maintenance option. A PINS form may be submitted, but is not required, at the initiation of a project to reaffirm or withdraw an American National Standard.

#### **2.5.1.2 Assertions of conflict or duplication**

If a developer receives written comments within 30 days from the publication date of a PINS announcement in *Standards Action*, and said comments assert that a proposed standard duplicates or conflicts with an existing American National Standard (ANS) 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 90 days from the comment deadline. Such a deliberation shall be organized by the developer 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 90-day period and the developer 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.

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<sup>6</sup> Including the national adoption of ISO and IEC standards as American National Standards, but excluding actions set-forth in 2.5.1.1.

### 2.5.1.3 PINS Deliberation Report

The outcome of a PINS deliberation shall be conveyed in writing (the “Deliberation Report”) within 30 days after the conclusion of the deliberation by the developer to the commenter and to ANSI. Upon submission of the Deliberation Report, the developer may continue with the submission of the proposed standard for public review. If additional deliberations take place, they should not delay the submission of the proposed standard for public review, and an updated Deliberation Report shall be conveyed within 30 days after each deliberation. Any actions agreed upon from the deliberations shall be carried out in a reasonably timely manner, but normally should not exceed 90 days following the deliberation. Subsequently, the developer shall include all of the Deliberation Report(s) with the BSR-9 submittal to the ANSI Board of Standards Review (BSR) for consideration should the developer ultimately submit the subject standard to ANSI for approval. Stakeholders who were involved in the PINS deliberation process may also file separate Deliberation Report(s) with ANSI and the developer within 30 days after conclusion of any deliberation for consideration by the BSR, if the standard is submitted to ANSI for approval.

In the case of ANSI Audited Designators, the Audited Designator shall provide a Deliberation Report to the commenter and to ANSI within 30 days after each deliberation. The Audited Designator shall review the results of the deliberation prior to designating a standard as an ANS.

While the outcome is not binding, unless binding provisions are agreed to by the developer, participants are encouraged to develop a consensus on whether and how the standards development project should proceed. See also 4.3.

### 2.5.2 Public Review<sup>7</sup>

In addition, 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, or its equivalent, for listing in *Standards Action* in order to provide an opportunity for public comment. If it is the case, then a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard shall be included as part of the description of the scope summary that is published in *Standards Action*. The comment period shall be one of the following:

- A minimum of thirty days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of forty-five days if the document is available in an electronic format, deliverable within one day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided to ANSI for announcement in *Standards Action*; or
- A minimum of sixty days, if neither of the aforementioned options is applicable.

Such listing may be requested at any stage in the development of the proposal, at the option of the standards developer, and may be concurrent with final balloting. However, any substantive change subsequently made in a proposed American National Standard requires listing of the change in *Standards Action*.

## 2.6 Consideration of views and objections

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *Standards Action*.

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

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<sup>7</sup> Although a 60-day public comment period is not required in all instances, a number of provisions in the *ANSI Essential Requirements*, when read in combination, satisfy the WTO’s 60-day rule. Before adopting a standard, ANSI-Accredited Standards Developers shall allow a period of at least 60 days in total for submission of comments on the draft standard if requested by an interested party within the territory of a Member of the WTO. Exceptions outlined in the rule are permitted due to issues of safety, health or environment. (See *WTO Agreement on Technical Barriers to Trade (TBT)*, Annex 3 Code of Good Practice for the Preparation, Adoption and Application of Standards (CGP) Substantive Provision L.)



informed in writing that an appeals process exists within procedures used by the standards developer. In addition, except in the case of Audited Designators, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved (see definition) must be reported to the ANSI BSR.

When this process is completed in accordance with the written procedures of the standards developer, the standards developer may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be so notified.

Each unresolved objection and attempt at resolution, and any substantive change<sup>8</sup> made in a proposed American National Standard shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond, reaffirm, or change their vote.

## **2.7 Evidence of consensus and consensus body vote**

Evidence of consensus in accordance with these procedures and the accredited procedures of the standards developer shall be documented. Consensus is demonstrated, in part, by a vote of the consensus body. The developer's procedures shall state specifically how consensus will be determined.

An example of the criteria for consensus includes a requirement that a majority of the consensus body cast a vote (counting abstentions) and at least two-thirds of those voting approve (not counting abstentions). The developer may submit for approval an alternative methodology for determining consensus.

The consensus body vote shall be conducted and reported in accordance with the rules set forth herein. Votes for the approval of a document or portion thereof as a candidate ANS may be obtained by letter, fax, recorded votes at a meeting or electronic means. All members of the consensus body shall have the opportunity to vote. When recorded votes are taken at meetings, members who are absent shall be given the opportunity to vote before or after the meeting.

1. ANSI-Accredited Standards Developers (ASDs) shall not change a vote unless instructed to do so by the voter. If the change of vote was not submitted in writing by the voter, then written confirmation of such a vote change shall be provided to the voter by the developer. It is never appropriate for an ASD to inform voters that if they are not heard from, their negative vote will be considered withdrawn and their vote will be recorded as an abstention or an affirmative. All negative votes that are not changed at the request of the voter shall be recorded and reported to the BSR as unresolved negatives by any ASD that has not been granted the authority to designate its standards as American National Standards without approval by the BSR.
2. ASDs shall record and consider all negative votes accompanied by any comments that are related to the proposal under consideration. This includes negative votes accompanied by comments concerning potential conflict or duplication of the proposed standard with an existing American National Standard and negative votes accompanied by comments of a procedural or philosophical nature. These types of comments shall not be dismissed due to the fact that they do not necessarily provide alternative language or a specific remedy to the negative vote.
3. ASDs are not required to consider negative votes accompanied by comments not related to the proposal under consideration, or negative votes without comments. The ASD shall indicate conspicuously on the letter ballot that negative votes must be accompanied by comments related to the proposal and that votes unaccompanied by such comments will be recorded as "negative without comments" without further notice to the voter. If comments not related to the proposal are submitted with a negative vote, the comments shall be documented and considered in the same manner as submittal of a new proposal. If clear instruction is provided on the ballot, and a negative vote unaccompanied by comments related to the proposal is received notwithstanding, the vote may be counted as a "negative without comment" for the purposes of establishing a quorum and reporting to ANSI. However, such votes (i.e., negative vote without comment or

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<sup>8</sup> Any substantive change made in a proposed American National Standard shall also be listed for public comment in accordance with 2.5.2 Public Review.

negative vote accompanied by comments not related to the proposal) shall not be factored into the numerical requirements for consensus, unless the ASD's procedures state otherwise. The ASD is not required to solicit any comments from the negative voter. The ASD is not required to conduct a recirculation ballot of the negative vote. The ASD is required to report the "no" vote as a "negative without comment" when making their final submittal to the BSR unless the ASD has been granted the authority to designate its standards as American National Standards without approval by the BSR.

4. The ASD shall maintain records of evidence regarding any change of an original vote.
5. Except in regard to votes on membership and officer-related issues, each member of a consensus body should vote one of the following positions (or the equivalent):
  - a) Affirmative;
  - b) Affirmative, with comment;
  - c) Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection);
  - d) Abstain.
6. For votes on membership and officer-related issues, the affirmative/negative/abstain method of voting shall be followed. Votes with regard to these issues need not be accompanied by reasons and need not be resolved or circulated to the consensus body.

## **2.8 Appeals**

The provision for appeals is an important element of due process. This section gives general criteria regarding the right to appeal, to whom appeals are made and what may be appealed.

### **2.8.1 Right to Appeal: Appeals at the standards developer level**

The written procedures of an ANSI-Accredited Standards Developer (ASD) shall contain an identifiable, realistic, and readily available mechanism for the impartial handling of procedural appeals regarding any action or inaction. Appeals shall be addressed promptly and a decision made expeditiously and issued in writing. A standards developer may choose to offer an appeals process to address appeals on other than procedural issues. Procedural appeals include whether a technical issue was afforded due process. Appeals procedures shall provide for participation by all parties concerned without imposing an undue burden on them. Consideration of appeals shall be fair and unbiased and shall fully address the concerns expressed.

Parties who are directly and materially interested in and who have been or will be adversely affected by any procedural action or inaction by a standards developer with regard to the development of a proposed American National Standard or the revision, reaffirmation, or withdrawal of an existing American National Standard, have the right to appeal. The burden of proof to show adverse effect shall be on the appellant. Appeals of actions shall be made within reasonable time limits; appeals of inactions may be made at any time. Appeals shall be directed to the standards developer responsible for the action or inaction in accordance with the appeals procedures of the standards developer. If a fee for a procedural appeal is charged, then it shall be predetermined, fixed and reasonable. A procedure for requesting a fee waiver or fee reduction shall be available.

### **2.8.2 Right to Appeal: Appeals at ANSI**

Parties who are directly and materially interested in and who have been or will be adversely affected by any procedural action or inaction by ANSI or by any ANS-related process have the right to appeal. ANSI will not normally hear an appeal of an action or inaction by a standards developer relative to the development of an American National Standard until the appeals procedures provided by the standards developer have been completed. As required in section 2.8.1, appeals at the ASD shall be addressed promptly and a decision made expeditiously and issued in writing. However, conclusion of the appeals process at the standards developer level is not a precondition for filing an appeal of an organization's continuing accreditation status with the ANSI Executive Standards Council (ExSC).

Claims of procedural non-compliance raised during the course of an active standards development process are to be addressed in accordance with the standards developer's appeals process. The standards developer's appeals process shall conclude before final submittal of evidence of consensus is made to

ANSI in support of the approval of a standard as an American National Standard.

Except in the case of an Audited Designator, an appeal of the approval of a standard as an American National Standard is to be filed in accordance with the *Operating Procedures of the ANSI Board of Standards Review* (BSR). Complaints concerning ANSI Audited Designators, including the approval of a standard as an American National Standard, are governed by the *Operating Procedures of the ANSI Executive Standards Council* (ExSC).

Appeals of actions shall be made within the time limits specified in applicable procedures; appeals of inactions may be made at any time. Such appeals shall be directed to ANSI in accordance with the procedures of the appropriate ANSI Committee (e.g., Board of Standards Review, Executive Standards Council).

### **3.0 Normative American National Standards Policies**

Every ANSI-Accredited Standards Developer (ASD) shall comply with the normative policies contained in this section. The ASD may choose to: 1) include the text that follows, as appropriate, in its accredited procedures along with any additional information as required; or 2) submit to ANSI a written statement of full compliance with these policies in addition to policy statements that satisfy the requirements set-forth in this section.

#### **3.1 ANSI patent policy - Inclusion of Patents in American National Standards**

There is no objection in principle to drafting an American National Standard (ANS) in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

Participants in the ASD/ANSI standards development process are encouraged to bring patents with claims believed to be essential to the attention of the ANSI-Accredited Standards Developer (ASD).

If an ASD receives a notice that a proposed, revised or approved ANS may require the use of such a patent claim that is not already covered by an existing assurance, the procedures in this clause shall be followed.

##### **3.1.1 Statement from patent holder**

The ASD shall receive from the patent holder or a party authorized to make assurances on its behalf, in written or electronic form, either:

- a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
- b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:
  - i) under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
  - ii) without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

Such assurance shall indicate that the patent holder (or third party authorized to make assurances on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest.

The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

##### **3.1.2 Record of statement**

A record of the patent holder's statement shall be retained in the files of the ASD and shall be made publicly

available (at the ASD's election, either on the ASD's website or ANSI's Letter of Assurance (LOA) repository).

### **3.1.3 Notice**

When the ASD receives from a patent holder the assurance set forth in 3.1.1.b above, the standard shall include a note substantially as follows:

NOTE – The user's attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.

By publication of this standard, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. If a patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then details may be obtained from the standards developer.

### **3.1.4 Responsibility for identifying patents**

Neither the ASD nor ANSI is responsible for identifying patents for which a license may be required by an American National Standard or for conducting inquiries into the legal validity or scope of those patents that are brought to their attention.

## **3.2 Commercial terms and conditions**

Except as otherwise permitted by these *Essential Requirements*, ANS shall not include terms or conditions that are primarily contractual or commercial in nature, as opposed to technical, engineering or scientific in nature. Thus, for example, an ANS shall not include contractual requirements (3.2.1); endorse or require the use of proprietary products or services (3.2.2); or endorse or require the use of particular conformity-assessment bodies, testing facilities or training organizations (3.2.3).

### **3.2.1 Contractual Requirements**

Except as provided below, ANS shall not include contractual requirements such as those relating to particular products or services, guarantees, warranties, reworks, indemnities, buybacks, price-related terms and other conditions of sale or use.

### **3.2.2 Endorsements of Proprietary Products or Services**

ANS shall not endorse or require the purchase or use of proprietary products or service providers as a condition of implementing the standard. Proprietary in this context means products or services that are the property of an owner and cannot be obtained or recreated without the consent of the owner. For example, an ANS may not endorse or require the purchase or use of brand-name tools or components, licenses, manufacturer lists, service provider lists or copyrighted materials.<sup>9</sup>

However, for informational purposes, where known sources exist for products or services necessary to comply with the ANS, it is permissible, but not obligatory, to identify the sources (which may include a source's name and address) in a footnote, an appendix, or reference to a website. The referenced products or services shall be reasonably available from the referenced sources, the words "or the equivalent" shall be added to the reference, and the reference shall also expressly state that identification of products or services is not an endorsement of those products or services or their suppliers.

### **3.2.3 Conformity Assessment, Testing and Training**

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<sup>9</sup> The term "copyrighted materials" is not intended to include: (a) manufacturers' instruction/safety manuals; or (b) third-party standards, when such documents are incorporated by reference into the text of an ANS for non-commercial technical, or safety-related purposes, as long as such references do not otherwise violate other provisions of the Commercial Terms and Conditions Policy (e.g., they cannot also include warranties, guarantees and like commercial clauses).

In connection with ANS that relate to the determination of whether products or services conform to one or more standards, the process or criteria for determining conformity may be standardized as long as the description of the process or criteria is limited to technical, engineering or scientific concerns and does not include what would otherwise be contractual or commercial terms.

It is permissible for health, safety or environmental protection reasons to include a generic requirement for third-party, *i.e.*, independent, conformity assessment, testing or training. ANS shall not dictate the use or non-use of a particular conformity-assessment body, testing facility or training organization.

However, for informational purposes, where known sources exist for products or services necessary to determine compliance with the ANS, it is permissible, but not obligatory, to identify the sources (which may include a source's name and address) in a footnote, an appendix, or reference to a website. The referenced products or services shall be reasonably available from the referenced sources, the words "or the equivalent" shall be added to the reference, and the reference shall also expressly state that identification of sources is not an endorsement of those sources.

### **3.3 Antitrust Policy**

American National Standards shall be developed in accordance with applicable antitrust and competition laws and meetings amongst competitors to develop American National Standards are to be conducted in accordance with these laws.

### **3.4 Evidence of compliance**

ANSI-Accredited Standards Developers shall retain records to demonstrate compliance with all aspects of these and the developer's accredited procedures. Such records shall be available for audit as directed by the ANSI Executive Standards Council (ExSC).

#### **3.4.1 An ANSI-Accredited Standards Developer has three options relative to new, revised or reaffirmed American National Standards maintained under the periodic maintenance option (see 4.7.1):**

1. Records shall be retained for one complete standards cycle, or until the standard is revised.
2. Records shall be retained based on the formula established by the ANSI ExSC as set-forth in the *ANSI Auditing Policy and Procedures*.
3. A developer that does not choose option 1 or option 2 will be audited more frequently and shall retain all records for all standards approved<sup>10</sup> as ANS subsequent to the most recent ANSI audit until completion of the current audit.

#### **3.4.2 An ANSI-Accredited Standards Developer has three options relative to new, revised or reaffirmed American National Standards maintained under the continuous maintenance option (see 4.7.2):**

1. Records shall be retained for a minimum of five (5) years or until approval of the subsequent revision or reaffirmation of the complete standard.
2. Records shall be retained based on the formula established by the ANSI ExSC as set-forth in the *ANSI Auditing Policy and Procedures*.
3. A developer that does not choose option 1 or option 2 will be audited more frequently and shall retain all records for all standards approved as ANS subsequent to the most recent ANSI audit until completion of the current audit.

#### **3.4.3 An ANSI-Accredited Standards Developer has three options relative to American National Standards maintained under the stabilized maintenance option (see 4.7.3):**

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<sup>10</sup> Approved: the approval process and appeals processes at ANSI have concluded.

1. Records shall be retained until the standard is reaffirmed, revised, or subsequently reviewed in connection with the stabilized maintenance of the standard as an ANS.
2. Records shall be retained based on the formula established by the ANSI ExSC as set-forth in the *ANSI Auditing Policy and Procedures*.
3. A developer that does not choose option 1 or option 2 will be audited more frequently and shall retain all records for all standards approved as ANS subsequent to the most recent ANSI audit until completion of the current audit.

Records concerning withdrawals of all American National Standards shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule.

### **3.5 Metric policy**

Each ANSI-Accredited Standards Developer shall have on file at ANSI a metric policy. International System of Units (SI) are the preferred units of measurement in American National Standards.

### **3.6 Interpretations policy**

Each ANSI-Accredited Standards Developer shall have on file at ANSI an interpretations policy. Official interpretations of American National Standards shall be made only by the accredited standards developer responsible for maintenance of that standard. ANSI shall not issue, nor shall any party have the authority to issue, an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations addressed to ANSI shall be referred to the responsible standards developer.

## **4.0 Normative American National Standards Administrative Procedures**

This section articulates the administrative and processing requirements associated with the American National Standards process.

The official language of the American National Standards (ANS) process, including all decisions made by ANS Program Oversight Committees, is English. The only version of a standards developer's procedures that are accredited by the American National Standards Institute (ANSI), and the only version of a document approved by ANSI as an ANS<sup>11</sup>, is the English language version.

### **4.1 Accreditation of American National Standards Developers**

A standards developer whose procedures meet the requirements of due process and criteria for approval and withdrawal of American National Standards contained herein and is incorporated, registered or otherwise recognized as a legal entity, may apply to ANSI for accreditation. To be accredited by ANSI, the developer's procedures and practices for standards development shall meet the criteria for accreditation as set forth below. The ANSI Executive Standards Council (ExSC) is the accrediting body for developers of American National Standards. Accreditation is a pre-condition for submitting a standard for consideration for approval as an American National Standard.

#### **4.1.1 Criteria for accreditation**

Accreditation shall be based on compliance, as determined by the ANSI ExSC, with the following criteria:

- a) the applicant is incorporated, registered or otherwise recognized as a legal entity;
- b) the operating procedures used for the development of evidence of consensus for approval, revision, reaffirmation, or withdrawal of standards as American National Standards shall satisfy the essential

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<sup>11</sup> An ANS that is an identical national adoption of an ISO or IEC standard which has been translated officially by ISO or IEC may carry the ANS mark. A modified national adoption may not.

requirements contained herein;

- c) with respect to American National Standards or candidate American National Standards, including the national adoption of ISO or IEC standards as American National Standards, the applicant shall agree to:
- 1) provide continuity of administrative oversight and support of its standards activities;
  - 2) provide for designation, publication, and maintenance of the standard(s) produced;
  - 3) provide for an appeals mechanism;
  - 4) cooperate with ANSI in standards planning and coordination activities of mutual interest;
  - 5) advise ANSI of the initiation and scope of new standards activities and revisions of existing standards expected to result in candidate American National Standards;
  - 6) submit to ANSI for public comment the requisite information concerning activities related to new candidate American National Standards and the national adoption of ISO or IEC standards as American National Standards as well as the revision, reaffirmation, or withdrawal of American National Standards;
  - 7) consider applicable international standards;
  - 8) comply with the procedures contained herein with respect to the national adoption of ISO and IEC standards as American National Standards; and
  - 9) pay to ANSI all relevant fees.
- d) as appropriate to the extent to which the applicant is involved with standardization, the applicant shall consider participation in international standards activities through ANSI; and
- e) with respect to submitting proposed American National Standards to ANSI for Board of Standards Review (BSR) approval, the applicant shall agree to comply with the normative policies and administrative procedures contained herein.

#### **4.1.2 Application for Accreditation as a Developer of American National Standards**

Application to ANSI for accreditation shall be in writing and shall include copies of the pertinent standards developing procedures and other documentation demonstrating compliance with the criteria specified in these procedures. If more than one set of standards developing procedures is used by an applicant, each procedure requires separate review for accreditation. The applicant shall submit its scope for informational purposes only, a description of its present program of standards activities and a list of candidate American National Standards. Also included shall be a statement from the applicant that details their coordination efforts to date and confirms their agreement to attempt to coordinate their standards activities with other ANSI-Accredited Standards Developers and with ANSI.

A notice announcing the application for accreditation shall be published in *Standards Action* with a call for comment. Copies of the pertinent standards developing procedures shall be available from the applicant, upon request.

Following the comment period, the ExSC shall consider the information supplied by the applicant and any comments and responses received, including reports on coordination from the appropriate ExSC designee if any, standards advisors, and the BSR. If comments are submitted that challenge support for an applicant's accreditation, the applicant shall supply documented evidence of sufficient support for consideration by the commenter and the ExSC. The ExSC shall determine whether accreditation should be approved. The applicant must satisfy the requirements established in the *ANSI Essential Requirements* before accreditation can be granted. If, during the course of the accreditation process, the developer makes a change to their originally submitted scope or to their originally submitted operating procedures, an additional announcement shall be published in *Standards Action*. If, however, the developer makes changes to the originally submitted operating procedures at the specific direction of the ExSC or their designee in order to bring their procedures into compliance with the *ANSI Essential Requirements*, an informational announcement shall be placed in *Standards Action* without additional public review. Accreditation will not be granted to an applicant whose procedures do not satisfy the requirements set forth herein. In the event that accreditation is not granted, the ExSC shall advise the applicant of the reasons, and the applicant shall have the opportunity to reapply. Upon accreditation, the applicant shall be notified and a notice shall appear in *Standards Action*.

### 4.1.3 Maintenance of accreditation

In order to maintain accreditation by ANSI, an ASD shall continue to maintain procedures meeting the requirements of due process and criteria for approval and withdrawal of American National Standards contained herein and continue to maintain its status as an incorporated, registered or otherwise recognized legal entity.

The ANSI Audit Director, under the supervision of the ExSC, shall arrange for audits of accredited standards developers at selected intervals or, at the request of the ExSC, due to special circumstances (BSR request, appeals action, etc.) to confirm adherence to the criteria for accreditation and to confirm that the procedures and practices of the accredited standards developer continue to be consistent with those which formed the basis for accreditation. The ANSI Audit Director shall report the audit findings to the ExSC who in turn shall take appropriate action in accordance with the *ANSI Auditing Policy and Procedures*.

If an accredited standards developer does not maintain one or more approved American National Standards, then the developer shall submit their accredited procedures for review and approval by the ExSC on a five-year cycle as well as a justification as to why they have not submitted any standards to ANSI for approval and why their accreditation remains relevant. The ExSC may suspend or withdraw the accreditation if the justification is not provided or is otherwise unsatisfactory.

ANSI-Accredited Standards Developers granted authority to designate their standards as American National Standards without BSR approval shall submit to a regular audit in accordance with the *ANSI Auditing Policy and Procedures*. When ANSI issues revised or additional criteria for accreditation, the accredited standards developer shall comply with them within a reasonable time period designated by the ExSC in order to maintain accreditation.

Whenever any revision is made to a standards developer's procedures on record at ANSI, the ExSC shall be notified and provided with a detailed description of the changes. If the changes are considered by the ExSC to be non-substantive, the standards developer will be notified and, upon such notification, may begin to operate under the revised procedures. If the changes are considered by the ExSC to be substantive, notice of these changes shall appear in *Standards Action* with a call for comment. Copies of the revised procedures shall be made available by the applicant to any party, upon request. If a developer submits their procedures in an electronic format and authorizes ANSI to post them on *ANSI Online* for purposes of public review, then the associated call for comment period in ANSI's *Standards Action* shall be 30 days and shall be announced as such.

If the standards developer decides to implement revised procedures prior to the final approval of the ExSC, they may do so provided that a) records concerning the implementation are maintained and available for use by the ANSI Audit Program; b) the developer certifies that the changes are in compliance with the *ANSI Essential Requirements*; and c) the developer accepts responsibility for all actions taken with regard to a candidate American National Standard, including resubmittal, if the ExSC does not approve a particular procedural provision.

Following the comment period, the ExSC shall consider the comments received, the latest status reports, the latest audit of the accredited standards developer, and any available additional information to determine whether to continue the accreditation. Notice of continuance shall be sent to the accredited standards developer and shall appear in *Standards Action*.

When the ExSC requests an accredited standards developer to revise its approved procedures to bring them into compliance with the *ANSI Essential Requirements*, the ExSC shall decide on a case-by-case basis whether reaccreditation, including public review, is also required.

### 4.1.4 Withdrawal of accreditation

The ExSC may advise and request any accredited standards developer to take corrective action if the conditions upon which accreditation was granted are not maintained. If such action is not taken within the time period designated, the ExSC shall provide at least a thirty day notice to the standards developer stating that, unless specified conditions are corrected, its accreditation and the approval of all American National Standards under all affected accreditations shall be withdrawn. Unless the necessary corrective actions are taken within the specified period, the ExSC shall withdraw the accreditation and approval of all affected American National Standards sponsored by the developer. The standards developer shall be notified of withdrawal of the accreditation and a notice shall appear in *Standards Action*.



## 4.2 Approval of actions in connection with American National Standards

A standard developed by an ANSI-Accredited Standards Developer may be approved as an American National Standard by the ANSI Board of Standards Review (BSR) or by an ANSI Audited Designator. In either case, the essential due process and consensus criteria defined herein shall apply. In addition, approval assures the user that each American National Standard is generally acceptable to those that participated in the development of consensus for the standard.

Evidence of procedural compliance in support of the approval of a proposed new American National Standard or a proposed revision or reaffirmation of an American National Standard ~~to be approved by the BSR shall be submitted included in the BSR-9 submittal. The BSR-9 submittal shall be provided to the secretary of the BSR within one (1) year from the close of the comment period listed in *Standards Action* using the appropriate form provided by ANSI,~~ unless the standards developer notifies the secretary of the BSR in writing of good cause for a different schedule for submittal. Failure to make the submittal within two (2) years from the close of the comment period listed in *Standards Action* shall require consideration by the BSR, i.e., withdrawal, extension for cause, or another listing in *Standards Action*. ANSI-Accredited Standards Developers that have been granted the status of ANSI Audited Designator shall take action in connection with candidate American National Standards in a timeframe that is consistent with that specified for all other ANSI-Accredited Standards Developers.

### 4.2.1 Approval by the ANSI Board of Standards Review

Approval, withdrawal, revision or reaffirmation of an American National Standard is based on the evidence submitted that the requirements set forth herein have been met.

The ANSI Board of Standards Review (BSR) shall review ~~standards BSR-9 submittals~~ to ANSI with unresolved objections on record. This includes negative consensus body votes as well as public review comments. Standards submitted without objections and identical national adoptions processed in accordance with the expedited procedures contained in the *ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards* may be administratively approved by the BSR. The BSR does not have jurisdiction over the standards of ANSI Audited Designators unless an ANSI Audited Designator chooses to submit one or more standards to the BSR for approval.

#### 4.2.1.1 Criteria for approval of an American National Standard

With respect to any proposal to approve, revise or reaffirm an American National Standard (including the national adoption of an ISO or IEC standard as an American National Standard) for which one or more unresolved objections have been reported, the BSR shall evaluate whether:

- a) the standard was developed in accordance with the procedures upon which the developer was granted accreditation, with particular attention given to whether due process was followed, consensus was achieved, and an effort was made to resolve any objections to the standard;
- b) any appeal to the standards developer with respect to the standard was completed;
- c) notice of the development process for the standard was provided to ANSI in accordance with PINS or its equivalent;
- d) any identified conflict with another American National Standard was addressed in accordance with these procedures;
- e) other known national standards were examined with regard to harmonization and duplication of content and if duplication exists, there is a compelling need for the standard;
- f) ANSI's patent policy is met, if applicable;
- g) ANSI's policy on commercial terms and conditions is met, if applicable;
- h) the standards developer provided the following or evidence thereof:
  1. title and designation of the proposed American National Standard;

2. indication of the type of action requested (that is, approval of a new American National Standard or reaffirmation, revision, or withdrawal of an existing American National Standard);
3. a declaration that applicable procedures were followed;
4. a declaration that the proposed standard is within the scope of the previously registered standards activity;
5. a declaration that conflicts with another American National Standard have been addressed in accordance with these procedures;
6. a roster of the consensus body that indicates: the vote of each member including abstentions and unreturned ballots, if applicable; the interest category of each member; and a summary thereof;
7. a declaration that all appeal actions related to the approval of the proposed standard have been completed;
8. a declaration that the criteria contained in the ANSI patent policy have been met, if applicable; and
9. identification of all unresolved negative views and objections, with names of the objector(s), and a report of attempts toward resolution.

If the BSR determines, based on the weight of the evidence presented, that the above-stated criteria have been satisfied, the standard shall be approved as an American National Standard. The BSR shall deny approval, if, based on the weight of the evidence presented, the BSR determines that the American National Standard:

- a) is contrary to the public interest;
- b) contains unfair provisions;
- c) is unsuitable for national use;

or that the ASD has failed to make a good faith effort to resolve conflicts.

Standards approved as American National Standards shall be designated, published, and maintained in accordance with the procedures contained herein. A substantive change that has not been afforded due process in accordance with these procedures may not be made in an approved American National Standard.

The BSR shall not approve standards that duplicate existing American National Standards unless there is a compelling need.

Notice of the BSR's final action on all standards shall be published in *Standards Action*.

#### **4.2.1.2 Reaffirmation of an American National Standard**

The due process and consensus requirements defined herein apply to reaffirmations as they do to all approval actions related to American National Standards. The procedures used for reaffirmation of an American National Standard by an accredited standards developer shall be implemented according to the developer's ANSI accredited procedures. Reaffirmations shall provide an opportunity for public comment.

Reaffirmations shall be accomplished without any substantive change to the main text of the standard. All non-substantive changes in the main text of the standard shall be explained, or noted, in a foreword. An American National Standard undergoing an update of references to standards necessary to implement the American National Standard shall be processed as a revision unless the updated reference is only a reaffirmation of the referenced standard. Any substantive changes in such references require processing as a revision.

The ANS shall clearly indicate on its cover or title page that it is a reaffirmation.

#### **4.2.1.3 Criteria for withdrawal**

##### **4.2.1.3.1 Administrative withdrawal**

An American National Standard shall be withdrawn five years following approval, if the standard has not been revised or reaffirmed, unless an extension has been granted by the ExSC or its designee. An American National Standard that has not been reaffirmed or revised within the five-year period, and that has been recommended for withdrawal by the ExSC or its designee, shall be withdrawn at the close of a 30-day public review notice in *Standards*

*Action.* American National Standards that have not been revised or reaffirmed within ten years from the date of their approval as American National Standards shall be withdrawn and such action shall be announced in *Standards Action*.

#### **4.2.1.3.2 Withdrawal by ANSI-Accredited Standards Developer**

An American National Standard must be supported by an ANSI-Accredited Standards Developer. If an accredited standards developer wishes to withdraw its approval of one or more of its American National Standards, it may do so without a vote of the relevant consensus body. If an accredited standards developer does withdraw one or more of its American National Standards, then the standards developer shall notify ANSI immediately and the standard shall be withdrawn as an ANS and announced in *Standards Action*.

#### **4.2.1.3.3 Discontinuance of a standards project**

An accredited standards developer may decide to abandon the processing of a proposed new or revised American National Standard or portion thereof at its own discretion and without a vote of the relevant consensus body.

Accredited standards developers must notify ANSI immediately of such actions which will be announced in *Standards Action*.

#### **4.2.1.3.4 Withdrawal for Cause**

Requests for withdrawal of an ANS for cause shall be approved by the BSR only upon a sufficient showing that one or more of the following conditions applies:

- a) ANSI's patent policy was violated;
- b) ANSI's requirements for designation, publication, and maintenance were violated;
- c) an American National Standard is contrary to the public interest;
- d) an American National Standard contains unfair provisions;
- e) an American National Standard is unsuitable for national use;
- f) the ASD has failed to make a good faith effort to resolve conflicts; or
- g) if it is determined by the ANSI ExSC as a result of an audit or appeal that ANSI's due process provisions were not satisfied.

Except in the case of an ANSI Audited Designator, a request for withdrawal for cause of an American National Standard may be submitted to the BSR by any directly and materially interested party<sup>12</sup> who has been or will be adversely affected by the ANS, or by the ExSC. Except when requested by the ExSC, the burden of proof to show adverse effect shall be on the requestor. The request shall be in writing, filed in accordance with appeals filing specifications, directed to the Secretary of the BSR and accompanied by a filing fee. This fee may be waived or reduced upon sufficient evidence of hardship.

If the request is submitted by a directly and materially interested party who has been or will be adversely affected by the ANS:

- a) the secretary of the BSR shall refer the request for withdrawal to the standards developer for the developer to review and respond within 30 calendar days to the requester and the secretary of the BSR;
- b) if the standards developer concurs with the proposed withdrawal, public notice shall be given and the standard shall be withdrawn in accordance with the developer's procedures;
- c) if the standards developer does not concur with the proposed withdrawal, the standards developer shall inform the requester and the secretary of the BSR and include reasons;
- d) the requester shall advise the secretary of the BSR, and the developer, within 30 calendar days of their receipt of the developer's response, either that the requester wishes the withdrawal process to continue or not;
- e) if the requester requests continuance of the withdrawal process, the matter shall be referred to the BSR via letter ballot for decision on subsequent action.

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<sup>12</sup> "Party" includes an individual, company or organization (such as a consumer advocacy group, government body, professional society or trade association).

If the request is submitted by the ExSC, as a result of an Audit or an appeal:

- a) the secretary of the BSR shall provide the standards developer with an opportunity to withdraw the standard without review by the ANSI BSR;
- b) if the standards developer concurs with the proposed withdrawal, public notice shall be given and the standard shall be withdrawn in accordance with the developer's procedures;
- c) if the standards developer does not concur with the proposed withdrawal, the secretary of the BSR shall provide the standards developer with a reasonable timeframe within which the developer may supplement the original record upon which the standard was approved;
- d) the ExSC request and the original BSR-9 submittal together with any supplemental information provided by the developer shall be provided to the BSR via letter ballot for decision on subsequent action.

Extensions of time to submit documentation related to a withdrawal for cause shall be granted at the discretion of the chairperson of the BSR, or if the chairperson is unavailable, by the secretary of the BSR. Extensions shall be requested prior to the deadline date and shall include a justification therefore.

The BSR shall determine, based on the weight of the evidence presented, one of the following:

- a) that one or more of the above-stated criteria have been satisfied, and accordingly the approval of the standard as an American National Standard shall be withdrawn; or
- b) that further action is warranted to confirm that all procedural requirements have been satisfied prior to making a decision as to whether the standard shall be withdrawn or remain an American National Standard. In this case the BSR shall provide specific direction to the developer and shall also determine the status of the standard pending successful completion of such action; or
- c) that none of the above-stated criteria have been met, and approval of the standard as an American National Standard shall be maintained.

The decision of the BSR in this regard shall not be appealed to the BSR, but may be appealed to the ANSI Appeals Board pursuant to section 11, *Appeals Process*, of the *ANSI Appeals Board Operating Procedures*.

#### **4.2.1.4 Final notice**

Notice of final action on all standards shall be published in *Standards Action*.

#### **4.2.2 Approval of an American National Standard by an ANSI Audited Designator**

A standard may be approved as an American National Standard by the ANSI Board of Standards Review or by an ANSI Audited Designator. An Audited Designator is an ANSI-Accredited Standards Developer to whom the ANSI Executive Standards Council has granted the authority to designate their standards as American National Standards without such standards being reviewed and approved by the ANSI Board of Standards Review. Requirements associated with ANSI Audited Designator status and their approval of standards as American National Standards are contained in Section 5 herein.

#### **4.3 Planning, coordination and public notice**

ANSI's planning and coordinating activities depend on the cooperation and participation of standards developers and affected interests. Various methods are used to plan and coordinate voluntary standards activities. A considerable amount of planning and coordinating activity routinely takes place at the standards development level by the standards writing consensus bodies or their subgroups. Specific coordination requirements are set forth in other sections of this document.

Overall responsibility for ANSI's national and international planning and coordinating functions is assigned by the Board of Directors to the Executive Standards Council (ExSC). The ExSC delegates specific activities as opportunity and needs arise, appointing designees or standards advisors, as appropriate.

Coordination usually can be accomplished by standards developers through the implementation of one or more of the following:

- a) clear delineation of scope, purpose, and intended application of each standard;
- b) public notice of standardization activities;

- c) joint and cooperative activities of the individual organizations, including liaison representation;
- d) organization of an independent but representative body acceptable to the involved parties to coordinate standards needs and projects and to develop standards as required;
- e) liaison between national standards developers and the organization responsible for the U.S. position on corresponding international standards; and
- f) use of the ANSI PINS system, including the PINS Deliberation process.

To achieve a consistent set of American National Standards and to represent the United States in non-treaty international standards activities, it is important that ANSI continue to promote the harmonization of ongoing standards activity, minimize duplication, and avoid the promulgation of conflicting American National Standards.

#### 4.4 Designation of American National Standards

A standard that is approved as an American National Standard shall have its cover or title page marked with an approval logo<sup>13</sup> furnished by ANSI or the words “an American National Standard.” In addition, American National Standards shall be marked in such a way as to identify the version of the standard or shall be identified by a unique alphanumeric designation in accordance with the guidelines contained herein.

The ANSI approval logo and the words “an American National Standard” shall not be used to identify any standard that has not received approval as an ANS by the ANSI Board of Standards Review or been approved by an accredited standards developer who has been granted authority to designate its standards as American National Standards.

Portions of a published document that were not approved through the ANS consensus process shall not contain requirements necessary for conformance with the approved American National Standard (ANS) and shall be (1) clearly identified at the beginning and end of each such portion of the document, or (2) such information shall be overprinted on the cover page. These portions of the document shall be marked with the following, or similar, explanatory language:

“The information contained in this (portion of a document) is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI’s requirements for an ANS. As such, this (portion of a document) may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the standard.”

American National Standards shall be identified by a unique alphanumeric designation (e.g., ANSI/ASD 123-2021). Multiple designations should be avoided. If a standard has multiple designations, an attempt shall be made by those concerned to arrive at a single designation.

#### 4.5 Publication of American National Standards

American National Standards shall be published in English and made available as soon as possible, but no later than six months after approval as an American National Standard (ANS). ~~The standards developer shall publish the standard or shall grant the right of publication to ANSI.~~ The ANS mark and the words “an American National Standard” may appear on the English-language version of an ANS only and not on a translation of an ANS.

If an American National Standard is not published within six months following its approval, the standards developer may request an extension of this deadline from the BSR or its designee. Such a request shall be in writing, shall supply the reason for the delay, and shall indicate a firm final date for publication. At its discretion, the BSR or its designee may grant an additional period of time for publication. Audited Designators are not required to request an extension, but shall ensure an equivalent publication schedule and maintain documentation related to any publication delays.

The BSR or its designee ~~shall~~ may publish a notice in *Standards Action* of intent to withdraw approval if the standards developer a) fails to publish the standard ~~or fails to grant ANSI the right to publish~~ within six months after its approval as an American National Standard and does not request an extension of the deadline despite follow-up

<sup>13</sup> An “Approved American National Standard” mark is available from ANSI.

or b) fails to meet the extended deadline.

#### **4.6 National Adoption of ISO or IEC Standards as American National Standards**

ANSI-Accredited Standards Developers that wish to adopt an ISO or IEC standard as an American National Standard shall comply with the requirements set forth in the *ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards*.

#### **4.7 Maintenance of American National Standards**

American National Standards shall be kept current and relevant by means of timely revision, reaffirmation or action to stabilize. Obsolete standards shall be withdrawn. Except in the case of the national adoption of ISO and IEC standards as American National Standards, when the maintenance provisions contained in the *ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards* shall apply, standards developers are permitted three options – periodic maintenance, continuous maintenance or stabilized maintenance – as outlined below.

##### **4.7.1 Periodic maintenance of American National Standards**

Periodic maintenance is defined as the maintenance of a standard by review of the entire document and action to revise or reaffirm it on a schedule not to exceed five years from the date of its approval<sup>14</sup> as an American National Standard.

In the event that a PINS or BSR-8/108 has not been submitted for an American National Standard within five years after its approval, the standards developer may request an extension of time to reaffirm or revise the standard, or shall withdraw the standard. The request for an extension of time shall be submitted to ANSI within thirty days following five years after the approval date of the American National Standard. Requests for extensions shall provide the program and schedule of work that will lead to revision, reaffirmation, or withdrawal. The extension may be granted by the ExSC or its designee.

No extension of time beyond ten years from the date of approval shall be granted for action on a standard. Except in the case of a national adoption,<sup>15</sup> an ANS maintained under the periodic maintenance option shall not retain its status as a current American National Standard beyond ten years from the date of approval. Such approval automatically expires on the tenth anniversary date of approval as an American National Standard.

In the event that an American National Standard approved by a standards developer who has been granted authority to designate its standards as American National Standards is not reaffirmed, revised, or withdrawn within five years after its approval, the standards developer shall follow its own procedures to ensure that work is proceeding and shall retain confirming documentation. Except in the case of a national adoption,<sup>16</sup> an ANS maintained under the periodic maintenance option shall not retain its status as a current American National Standard beyond ten years from the date of approval. Such approval automatically expires on the tenth anniversary date of approval as an American National Standard.

##### **4.7.2 Continuous maintenance of American National Standards**

Continuous maintenance is defined as the maintenance of a standard by consideration of recommended changes to any part of it according to a documented schedule for consideration and action by the consensus body. The standard shall be maintained by an accredited standards developer. A documented program for periodic publication of revisions shall be established by the standards developer. Processing of these revisions shall be in accordance with these procedures. The published standard shall include a clear statement of the intent to consider requests for change and information on the submittal of such requests. Procedures shall be established for timely, documented consensus action on each request for change and no portion of the standard shall be excluded from the revision process. In the event that no revisions are approved for a period of ten years, and the ANS has not been reaffirmed, the ANS approval automatically expires on the tenth anniversary date of its approval as an ANS.

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<sup>14</sup> “Approval” as an ANS refers to an action to approve a new document or reaffirm or revise an existing ANS.

<sup>15</sup> See *ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards*.

<sup>16</sup> Ibid.

### 4.7.3 Stabilized maintenance of American National Standards

A standard that is maintained under the stabilized maintenance option shall satisfy the following eligibility criteria:

- a) the standard addresses mature technology or practices, and as a result, is not likely to require revision; and
- b) the standard is other than safety or health related; and
- c) the standard currently holds the status of American National Standard and has been reaffirmed at least once; and
- d) at least ten years have passed since the approval or last revision of the standard as an ANS; and
- e) the standard is required for use in connection with existing implementations or for reference purposes.

The due process and consensus requirements defined herein apply to the decision to maintain an ANS under the stabilized maintenance option. A developer who wishes to maintain one or more ANS under the stabilized maintenance option shall include a provision or notification to this effect in its accredited procedures

An ANS maintained under the stabilized maintenance option is not required to be revised or reaffirmed on a routine 5-year cycle; however, it shall be subject to review of such status by the sponsoring standards developer on a 10-year cycle. If it is determined in connection with this review that the standard shall continue to be maintained under the stabilized maintenance option and as such does not require revision or withdrawal, then this shall be communicated to ANSI by the standards developer and a related announcement shall be made in *Standards Action*. Notification to ANSI shall be accomplished via the submittal of an informational announcement if the standard will continue to be maintained under the stabilized maintenance option or will be withdrawn, or via a PINS, if the standard will be revised.

If a recommendation is made at any time by a directly and materially interested party that a standard maintained under the stabilized maintenance option requires revision or should be withdrawn, then that recommendation shall be considered in the same manner as a new proposal but within a maximum of 60 days from receipt. A recommendation should include rationale to begin a revision, and shall not be dismissed due to the fact that it does not necessarily suggest a specific revision. The submitter of such a recommendation shall be responded to in writing by the standards developer within 60 days of the receipt of the recommendation and advised of the decision relative to the maintenance status of the standard.

An ANS that is maintained under the stabilized maintenance option shall include a clear statement of the intent to consider requests for change and information on the submittal of such requests.

The decision to maintain an ANS under the stabilized maintenance option and the process by which it is maintained shall be subject to appeal to the standards developer. A subsequent appeal to ANSI may be made to the ANSI Executive Standards Council based on a claim of procedural non-compliance.

## 5.0 Normative policies and procedures for ANSI Audited Designators

An ANSI Audited Designator is an ANSI-Accredited Standards Developer (ASD) who has demonstrated an extraordinary record of successful voluntary American National Standards (ANS) development and to whom the ANSI Executive Standards Council (ExSC) has granted the authority to designate its standards as American National Standards (ANS), without review and approval by the ANSI Board of Standards Review (BSR). This section articulates the administrative and processing requirements associated with Audited Designators.

### 5.1 Application for ANSI Audited Designator Status

An ASD who in good faith believes it could meet the extraordinary requirements for Audited Designator status may apply to ANSI to be considered an Audited Designator in accordance with this section. The applicant shall complete an application form developed by ANSI for this purpose and the ExSC shall make an initial determination whether the form makes a sufficiently strong showing that the Audited Designator criteria could be met. If so, the ExSC shall direct staff to issue a notice announcing the application in *Standards Action* with a call for comment. Simultaneously, an initial audit of the applicant shall be scheduled, in accordance with the *ANSI Auditing Policy and Procedures* unless a complete regular audit was conducted within the last year (twelve months) in which case the ExSC may allow that audit to be considered in connection with the application process.

The ExSC shall consider the entire application using the factors set forth in Section 5.2. This review includes the

completed application form, any comments received in response to the public notice of the application, any responses to those comments provided by the applicant, a copy of the most recent audit report as well as any prior audits undertaken since the applicant was first accredited by ANSI (and all audit responses), and any other information the ExSC believes is relevant to its consideration of the application. The ExSC may request additional information it believes is relevant to the application or to the criteria used to evaluate it and may ask the applicant additional questions or for responses to the ExSC's questions. Based upon this record, the ANSI ExSC will issue its decision to the applicant. Any decision to deny the application may thereafter be appealed by the applicant to the ANSI Appeals Board. When an application has been finally approved by ANSI, a notice so indicating shall be made in *Standards Action*.

## **5.2 Criteria Used to Assess Applications for ANSI Audited Designator Status**

In determining whether an ASD has demonstrated an extraordinary record of successful American National Standards development, the ExSC, shall consider, among other things, whether the applicant:

1. has held the status of ASD continuously for more than ten (10) years.
2. sponsors at least 100 ANS at the time of application.
3. has a record of a minimum of two (2) satisfactory audits with no requirement issued by the ExSC to undergo a special audit.
4. has not had its accreditation suspended or withdrawn within the last 10 years.
5. has not had ANS status withdrawn for cause from any of its documents within the last 10 years.
6. has demonstrated that it has submitted all annual Compliance Forms by the established deadline, within the last 10 years.
7. can demonstrate an appropriate handling of procedural appeals.
8. has demonstrated a history of giving prompt consideration to the written views and objections of all participants in ANS development processes.
9. has demonstrated that it has accurately communicated its status as an ASD to the public with respect to its standards development work and accreditation status, and has complied with *ANSI's Guidelines on the use of ANSI marks*.
10. has faithfully and consistently adhered to all of the policies, rules, procedures and requirements applicable to ASDs and the development of ANS.
11. notwithstanding the above, has demonstrated its commitment to act in good faith and in the best interest of ANSI in connection with American National Standards development, and that the designation of Audited Designator is appropriate.

Upon a final decision to grant an ASD's application for Audited Designator status, the developer shall enter into a written agreement with ANSI (Agreement), which shall include commitments by the ASD to meet the requirements listed below. The agreement shall be for a term of no longer than two (2) years. Any additional terms included in the agreement may be modified as circumstances require with the prior approval of ANSI's President and the ASD (as long as such additional term(s) do not conflict with any of ANSI's procedures and policies).

## **5.3 Maintenance of Audited Designator Status**

The Audited Designator shall:

- a) retain membership in ANSI and pay dues to ANSI in accordance with the policies established by ANSI's Board of Directors;
- b) conduct its activities at all times in conformity with the criteria upon which it was accredited;
- c) submit to audits of its operations by ANSI to demonstrate compliance with terms of the delegation and pay the fees associated therewith (see the *ANSI Auditing Policy and Procedures* for further details on the audit requirements);
- d) provide information required by ANSI in connection with PINS or its equivalent, in a timely manner;



- e) provide information required by ANSI in connection with initiating the ANSI public comment period, in a timely manner;
- f) promptly notify ANSI each time that a standard is designated as an American National Standard without BSR review;
- g) not designate as an American National Standard any standard if it:
  - 1) is contrary to the public interest;
  - 2) contains unfair provisions;
  - 3) is unsuitable for national use; or
  - 4) ANSI's requirements for designation, publication, and maintenance were violated;
- h) make a good faith effort to resolve conflicts;
- i) promptly notify ANSI of any suit or claim made against the developer arising from a standard designated as an American National Standard without BSR review, and provide periodic updates sufficient to apprise ANSI of the status of any such suit or claim;
- j) indemnify ANSI in connection with any suit or claim that may be made against ANSI arising from a standard designated as an American National Standard without BSR review,<sup>17</sup> which indemnity must include a commitment to advance all reasonable attorneys' fees and expenses incurred in connection with investigating or defending any such suit or claim;<sup>18</sup>
- k) consider an American National Standard designation for all of its standards;
- l) immediately cease to apply the ANS designation to any standard approved after the developer has been notified by ANSI that its accreditation has been suspended and/or withdrawn;
- m) comply with ANSI's patent policy, including the following:
  - Any patent holder's statements or letters of assurances (LoAs) received will comply with ANSI's (and the ASD's) Patent Policy (See 3.1) and will be made publicly available either on the ASD's website or on ANSI's LOA repository.
  - Any negative LoAs (i.e., those indicating the patent holder is unwilling to license essential patent claims) received will be provided directly to the Secretary of the ExSC within 30 days of receipt.
- n) comply with the *Commercial Terms and Conditions* provision contained in the *ANSI Essential Requirements*. (See 3.2).

In addition, the Agreement shall provide for termination by ANSI upon any material breach of its terms by the developer, following notice and an opportunity to cure any such breach. The developer shall have the right to appeal any such decision pursuant to ANSI's appeals procedures.

#### **5.4 Requirements for Reporting ANS Approval (BSR 109)<sup>19</sup>**

With respect to submitting American National Standards to ANSI without BSR approval, the qualified applicant shall agree to provide to ANSI the following information using the BSR-109 form or equivalent:

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<sup>17</sup> The sufficiency of the indemnity will be evaluated on a case-by-case basis in light of the assets of the applicant. ANSI reserves the right to deny approval to any applicant should ANSI determine an offer of indemnity to be insufficient.

<sup>18</sup> It is understood that, absent a conflict of interest, the developer may designate its own attorneys as the attorneys for ANSI as well.

<sup>19</sup> An ASD who received an Audited Designator status prior to the adoption of the 2024 amended procedures contained in this section shall be exempted from the strict application of the criteria set forth in section 5.2. When such an ASD applies for renewal of its Audited Designator status, however, ANSI shall consider whether during the preceding period the ASD has fulfilled the "maintenance" obligations as set forth in section 5.3.

- a) title and designation of the American National Standard;
- b) indication of the type of action (that is, approval of a new American National Standard or reaffirmation, revision, or withdrawal of an existing American National Standard);
- c) declaration that applicable procedures were followed;
- d) a declaration that the standard is within the scope of the previously registered standards activity;
- e) a declaration that other national standards have been examined with regard to harmonization and duplication of content, and if duplication exists, there is compelling need for the standard;
- f) a declaration that the Audited Designator has made a good faith effort to resolve conflicts;
- g) a declaration that all appeal actions related to the approval of the proposed standard have been completed;
- h) a declaration that the criteria contained in the ANSI patent policy (and the ASD's patent policy) have been met, if applicable;
- i) a declaration that the criteria contained in the ANSI commercial terms and conditions policy have been met, if applicable;
- j) approval date of the American National Standard.

## **5.5 Complaints**

Any complaint, (whether expressed as a complaint, appeal, or request for withdrawal of the ANS designation) concerning any actions or inactions, including approval or disapproval of an American National Standard, by an Audited Designator shall be governed by the provisions of the *Operating Procedures of the ANSI Executive Standards Council*.

## Annex A: Definitions

- ANSI Accreditation: The approval by the ANSI Executive Standards Council (ExSC) of the written procedures submitted by a standards developer relative to the development and documentation of evidence of consensus in connection with standards that are expected to be approved as American National Standards. Accreditation by ANSI signifies that the procedures submitted by the standards developer satisfy the essential requirements contained herein.
- ANSI Audited Designator: An Audited Designator is an ANSI-Accredited Standards Developer to whom the ANSI Executive Standards Council has granted the authority to designate their standards as American National Standards without such standards being reviewed and approved by the ANSI Board of Standards Review but such developer is subjected to additional audits.
- Continuous maintenance: Continuous maintenance is defined as the maintenance of a standard by consideration of recommended changes to any part of it according to a documented schedule for consideration and action by the consensus body.
- Consensus: Consensus means substantial agreement has been reached by directly and materially interested parties. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution.
- Consensus body: The group that approves the content of a standard and whose vote demonstrates evidence of consensus.
- Periodic maintenance: Periodic maintenance is defined as the maintenance of a standard by review of the entire document and action to revise or reaffirm it on a schedule not to exceed five years from the date of its approval as an American National Standard.
- Proxy: A written and signed document by which a voting member of a consensus body authorizes another party to vote in the member's stead, if allowed by the developer's procedures.
- Resolved: A negative vote cast by a member of the consensus body or a comment submitted as a result of public review where the negative voter agrees to change his/her vote or the negative commenter accepts the proposed resolution of his/her comment.
- Stabilized Maintenance: A standard that is maintained under the stabilized maintenance option shall satisfy the following eligibility criteria:
  - a) the standard addresses mature technology or practices, and as a result, is not likely to require revision; and
  - b) the standard is other than safety or health related; and
  - c) the standard currently holds the status of American National Standard and has been reaffirmed at least once; and
  - d) at least ten years have passed since the approval or last revision of the standard as an ANS; and
  - e) the standard is required for use in connection with existing implementations or for reference purposes.
- Substantive Change: A substantive change in a proposed American National Standard is one that directly and materially affects the use of the standard. Examples of substantive changes are below:
  - "shall" to "should" or "should" to "shall";
  - addition, deletion or revision of requirements, regardless of the number of changes;
  - addition of mandatory compliance with referenced standards.
- Unresolved: Either (a) a negative vote submitted by a consensus body member or (b) written comments, submitted by a party during public review expressing disagreement with some or all of the proposed standard, that have not been satisfied and/or withdrawn after having been addressed according to the developer's approved procedures.

## **Annex B: Procedures for the Development of a Provisional American National Standard (ANS) or a Provisional Amendment to an ANS**

### **B.1 Procedures for the Development of a Provisional American National Standard (ANS) or a Provisional Amendment to an ANS**

When an alternative process is not otherwise reflected in an ANSI-Accredited Standards Developer's (ASD's) accredited procedures, these procedures set forth the requirements for the issuance of a Provisional ANS or a Provisional Amendment to an existing ANS and may be used when all of the following circumstances apply:

- When implementation of the Provisional ANS or Provisional Amendment may result in an improvement to the safeguarding of life, and there is a well-established need for the prompt dissemination of information that addresses an emergency situation or other special circumstance;
- When the use of the accredited procedures of the ASD would cause an undue delay in the issuance of a related standard; and
- When an ASD supports the development of a Provisional ANS or a Provisional Amendment with the intention of initiating the processing as an ANS, of the Provisional ANS or the Provisional Amendment to an ANS, within 45 days of its approval date. Processing of the ANS shall be in accordance with the ASD's accredited procedures, including ANSI public review in *Standards Action* and consensus body ballot.

#### **B.1.1 Public notice**

An announcement identifying the standard and describing the circumstances that warrant the issuance of a Provisional ANS or Provisional Amendment shall be provided to ANSI in a timely manner for publication in ANSI's *Standards Action* along with relevant developer contact information. The requirements in clause 2.5 *Notification of standards development and coordination* shall not apply with regard to a Provisional ANS or Provisional Amendment that is promulgated in accordance with these procedures.

#### **B.1.2 Minimum consensus body ballot period**

A developer using these procedures may utilize the minimum ballot period established by their accredited procedures for an ANS or the consensus body may establish a ballot period that is not less than two weeks.

#### **B.1.3 Approval of a Provisional ANS or a Provisional Amendment to an ANS**

Approval of a Provisional ANS or a Provisional Amendment to an ANS requires approval by the consensus body of at least two-thirds of those voting, excluding abstentions.

#### **B.1.4 Comment resolution**

All comments accompanying the ballot shall be circulated to the consensus body in order to afford all members an opportunity to respond, reaffirm, or change their vote. For recirculation of comments, a minimum period of not less than one week is required. An attempt to resolve the comments received relative to the Provisional ANS or Provisional Amendment is not required.

#### **B.1.5 Right to appeal**

The right to appeal shall not be required in connection with the issuance of a Provisional ANS or Provisional Amendment. After the standard or revision has been issued, if a directly and materially interested party who has been or will be adversely affected believes that the Provisional ANS or Provisional Amendment should be withdrawn, then the *Withdrawal for cause* procedures detailed in the *ANSI Essential Requirements: Due process requirements for American National Standards* shall apply.

#### **B.1.6 Approval notification to ANSI**

Notice of the approval of a Provisional ANS or Provisional Amendment by an ASD shall be submitted to ANSI within 5 days of the approval of the document. The notice shall include the designation and title of the new or affected document, the approval date and a certification that the developer has followed these procedures. An informational announcement shall be published in *Standards Action*.

#### **B.1.7 Processing the Provisional ANS as an American National Standard**

The ASD shall initiate the processing, as an ANS, of the Provisional ANS, or the Provisional Amendment to the ANS, within 45 days of its approval date. This processing shall be in accordance with the ASD's accredited procedures and shall include publication of a PINS, either before or after publication of the initial announcement in *Standards Action* that identified the Provisional ANS or Provisional Amendment to the ANS and described the circumstances that warranted its issuance per B.1.1 and before ANSI public review of the draft proposed ANS or

amendment in *Standards Action* and consensus body ballot. Following the publication of the PINS, all of the other requirements of 2.5 *Notification of standards and coordination* associated with a PINS apply.

#### **B.1.8 Withdrawal**

A Provisional ANS or Provisional Amendment shall exist for no longer than two years from the date on which it is approved by the ASD. If consensus is achieved and the affected standard (either the Provisional ANS or the ANS as modified by the Provisional Amendment) is published as an ANS, the Provisional ANS or Provisional Amendment is superseded and shall be withdrawn. If consensus is not achieved, the Provisional ANS or Provisional Amendment shall be withdrawn at that time, but no later than two years from the date on which it was approved. A notice of the withdrawal shall be published in ANSI's *Standards Action*.

#### **B.1.9 Identification of a Provisional ANS or Provisional Amendment**

A standard or an amendment to a standard promulgated in accordance with these procedures shall be referred to as a Provisional American National Standard or Provisional Amendment, respectively, and identified clearly as such on the cover or title page. In addition, a standard processed as a Provisional American National Standard, shall be identified by a unique alphanumeric designation in accordance with the following guidelines:

ANSI/ABCD 123 (PS), where ABCD reflects the developer's acronym.

And an American National Standard with a provisional amendment shall be identified as follows:

ANSI/ABCD 123 (PA)

The following or similar text shall be included in the foreword of a Provisional Standard or adjacent to a Provisional Amendment when included in the text of an ANS:

"This document or some of the information contained in this document has been processed in accordance with ANSI's requirements for a Provisional American National Standard or Provisional Amendment to an ANS. The same or similar document or amendment (as applicable) will undergo the standards development process set forth in the ASD's accredited procedures. This Provisional ANS or pertinent Provisional Amendment(s) shall be withdrawn on or before the two year anniversary date of its approval as such."

The ANSI approval logo and the words "an American National Standard" shall not be used to identify an entire standard that has not received ANSI approval or been approved by an accredited standards developer who has been granted authority to designate its standards as American National Standards.

#### **B.1.10 Audit of Use of Provisional ANSI Process**

Evidence of compliance with these procedures shall be retained. This documentation shall be examined during the next scheduled audit of the developer.