ANSI Essential Requirements: Due process re quirements 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 person (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 persons who are directly and materially affected by 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

Notification of standards activity shall be announced in suitable media as appropriate to demonstrate an opportunity for participation by all directly and materially affected persons.

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 interested person.

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 or its designee.

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 affected interests. 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), affiliation¹ and interest category of each member of the consensus body shall be made available to interested parties upon request.

2.2 Lack of dominance

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

2.3 Balance

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 all materially affected parties and differentiate each category from the other categories. Such definitions shall be available upon request. In defining the interest categories appropriate to a standards activity, consideration shall be given to at least the following:

- a) producer;
- b) user;
- c) general interest.

Where appropriate, additional interest categories should be considered.²

¹ "Affiliation" 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, that person's employer, sponsor and interest category should be available. Contact information is not required.

² Further interest categories that may be used to categorize directly and materially affected persons 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) Professional society; I) Regulatory agency; j) Testing laboratory; k) Trade association.

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 Standards³. 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 procedures⁴. 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

Notification of standards activity shall be announced in suitable media as appropriate to demonstrate the opportunity for participation by all directly and materially affected persons. At the initiation of a project to develop or revise an American National Standard⁵, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*. 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 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.

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

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³ Note that clause 4.2.1.3.4

for consideration as an ISO or ISO/IEC JTC-1 standard. If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published. A PINS form may be submitted, but is not required, at the initiation of a project to reaffirm or withdraw an American National Standard. Comments received in connection with a PINS announcement shall be handled in accordance with these procedures.

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.

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 standar

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 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.

3.5 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 person 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.

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 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:

- 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 requirements contained herein;
- b) 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;
 - provide for designation, publication, and maintenance of the standard(s) produced;
 - 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;
 - 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.
- c) 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
- d) 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.

4.2.1.1 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 Na

- 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, an application for withdrawal of an American National Standard may be submitted to the BSR by any materially interested party or the ExSC. An application submitted by any materially interested party shall be accompanied by a filing fee. This fee may be waived or reduced upon sufficient evidence of hardship.

If the request is submitted by a materially interested party:

- 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;
- 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 requestor 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.

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;
- 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
- 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
- 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

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 logo⁷ 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 require

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 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. In no case shall a standard maintained under the periodic maintenance option 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 notify the Institute and provide the estimated time of completion. In no case shall a standard maintained under the periodic maintenance option 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.

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- 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 have been met, if applicable;
- i) 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 affected interests. 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 person 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 person 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 Provis ional 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

B.1.8 WithdrawalA Provisional ANS or Provisional Amendment shall exist for no longer than two years from the date on which it is