



Procedures for the Development of American National Standards within the VITA Standards Organization (VSO)

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1 General

Standards projects start within the VSO as described in the VSO's Policies and Procedures. Once a project has successfully completed the VSO process the working group responsible for the project may decide to work for ANSI recognition. The method used to achieve ANSI recognition is described in this document. These procedures are derived from and are compliant with ANSI's Essential Requirements document.

1.1 Use of Electronic Media

Electronic means for publication and transmission of information shall be used wherever possible to reduce costs, improve efficiency, and reduce the time to achieve standardization. However, anyone who is part of the ballot process or desires to be part of the ballot process and does not have access to electronic means may request notifications, ballots, proposed standards, and other communications in paper format.

Any reference to documents or communications in these procedures should be understood to include the use of electronic means unless stated otherwise.

2 Coordination of Standards Efforts with Other Groups

Good faith efforts shall be made by the responsible working group to resolve potential conflicts between and among existing American National Standards and the proposed American National Standard.

2.1 PINS – Project Initiation Notification System

The working group shall follow the requirements stated in section 2.5.1 of ANSI's Essential Requirements regarding the submission and handling of PINs.

2.2 Public Review

The working group shall follow the requirements stated in ANSI Essential Requirements section 2.5.2 regarding the conduct of Public Review in the development of a proposed standard.

3 Development of the Balloters List

The standards development committee (the working group) shall develop a list of potential balloters consisting of those organizations, companies, government agencies, standards developers, individuals, etc., known to be, or who have indicated that they are, directly and materially affected by the standard. The ballot list shall be constructed to meet the requirements described in ANSI's Essential Requirements (sections 1.2, 1.3, 2.2 and 2.3) regarding balance and lack of dominance. No individual shall represent more than one balloter.

In order to determine if potential balloters are interested in participating, the standards development committee shall conduct a pre-ballot interest survey, in which the standards development committee informs the potential balloters in writing about the use of the ballot method for developing evidence of consensus, and, if the potential balloters are interested in participating, obtains an appropriate interest category classification. The standards development committee's communications shall contain the title, designation, scope, description of the standard along with the history of its development, purpose and intended application of the standard, and an explanation of the ANSI function. The time for response shall be at least 14 days from the date of the standards development committee's communication and shall be so noted in the communication.

3.1 Interest Categories

Potential balloters will be asked to specify one of the following interest categories when registering for a ballot.

- Producer – produces the end result of the standard or supplies components used in the standard.
- User – uses the end result of the standard.
- Government/Military – user or producer of the standard in government or military setting.
- Research – user or producer of the standard in a research setting.
- General Interest – neither a user nor producer.

The affiliation¹ and interest category of each member of the balloting body shall be made available to interested parties upon request.

Once an interest survey has been completed for a standard, it need not be repeated for subsequent balloting of the document. In addition, the standards development committee may conduct a single interest survey for a group or category of standards. A balloter who has indicated a desire to be on the standards development committee's list for a particular category or categories of standards shall receive the proposed standard(s), electronic ballot(s), and all appropriate information.

4 Conduct of the Ballot

The standards development committee shall transmit, at minimum, the following information to all balloters and other interested parties so requesting unless the developer has previously supplied this information:

- a) the purpose and intended application of the standard;
- b) a brief history and explanation of how the standard was developed;
- c) an explanation of ANSI's function in the voluntary consensus standards system;
- d) a copy of the ballot list, consisting of the name, affiliation, and category of interest of each balloter;
- e) a copy of the complete proposed American National Standard or the relevant portion under consideration when the balloter has previously received the complete standard;
- f) official ballot(s) to all balloters.

Upon request, the standards development committee shall provide to the balloter a reasonable number of copies of the document being considered, to allow for a speedy determination of position by the balloter. Should the document contain material that is not to be considered for approval as an American National Standard, such as an introduction or annex, a clear statement shall be included indicating those portions of the standard that are to be considered for approval by ANSI.

The ballot form used by the standards development committee shall provide opportunity for the balloter to indicate its position (i.e., affirmative (with or without comment), negative (with reasons), abstention (with or without comment), with the advice that, in order to receive consideration, objections must be accompanied by supporting written reasons and, where possible, proposals for a solution to the problem raised. At least one follow-up shall be sent to balloters not responding.

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 and interest category should be available. Contact information is not required.

The ballot may be closed at the end of 30 days, or sooner if all balloters have responded. An extension of up to 10 days shall be granted upon request from any balloter giving a legitimate reason.

Those not on the ballot list who have a direct and material interest in the standard have an opportunity to participate in the review of the standard during the public review process, announced in *Standards Action*.

Approval of a new standard, revision or reaffirmation of an existing standard, or an addendum to part or all of an existing standard shall require a majority of the ballot list and a 2/3rds majority of the votes cast. Abstentions are not counted.

5 Disposition of Comments from Ballot and Public Review

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 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 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 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. The consensus body shall have 14 calendar days from the date of the notification to change their vote.

6 Evidence of Consensus

Consensus is demonstrated, in part, by a vote of the consensus body. Such a 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. The Standards Development Committee (SDC) 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 SDC 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 outstanding negatives.
2. SDCs 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. SDCs are not required to consider negative votes accompanied by comments not related to the proposal under consideration, or negative votes without comments. The SDC 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 negative vote accompanied by comments not related to the proposal) shall not be factored into the numerical requirements for consensus. The SDC is not required to solicit any comments from the negative voter. The SDC 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.
 4. The SDC 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) APPROVE;
 - b) APPROVE, with comment;
 - c) DISAPPROVE, 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 (for any reason).
 6. For votes on membership and officer-related issues, the approve/disapprove/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.

7 Submittal of Standard

Upon completion of the procedures for ballot, for disposition of views and objections, and for appeals, the proposed standard may be submitted to ANSI for approval.

The information to be supplied to ANSI shall include:

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.

7.1 Project Discontinuance

See Section 17.2

8 Appeals

Appeals shall be addressed promptly and a decision made expeditiously. Consideration of appeals shall be fair and unbiased and shall fully address the concerns expressed.

The provision for appeals is important for the protection of directly and materially affected interests and of standards developers and is required as a part of due process. This section gives general criteria regarding the right to appeal, to whom appeals are made and what may be appealed.

8.1 Appeals at VITA

Right to Appeal: Persons who have directly and materially affected interests in the actions or the inactions of the VITA Standards Organization (VSO) have the right to appeal. Person(s) wishing to appeal should submit their appeal in writing to the Chair of the VSO. The appeal should state the nature of the concern, any alleged adverse effects, and remedial action that would satisfy the concerns of the appellant.

The Chair of the VSO must convene an appeals board meeting within 30 days of receiving the appeal and will carry out the role of respondent.

The appeals board shall consist of three individuals who have not been directly involved in the matter in dispute, and who will not be materially or directly affected by any decision made or to be made in the dispute. At least two members shall be acceptable to the appellant and at least two shall be acceptable to the respondent. In the event that the appellant and respondent cannot agree on acceptable individuals they shall each select one individual and the Executive Director of VITA shall select the third individual.

The appeals board shall render a judgment in writing within 30 days of their first meeting. The judgment shall be agreed to by at least two out of the three appeals board members. All judgments by the appeals board are final within the VSO.

8.2 Appeals at ANSI

Persons who have directly and materially affected interests 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. Appeals of actions shall be made within reasonable time limits; 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 board or council (e.g., Board of Standards Review, Executive Standards Council).

9 Interpretations of Standards

Section 9 of the VSO Policies and Procedures outlines the steps required when an interpretation of a standard is requested.

10 Patent Policy

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.

The procedures and policies set forth in Section 10 of *VSO Policies and Procedures* (including Appendices 6, 7 and 8 thereto) shall apply to all Working Group Members and the VITA Member Companies they represent.

If VITA receives notice that a proposed or existing American National Standard may require the use of such a patent claim, the procedures of the ANSI Patent Policy set forth in this section shall also be followed.

10.1 Statement from patent holder

VITA 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 claims(s); or
- b) assurance that a license to such essential patent claims(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 discriminations; 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, 11 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.

10.2 Record of statement

A record of the patent holder's statement shall be placed and retained in the files of both VITA and ANSI.

10.3 Notice

When the VITA receives from a patent holder the assurance set forth in 10.1, 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.

10.4 Responsibility for identifying patents

Neither the ASD nor ANSI is responsible for identifying all 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.

11 Commercial Terms and Conditions

Provisions involving business relations between buyer and seller such as guarantees, warranties, and other commercial terms and conditions shall not be included in an American National Standard. The appearance that a standard endorses any particular products, services or companies must be avoided. Therefore, it generally is not acceptable to include manufacturer lists, service provider lists, or similar material in the text of a standard or in an annex (or the equivalent). Where a sole source exists for essential equipment, materials or services necessary to comply with or to determine compliance with the standard, it is permissible to supply the name and address of the source in a footnote or informative annex as long as the words “or the equivalent” are added to the reference. In connection with standards that relate to the determination of whether products or services conform to one or more standards, the process or criteria for determining conformity can be standardized as long as the description of the process or criteria is limited to technical and engineering concerns and does not include what would otherwise be a commercial term.

12 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.

13 Record Retention Policy

13.1 American National Standards - Periodic Maintenance Option

Records concerning new, revised, or reaffirmed American National Standards maintained under the periodic maintenance option shall be retained for one complete standards cycle, or until the standard is revised.

13.2 American National Standards – Stabilized Maintenance Option

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.

13.3 Withdrawn Standards

Records concerning withdrawals of all American National Standards shall be retained for at least five years from the date of withdrawal.

14 Metric Policy

Standards that require measurements shall provide such measurements in either International System of Units (SI) or United States Customary units. Both SI and United States Customary Units may be provided if appropriate. If both units are provided, the primary or preferred unit shall be indicated.

15 Designation of American National Standards

VITA shall adhere to the procedures outlined in Section 4.4, "Designation of American National Standards", of ANSI's Essential Requirements.

15.1 Reaffirmation of an American National Standard

VITA shall adhere to the procedures outlined in Section 4.2.1.2, "Reaffirmation of an American National Standard", of ANSI's Essential Requirements.

16 Publication

American National Standards shall be published by VITA and made available as soon as possible, but no later than six months after approval as an American National Standard.

If VITA cannot publish an American National Standard within six months following its approval, VITA shall request an extension of this deadline from the ExSC 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 ExSC or its designee may grant an additional period of time for publication.

17 Maintenance and Withdrawal of Standards

17.1 Maintenance

VITA shall use both periodic maintenance (see ANSI's Essential Requirements, section 4.7.1) and stabilized maintenance (see ANSI's Essential Requirements, section 4.7.3) as appropriate to maintain its American National Standards.

For standards eligible for stabilized maintenance, VITA may decide to move a standard to stabilized maintenance by a majority vote at a regularly scheduled meeting. Refer to VSO P&P, section 5.1, for VSO meeting voting rules and eligibility requirements.

For standards undergoing periodic maintenance, VITA shall decide to revise or reaffirm an American National Standard before its fifth year anniversary by a majority vote at a regularly scheduled VSO meeting. Refer to VSO P&P, section 5.1, for VSO meeting voting rules and eligibility requirements.

17.2 Withdrawal of Standards

VITA shall adhere to the procedures outlined in section "4.2.1.3 Criteria for withdrawal" of ANSI's Essential Requirements when it becomes necessary to withdraw one of its American National Standards.

VITA may decide to withdraw an American National Standard at any time by a 2/3rds majority vote at a regularly scheduled VSO meeting. Refer to VSO P&P, section 5.1, for VSO meeting voting rules and eligibility requirements.

18 Revision History

Date	Revision - Comment
Sep 2003	0.1 – Initial Draft
Dec 2, 2003	0.2 – Changed ballot approval requirement
Feb 13, 2004	0.3 – Included accepted ballot comments and revisions required due to changes in Essential Requirements 2004.
Nov 09, 2004	0.4 – Remove “intent to ballot” notification to ANSI that was part of canvass method, but is no longer required.
Feb 18, 2005	0.5 – Change should to shall in last sentence of first paragraph in section 2.1. - Add section 16 Withdrawal of a Standard
Feb 21, 2006	0.6 – Revisions to Sections 5 and 11 to match ANSI Essential Requirements 2006.
Sep 23, 2006	0.7 – Revisions as a result of 2006 ANSI audit.
Oct 8, 2006	0.8 – Add Maintenance and other revisions to section 16
Jan 17, 2007	0.9 – Replace section 10, Patent Policy, with “ex ante” Patent Policy agreed to at January 17, 2007, VSO meeting.
June 2007	0.9a – revisions to meet requests by ANSI ESC
July 16, 2007	1.0 – add stabilization maintenance
Nov 14, 2007	1.1 – add retention policy to match stabilization
Feb 3, 2009	1.2 – Bring document into compliance with various ER 2008 and ER 2009 revisions.
Mar 11, 2009	1.2a – Added the word “demonstrably” to section 10.1 a) before the word “free” to harmonize with ANSI Essential Requirements.
Nov 2011	1.3 Section 5 – change recirculation period from 21 to 14 days Section 6 – change ballot terms to those used in practice Section 13 – change Metric Policy to allow either SI or United States Customary Units, or both if appropriate Section 14, 14.1 – refer to ANSI’s Essential Requirements
Jan 11, 2014	1.4 Changes to harmonize with ANSI Essential Requirements 2013 - Removed text in 2.1 and 2.2 and pointed to appropriate sections in ANSI Essential Requirements. Changes to harmonize with ANSI Essential Requirements 2014 - Changed draft to proposed. Removed 7.1 and pointed 7.1 to 16.2 which points to ANSI Essential Requirements 4.2.1.3
Feb 4, 2015	1.5 by JK 1) revised 10.1 Statement from Patent Holder per 2015 3.1 ANSI Patent Policy; 2) added 12 Antitrust Policy per new 3.3 Antitrust Policy 3) various editorial/format edits to harmonize with ANSI Essential Requirements 2015.
Feb 11, 2016	1.5a – Cosmetic changes prior to publishing. JG