



ANSI Auditing Policy and Procedures

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Editorial updates only

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Contents

FOREWORD 3

1 INTRODUCTION 4

2 AUTHORITY AND RESPONSIBILITIES 4

3 EXTENT OF AUDITS 4

4 FREQUENCY OF AUDITS 5

5 AUDITS FOR CAUSE 6

6 AUDIT PROCEDURES 7

7 HEARINGS AND APPEALS 8

8 SELF-AUDITS 8

ANNEX A - SELF-AUDITS BY ANSI-ACCREDITED STANDARDS DEVELOPERS 9

ANNEX B- ANSI REPORTING FORMAT 10

Foreword

Having an auditing process at ANSI helps strengthen the voluntary consensus standards system as a whole. The purpose of auditing ANSI accredited standards developers is to provide assurance that approved procedural rules for standards development are being followed. Auditing provides ANSI and the accredited standards developers with an evaluation of actual standards development operations and practices.

The ANSI Auditing Policy and Procedures was originally approved by the ANSI Board of Directors March 22, 1995. Additional revisions were approved by the Board of Directors on September 25, 1996 and December 12, 1996. Those revisions included the addition of material in sections 6.6 and 6.7 concerning confidentiality and conflict of interest; the addition of a mail-in audit option; the elimination of the BSR as a review and management body; the elimination of separate audit requirements for for-profit accredited standards developers; the revision of the audit cycle for audited designators; and, a revision to the scope of the audits.

The primary revisions approved in the April 1998 edition include: the scope of the audit, additional details with regard to complaints against audited designators and the elimination of the ExSC's review of the Audit Program's annual report. A further revision, approved by the NIC in July 1998, was added that provides detail to the Conflict of Interest clause.

The version of these procedures that was approved by the NIC in September 2000 and issued in January 2001 contained several key changes: 1) elimination of text that duplicates requirements contained in the ANSI Procedures for the Development and Coordination of American National Standards (ANSI Procedures), which is the overarching document relative to ANSI-accreditation; 2) elimination of detailed text related to complaints and appeals – this text was transferred to the Operating Procedures of the ANSI Executive Standards Council (ExSC), which is the accrediting body for American National Standards developers; 3) clarification of audit requirements relative to standards maintained under the continuous maintenance option as described in the ANSI Procedures; and 4) clarification of the extension request procedure.

The 2002 edition of these procedures includes two revisions: 1) reinstatement and clarification of text relative to audit requirements associated with the interpretations policy and other policies that each ANSI-accredited standards developer must maintain; and 2) replacement of specific procedures applicable to complaints against ANSI Audited Designators with a reference to the *Operating Procedures of the ANSI Executive Standards Council*, in which the applicable procedures are contained.

The 2003 edition of these procedures includes: 1) revisions that increase flexibility with regard to the scope and scheduling of an audit; and 2) update of references to the *ANSI Essential Requirements: Due process requirements for American National Standards*, which replaces the *ANSI Procedures for the Development and Coordination of American National Standards* effective 2003.

The 2005 edition of these procedures includes options that provide increased flexibility for standards developers with regard to requirements related to evidence of compliance.

The 2007 edition of these procedures incorporates editorial updates only including the labeling of Annexes A and B as informative and the addition of questions that reflect current requirements as set forth in the procedures that govern the American National Standards process.

The 2008 edition of these procedures incorporates editorial updates and an update to Annex B to reflect the 2008 edition of the *ANSI Essential Requirements*.

The 2009 edition of these procedures includes updated conflict of interest procedures and editorial updates to Annex B to reflect the 2009 edition of the *ANSI Essential Requirements*.

The 2010 edition includes a clarification to clause 5.1. The 2013 and 2015 editions include editorial updates only.

ANSI Auditing Policy and Procedures

1 Introduction

The American National Standards Institute (ANSI) accredits and coordinates several hundred organizations and committees that develop standards for approval as American National Standards based in part on evidence of due process and consensus. ANSI provides the criteria, and procedures for achieving due process and determining consensus as well as other requirements for the development, approval, maintenance and coordination of American National Standards. These ANSI criteria and requirements are accepted by each accredited standards developer as a condition of accreditation. See *ANSI Essential Requirements: Due process requirements for American National Standards*, hereafter referred to as the “*ANSI Essential Requirements*”.

ANSI’s auditing process is intended to confirm adherence to the criteria for accreditation and to confirm that the procedures and practices of accredited standards developers continue to be consistent with current ANSI requirements and those that formed the basis for accreditation. Auditing also is intended to increase the level of credibility and the effectiveness of due process for all persons who are directly and materially affected by the development of a proposed American National Standard. In addition, auditing supports and strengthens the voluntary consensus standards system and enhances the reputation and integrity of ANSI-accredited standards developers. Auditing can also assist standards developers in improving their operations and in detecting potential problems.

ANSI’s auditing process extends to all ANSI accredited standards developers regardless of the methods they use. It also includes audits of those accredited standards developers who have been delegated the authority to apply the ANS designation without review by the Board of Standards Review (BSR).

The ANSI auditing process includes independent audits conducted by ANSI or ANSI-designated auditors at standards developer sites or by remote audits and review by ANSI of all audit reports. The Executive Standards Council (ExSC) has authorized the ANSI Audit Director, at his or her discretion, to determine which standards developers may select the remote audit option. These audits shall be conducted at standards developer sites by an audit team organized by ANSI under the direction of the ExSC, or, in the case of remote audits, following receipt of all requested documentation. All fees and expenses associated with the conduct of any ANSI audit shall be the responsibility of the accredited standards developer.

2 Authority and responsibilities

The authority by which ANSI audits accredited standards developers is described in the *ANSI Essential Requirements*, which assigns responsibility for auditing to the ANSI Audit Director under the supervision of the ExSC and responsibility for the accreditation of standards developers to the ANSI ExSC.

The ANSI Audit Director’s authority includes arranging for audits of accredited standards developers, overseeing of the audits themselves, and transmitting audit findings and recommendations to the ExSC (see the *ANSI Essential Requirements*.)

The ExSC’s authority includes developing audit procedures, reviewing such audit reports and recommendations received from the ANSI Audit Director confirming adherence to the criteria for accreditation, and confirming that the procedures and practices of accredited standards developers continue to be consistent with current *ANSI Essential Requirements*. The ExSC is also responsible for taking any necessary action based on its audit findings.

3 Extent of audits

Audits shall involve a review of the operations of ANSI-accredited standards developers as they relate to standards development and associated activities, including continuity of administrative oversight and support of the standards activities. A sampling of operations and documents shall be used to obtain a representative review. The scope of these audits shall be determined by the ExSC at the conclusion of the review process of the regular audits. The scope shall include 5%-10% of the standards developer’s standards designated as American National Standards (i.e., new standards, reaffirmations, and revisions) since the last audit with a minimum of 5 standards (or all standards if there are fewer than 5). For those developers with more than 250 standards eligible

to be audited, the number of standards to be audited shall range between 12 and 40. Audits shall not involve the accounting or financial aspects of standards developers.

For standards maintained under continuous maintenance, normally a single revision cycle shall be selected for audit from the standard undergoing the audit; however, additional revision cycles within the record retention period may be audited if deemed necessary by the auditor.

Audits shall take into consideration the practices and actions, records and reports of accredited standards developers in implementing their operating procedures to comply with ANSI criteria, rules, procedures and requirements as set forth in the *ANSI Essential Requirements*. This includes whether the requirements relative to interpretations, patents, evidence of compliance, commercial terms and conditions, antitrust and the use of international system of units (SI) in standards are met. The audit shall review whether requests for interpretations are being handled by the standards developer in accordance with its policy on interpretations. If the policy is to provide interpretations, the Audit will review whether such interpretations are being developed in accordance with the policy.

The ANSI reporting format to be used by the auditors is provided in annex B.

4 Frequency of audits

The frequency of ANSI audits shall be as outlined below.

4.1 Initial audits

An audit shall be scheduled immediately after the BSR approves the first standard(s) submitted by an accredited standards developer. Following this audit, the regular audits will be scheduled in accordance with 4.2 and 4.3, and clause 5 of these procedures.

4.2 Regular audits

All accredited standards developers shall be audited, at a minimum, once every five years. However, the audit cycle may be extended at the discretion of the ExSC. This determination will be made by the ExSC for the subsequent audit at the conclusion of the review process of the prior audit. Special audits may be scheduled at the request of the ExSC.

4.3 Audits of accredited standards developers delegated the authority to apply the ANS designation without BSR review

Prior to being delegated the authority to apply the ANS designation without BSR review, the accredited standards developer shall be subject to an audit. The results of the initial audit shall be reviewed by the ExSC. The audited designator shall then be subject to an audit two years from the date of approval as an audited designator and then an audit three years after the preceding audit. Thereafter, the audit shall take place every five years unless, as a result of the regular audit or an audit for cause, a more frequent audit cycle is deemed necessary by the ExSC.

4.4 Evidence of Compliance Audit Sample Selection Formula

This formula provides the option to establish a sample of records subject to audit on an ongoing basis within a five-year window, thus allowing the standards developer to discard records immediately that are not included in the sample. The standards developer shall notify the ANSI Audit Director of their interest in utilizing this option and the ANSI Audit Director shall notify the ANSI ExSC accordingly. Unless the ANSI ExSC objects to the standards developer's request based on accreditation or audit related issues, the ANSI Audit Director shall establish an agreement with the standards developer to implement this option.

The standards developer shall submit periodically, based on an agreed upon schedule, a list of standards that have been approved as American National Standards and that satisfy the established criteria. The standards developer shall report to ANSI additions to this list, but shall not delete standards from the list without prior approval by ANSI. The ANSI Audit Director shall identify the standards that will be subject to audit based upon established criteria and so notify the standards developer in a timely manner. The standards developer is required to retain records for all standards selected for audit.

The following criteria have been established for those standards developers selecting this option:

- 1) Standards developer shall retain records related to 25% of all American National Standards approved since the last audit;
- 2) Standards developer shall retain records for standards with unresolved objections (from consensus body and/or public review) such that standards with unresolved objections constitute 25% of all standards for which records are retained or records for all standards with unresolved objections, whichever is fewer;
- 3) Standards developer shall retain records for a minimum of one standard, and preferably two or more standards as specified by the ANSI Audit Director, from each consensus body, committee or subcommittee that has produced one or more standards approved since the previous audit;
- 4) Standards developer shall retain records for a minimum of one standard, and preferably two or more standards as specified by the ANSI Audit Director, from each of the different product, service, or technical areas addressed by the standards program;

In addition:

- 5) Standards developer shall retain records of all appeals including records of the entire related standards development process since the last audit;
- 6) Standards developer shall retain records for any interpretations issued since the last audit, whether for standards approved prior to or since the last audit;
- 7) Standards developer shall retain records for any standard approved since the last audit that included patent issues; and
- 8) Standards developer shall retain records for any standards approved since the last audit that are sponsored jointly with another organization, whether or not the organization is accredited by ANSI as a standards developer.

5 Audits for cause

In scheduling an audit for cause (whether at its own initiative or at the request of the BSR), the ExSC shall consider all the evidence presented and make a determination whether or not an audit for cause is appropriate and when said audit should be scheduled (i.e., at the next regular audit, or a special audit). In conducting a special audit, in addition to the regular audit procedures, the audit team would be provided with instructions specific to that audit (i.e., thorough review of a particular development committee, the development of a particular standard, a portion of the process, etc.).

5.1 Audits scheduled due to serious procedural violations

In those instances where non-trivial procedural violations are discovered during a regular audit, the ExSC may allow the standards developer the opportunity to correct the deficiencies. In these instances, the ExSC shall determine if the standards developer's accreditation should be suspended pending compliance with the standards developer's procedures and current ANSI requirements. A special audit shall be conducted when appropriate to verify such compliance. Alternatively, the ExSC may withdraw accreditation and require the standards developer to reapply, if it should continue to desire accreditation.

5.2 Audits scheduled at the request of the BSR

If the BSR, during its regular review of standards, has concerns regarding a standards developer's compliance with its procedures and current ANSI requirements, it may request the ExSC to schedule an audit for cause. After reviewing the specific concerns, the potential procedural violations and all examples of such, any other information from the BSR, and the last regular audit, the ExSC shall make a determination as to whether a special

audit is necessary, or if the audit team will be provided with special instructions at the next regularly scheduled audit.

5.3 Audits or other actions scheduled as the result of formal complaints

See the *Operating Procedures of the ANSI Executive Standards Council*.

6 Audit procedures

6.1 Selection of audit team and audit-team leader

The ANSI Audit Director shall appoint an audit team and audit team leader for each audit of a selected standards developer (the “auditee”). Audit teams shall consist of one, two, or three individuals, selected from an ANSI-organized pool of available and qualified people. An audit team member may be replaced by the ANSI Audit Director with or without cause.

6.2 Qualification of auditors

Individuals selected to serve as auditors shall have the following qualifications:

- a) experience in, and knowledge of, the voluntary consensus standards system including ANSI criteria for accreditation, due process, and consensus;
- b) general knowledge of auditing principles and methods obtained through any combination of experience, education, or ANSI training;
- c) the ability to act objectively and independently;
- d) the ability to analyze information and to express findings clearly, concisely, and in a timely manner.

6.3 Initiation of an audit

The audit-team leader shall attempt to schedule the audit to be conducted within thirty (30) working days from the appointment of the audit team. The audit-team leader shall provide the auditee with a list of particulars that the audit team intends to verify or examine during the audit and any other information that the audit team believes will help the auditee prepare for the audit.

6.4 Audit report and auditee response

The completed audit report shall be forwarded by the audit team leader to the ANSI Audit Director within thirty (30) working days after the completion of the audit. The ANSI Audit Director shall transmit a copy of the report to the auditee with a request that the auditee submit any comments to ANSI within thirty (30) working days of receipt of the report. The auditee may request an extension from the Audit Director. Such a request shall be considered on a case-by-case basis. The auditee comments may include plans and a timetable for corrective action relating to any recommendations contained in the audit report.

6.5 Action on audit reports

The ExSC shall review the audit material transmitted to it by the ANSI Audit Director, take appropriate action, and notify the auditee of its action. The action taken may include a finding that the conditions upon which accreditation was granted have been satisfactorily maintained. If the action taken includes a finding that the conditions upon which accreditation was granted have not been satisfactorily maintained, the auditee shall be requested to take defined corrective action in accordance with 4.1.3 of the *ANSI Essential Requirements* and 5.1 of this document.

6.6 Conflict of interest

6.6.1 Audit Team: The ANSI Audit Director shall not appoint auditors to an audit team who have a known conflict of interest that may affect their ability to perform an unbiased audit. Appointed auditors shall notify the ANSI Audit Director of any real or apparent conflict of interest as soon as practicable after notification of their appointment.

An appointed auditor shall act at all times in a manner that promotes confidence in the integrity and impartiality of ANSI’s processes and procedures and should avoid a conflict of interest or the appearance of a conflict of interest in connection with all audit related activities. A conflict of interest can arise from any relationship between the auditor and auditee, whether past or present, that reasonably raises a question of an auditor’s impartiality.

The auditee shall be provided with the name of the appointed auditor and be given the opportunity to advise ANSI of a potential conflict of interest on the part of the auditor. If the auditee asserts that a conflict of interest exists, then the Audit Director shall appoint a different Auditor.

6.6.2 Reviewing Body: A member (or his/her employer) of a reviewing body having a conflict of interest with the auditee shall not be allowed to receive or review a copy of the audit report and will not be allowed to participate in the discussion of the audit unless otherwise agreed to by the auditee. The conflict of interest procedures applicable to the reviewing body shall apply.

6.7 Confidentiality of Audit Reports

All audit information and audit reports shall remain confidential and shall not be disclosed to any person other than the auditee, appropriate ANSI staff, the auditors, and, as appropriate, members of the reviewing bodies. The auditee may provide the audit information and reports received to whomever it deems appropriate.

7 Hearings and appeals

7.1 Request for hearing on an action of the ExSC

The auditee may submit a written request for a hearing before the ExSC with respect to the action taken by the ExSC in 5.1 or 6.5 above, provided such request is received at ANSI within 15 working days after receipt of notification of the ExSC action and is otherwise submitted in accordance with the hearing procedures contained in clause 17 *ExSC hearing of appeals* of the *Operating Procedures of the ANSI Executive Standards Council*.

7.2 Appeal of ExSC action

Final action by the ExSC may be appealed to the ANSI Appeals Board in accordance with the *ANSI Appeals Board Operating Procedures*.

8 Self-audits

Accredited standards developers may find it useful to conduct self-audits. The purpose of self-audits is to permit an accredited standards developer to identify areas where improvement and increased efficiency are possible. They also provide an opportunity to identify any areas where policies or procedures may not be in conformance with the *ANSI Essential Requirements*. Annex A contains suggested self-audit procedures. The results of any self-audit are not required to be submitted to the ExSC for review. In addition, accredited standards developers are not required to use annex B in conducting self-audits.

Informative Annex

Annex A - Self-audits by ANSI-Accredited Standards Developers

ANSI-Accredited Standards Developers may find it useful to conduct self-audits. The purpose of self-audits is to permit an accredited standards developer to identify areas where improvement and increased efficiencies are possible. They also provide an opportunity to identify any areas where policies or procedures may not be in conformance with the *ANSI Essential Requirements*. The results of any self-audit are not required to be submitted to the ExSC for review. In addition, ANSI-Accredited Standards Developers are not required to use Annex B in conducting self-audits. However, it is a useful tool for those who wish to use it.

Self-audits should involve a review of the operations of the ANSI-Accredited Standards Developer as they relate to standards development and associated activities, including continuity of administrative oversight and support of its standards activities. A sampling of operations and documents should be used to obtain a representative review.

Audits should take into consideration the practices and actions, records, and reports of the ANSI-Accredited Standards Developer in implementing its operating procedures to comply with ANSI criteria, rules, procedures and requirements.

In connection with self audits, it is recommended that individuals selected to serve as auditors should be experienced in, and have knowledge of, the voluntary consensus standards system including ANSI criteria for accreditation, due process and consensus. In order to avoid any real or apparent conflict of interest, individuals serving as auditors preferably should not be directly involved in the standards work of the standards developer, either as a volunteer or as a staff member.

An audit report, including findings and recommendations, should be prepared by the auditors and provided to the Accredited Standard Developer in a timely manner, preferably within 40 working days of completion of the audit. The ANSI Audit Reporting Format (Annex B) may be used.

Informative Annex

Annex B- ANSI reporting format

This audit applies only to ANSI requirements relative to proposed and approved American National Standards and Technical Reports registered with ANSI processed by the ANSI Accredited Standards Developer being audited.

Name of Accredited Standards Developer: _____

Date of accreditation: _____

Address: _____

Date(s) of audit: _____

Name(s) and address(es) of auditor(s) _____

Responses to the questions below, and explanations where necessary, must be based on evidence found during the audit. Such evidence should substantiate the answer (and explanation) given.

1 Procedures governing the development of evidence of consensus for approval, revision, reaffirmation, or withdrawal of standards as American National Standards.

1.1 Have your procedures been revised since the date of accreditation or reaccreditation? (4.1.1 (a) and 4.1.3)¹ Yes ___ No ___

1.1.1 If yes, have the revised procedures been formally transmitted to ANSI? (4.1.1 (a) and 4.1.3) Yes ___ No ___

1.1.1.1 If yes, is there documentation verifying this transmittal? Yes ___ No ___

1.1.1.2 If no, what is the explanation?

1.1.2 If your procedures have not been revised, what is the explanation?

1.2 Are the current procedures transmitted to new participants, as well as to officers of the consensus body? Yes ___ No ___

1.2.1 If no, what is the explanation?

1.3 Are the procedures readily available to any interested person? (1.9) Yes ___ No ___

1.3.1 If no, what is the explanation?

¹All numerical references within this annex are to the *ANSI Essential Requirements: Due process requirements for American National Standards*, January 2016 edition.

- 1.4 Are the names, affiliations and interest categories of the consensus body members available to interested parties upon request? (2.3) Yes___ No___
- 1.4.1 If no, what is the explanation?
- 1.5 Are the interest categories discretely defined?(2.3) Do they cover all materially affected parties and differentiate each category from the other categories? Yes ___ No ___
- 1.5.1 If no, what is the explanation?
- 1.5.2 Are the interest categories and definitions available upon request? (2.3) Yes___ No___
- 1.5.3 If they are not available upon request, what is the explanation?
- 1.6 Do your procedures state specifically how consensus will be determined? (2.7) Yes___ No___
- 1.6.1 If so, please state the numerical requirements required to achieve consensus.
- 1.7 Does your organization intend to utilize the expedited procedures for the national adoption of an ISO or IEC standard as an ANS? Yes___ No___
- 1.7.1 If yes, has a provision or notification to this effect been included in your organization's accredited procedures? (see *ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards*) Yes___ No___
- 1.8 Do the procedures address the withdrawal of American National Standards and the discontinuance of a standards project including the appropriate notification to ANSI? (4.2.1.3 and 4.2.1.3.3) Yes___ No___
- 1.8.1 If no, what is the explanation?

2. Administrative oversight and support of standards activities

- 2.1 Is there a supervisory body that reviews standards development activities and progress? (4.1.1.b(1)) Yes ___ No ___
- 2.1.1 If yes, what is the name of the body?
- 2.1.2 If no, what, if any, mechanism exists to review the standards development activities and progress?
- 2.2 Is participation monitored for each of the following: openness, dominance, balance, activity, and interest classification? (4.1.1.b.(1)) Yes ___ No ___
- 2.2.1 If no, what is the explanation?
- 2.3 Are administrative functions (such as handling requests to participate, preparation and distribution of minutes, letter ballots and draft standards, responses to comments, record keeping, etc.) being handled effectively? (4.1.1.b(1)) Yes ___ No ___
- 2.3.1 If no, what is the explanation?
- 2.4 Are there written internal administrative procedures for handling requests to participate, preparation and distribution of minutes, letter ballots and draft standards, responses to comments, record keeping, etc.? Yes ___ No ___
- 2.4.1 If no, what is the explanation?
- 2.5 Is there a readily available and identifiable source within the accredited standards developer to obtain additional information on any standards activity? Yes ___ No ___

- 2.5.1 If yes, who is that source?
- 2.5.2 If no, what is the explanation?
- 2.6 Are responsible parties within the accredited standards developer knowledgeable of ANSI requirements for openness, due process, project notification requirements, etc.? Yes ___ No ___
 - 2.6.1 If yes, who are the responsible parties?
 - 2.6.2 If no, what is the explanation?
 - 2.6.3 What staff training on the ANSI requirements is available?
 - 2.6.4 If training is available, do the training materials contain the current policies and procedures? Yes ___ No ___
 - 2.6.5 If training is available, who normally provides the staff training?
 - 2.6.6 If training is available, who normally provides the volunteer training?
 - 2.6.7 If training for officers (and other members) is available, is it optional or required?
 - 2.6.8 If training is required, how is this requirement enforced?

3 Evidence (Records) of compliance with ANSI due process requirements

- 3.1 How are records of standards activities and compliance with ANSI requirements prepared and maintained?
 - 3.1.1 Where are the records kept?
 - 3.1.2 How long are standards-related records maintained?
- 3.2 Is there a record retention policy that provides for retention of evidence of compliance with the *ANSI Essential Requirements* for a period of time after approval of new, revised, reaffirmed, or withdrawn American National Standards? (3.3) Yes ___ No ___
 - 3.2.1 If no, what is the explanation?
- 3.3 Is there compliance with record retention policies? (3.3) Yes ___ No ___
 - 3.3.1 If no, what is the explanation?
- 3.4 How is the record retention policy made available to staff or other interested parties?
- 3.5 Is a membership record for each member of the consensus body (and other related standards development bodies) maintained? Yes ___ No ___
 - 3.5.1 If no, what is the explanation?
 - 3.5.2 If yes, does this record include invitations and replies from materially affected interests? Yes ___ No ___
 - 3.5.3 If yes, does this record include membership requests from interested parties and replies from the accredited standards developer? Yes ___ No ___
- 3.6 Are minutes of all relevant ANS bodies maintained? Yes ___ No ___
 - 3.6.1 If no, what is the explanation?
 - 3.6.2 If yes, are the minutes of meetings sufficiently detailed, including, for example, responses to comments that may have been discussed? Yes ___ No ___
 - 3.6.2.1 If no, what is the explanation?

3.7 Are records for each letter ballot issued to the consensus body (and other relevant bodies) maintained? Yes ___ No ___

3.7.1 If no, what is the explanation?

3.7.2 If yes, do these records contain the receipt and disposition of each comment and negative ballot submitted? Yes ___ No ___

3.7.2.1 If no, what is the explanation?

4 Cooperation and communication with ANSI

4.1 When, in the standards development process, are PINS forms reporting standards activities submitted to ANSI? (2.5, 4.1.1.b (5), 4.3, 5.2.d)

4.2 Are PINS forms submitted to ANSI on a timely basis? (2.5, 4.1.1.b (5), 4.3, 5.2.d)
Yes ___ No ___

4.2.1 If no, what is the explanation?

4.2.2 Are PINS forms submitted for National Adoptions? (2.5.1)

Yes___ No___ N/A ___

4.2.3 Are PINS forms submitted to ANSI via the online form option? Yes___ No___

4.2.4 If not, why?

4.3 Are clear and adequate descriptions of the scope and purpose of proposed activities included on the PINS Form and other relevant project announcements? (2.5)

Yes ___ No ___

4.3.1 If no, what is the explanation?

4.4 Has the developer received written comments within 30 days of the publication date of a PINS announcement in Standards Action in which comments assert that a proposed standard duplicates or conflicts with an existing ANS or a candidate ANS that was previously announced in Standards Action? Yes ___ No ___

4.4.1 If yes, provide evidence of compliance with clause 2.5.1.2 and 2.5.1.3 (PINS Deliberation Report).

4.4.2 If the requirements of 2.5.1.2 and 2.5.1.3 were not implemented, what is the explanation?

4.5 When in the standards development process are proposed American National Standards submitted to ANSI for public review (using the BSR-8 form or equivalent)? (2.5.2)

4.5.1 Are the BSR-8 forms completed correctly? Yes ___ No ___

4.5.2 Are BSR-8s submitted to ANSI via the online form option? Yes___ No___

4.5.3 If not, why?

4.6 **For Audited Designators only:** If the accredited standards developer has been delegated the authority to designate its standards as ANSs without BSR review, when in the standards development process are proposed American National Standards submitted to ANSI for public announcement (using the BSR-108 form or equivalent)? (5.2 (e))

4.6.1 Are the BSR-108 forms completed correctly? Yes ___ No ___

- 4.6.2 Are the BSR-108 forms submitted in a timely manner? Yes ___ No ___
- 4.6.3 Are BSR-108 forms submitted to ANSI via the online form option?
Yes ___ No ___
- 4.6.4 If not, why?
- 4.7 When in the standards development process are proposed American National Standards submitted to ANSI for final approval (using the BSR-9 form)? (4.2.1)
- 4.7.1 Are the BSR-9 forms completed correctly and do they include all required information? Yes ___ No ___
- 4.7.2 Are the BSR-9 forms submitted within one year from the close of the public review period (4.2)? Yes ___ No ___
- 4.7.2.1 If no, what is the explanation?
- 4.8 **For Audited Designators only:** If the accredited standards developer has been delegated the authority to designate its standards as ANSs without BSR review, are the announcements of approval as ANSs being submitted within ten working days of approval (using the BSR-109 form)? (5.2(f)) Yes ___ No ___
- 4.8.1 If no, what is the explanation?
- 4.8.2 Are the BSR-109 forms completed correctly and do they include all required information? Yes ___ No ___
- 4.8.3 Are the BSR-109 forms completed within one year from the close of the public announcement period? Yes ___ No ___
- 4.8.3.1 If no, what is the explanation?
- 4.9 Are responses made to ANSI requests for comments, ideas, and actions, with regard to standards planning and coordination activities, of mutual interest? (4.1.1.b (4)) Yes ___ No ___
- 4.9.1 If no, what is the explanation?
- 4.9.2 Does the accredited standards developer have representation on any ANSI Board, Council, or Standards Collaborative? Yes ___ No ___
- 4.9.3 If yes, does the representative participate actively (i.e., respond to letter ballots, attend meetings, etc.)? Yes ___ No ___
- 4.9.3.1 If no, what is the explanation?

5 Notification of standards activity to directly and materially affected persons

- 5.1 What is the URL of your web site for standards related activities?
- 5.2 Are announcements (direct mailings, press releases, articles in the trade press, advertisements, www postings, etc.) used to solicit participation by directly and materially affected interests? (2.5) Yes ___ No ___
- 5.2.1 If no, what is the explanation?
- 5.2.2 If yes, what are the primary means of announcement?
- 5.2.3 If yes, when in the process are these announcements released?
- 5.2.4 If yes, how are responses to such announcements considered? (2.1)

6 Coordination with other standards developers

- 6.1 What methods exist to provide a consistent review of existing standards and standards being developed, both nationally and internationally, for the purpose of avoiding duplication of effort and conflicting standards? (4.3)
- 6.2 Have there been any claims of conflict or duplication as described in the *ANSI Essential Requirements* (2.4) Yes ___ No ___
- 6.2.1 If yes, please explain what efforts have been made to demonstrate good faith efforts to resolve the conflict and provide relevant documentation? (1.4, 2.4)
- 6.3 What channels of communication with other standards developers are utilized for coordination? (4.3)
- 6.4 Do formal (written agreement) liaisons exist between the accredited standards developer and other standards developers? (4.3) Yes ___ No ___
- 6.4.1 If yes, please provide a list.
- 6.5 Is there a parallel or related international standards development program? Yes ___ No ___
- 6.5.1 If yes, please provide a list of the international activities.
- 6.5.2 If yes, does the accredited standards developer participate in the international standards activity? (Secretariat, TAG Administrator, Member of US delegation)
- 6.5.3 If yes, are national standards of the accredited standards developer proposed for international adoption? Yes ___ No ___ N/A ___
- 6.4.3.1 If no, what is the explanation?
- 6.5.4 Are appropriate ISO and/or IEC standards considered by the standards developer for adoption as American National Standards? (4.1.1.b(7)) Yes ___ No ___ N/A ___
- 6.5.4.1 If no, what is the explanation?

7 Openness of participation

- 7.1 What is the mechanism used for the initial establishment of a consensus body?
- 7.2 Is participation open to all persons (organizations, companies, government agencies, individuals, etc.) who are directly and materially affected by the activity in question? (1.1) Yes ___ No ___
- 7.2.1 If no, what is the explanation?
- 7.3 Is participation conditional upon membership in any organization? (1.1) Yes ___ No ___
- 7.3.1 If yes, what is the explanation?
- 7.4 Is there a fee for participation? (1.1) Yes ___ No ___
- 7.4.1 If yes, do procedures exist to provide a waiver of fees to qualified applicants? Yes ___ No ___
- 7.4.2. If yes, have any requests for waiver been received in the last five years? Yes ___ No ___
- 7.4.2.1 If yes, what was the disposition of these requests?

7.4.2.2 If yes, does the fee present a barrier to participation (please explain)?
Yes ___ No ___

7.5 In the last five years, have any requests for participation been denied? Yes ___ No ___

7.5.1 If yes, what is the explanation?

7.6 Has the level of participation of each member of the consensus body (and other relevant bodies) been monitored to ensure active participation? Yes ___ No ___

7.6.1 If no, what is the explanation?

7.7 If a member of the consensus body (and other relevant bodies) is found to be a poor participant or non-participant, are attempts made to rectify the delinquency? Yes ___ No ___

7.7.1 If no, what is the explanation?

7.8 Has any member of the consensus body (and other relevant bodies) been suspended for non-participation within the last five years? Yes ___ No ___

7.8.1 If yes, what methods were employed to elicit a more active participation and how was the member(s) suspended?

8 Balance and lack of dominance

8.1 What are the interest categories associated with the consensus body and how is membership reviewed regularly? (1.3, 2.3)

8.1.1 What is the current balance of the above interest categories? (2.3)

8.1.2 Does each of the identified interest categories have adequate representation?
Yes ___ No ___

8.1.2.1 If no, what efforts have been made to attract additional members?

8.1.3 Is participation by the underrepresented group actively sought? Yes ___ No ___

8.1.3.1 If no, what is the explanation?

8.1.4 Are users represented on the consensus body? Yes ___ No ___

8.2 What mechanism does the accredited standards developer utilize to achieve and maintain a balanced membership on the consensus body (and other relevant bodies)?

8.3 Have any claims of dominance been made? (2.2) Yes ___ No ___

8.3.1 If yes, what is the explanation?

9 Balloting procedures and results

9.1 Is balloting being handled expeditiously and in accordance with the procedures that formed the basis for accreditation of the standards developer? (4.1.1.d) Yes ___ No ___

9.1.1 If no, what is the explanation?

9.1.2 Are there internal ballot procedures available to appropriate staff? Yes ___ No ___

9.2 Are unresolved objections, including attempts at resolution of objections and substantive changes, reported to the participants, providing an opportunity to change the initial vote (2.6)? Yes ___ No ___

9.2.1 If no, what is the explanation?

9.3 Are all members of the consensus body provided the opportunity to vote? (2.7) Yes___
No__

9.3.1 If no, what is the explanation?

9.3.2 When recorded votes are taken at meetings, are the members who are absent given the opportunity to vote before or after meetings? (2.7) Yes__ No__

9.3.2.1 If no, what is the explanation?

10 Consideration of views and objections

10.1 Is there a record of each comment and objection resulting from the balloting, public review responses, and other views and inputs received? (3.4) Yes ___ No ___

10.1.1 If no, what is the explanation?

10.2 Was there an effort to resolve all objections? (2.6) Yes ___ No ___

10.2.1 If no, what is the explanation?

10.3 Was each objector advised of the disposition of the objection, in writing, with an opportunity to withdraw or maintain the objection? (2.6) Yes ___ No ___

10.3.1 If no, what is the explanation?

10.3.2 Are unresolved objectors notified in writing of their right to appeal? (2.6)
Yes ___ No ___

10.3.2.1 If no, what is the explanation?

10.4 How are unresolved objections reported to the consensus body in order to afford an opportunity to respond, reaffirm, or change their votes? (2.6)

10.4.1 Are all members of the consensus body afforded an opportunity to respond, reaffirm or change their vote? Yes ___ No ___

10.4.2 If no, what is the explanation?

10.5 If substantive changes are made to a proposed standard(s) after it is balloted, are they reported to the consensus body in order to afford all members an opportunity to respond, reaffirm, or change his/her initial vote? (2.6) Yes ___ No ___ N/A ___

10.5.1 If no, what is the explanation?

10.6 Are such substantive changes announced in ANSI's *Standards Action* and in other appropriate media for public review? (2.5) Yes ___ No ___ N/A ___

10.6.1 If no, what is the explanation?

10.7 Does a procedure exist to ensure that comments submitted with a vote that are not related to the proposal under consideration are handled as new proposals? (2.7) Yes___
No ___

10.7.1 If no, what is the explanation?

11 Appeals

11.1 What appeals have been received since the last audit and what was the final disposition?

11.2 What methods are used to notify unresolved objectors in writing of their right of appeal?

- 11.3** Are there written appeals procedures that are readily available upon request? (1.8) Yes ___ No ___
- 11.3.1** If no, what is the explanation?
- 11.3.2** If yes, do the written procedures contain an identifiable, realistic and readily available appeals mechanism? (1.8) Yes ___ No ___
- 11.3.2.1** If no, what is the explanation?
- 11.4** Are appeals addressed promptly? (1.8) Yes ___ No ___
- 11.4.1** If no, what is the explanation?
- 11.5** Have the involved parties had the right to present their cases? (1.8) Yes ___ No ___
- 11.5.1** If no, what is the explanation?
- 11.6** Is a fee for a procedural appeal charged? (2.8.1) Yes ___ No ___
- 11.6.1** If a fee is charged, is it predetermined, fixed and reasonable? (2.8.1)
- 11.6.2** If a fee is charged, is there a procedure for requesting a fee waiver or fee reduction? (2.8.1) Yes ___ No ___
- 11.7** Is there a record of each appeal and are such records available to the involved parties? (3.3) Yes ___ No ___
- 11.7.1** If no, what is the explanation?

12 Publication and maintenance of American National Standards

- 12.1** Are American National Standards developed by the accredited standards developer published promptly, i.e., no later than six months after approval by ANSI? (4.5) Yes ___ No ___
- 12.1.1** If no, what is the explanation? Was an extension requested?
- 12.1.2** What method is used to notify interested parties of the availability of published American National Standards?
- 12.2** Are such standards marked on the cover or title page with the ANSI approval logo or the words “an American National Standard”? (4.4) Yes ___ No ___
- 12.2.1** If no, what is the explanation?
- 12.2.2** What additional methods are used to indicate that the standard has been approved as an American National Standard?
- 12.3** Is there a unique alphanumeric designation identifying each standard and each version? (4.4) Yes ___ No ___
- 12.3.1** If no, what is the explanation?
- 12.4** What methods exist to ensure that American National Standards are reviewed at least every five years for revision, reaffirmation, or withdrawal? (4.7)
- 12.5** Are any American National Standards beyond the five-year limit for review? (4.7) Yes ___ No ___

12.5.1 If yes, has an extension been requested from ANSI or a PINS or BSR-8 published? (4.7.1) Yes ___ No ___

12.5.1.1 If no, what is the explanation?

12.5.2 If yes, has ANSI granted an extension? Yes ___ No ___

12.5.2.1 If no, what is the explanation?

12.6 Are any American National Standards beyond the ten-year age limit? (4.7.1) Yes ___ No ___

12.6.1 If yes, what is the explanation?

12.7 Does your organization maintain any standards under the stabilized maintenance option? (4.7.3) Yes ___ No ___

12.7.1 If so, please provide a list by designation.

12.7.2 Do your accredited procedures include a provision or notification regarding the procedures that are used in connection with standards that are maintained as stabilized ANS? (4.7.3)

Yes ___ No ___

12.8 Does your organization maintain standards under Continuous Maintenance (4.7.2)?

12.8.1 If so, please provide a list by designation.

12.9 Have any ANS that were maintained under continuous maintenance been switched to periodic maintenance due to a change in activity level? (e.g., No revision within 4-5 years) (4.7.2) yes ___ No ___

12.10 Does your organization maintain any Provisional ANS or its equivalent (Annex B)? Yes ___ No ___

12.10.1 If so, please identify them and the applicable procedural provisions.

13 Interpretations

13.1 Is the current interpretations policy on file at ANSI? (3.6) Yes ___ No ___

13.1.1 If no, what is the explanation?

13.2 Are interpretations of American National Standards provided by the accredited standards developer? (3.6) Yes ___ No ___

13.2.1 If yes, are the interpretations made in the name of the accredited standards developer and not ANSI? (3.5) Yes ___ No ___

13.2.2 If yes, what is the number of interpretations of American National Standards provided by the accredited standards developer since the last audit?

13.2.3 If yes, how are these interpretations made available to the users of the American National Standard?

14 Patent policy

14.1 Does the accredited standards developer have a patent policy (3.1)? Yes ___ No ___

14.1.1 If no, what is the explanation?

14.1.2 If the developer does not have its own Patent Policy, has the Accredited Standards Developer provided a statement to ANSI that it will comply with the ANSI Patent Policy? Yes ___ No ___

14.1.3 If the developer does have its own patent policy, does it comply with the ANSI Patent Policy? Yes ___ No ___

14.1.4 If yes, is a copy of the policy or Compliance Statement on file with ANSI? Yes ___ No ___

14.2 Has the accredited standards developer had any disputes or appeals concerning patents within the last five years? Yes ___ No ___

14.2.1 If yes, what were the results?

14.3 Has the accredited standards developer drafted an ANS in terms that include the use of an essential patent claim within the last five years? Yes ___ No ___

14.4 If so, please provide the designations of the affected ANS.

14.5 How does the ASD maintain copies of essential patent claims and how are they transmitted to ANSI?

14.6 Does the accredited standards developer's patent policy address patent transfers and disclosure of essential patents?

14.6.1 If not, why?

14.7 Do all patent letters of assurance dated March 3, 2015 or after address patent transfers? Yes ___ No ___

14.7.1 If not, why? Please identify all relevant ANS by designation:

15.1 Antitrust Policy

15.1 Does the accredited standards developer's procedures include an antitrust policy that complies with the *ANSI Essential Requirements* (3.3)? Yes ___ No ___

15.1.1 If the procedures do not include an antitrust policy that complies with the *ANSI Essential Requirements*, what is the explanation?

16 Other

16.1 What mechanism exists for the prompt consideration of a proposal made for developing new standards or revising or withdrawing existing American National Standards? (1.5, 2.1)

16.2 Does the accredited standards developer have a metric policy (3.5)? Yes ___ No ___

16.2.1 If no, what is the explanation?

16.2.2 If yes, is a copy on file with ANSI (3.5)? Yes ___ No ___

16.3 Does the accredited standards developer have a policy concerning commercial terms and conditions? (3.2) Yes ___ No ___.

16.3.1 If the developer does not have its own Commercial Terms and Conditions Policy, has the Accredited Standards Developer provided a statement to ANSI that it will comply with the ANSI Commercial Terms and Conditions Policy? Yes ___ No ___

16.3.2 If the developer does not have either, what is the explanation?

16.3.3 If the developer does have its own Commercial Term and Conditions Policy is a copy on file with ANSI? (3.2) Yes ___ No ___

- 16.4** How does the accredited standards developer handle allegations that a standard or portion of a standard unreasonably restrains trade or is anti-competitive? (3.2 and 4.2.1.1)
- 16.5** What method does the accredited standard developer use to assure that adequate representation of consumers' concerns is obtained in connection with consumer product standards? (1.3)
- 17** Do these procedures (or a separately maintained document) address the issuance of Draft American National Standards for Trial Use? (Annex B) Yes ___ No ___
- 17.1** If yes, the developer must remove the provision from its accredited procedures or eliminate reference to "American National Standards" as Draft American National Standards for Trial Use no longer are recognized by ANSI. Yes ___ No ___
- 18** Do these procedures (or a separately maintained document) address the registration of Technical Reports with ANSI? Yes ___ No ___
- 18.1** If yes, has a copy of the relevant text been provided to the ANSI ExSC for review and approval? Yes ___ No ___
- 19** Have there been or are there any pending lawsuits regarding any American National Standards? Yes___ No___
- 19.1** If yes, explain.
- 20** Have there been or are there presently any investigations being conducted by any legal or regulatory agencies such as the Federal Trade Commission, the Department of Justice, etc? Yes___ No___
- 20.1** If yes explain.
- 21** Has your organization filed under Public Law 108-237 The Standards Development Organization Advancement Act of 2004 (HR 1086)? Yes___ No___