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) 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?

__________________________

1 All numerical references within this annex are to the ANSI Essential Requirements: Due process requirements for American National Standards, January 2015 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 ANSI? (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 ANSI 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 ANSI 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?

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:

14.8 Antitrust Policy

14.8.1 Does the accredited standards developer’s procedures include an antitrust policy that complies with the ANSI Essential Requirements (3.3)? Yes__ No___

14.8.1.1 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 ___