



TIPS AND TECHNIQUES FOR ANSI-ACCREDITED STANDARDS DEVELOPERS

ANSI STANDARDS DEVELOPER AUDIT GUIDANCE AND CHECKLIST FOR ELECTRONIC RECORDS

ANSI Essential Requirements (2016 edition)

1.0 Background

Many ANSI-Accredited Standards Developers (ASDs) have increased their reliance on electronic records. As a developer's records related to evidence of compliance with the American National Standards (ANS) process are subject to an ANSI audit, this guidance document and the checklist that follows in clause 3.0, have been created to assist developers with the organization of electronic files to achieve efficiencies within this context. For specific document retention requirements, please refer to clause 3.3 *Evidence of Compliance* which is contained in the *ANSI Essential Requirements: Due process requirements for American National Standards*.

Note as well that a separate checklist is available for *Technical Reports Registered with ANSI* and documentation required for *Provisional ANS* tracks the requirements in Annex B of the ANSI Essential Requirements (www.ansi.org/essentialrequirements).

2.0 Suggestions to facilitate electronic record maintenance

The following suggestions are offered to facilitate electronic record maintenance:

- Record requirements associated with electronic audits are equivalent to those that are applicable to paper-based audits.
- ASD records should be well organized for ease of retrieval and efficiency of use.
- ASD labeling systems should be clear and descriptive of content to allow identification of the nature of content without opening the electronic record. ASD labeling systems alternatively may include an alphanumeric designation for each document and a separate clear and descriptive index of all documents.
- ASD labeling systems should be used consistently by all persons responsible for creating document labels to ensure accurate document retention and to facilitate document retrieval.

- ASD electronic records should include each document in its entirety, together with supporting documentation, to allow full review by the ASD and the auditor.
- The ASD should include a quality control review with respect to the conversion of hard copy documents to electronic records to ensure that, in each instance, the entire document is accurately and completely converted.
- The ASD should examine compatibility issues with ANSI to ensure accessibility of records by the auditor.
- The ASD should ensure that records are captured electronically in a manner that prevents changes to the records by anyone other than the person creating the original document. Alternatively, the system should allow changes only when information concerning the date, the name of the person making the change, and the reason for the change are documented. This is most important for electronic balloting systems.
- For audits that involve the review of electronic balloting, the ASD should provide a balloting summary from the electronic system that clearly identifies each voting member on the ANS consensus body. A roster for non-voting members should ideally be produced as a separate document. This will facilitate the reconciliation of final voting results attributable to voting members of the consensus body only. If a combined list of ANS consensus body members and others is the only option, then the ANS consensus body members should be included in a separate and clearly identified segment of the list, with interest category, vote and numerical approval information shown separately for segment of the list that shows ANS voting results.
- The ASD should ensure that all records necessary for performance of an audit are available.
- The ASD should make available to the auditor the electronic repository of all necessary records.

2.1 Suggested Ways to Provide Electronic Records/Documentation to the Auditor:

In general, data and electronic records should be retained and organized in accordance with Attachment A. In addition, a developer is encouraged to consider the following:

- Establish a secure site (i.e., Wiki, FTP, dropbox, etc.) for electronic postings. Only appropriate staff from the developer (auditee), the ANSI auditor and the ANSI Audit Director should have access; or
- Provide the audit records to ANSI on a secure Memory Stick or a CD.

Note: Audit records will not generally be accepted if transmitted electronically in multiple e-mails unless the Audit Director has agreed to this format in advance.

3.0 Implementation of Suggested Checklist (Attachment A)

Using Attachment A, a standards developer is able to categorize the records related to evidence of compliance with ANSI's requirements so that each file can be properly identified by an auditor. In addition, a developer can ensure that only records pertaining to the development of the standard(s) being audited are identified for the auditor. A list of items provided for the audit based upon this checklist, together with all appropriate file addresses, should be provided by the developer to facilitate accurate access to records.

Electronic records should be divided into the following categories:

- Policies and Procedures
- Membership Records
- ANSI Forms and Information Provided to ANSI, including:
 - Evidence of Consensus and Consideration of Objections from the Consensus Body
 - Evidence of Consensus and Consideration of Objections from Public Review Commenters
- Other Records (related to selected ANS, Provisional ANS and Technical Reports Registered with ANSI)
- Evidence of Approval by ASD and by ANSI
- Appeals

Comments on the checklist are welcome. Please contact Jay Moskowitz, Director, Standards Developer Audit Program at (212) 642-8925 or by e-mail at jmoskowi@ansi.org.

Attachment A

Audits that Involve Review of Electronic Records Checklist

Policies and Procedures	File Name or Location
Any policies provided during the course of the audit shall be labeled and identified (e.g., Evidence of Compliance, Interpretation, Metric, Appeals Policy, Commercial Terms and Conditions, Antitrust Policy and Patent Policy). (3.0 of ANSI ER)	
Internal ballot procedures and supplemental guidelines or procedures, if applicable.	
Compliance Forms. (4.1.3)	
Procedures used to develop standards that will be audited. (1.9)	

Membership Records	File Name or Location
All membership records for the consensus body and other standards development bodies including invitations and replies from materially and affected interests.	
Membership records including requests from interested parties and replies from the accredited standards developer.	
Evidence of outreach efforts (e.g., direct mailings, press releases, articles in trade press, advertisements, www, etc) to solicit additional participation – in particular for under-represented interest categories (i.e., targeted outreach), when the consensus body appears not to be balanced or has a low number of members. (2.3)	

ANSI Forms and Information provided to ANSI	File Name or Location
Evidence of action taken to approve and/or initiate the project. (2.5)	
PINS Forms for those standards that will be reviewed including ANSI acknowledgement of receipt. (2.5)	
If any PINS deliberations were held, provide evidence of compliance with sections 2.5.1.2 and 2.5.1.3 of the <i>ANSI Essential Requirements</i> (including a copy of the PINS Deliberation Report(s) and any other related documentation) (2.5.1.2 and 2.1.5.3)	
BSR-8/108 Forms for those standards that will be reviewed including notification from ANSI when the Public Review will take place. (2.5)	
BSR-9/109 Forms for those standards that will be reviewed, including complete documentation that was submitted to ANSI in connection with the standard's approval. (4.2.1.1.h)	
BSR-10 Forms for those standards that are maintained under the Stabilized Maintenance option and are subject to audit. (4.7.3)	
Records of requests for any extensions (BSR-11) and responses provided by ANSI. (3.3)	

Evidence of Consensus and Consideration of Objections from the Consensus Body	File Name or Location
Evidence of “good faith efforts” to resolve potential conflicts and to coordinate standardization activities intended to result in harmonized American National Standards (1.4 and 2.4)	
Evidence of follow-up done on votes not cast, if required by accredited procedures.	
Evidence that consensus body members who will be absent or are absent when formal recorded votes are taken at meetings are given the opportunity to vote before or after the meeting. (2.7)	
Record of each comment and objection from members of the consensus body. (2.6)	
Record of how and by whom negative vote(s) were resolved or documented attempts at resolution from the consensus body. (2.6)	
Evidence that any unresolved objections along with their comments and attempts at resolution were reported to the consensus body and the consensus body was afforded the opportunity to respond, revise or reaffirm their votes. (2.6)	
Records for each ballot taken by the consensus body and other relevant bodies including changing of any votes. (2.7)	
Consensus body roster listing: all members; the interest category of each; and how each member voted. (4.2.1.1h)	
Evidence that any persons with unresolved objections from the consensus body were notified in writing of the right to appeal. (2.6)	
Evidence that substantive changes made to the standard were balloted to the consensus body and subjected to an ANSI public review. (2.5, 2.6)	

Evidence of Consensus and Consideration of Objections from the Consensus Body	File Name or Location
Record of each comment and objection from public review commenter(s). (2.6)	
<p>Record of how and by whom negative comments and objections were resolved and documentation related to attempts at resolution of public review commenters. (2.6)</p> <p>Evidence that unresolved objections received from public review along with their comments and attempts at resolution were reported to the consensus body and the consensus body was afforded the opportunity to respond, revise or reaffirm their votes. (2.6, i.e., evidence of recirculation)</p>	
Records for each ballot (e.g., ANS approval, recirculation ballot, etc.) taken by the consensus body and other relevant bodies in response to public review commenters including documentation of any vote changes. (2.6)	
Consensus body roster listing all members with the interest category of each and how each member voted. (4.2.1.1.h)	
Evidence that any persons with unresolved objections from public review were notified in writing of the right to appeal to the standards developer. (2.6)	
Evidence that substantive changes made to the standard were balloted to the consensus body and subjected to ANSI public review. (2.5, 2.6)	

Other Records for ANS, Provisional ANS or TRs Registered with ANSI that are the subject of the Audit	File Name or Location
Minutes/meeting reports of all relevant bodies (consensus body, subgroups, etc.)	
Records of any interpretation requests and how they were handled. (3.5)	
Records of patent holder statements (including evidence that compliant patent letters of assurance for essential patents were provided to ANSI.) (3.1)	
Copies of published ANS, Provisional ANS or TRs. (4.5)	
Evidence that all necessary corrective actions were implemented to address all audit findings from the previous audit.	

Evidence of Approval	File Name or Location
ANSI notification of approval of American National Standard. (3.3)	

Appeals	File Name or Location
Records of each appeal associated with a standard that will be audited.(1.8, 2.8, 3.3)	