



TIPS AND TECHNIQUES FOR ANSI-ACCREDITED STANDARDS DEVELOPERS

COMPLIANCE REFERENCE GUIDE: PHASES OF AN ANSI AUDIT OF AN ANSI-ACCREDITED STANDARDS DEVELOPER

The ANSI Standards Developer Audit Program is intended as a quality assurance review of an ANSI-Accredited Standards Developer's compliance with its accredited procedures and current ANSI requirements. Additionally, it is intended, when appropriate, to offer suggestions for potential process improvement and efficiencies. The ANSI Executive Standards Council (ExSC) has oversight of the ANSI Standards Developer Audit Program and makes all final decisions in connection with an audit and a developer's accreditation status. The procedures that govern the implementation of an ANSI Audit of an ANSI-Accredited Standards Developer are contained in the *ANSI Auditing Policy and Procedures*. The procedures that govern the American National Standards (ANS) process are contained in the *ANSI Essential Requirements: Due process requirements for American National Standards*.

1. Preparation: Contact initiated by ANSI based on a routine audit schedule applicable to all ANSI-Accredited Standards Developers

Initial contact, scheduling and if applicable cost estimates (for special audits and recently accredited standards developers only).

Audit questionnaire provided to developer to complete and return to the Audit Director along with a list of the auditee's American National Standards (ANS) including approval dates, the auditee's latest set of procedures and any additional guidelines or supplemental procedures.

Information gathering and review of auditee's procedures, questionnaire and all relevant information that pertains to the audit.

Pre-audit teleconference with auditee. The teleconference is intended to confirm that the audit will take place in the scheduled timeframe. Additionally, clarification of the scope and content of the audit is provided. The teleconference allows ANSI the opportunity to provide the auditee with any questions that will expedite the process. The teleconference also provides an

opportunity for the auditee to ask any questions, address any concerns the auditee may have and to highlight any standards the auditee would like ANSI to review during the audit.

2. Conduct of Audit

An audit is conducted on-site or remotely. The same documentation is reviewed in either case. Whether a developer maintains electronic or hard copy records, comparable documentation is required and is reviewed. Most audits are conducted remotely. Auditors are required to use ANSI-developed report templates to document their findings, observations and suggestions. The use of standardized report templates developed by the Audit Director with the approval of the ANSI Executive Standards Council, ensures a high degree of consistency, thoroughness and quality.

If an on-site audit is conducted, an informal post-audit conference at the conclusion of the audit will take place. This provides an opportunity for the developer and the auditor(s) to clarify issues that may arise during the course of the audit and to ensure that the auditor's understanding of the implementation of a developer's procedures is consistent with that of the auditee.

3. Post-Audit

Development of audit report with transmittal letter and proper attachments.

A draft summary of findings, observations and suggestions is provided to the standards developer prior to a post-Audit teleconference, which is held to enable the auditors and the standards developer to discuss these findings, observations and suggestions. This teleconference also provides an additional opportunity for the standards developer to clarify relevant information or procedures.

A final audit report is transmitted to the auditee. This report includes a summary of the procedures used by the ANSI-Accredited Standards Developer, findings identified by the auditor, observations regarding procedural implementation issues and suggestions for improving observed/audited processes. If the standards developer was audited previously, then the audit report also addresses previous audit findings and the developer's implementation of corrective actions related to them. The auditee is required to respond in writing within thirty days of receipt of the report. The auditee's response is expected to include plans and a timetable for any required corrective actions related to any findings contained in the audit report. Extensions of time to respond to the audit may be granted by the Audit Director.

4. **Audit Report and Outcomes**¹

The Audit Report and response from the developer are reviewed by the Audit Director and the ANSI Executive Standards Council (ExSC) Audit Sub-Committee. The Audit Sub-Committee may: close the Audit based on the record before it; decide to keep the audit open until such time as the developer submits revised procedures to address the procedural audit findings and is reaccredited; or request that the full ANSI ExSC review the audit report and the developer's response to determine an appropriate action.

Any recommendations by the Audit Sub-committee that may result in a requirement that the standards developer undergo a special audit are presented to the ANSI ExSC at a meeting during an Executive Session. The outcome of that discussion is communicated to the standards developer in writing thereafter by the Audit Director. Some of the outcomes include:

- Audit is closed without further action.
- Procedural revisions are required prior to the closing of an Audit.
- Special audit required (cost is borne by the standards developer).
- Remand the standard to the ANSI BSR.
- A developer's accreditation may be suspended; if adequate corrective actions are not taken, then the accreditation may be withdrawn at a later date.

Decisions of the ANSI ExSC relative to an ANSI Audit may be appealed first to the ANSI ExSC and then finally to the ANSI Appeals Board.

Audit Reports are confidential and are not provided by ANSI to anyone other than members of the ANSI ExSC and, if a special audit is deemed necessary, then to the members of the ANSI Board of Standards Review² (BSR) in connection with their review of evidence of consensus related to a candidate American National Standard. Standards developers may provide the ANSI Audit Report to anyone they wish.

¹ The ANSI ExSC Conflict of Interest Procedures apply to the review of every standards developer's audit report and related documentation.

² Except in the case of an Audited Designator, the ANSI BSR Conflict of Interest Procedures apply to the review of audit documentation in connection with the review of a candidate ANS for approval.