ANSI
American National Standards Institute

American National Standards Process Summary

Mission

To enhance the global competitiveness of U.S. business and the American quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and ensuring their integrity.

ANSI

ANSI is...

- Only accreditor of U.S. Standards Developers

- Only body that approves standards as American National Standards (ANS)

- Represents the US Internationally at ISO (International Organization for Standardization)

- Represents the US Internationally through its US National Committee at the IEC (International Electrotechnical Commission)

ANSI

ANS Governance Bodies

- Executive Standards Council (ExSC)
  - Accredits American National Standards Developers
  - Accredits US Technical Advisory Groups (TAGs) to ISO
  - Oversees Accredited Standards Developer Audit Program
  - Maintains most ANSI procedures and policies
  - Hears appeals and considers complaints

- Board of Standards Review (BSR)
  - Approves American National Standards
  - Hears appeals and considers withdrawal requests

- ANSI Appeals Board (AB)

ANSI

BSR Detail

- Around 10 members
- Review any standards with objections (3 to 5 per week)
- Includes all supporting documentation (20-100+ pages)
- Ensure due process given, procedures followed
- In particular, recirculation, reasons, right to appeal
- Occasional appeal hearings in NYC, rule based on process, not technical content
- Good way to learn the ins and outs

ANSI

Standards Developer Accreditation

- Only ANSI-Accredited Standards Developers may submit their standards through the American National Standard approval process

- ANSI-accreditation signifies that the standards developer is committed to an open, fair and time-tested consensus process that benefits stakeholders and the American public

- ANSI-Accredited Standards Developers are accredited to the requirements contained in the *ANSI Essential Requirements: Due process requirements for American National Standards*

Benefits of Accreditation and ANS approval

- Hallmarks of the ANS Process
  - Openness, due process, consensus by a balance of materially-affected interests, consideration of views and objections
  - Transparency of the process
  - Fundamental fairness - Ensures level playing field
- Minimizes some legal risks by requiring procedural safeguards (re: antitrust, product liability/negligence, etc.)
- Government acceptability (e.g. National Technology Transfer & Advancement Act of 1995)
- Accreditation is a prerequisite for the National Adoption of an ISO or IEC standard as an ANS

ANSI Accreditation Requirements

- A standards developer's written procedures for the development and approval of proposed American National Standards must meet ANSI due process and consensus requirements

1. Openness
2. Balance and Lack of Dominance
   - Discrete interest category definitions
3. Public comment opportunity
4. Consideration of Views and Objections

ANSI Accreditation Requirements

3. Comment Resolution
4. Recirculation Opportunity
5. Consensus Body Vote
6. Numerical Requirements for Consensus
7. Standards Developer Appeals Process
8. Policy for Retention of Evidence of Compliance
9. Compliance with ANSI's Patent Policy
10. Compliance with ANSI's Commercial Terms and Conditions Provisions
11. Interpretations and Metrics Policies

Maintenance of Accreditation

- Procedural audit typically once every 5 years

- Submission of periodic compliance forms when ANSI's procedural requirements change

- Submission of procedural revisions for approval (reaccreditation process: similar to steps in the accreditation process)

- Payment of ANSI Membership/Maintenance of Accreditation Dues

THE AMERICAN NATIONAL STANDARD DESIGNATION

SIGNIFIES THAT STANDARDS…

➢ Are developed using fair, open process that ensures a level playing field

➢ Meet the needs of materially affected interests

➢ Are voluntary – compliance is not required unless adopted by regulation or statute

ANSI

CONSENSUS...

...MEANS SUBSTANTIAL AGREEMENT HAS BEEN REACHED BY DIRECTLY AND MATERIALLY AFFECTED INTERESTS CATEGORIES. THIS SIGNIFIES THE CONCURRENCE OF MORE THAN A SIMPLE MAJORITY, BUT NOT NECESSARILY UNANIMITY. CONSENSUS REQUIRES THAT ALL VIEWS AND OBJECTIONS BE CONSIDERED, AND THAT AN EFFORT BE MADE TOWARD THEIR RESOLUTION

ANS APPROVAL PROCESS

- Each Standard, every five years
- Stage 1: **PINS form** to ANSI
  - Announcement of project initiation *Standards Action.*
  - PINS deliberation if claim of conflict or duplication is raised
- Stage 2: Approval of draft
  - Consensus body approves text of draft standard
  - Must meet numerical requirements for consensus as described in developer's accredited procedures (e.g. approval by a majority of consensus body and 2/3 of those voting, etc.)
- Stage 3: Public Review
  - **BSR-8 form** initiates announcement in *Standards Action.* Developer may also announce in industry publications, etc. (multiple public reviews are possible)

ANSI

ANS APPROVAL PROCESS

➢ <u>Stage 4:</u> Comment resolution

  • Public and consensus body member comments

➢ <u>Stage 5:</u> Recirculation (if applicable)

  • Unresolved negative comments from consensus body members and public review commenters as well as any substantive changes to the text, must be recirculated to the entire consensus body to allow them to vote, reaffirm a vote or change a vote

➢ <u>Stage 6:</u> Appeals at developer level

ANS Approval Process

➤ <u>Stage 7:</u> Submittal to ANSI for approval

- Submittal of final standard for approval with evidence of consensus (**BSR-9 form**)

➤ <u>Stage 8:</u> Notification

- Notification of final approval/disapproval

➤ <u>Stage 9</u>: Appeal at ANSI

- Hearing is scheduled if appeal is filed

ANSI

Appeals
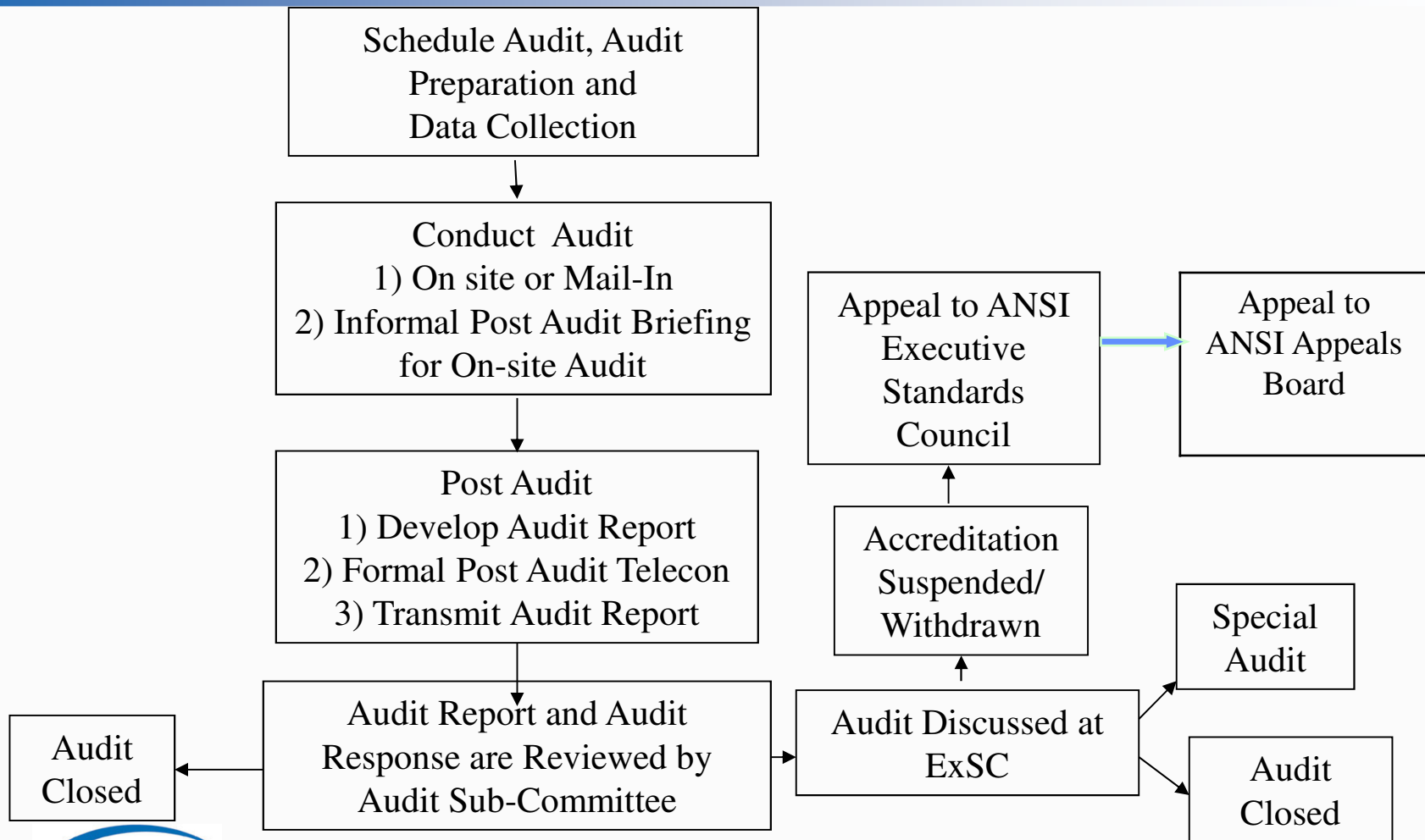
- Informal resolutions encouraged

- Appeals to a developer: in accordance with accredited procedures

- Appeals to ANSI:

  ➢ Board of Standards Review (BSR) – ANS

  ➢ Executive Standards Council (ExSC) – accreditation and procedural compliance issues

  ➢ Appeals Board – final level after the BSR or ExSC appeal concludes

ANSI

Audit Process – Summary Flow

```
┌─────────────────────────────┐
│    Schedule Audit, Audit    │
│       Preparation and       │
│       Data Collection       │
└─────────────────────────────┘
              │
              ▼
┌─────────────────────────────┐
│        Conduct  Audit       │
│  1) On site or Mail-In      │
│  2) Informal Post Audit     │      ┌──────────────┐         ┌──────────────┐
│     Briefing for On-site    │      │ Appeal to    │         │  Appeal to   │
│     Audit                   │      │ ANSI         │ ──────▶ │ ANSI Appeals │
└─────────────────────────────┘      │ Executive    │         │    Board     │
              │                      │ Standards    │         │              │
              ▼                      │ Council      │         │              │
┌─────────────────────────────┐     └──────────────┘         └──────────────┘
│        Post Audit           │            ▲
│  1) Develop Audit Report    │      ┌──────────────┐
│  2) Formal Post Audit       │      │ Accreditation│
│     Telecon                 │      │ Suspended/   │          ┌──────────┐
│  3) Transmit Audit Report   │      │ Withdrawn    │          │ Special  │
└─────────────────────────────┘      └──────────────┘          │  Audit   │
              │                             ▲                   └──────────┘
              ▼                                                      ▲
┌────────┐  ┌──────────────────────┐  ┌──────────────┐
│ Audit  │◀─│ Audit Report and     │─▶│ Audit        │
│ Closed │  │ Audit Response are   │  │ Discussed at │         ┌──────────┐
│        │  │ Reviewed by Audit    │  │ ExSC         │─────────│  Audit   │
│        │  │ Sub-Committee        │  │              │         │  Closed  │
└────────┘  └──────────────────────┘  └──────────────┘         └──────────┘
```

ANSI

ANSI's Standards Action

- www.ansi.org/standardsaction

- Available freely to the public

- Published every week

- Includes national and international activity

- Announces: PINS (project initiation notices); public review periods for American National Standards: accreditations and standards; and final approval decisions.

- Announces meetings, all actions re: ANS; any proposed revisions to ANSI procedural requirements, etc.