



Overview of the American National Standards Process

Presented by

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NIST Panel on Open Standards
March 13, 2006

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 is...

- The accreditor of U.S. Standards Developers
- The body that approves standards as American National Standards (ANS)
- The representative of the US Internationally at ISO (International Organization for Standardization)
- The representative of the US Internationally through its US National Committee at the IEC (International Electrotechnical Commission)

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)

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*

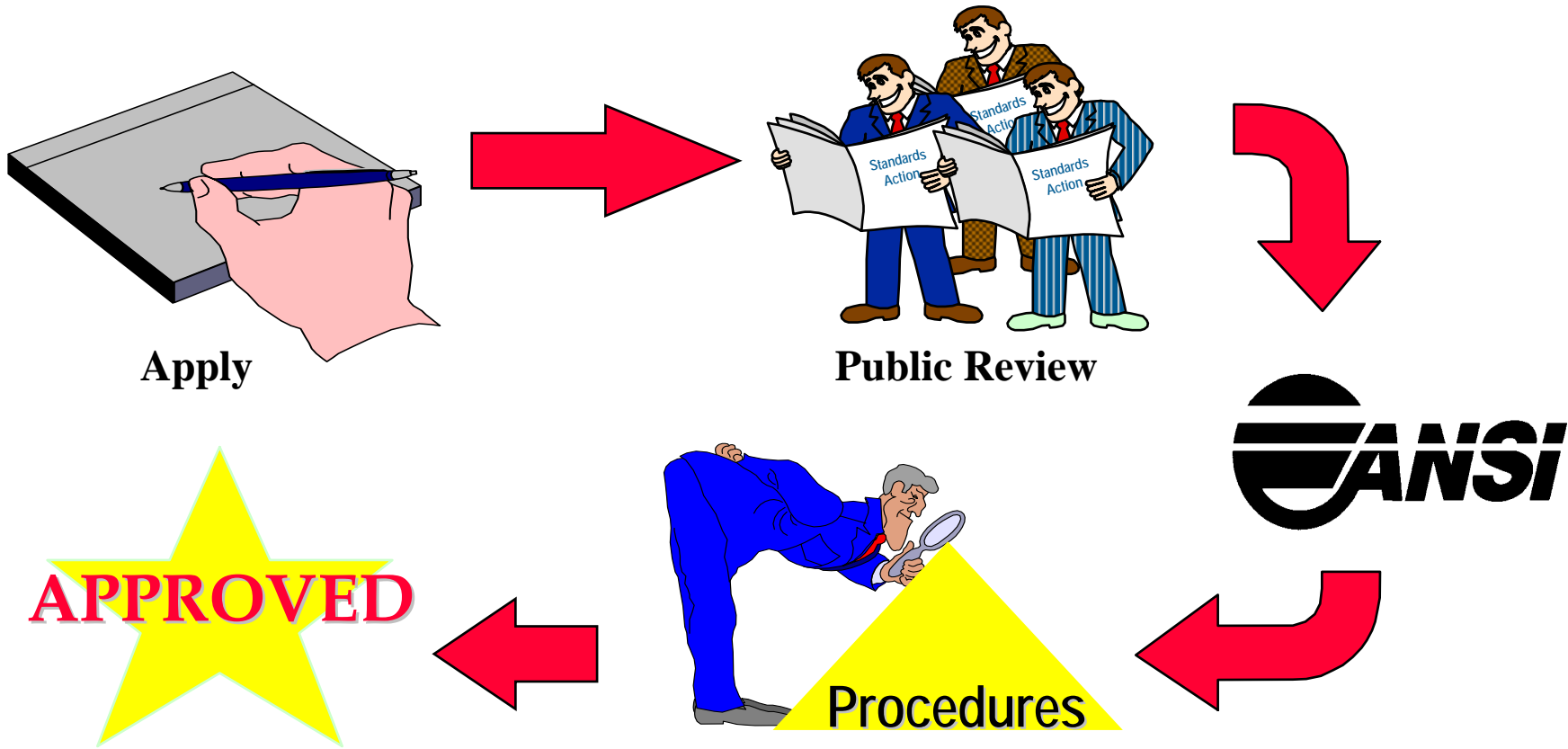
ANSI Accreditation Requirements

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

ANSI Accreditation Requirements

- 1. Openness
- 2. Balance and Lack of Dominance
- 3. Consideration of Views and Objections
- 4. Appeals Process
- 5. Audit Requirement
- 6. Patent Policy

Accreditation Process



Apply

Public Review

Review of Due Process Requirements

Accreditation

Procedures



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

Accredited Standards Developers

- Currently there are about 200 ASDs
- Developing standards in virtually all industry sectors including:
 - *manufacturing;*
 - *health and medical devices;*
 - *telecommunications,*
 - *information technology and interoperability.*

The *American National Standard* Designation

Signifies that standards...

- Are developed using fair, open process that ensures a level playing field
- Meet the needs of producers, users, the public and other relevant interest groups
- Are voluntary – compliance is not required unless adopted by regulation or statute

ANS Approval Process

- Stage 1: PINS form to ANSI
 - Announcement of project initiation
- 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)

ANS Approval Process

- Stage 4: Comment resolution
 - Public and consensus body member comments

- Stage 5: Recirculation (if applicable)
 - Unresolved negative comments from consensus body members and public review commenters must be recirculated for consensus body review

- Stage 6: Appeals at developer level

ANS Approval Process

- Stage 7: Submittal to ANSI for approval
 - Submittal of final standard for approval with evidence of consensus (BSR-9 form)

- Stage 8: Notification
 - Notification of final approval/disapproval

- Stage 9: Appeal at ANSI
 - Hearing is scheduled if appeal is filed

ANSI's View of What “Open” Means

- When ANSI uses the term “open” or “openness” in connection with standards, it is referring to this process for ANSI accreditation and ANS approval, a process that reflects:
 - Consensus
 - Broad-based public review and comment
 - Consideration of and responses to such comments
 - Appeals
 - Promotion of access to essential IPR without undue financial burden while permitting reasonable license fees and/or other reasonable and non-discriminatory terms.
- for more information: www.ansi.org/standards/cips

Beyond ANSI's ANS, Other Ways ANSI Brings together Diverse Groups to Respond to National Priorities

- A key mission for ANSI in 2006 is to “promote standards panels as a mechanism to address standards coordination and facilitation needs related to emerging national priorities.”
- Panels are formed to address a specific subject area or critical issue where standards coordination and facilitation is needed in a timely manner
- Panels bring diverse groups together and allow ANSI to work with standards developers and with public and private sector subject matter experts to determine current state of standardization and what needs to be done
- Panels allow ANSI to quickly respond to a national priority

Examples of Panels at ANSI

- Information Infrastructure Standards Panel (IISP) formed in 1994; turned into a maintenance committee in 1998
 - *Mission: Promote cross-sectoral efforts in order to highlight and resolve major standards issues and accelerate the deployment of the Information Infrastructure*
- Homeland Security Standards Panel (HSSP) formed in 2003
 - *Mission: Facilitate the development and enhancement of homeland security standards*

Examples of Panels at ANSI

- Nanotechnology Standards Panel (NSP) formed in 2004
 - *Mission: Serve as the cross-sector coordinating body and provide the framework within which stakeholders can work cooperatively to promote, accelerate and coordinate the timely development of useful voluntary consensus standards to meet identified needs related to nanotechnology.*
- Healthcare Information Technology Standards Panel (HITSP) formed in 2005
 - *Mission: Serve as a cooperative partnership between public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software applications, as they will interact in local, regional and nationwide health information network of the U.S.*