

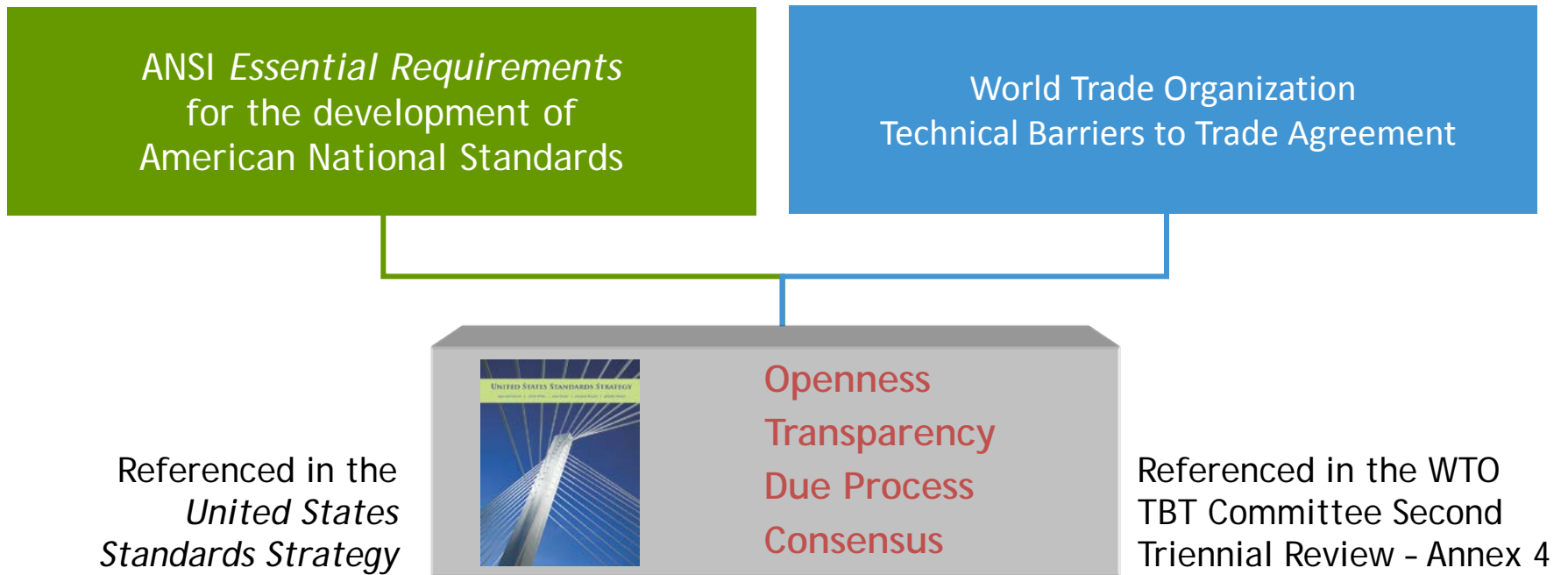


Avoiding Duplication and Achieving Consensus in Standardization: **ANSI Essential Requirements**

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U.S. Standardization System

- ANSI accreditation of SDOs and U.S. TAGs promotes alignment with the WTO's Internationally Recognized Principles for Standards Development



Setting the stage: ANSI's Definition of Consensus*

- Substantial agreement has been reached by directly and materially affected interest 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.
 - *Every ANSI-Accredited Standards Developer's procedures include a definition of consensus; the definitions vary but must be applied as written and must be consistent with ANSI's definition*
 - *More than a numerical determination – numbers + a fair process and compliance with ANSI's requirements*

*Annex A of *ANSI Essential Requirements: Due process requirements for American National Standards*: www.ansi.org/essentialrequirements

Accreditation as a Standards Developer: for American National Standards (ANS)

At ANSI:

- Accreditation as a standards developer relates to the procedures used in relation to American National Standards (ANS) only.
- Accreditation means that a standards developer's procedures with respect to ANS meet the due process based criteria established in the "ANSI Essential Requirements".
- Once accredited, a standards developer uses those procedures to develop evidence of consensus with respect to the content of a proposed ANS.

What is ANSI's role in the ANS process?

ANSI Members/Program Oversight Committees

- Oversee the integrity of the ANS consensus process by assessing evidence of procedural compliance with ANSI's *Essential Requirements*
- Accredite (and reaccredite) standards developers (procedures)
- Approve individual standards as American National Standards (ANS)
- Audit ANS for procedural compliance
- Hear procedural appeals related to ANS
 - Were procedures followed?
 - Was a comment afforded due process?
 - Is a developer in compliance with ANSI's requirements?
- Consider whether an ANS designation should be withdrawn for cause (at any time)
- Maintain and revise the procedures that govern the ANS process

ANSI Essential Requirements (2015)

- All ASDs are bound by the *ANSI Essential Requirements* and their ANSI-Accredited Procedures
- Broad flexibility in consensus process models used by ASDs, some variables:
 - Layers of review and approval
 - Numerical requirements
 - Votes at meetings or via ballot
 - In-person meetings, webinars, teleconference, mail/hard copy
 - Concurrent or sequential steps
 - Use of electronic systems to support the consensus process
 - Starting with a draft or from scratch
 - Any document that is not yet an “ANS” is “draft” or “proposed”

Overarching Consideration of ANS Process: Due Process

- Due process means that any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by:
 - expressing a position and its basis
 - having that position considered
 - appealing if adversely affected
- Due process allows for equity and fair play
 - Fairness and consistency are safeguards

ANSI Essential Requirements - Criteria for ANS consensus

- *ANSI's Essential Requirements* (see clauses 1.0 & 2.0)
 - Openness
 - Lack of dominance
 - Balance
 - **Coordination and harmonization**
 - Notification of standards development
 - **Consideration of views and objections**
 - **Consensus vote**
 - Procedural appeals
 - Written procedures

1.1 Openness

- Participation shall be open to all persons who are directly and materially affected by the activity in question.
- There shall be no undue financial barriers to participation.
- Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

1.2 Lack of Dominance

- The standards development process shall not be dominated by any single interest category, individual or organization.
- *Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.*

1.3 Balance

- The standards development process should have a balance of interests.
 - Balance is important and shall be sought
- Participants from diverse interest categories **shall** be sought with the objective of achieving balance.
 - Evidence of outreach shall be available to the BSR via the BSR-9 submittal and in connection with an ANSI Audit
- *Balance and lack of dominance are two different concepts: for example, a balanced consensus body does not preclude the exercise of dominance (as defined within the ANSI Essential Requirements)*

1.4 Coordination and Harmonization

- Good faith efforts shall be made to resolve potential conflicts between and among existing ANS and candidate/proposed ANS
 - ANSI's jurisdiction reaches ANS and already announced proposed ANS *only*
 - ANSI's definition of conflict applies (next slide)
 - ANSI BSR makes final decision (unless AD, then ExSC review)

2.4 Coordination and Harmonization

2.4.1 Definition of Conflict

- Conflict within the ANS process refers to a situation where, viewed from the perspective of a future implementer,
- the terms of one standard are inconsistent or incompatible with the terms of the other standard
- such that implementation of one standard under terms allowable under that standard would preclude proper implementation of the other standard in accordance with its terms.

2.4 Coordination and Harmonization

2.4.2 Coordination/Harmonization

- ANSI-Accredited Standards Developers shall make a good faith effort to resolve potential conflicts and to coordinate standardization activities intended to result in harmonized American National Standards^[3].
- A “good faith” effort shall require substantial, thorough and comprehensive efforts to harmonize a candidate ANS and existing ANSs. Such efforts shall include, at minimum, compliance with all relevant sections of these procedures^[4].
- Developers shall retain evidence of such efforts in order to demonstrate compliance with this requirement to the satisfaction of the appropriate ANSI body.

[3] Note that clause 4.2.1.3.4 *Withdrawal for Cause* provides a mechanism by which an interested party may at any time request the withdrawal of an existing ANS.

[4] For example, see clauses 2.1, 2.4, 2.5, 2.6 and 4.3. (Next slide.)

Good Faith Efforts Relate To...

- 2.1 Openness
- 2.4 Coordination and harmonization
- 2.5 Notification of standards development and coordination
- 2.6 Consideration of views and objections
- 4.3 Planning, coordination and public notice
- “Good faith efforts” reflected in:
 - Timely and clear communications
 - Response to inquiries and proposals
 - Genuine and appropriate efforts to discuss issues
 - Documented efforts

2.5.1.2 Assertions of conflict or duplication

- If a developer receives written comments within **30 days** from the publication date of a PINS announcement in Standards Action
 - *And comments assert that a proposed standard duplicates or conflicts with an existing ANS or a candidate ANS that has been announced previously (or concurrently) in Standards Action*
- a *mandatory deliberation* of representatives from the relevant stakeholder groups shall be held within **90 days** from the comment deadline
- the *purpose* of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project

2.5.1.2 Assertions of conflict or duplication

- The *purpose* of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project.
- PINS Deliberation Common Outcomes
 - Agreement to undertake a joint standard
 - One party abandons a project or modifies scope
 - Parties agree to continue discussions/coordination throughout the process, e.g., liaison members
 - Involved parties agree to disagree and proceed

2.6 Consideration of Views and Objections

- Each unresolved objection and attempt at resolution, and any substantive change made in a proposed American National Standard shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond, reaffirm, or change their vote.
 - This is the “recirculation”, “reconsideration” requirement
 - All members of the ANS consensus body, not just those that voted on the main/first ballot to approve as an ANS
 - Include unresolved objections, attempt at resolution and any substantive change
 - If a voter does not respond to a recirculation opportunity, then his/her original vote stands, otherwise, the vote on recirculation trumps the original vote
 - See recirculation interpretations (www.ansi.org/asd)

1.7 Consensus Vote

- Evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer shall be documented.
 - All related evidence is subject to review by the ANSI BSR or ANSI ExSC and ANSI Audit
 - *NB: A vote to approve a response to comments is NOT the same as a final vote to approve a standard as an ANS*
 - *Please be mindful of the language that you use on ballots – be clear and concise*

2.7 Consensus Vote

- To recap, pay close attention to clause
2.7 Evidence of consensus and consensus body vote
 - Numerical requirement is only part of the definition of consensus
 - Documentation of votes and vote changes required
 - When votes to approve a standard as an ANS are taken at a meeting, absent members shall be given the opportunity to vote before or after the meeting – separate from the recirculation
 - Reporting and handling negative votes without comment
 - Flexibility re: negative votes unrelated to revision underway
 - Philosophical comments or repeat comments cannot be ignored
 - With clear instruction, a negative vote without comment or a negative vote accompanied by comments not related to the proposal, does not require an attempt at resolution

ANSI and the US Standards System...

- A public-private partnership developing strategies and standards-based solutions for a strong nation and a safer, healthier world...
 - STRENGTH – openness, fairness and diversity make the US standards system strong
 - INNOVATION – standards spur and support innovation
 - ACTION – standards are responsive to human and market needs
 - GROWTH – standards facilitate economic growth and keep us competitive
 - PRODUCTIVITY – standards promote and support productivity
 - SOLUTIONS – standards-based solutions address issues of national, regional and international importance
 - PARTNERSHIP – everyone has a voice and all are welcome
 - COLLABORATION – stakeholders work together to develop solutions

Helpful Resources

- ANSI Essential Requirements: www.ansi.org/essentialrequirements
- Summary of ANS process steps: www.ansi.org/anskeysteps
- List of ANSI-Accredited Standards Developers: www.ansi.org/asd
- ANS Value Brochure: www.ansi.org/ansvalue
- ANSI Standards Action (weekly information about proposed and approved ANS): www.ansi.org/standardsaction
- NSSN: www.nssn.org
- Standards Boost Business: www.standardsboostbusiness.org
- Learn more: www.standardslearn.org
- Staff are available via psa@ansi.org

For More Information

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