Overview of the ANSI Essential Requirements:

Sections 1.0 & 2.0

- The webinar will start at 2pm Eastern
- All participants are muted for the duration of the webinar
- Slides will be distributed to all via email
- Please use the CHAT option to submit a question and send it to “All Panelists” (Not to Host)
- This session will be recorded and the recording may be available at a later date
Let’s get started...

• On behalf of ANSI, thanks very much for joining us today
• A huge thank you to those of you who are already involved in standards...you literally make the world a better place
• Goals (Agenda) for the next 120 minutes:
  ✓ Walk through the 2022 ANSI Essential Requirements (www.ansi.org/essentialrequirements)
  ✓ Raise your awareness
  ✓ Answer your questions
• Deeper dives will be discussed during June-July 2022 webinar series, so please register in advance
Just a reminder...
ANS-Related ANSI Staff - psa@ansi.org

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• Patty Griffin, ANSI Sr VP & General Counsel – NY
• Procedures & Standards Administration - NY
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  • Mary Weldon – NY – 4908, mweldon@ansi.org
• psa@ansi.org = our common email box
American National Standards
Let’s focus on one topic: American National Standards (ANS)

- 238 ANSI-accredited standards developers (ASD) [www.ansi.org/asd](http://www.ansi.org/asd)
- ANSI Essential Requirements: due process requirements for American National Standards ([www.ansi.org/essentialrequirements](http://www.ansi.org/essentialrequirements))
  - “ANSI Essential Requirements” and an ASD’s accredited procedures govern the ANS process
- Only ASDs may submit standards for approval as ANS
  - Accreditation by ANSI is a pre-condition for submitting a standard for approval as an ANS
  - All ANS are maintained on a regular cycle to ensure currency
- Approximately 13,000 American National Standards
- All ASDs are subject to ANSI’s neutral third-party oversight including a regular procedural audit
  - Not all standards developed by these organizations are approved as ANS
  - ANSI’s rules apply only to ANS

Learn more: [www.ansi.org/ansvalue](http://www.ansi.org/ansvalue)
Enhanced ANSI Website (www.ansi.org)

✓ ANS - Background:
https://www.ansi.org/american-national-standards/ans-introduction/overview#introduction

✓ ASD – Developer focused:
https://www.ansi.org/american-national-standards/info-for-standards-developers/standards-developers

✓ General Public - participation:
https://www.ansi.org/american-national-standards/info-for-the-general-public/general-public

✓ Standards Action page with resources
https://www.ansi.org/resource-center/standards-action
Where can I find ANS information?

www.ansi.org/asd

1. List of ANSI-Accredited Standards Developers (ASD) with a scope and contact
2. List of **proposed** ANS (point-in-time)
3. List of **approved** ANS (point-in-time)

www.ansi.org/StandardsAction

- ANSI’s free public notice vehicle for ANS
- Published weekly on Friday afternoon
- Includes proposed ANS and open public comment opportunities, recruitment and meeting notices, plus...
Who makes decisions about ANS-related actions?

3 main committees populated by ANSI members:

- ANSI Executive Standards Council (ExSC)
- ANSI Board of Standards Review (BSR)
- ANSI Appeals Board
  - All serve as fiduciaries and neutral, knowledgeable professionals
  - Oversight role and decision-making is subject to conflict of interest procedures

See next slide
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
- Maintain and revise the procedures that govern the ANS process - ExSC
- Accredit (and re-accredit) standards developers (procedures) - ExSC
- Approve individual standards as American National Standards (ANS) – BSR, Audited Designators
- Audit ANS for procedural compliance - ExSC
- 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, after ANS approval) - BSR
The “ANSI Essential Requirements”
Our Framework For Today…

• ANSI Essential Requirements: Due process requirements for American National Standards - January 2022
  • www.ansi.org/EssentialRequirements
  • Governs the ANS process
Review: Cardinal Principles of the Consensus Process

- Due Process
- Consensus
- Openness
- Balance
Overarching Consideration of ANSI Process: Due Process (Section 1.0 Intro)

• ANSI perspective: **Due process** means that any party (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
Overarching Consideration of ANS Process: Due Process

✓ The ANSI Essential Requirements (www.ansi.org/essentialrequirements) in their entirety provide a framework for due process

✓ Proper implementation of the ANSI Essential Requirements and an ANSI-Accredited Standards Developer’s (ASD’s) procedures promote openness and consensus and mitigate risk

➢ To support due process: 1) a developer’s procedures should be readily available; and 2) communications should specify timeframes and deadlines, which should be clear, known and adhered to by all
ANSI Essential Requirements

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• ANSI’s *Essential Requirements* (see sections 1.0 & 2.0)

  1.1 Openness (2022)
  1.2 Lack of dominance
  1.3 Balance (2022)
  1.4 Coordination and harmonization
  1.5 Notification of standards development (2022)
  1.6 Consideration of views and objections
  1.7 Consensus body vote
  1.8 Procedural appeals (2022)
  1.9 Written procedures
ANSI Essential Requirements (Continued)

• All ASDs and accredited procedures must comply with ANSI’s requirements related to (see 3.0):
  • ANSI Patent Policy (3.1) - 2020
  • Commercial terms & conditions (3.2) - 2021
  • Antitrust policy (3.3)
  • ANS record retention/evidence of compliance (3.4)
  • Metric policy (3.5)
  • Interpretations policy (3.6)
  • Publication (4.4) & maintenance requirements (4.7)

• 4.0 Normative ANSI Administrative Procedures
• 5.0 ANSI Audited Designator
• Annex A: Definitions (select, not all)
• Annex B: Provisional ANSI
ANSI’s Definition of Consensus – as Consensus is the goal

• Consensus requires due process
  • More than a numerical determination

• Consensus requires that all views and objections be considered, and that an effort be made toward their resolution.
  • Consensus means substantial agreement has been reached by directly and materially interested parties. 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.

➢ When assessing your standards development process, ask yourself:
  • Was the process open and fair and implemented as written?
  • Were good faith efforts made to:
    • Make the process and information about it accessible
    • Provide public notice
    • Engage stakeholders
    • Engage underrepresented stakeholders
    • Provide meaningful opportunities to participate
Consensus Body (Voting Group, Committee, TC, Canvass List, etc.) - applicability of 1.0 & 2.0

• ANSI Definition: The group that approves the content of a standard and whose vote demonstrates evidence of consensus.

• Must be identifiable in a developer’s procedures

• ANSI’s relevant procedural requirements apply to the ANS consensus body only, unless a developer’s procedures state otherwise, e.g., working group
Something to think about today re access to information: How easily can stakeholders …

- Find your ANSI-Accredited Procedures?
- Recommend changes to your procedures?
- Learn about the formation of a consensus body?
- Understand how to apply to join a consensus body?
- Find information about the development of a draft document and any meetings and deadlines?
- Find draft documents for comment?
- Understand how/when to submit public comments?
- Find or request an ANS Consensus Body Roster?
- Know who to contact with questions about a document or a process or your organization?
Early Questions?
Sections 1.0 *Essential Requirements for due process* & 2.0 *Benchmarks*
Summary of key revisions in the 2022 ANSI Essential Requirements

• **Openness:** move existing “Affiliation” footnote to main text to promote transparency

• **Balance:**
  • The interest category of a voting member is to reflect the business or other interests of their primary source of support for participation on the consensus body
    • Clarification concerning the use of a General Interest category
    • Edits to footnote re: “further interest categories”
  • New definitions: “sponsor” and “consultant”
  • Reinforcing statement that sub-categories of interest categories should not be used to circumvent balance requirements
Summary of key revisions in the 2022 ANSI Essential Requirements

• Project Initiation Notification System (PINS):
  ✓ **New requirement:** list anticipated interest categories expected to comprise the consensus body to promote transparency –
    • *PINS Form online already updated*
  ✓ **New requirement:** ASD must provide a written response to a request for further information on a project or to discuss it

**REMINDER:** If you use the Excel option for multiple PINS, please download the newly updated file. Please do not use the prior version as it does not have the new field. Thanks!
Summary of key revisions in the 2022 ANSI Essential Requirements

• Emphasis on timely and adequate notice of standards development activity in media suitable to demonstrate that a meaningful opportunity for participation by all directly and materially interested parties in a fair and equitable manner was provided.
  ✓ Website posting is good, but more is required

• Appeals: Clarifications to better explain ANSI’s appeals processes and reference to applicable procedures based on the type of appeal, e.g., ANS vs accreditation

• Appeals: Confirmation that an ASD-level appeals decision must be issued in writing
1.1 Openness

- Participation shall be **open** to all parties who are directly and materially interested in 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.
  - A developer cannot categorically exclude a type of entity or an individual from **applying for** ANS consensus body membership
  - “Undue financial barriers” – relative term, related to the market, but a developer should be able to defend any fee structure upon appeal
  - A developer cannot require that anyone join its or any organization in order to apply for/join an ANS consensus body
    - A “participation” fee, or the like, e.g., “affiliate” status, is an option
    - It is **not** sufficient to provide notice to your organization’s members only
1.1 & 2.1 Openness

- Timely and adequate notice of any action to create, revise, reaffirm, or withdraw a standard, and the establishment of a new consensus body shall be provided to all known directly and materially interested parties.

- Notice should include a clear and meaningful description of the purpose of the proposed activity and shall identify a readily available source for further information.
  - ASDs are expected to identify or know how to reach stakeholders in the scope of activity in which they are developing proposed ANS
  - Websites, social media, direct emails/mail, announcements at conferences and meetings, colleagues of consensus body members, professional organizations in the field, consumer organizations when relevant (see new guidance in July 2022), ANSI Standards Action (special announcements)
  - Don’t ever ignore the obvious
1.1 & 2.1 Openness

• **CB Roster:** In addition, the member’s name (or if membership is by organization, the name of the organization with a point of contact), affiliation and interest category of each member of the consensus body shall be made available to interested parties upon request.

• The **affiliation** of a consensus body member refers to the entity that the consensus body member represents, which may or may not be that person’s employer. If the consensus body member is serving in an individual capacity, then the name of the individual, their sponsors [1] (if any) and interest category shall be made available upon request. Contact information is not required.

• [1] A sponsor is defined as an organization that provides funds specifically to support the individual’s participation in the standards activities of the consensus body.

  ✓ *See 2022 Q&A for more on this topic*
1.5 Notification of Standards Development - *goes to “openness”*

- Timely and adequate notice of standards development activity shall be announced in **media suitable to demonstrate** that a meaningful opportunity for participation, debate and deliberation by all directly and materially interested parties in a fair and equitable manner was provided.
  - Notice required - more than *Standards Action* alone
  - Notice to more than your organization’s members
  - Section 2.5 covers: PINS, PINS Deliberation & Reporting and BSR-8/Public Review Requirements
Discussion of Common Misunderstandings - Openness

• Membership in an ASD’s organization vs. membership on an ANS consensus body

• Cannot categorically prohibit someone from applying for consensus body membership, but can create and require an application

• Participation fees (vs. Membership)
  • Vary by sector/market
  • Neither the ANSI ExSC nor the ANSI BSR approve fees, though they would adjudicate “undue barriers to participation”

• The opportunity to attend public portions of a consensus body meeting should exist and agendas should be available

• Public notice in ANSI Standards Action alone is not sufficient, but notice in ANSI Standards Action can help demonstrate targeted outreach (more under 1.3 and 1.5) – See GUIDANCE document
Good practices - Openness

• **Public notice** - posted on website, known sources of information regularly consulted by stakeholders, broad press releases, meeting notices and through social media
  • You should know your stakeholders! (More later…)

• **Procedures** are readily available

• Establish a routine “public notice” mechanism/distribution to ensure consistency (update lists/outlets regularly)

• Implement **consistent consensus body application and related review process**

• Establish a queue for eligible applicants if space on the consensus body is not available

• Consider **non-voting alternatives** to consensus body membership and public review
Considerations - Openness

• Implement a Code of Conduct
  • See ANSI’s [https://www.ansi.org/publicstatements/Code-of-Conduct](https://www.ansi.org/publicstatements/Code-of-Conduct)
  • Another example – ISO’s Code of Conduct

• Expectations for participation and consequences for failure to participate in good faith should be clear
  ✓ May be part of a consensus body membership application or a free-standing document, signed by participants/consensus body members
  ✓ Include in your organization’s accredited procedures or “welcome kit”
  ✓ Linked to agendas and meeting reports
  ✓ Reviewed at the start of a meeting
  ✓ Circulate annually in January of each year to all consensus body members
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.*

2.2 Lack of dominance

Unless it is claimed in writing (including electronic communications) by a directly and materially interested party that a single interest category, individual or organization dominated the standards development process, no test for dominance is required.

- If someone claims dominance in writing, it must be reviewed by the ASD, it cannot be ignored
- Evidence can refute or show the *exercise of undue influence* *(next slide)*
1.2 Lack of dominance - Guidance

A specific test for dominance is not defined in the ANSI Essential Requirements. However, in assessing whether an attempt is being made to exclude the fair and equitable consideration of other viewpoints, a developer may consider whether one or more person(s)/organization(s)/interest group(s):

- is deliberately acting in a way which precludes others from having the opportunity to express their viewpoints;
- submits comments that are intended to or always cause a new vote;
- takes actions to “control” the agenda, the meeting schedule, ballot issuance, membership on the consensus body and/or related work groups.
1.2 Lack of dominance - Guidance

• Some potential ways to reduce the likelihood of dominance arising include, but are not limited to:
  
  • A knowledgeable **Chair** is in place to ensure fairness and due process and a productive meeting
  
  • Participants’ sponsors should be known so it is clear whose interests are being represented/advanced (**transparency**)
  
  • A clear, public meeting **agenda** is issued and available in advance of a meeting discussion.
  
  • **Staff is knowledgeable** of applicable procedures and demonstrates compliance with them through actions, meeting reports, ballots, etc., and **Staff is neutral**
  
  • In relation to meeting discussions, as appropriate, consider utilizing a timekeeper/time clock - establish **time allocations** for each agenda item and publish this on the agenda
  
  • Keep a **queue** during meeting discussions (including virtual) and ensure all who wish to speak have that chance before someone gets a second or additional opportunity
  
  • Be mindful of the interest categories represented on the consensus body versus those represented at a meeting to ensure, to the greatest extent possible, an opportunity for **all viewpoints** to be heard and considered.
1.2 Lack of dominance - Guidance

- A claim of dominance is considered a procedural grievance that is to be reviewed by the developer in a timely manner ("real time", not at the end of the process) and is later eligible for review again within the appeals process at the standards developer level and subsequently, at ANSI.
  - Your written record speaks for itself
    - Always comply with your accredited procedures
    - Always take the high road
    - Always try to resolve issues informally
  - Your actions matter
    - Fairness to all is a balancing act...sometimes trying to resolve one person’s issue is viewed as unfair to all other members, so always assess the full picture
  - Your neutrality, as the administrator of the process, matters
  - Your accessibility, as the administrator of the process, matters
1.2 Lack of dominance - Guidance

• Address any claims of dominance in a timely and meaningful way
  • Document any such review
  • Engage officers, who are obliged to be neutral
  • Recuse any involved party with a conflict of interest

• Ensure that all involved staff are expert in your accredited procedures as they are safeguards against such claims – *if someone isn’t expert, be sure they read the procedures and refer to them*

• As appropriate, legal claims should be brought to the attention of your Legal Counsel
1.3 Balance

• The standards development process should have a balance of interests.

• Participants from diverse interest categories shall be sought with the objective of achieving balance.

• If a consensus body lacks balance in accordance with the historical criteria for balance (see 2.3), and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

  • Balance is important and shall be sought
  • Evidence of outreach – and targeted outreach as needed - shall be available to the BSR via the BSR-9 submittal and in connection with an ANSI Audit
    • Vigorous efforts, as needed, are expected
  • Balance and lack of dominance are two different concepts: for example, a balanced consensus body does not preclude the exercise of dominance
2.3 Balance

• Historically, the criteria for balance are that:
  a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards; or,
  b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards...

• *Your organization’s accredited procedures may differ – know what they say*

• **Targeted outreach** to solicit participation from one or more interest categories, when needed, is important and is required to be documented

• ANSI does not define “safety-related” standards, but a standard that includes “safety” in the title or scope is assumed to be one

• If safety-related standards are developed, then associated balance requirements must be addressed in an ASD’s procedures
2.3 Balance (2022 updates)

• The interest categories appropriate to the development of consensus in any given standards activity are a function of the nature of the standards being developed.

• Consensus body members, including consultants, typically are classified in accordance with the business or other interests of their employers or the sponsors they represent in connection with the standards development activity.

• In cases where a consensus body member receives funding from the sponsoring ANSI-Accredited Standards Developer (ASD) or other entities, that information shall be disclosed to determine if it will impact the member’s interest classification.

• A sponsor is defined as an organization that provides funds specifically to support the individual’s participation in the standards activities of the consensus body.

• For purposes of this section, a “consultant” is someone who agrees to provide professional service in exchange for compensation, financial or otherwise.
2.3 Balance

- Interest categories shall be **discretely defined**, cover directly and materially interested parties and differentiate each category from the other categories. Such definitions shall be available upon request.

- In determining the interest categories appropriate to a standards development activity, an ASD shall give consideration to at least the following three categories:
  a) Producer
  b) User
  c) General interest

- If, after consideration, a “**General Interest**” category is deemed appropriate, that interest category should include only those whose business or other interests are not covered by another discretely defined interest category.
2.3 Balance

• Where appropriate, additional interest categories should be considered.[3]

• However, interest categories shall not be created for the purpose of avoiding balance requirements.

[3] Further interest categories that may be used to categorize directly and materially interested parties consist of, but are not limited to, the following: a) Consumer; b) Directly affected public; c) Distributor and retailer; d) Industrial/commercial; e) Insurance; f) Labor; g) Manufacturer; h) Regulatory agency; i) Testing laboratory
2.3 Balance - Notes

• ANSI does not require the use of “user, producer, GI” – other interest categories are fine if appropriate to the nature of the standard

• Representatives of Trade Associations and Professional Societies, if directly and materially interested parties, are eligible for consensus body membership in the interest classification that reflects the business or other interests of their employer or the sponsor they represent

• Interest category definitions must be available upon request

• If your procedures identify and require the use of (shall use) x interest categories for a particular standard, then those are the ones you must use and report on the BSR-9
  • If appropriate, add flexibility to your written procedures
  • Targeted outreach may be required
2.3 Balance - Outreach Notes

- Typical outreach *in addition to the PINS & BSR-8 check-boxes* (routine SA) includes:
  - Targeted outreach as needed in 1 or more under-populated interest categories
  - Special/unique recruitment announcements in Standards Action
  - Website announcements: standing and special
  - Trade press
  - E-mail/letter based solicitations
  - Announcements at meetings and/or meeting reports
  - Social media posts
  - Recruitment webinars
  - Documented phone calls
  - Recruitment emails
  - Other
**Targeted Outreach - Standards Action**

- A general call for consensus body members is a good thing and checking the relevant box on a **PINS or BSR-8 form** at [https://www.ansi.org/portal/psawebforms](https://www.ansi.org/portal/psawebforms) automatically generates such an announcement
  - *This is NOT Targeted Outreach*

- Developers may request publication of announcements intended to **target and recruit** consensus body members in one or more specific interest categories. Please send the text of the announcement to **psa@ansi.org**:
  - Proposed standard's designation and title
  - Identify the underrepresented interest category(ies) on the consensus body along with the definitions of those interest categories
  - Interesting information about the project to generate interest
  - A contact/link to apply for consensus body membership and obtain additional information
  - Any relevant deadlines
Evidence of outreach

- Outreach (targeted as needed) to achieve balance is **required to be documented** and is subject to review by the ANSI BSR, ANSI ExSC, ANSI Appeals Board, Auditors
- Evidence is reviewed by the ANSI BSR via **BSR-9** submittal (or by Audited Designator prior to approval)
  - Keep a running list of your outreach and targeted outreach – event, date, interest categories reached – and include it with the BSR-9 as needed
  - If some of your outreach takes place, for example, at a conference, document/highlight the interest categories in attendance
  - Document outreach and targeted outreach, including screenshots *while the announcement is active on your website or social media, etc.*
Discussion of Common Misunderstandings

• General outreach is not sufficient if the ANSI consensus body is not balanced in accordance with the developer’s procedures (or the historical ANSI criteria)

• Outreach just to your organization’s membership is not sufficient

• The ANSI BSR routinely requests evidence of targeted outreach – so be clear in your efforts...which interest categories are you targeting?
Good practices...

- Review balance regularly and pause the process if the consensus body is not balanced, then undertake recruitment in the under-represented interest categories.

- Review your procedures – interest category can change by standard (build flexibility into your procedures).

- Review interest category definitions and make sure they are discrete and relevant to the standard.
  - Generally, “General interest” should only be available to those that do not fit another discretely defined category.
  - Generally, consultants should be categorized based on who is paying for their participation, i.e., principal sponsor.
    - disclosure and transparency is important and also goes to openness...

- Interest categories can change per standard if your procedures do not preclude this.
Good practices...

• Include interest category definitions on consensus body membership applications, rosters and related documents
  ✓ Improves transparency
  ✓ Improves selection process, if an applicant is expected to self-select their interest category

• Any change in a consensus body member’s interest category should be provided to the consensus body member for their review and written agreement to avoid any concerns that a reclassification was undertaken to manipulate balance on the consensus body
Bringing Consumers to the Table, as appropriate (not all standards require consumer participation)

• Targeted outreach should highlight the impact consumers can have on standardization activities and how the standard will impact them or their organization

• Consumer participation can ensure:
  • Standards are market relevant
  • Provide insight on acceptable levels of risk
  • Provide examples on how products are used (or predictably misused)
  • Provide insight on communication issues including labeling, product instructions and warnings

• Actions that can bring consumers to the table:
  • Outreach emails to potential consumers should highlight specific sections of the standard that would be of great interest to consumers (labeling, maximum speed, required force, etc.)
  • Provide a handbook for consumers detailing the standardization process and the impact on standards on the United States
    ➢ Try a video
  • Some ASDs providing funding, though this is not an ANSI requirement
Targeted Outreach to Consumers

• Typical methods of outreach may not reach consumers
• Targeted outreach to consumers can include:
  • Identify not-for-profit organizations via online searches or through networking that have a focus on the sector the standardization activity covers
  • Contact technical experts and members of academia to gauge interest and tap their network
• Some potential contacts:
  • Consumers Union, Consumer Federation of America, National Consumers League, technical departments of universities, academic societies, retired business executives, retired teachers, and appropriate governmental agencies
Keeping Consumers Engaged

• Suggestions from Consumer Representatives for improving meaningful engagement of consumers in standardization activities:
  • Educate involved ASD staff and participants as to why consumer participation matters to a particular standard
  • Cover travel and lodging expenses if in-person meetings are required, if feasible
  • If your organization funds consumers, see if you can advance the funds rather than reimburse after
  • Waive membership fees
  • Create a consumer mentoring program
  • Create opportunities for consumers to engage with other consensus body members
  • Create an after-action report for consumers to complete and provide feedback on their experiences
  • Ensure deadlines for review or commenting are reasonable
  • Utilize web conferencing technology when hosting meetings
New Guidance Documents - July 2022

• 3 new guidance documents related to engaging consumers in consumer-product-safety standards development
  ✔ Engaging consumers
  ✔ Disclosure
  ✔ Interest categories

• ANSI’s Consumer & Government Relations Relations Manager:
  ✔ Cleo Stamatos: Cstamatos@ansi.org
  ✔ Cell: 410-245-3483
General Concepts: *Good Faith Efforts* support transparency, fairness and consensus

- “Good faith efforts” are identifiable based on a review of the record by an ANSI Program Oversight Committee – BSR, ExSC, Appeals Board
  - Timely and clear communications
  - Response to inquiries and proposals
  - Genuine and appropriate efforts to engage and address issues related to consensus
  - Documented efforts to engage under-represented groups
  - Broad and documented public notice
  - Equivalent treatment for all
Good Practices - consistency promotes fairness

• Create templates, relevant to different phases in the consensus process, to include information about:
  • whom to contact for different issues
  • directions for submitting votes
  • directions for submitting public comments
  • appeals notification language, etc.
Good Practices - Make effective participation easy!

• ASD’s procedures are publicly available
• Consensus body members are automatically given a copy of accredited procedures and subsequent updates – and perhaps a mentor too
• Any supplemental procedures are updated whenever revisions are made to accredited procedures
• Procedures are clear and not overly complicated
  • Not every ASD has the ability to implement complex, multi-level procedures
• Deadlines are clearly noted
• Procedures provide some flexibility while still being compliant with the Essential Requirements
• Procedures are dated and a contact for further information is published in the document
• Training is available – videos, slide decks, staff as a resource
QUESTIONS?
1.4 Coordination and Harmonization

• Good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.
  • ANSI’s jurisdiction reaches ANS and proposed ANS only
  • ANSI’s definition of conflict applies
  • ANSI BSR makes final decision (unless AD)
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” are identifiable based on a review of the record by an ANSI Program Oversight Committee – BSR, ExSC, Appeals Board
  - Timely and clear communications
  - Response to inquiries and proposals
  - Genuine and appropriate efforts to discuss issues
  - Meaningful opportunities
  - Documented efforts
ANS Development Cycle — Overview

PINS Announcement; PINS Deliberation

Public Review; Consensus vote

Consideration of Views & Objections; Recirculation; Complete SDO Appeals

ANSI Appeals; Publication

Approval

Review of Due Process Requirements
PINS, BSR-8 and BSR-9

✓ Slides about forms are included
✓ We’ll take a quick look today, but future webinars will review PINS and forms in detail
✓ Separate Forms webinar – July 21, 2022 at 2pm Eastern
2.5.1 Notification of Standards Development - PINS information (2022)

- At the initiation of a project to **develop or revise** an American National Standard[^3], notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*.

- A statement shall be submitted and published as part of the PINS announcement that shall include:
  
  a) An explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO or ISO/IEC JTC-1 standard; and,

  b) Identification of the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard. (next slides)

  c) the interest categories that will or are expected to comprise the consensus body.

If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published.

If a developer receives a written request for additional information or for the opportunity to discuss the proposal from a directly and materially interested outside party or current consensus body member, during the 30-day PINS comment period, the ASD shall respond in writing within 30 days of the comment deadline.

[^3]:这种情况下的标准开发或修订
2.5.1 Notification of Standards Development - PINS comments

• Comments received in connection with a PINS announcement shall be handled in accordance with these procedures
  • 2.5 and its sub-parts
  • ASD’s related provisions
  • PINS informative guidance document – helpful but not binding
    • Sample PINS Deliberation Report format offered
2.5 Notification of Standards Development - PINS post-SA change to (b)

• If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published.
  • **Note:** If the Project Intent changes after a PINS or a BSR-8 is published, a new PINS would also be required in these instances:
    • From *Reaffirmation* to Revision or National Adoption
    • From *Withdrawal* to Revision or National Adoption
    • See PINS Chart (ExSC 004-2012)
2.5.1 PINS Exceptions - when is a PINS not required?

2.5.1.1 PINS Exceptions

• A PINS is not required for revisions of an American National Standard that is maintained under continuous maintenance and (1) is registered as such on the ANSI website, (2) has a notice in the standard that the standard is always open for comment and how to submit comments, and (3) has information on the developer’s website that the standard is under continuous maintenance and how to submit comments.

• A PINS is also not required in connection with the decision to maintain an ANS under the stabilized maintenance option.

• A PINS form may be submitted, but is not required, at the initiation of a project to reaffirm or withdraw an American National Standard.
2.5.2 Assertions of Conflict or Duplication - *Mandatory Deliberation*

- If a developer receives written comments within 30 days from the publication date of a PINS announcement in *Standards Action*, and said comments assert that a proposed standard duplicates or conflicts with an existing American National Standard (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.
  - Such a deliberation shall be organized by the developer and the commenter and shall be concluded before the developer may submit a draft standard for public review.
2.5.2 Assertions of Conflict or Duplication

• If the deliberation does not take place within the 90-day period
  • And the developer can demonstrate that it has made a good faith effort to schedule and otherwise organize it,
  • Then the developer will be excused from compliance with this requirement.

• 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
2.5.1.3 PINS Deliberation Report - timing

• The outcome of a PINS deliberation shall be conveyed in writing (the “Deliberation Report”) within 30 days after the conclusion of the deliberation by the developer to the commenter and to ANSI.
  • PINS Guidance document includes a sample and optional report format

• Upon submission of the Deliberation Report, the developer may continue with the submission of the draft standard for public review.
  • If additional deliberations take place, they should not delay the submission of the draft for public review, and an updated Deliberation Report shall be conveyed within 30 days after each deliberation.
  • Any actions agreed upon from the deliberations shall be carried out in a reasonably timely manner, but normally should not exceed 90 days following the deliberation.
2.5.1.3 PINS Deliberation Report - 1 or more

• Subsequently, the developer shall include all of the Deliberation Report(s) with the BSR-9 submittal to the ANSI Board of Standards Review (BSR) for consideration should the developer ultimately submit the subject standard to ANSI for approval.

• Stakeholders who were involved in the PINS deliberation process may also file separate Deliberation Report(s) with ANSI and the developer within 30 days after conclusion of any deliberation for consideration by the BSR, if the standard is submitted to ANSI for approval.
2.5.1.3 PINS Deliberation Report - Outcome

• In the case of ANSI Audited Designators, the Audited Designator shall provide a Deliberation Report to the commenter and to ANSI within 30 days after each deliberation. The Audited Designator shall review the results of the deliberation prior to designating a standard as an ANS.

• While the outcome is not binding, unless binding provisions are agreed to by the developer, participants are encouraged to develop a consensus on whether and how the standards development project should proceed. See also 4.3.
2.5 PINS Deliberation - Notes

• See Informative PINS Guidance Document (2022)
  • www.ansi.org/asd
  • Relevant procedural excerpts
  • Relevant ANSI ExSC interpretations
  • Examples of possible PINS Deliberation outcomes

• PINS Deliberation may take place via
  • In person meeting
  • Teleconference/webinar
  • In writing
  • Other?
2.5 PINS Deliberation - Notes

• 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 continue to develop separate standards
2.5.2 Notification of Standards Development - *Public Review/BSR-8 Form*

• In addition, proposals for new American National Standards and proposals to revise, reaffirm, or withdraw approval of existing American National Standards shall be transmitted to ANSI using the BSR-8 form, or its equivalent, for listing in *Standards Action* in order to provide an opportunity for public comment.

• If it is the case, then a statement of intent to submit the standard for consideration as an ISO or ISO/IEC JTC-1 standard shall be included as part of the description of the scope summary that is published in *Standards Action*.

➢ *Separate Forms webinar – July 21, 2022 at 2pm Eastern*
2.5.2 Notification of Standards Development - Public Review/BSR-8 Form

• The comment period shall be one of the following:
  • A minimum of **thirty days** if the full text of the revision(s) can be published in *Standards Action*;
    • **Up to 5 pages** in strikethrough-underline; recommend an intro explaining intent
    • **Not for a new ANS or reaffirmation of existing ANS**
  • A minimum of **forty-five days** if the document is available in an electronic format, deliverable within one day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided to ANSI for announcement in *Standards Action*; or,
  • A minimum of **sixty days**, if neither of the aforementioned options is applicable.
  • Such listing may be requested at any stage in the development of the proposal, at the option of the standards developer, and may be concurrent with final balloting.
  • However, any substantive change subsequently made in a proposed American National Standard requires listing of the change in *Standards Action*. 
2.5 Public Review - Notes

• Public Review in *Standards Action*
  • **Text that is not part of the proposed ANS** should be clearly labeled as such so comments related to it are not submitted (see also clause 4.4 Designation of ANS).
  • A **second or third, etc., BSR-8** is required if **substantive changes** are made to the draft after ANSI public review
    • Strikethrough and underline format is best, with an explanation
    • If the goal is to allow comments on a limited section only, state this in the scope of the BSR-8, which is published in Standards Action
Jay Moskowitz will cover the next topics...
**Substantive changes**

- **Substantive Change**: A substantive change in a proposed American National Standard is one that **directly and materially affects the use of the standard**. Examples of substantive changes are below:
  - “Shall” to “should” or “should” to “shall”;
  - Addition, deletion or revision of requirements, regardless of the number of changes;
  - Addition of mandatory compliance with referenced standards.

  ➢ *If your procedures do not include a process for determining whether changes are substantive vs. editorial, consult the Chair or Officers or drafting group or consensus body and document the results*

- A second or third, etc., public review is required if substantive changes are made to the draft after an ANSI public review
  - ✓ You may limit a public comment period to just the change since the last public comment, e.g., a word, a phrase, a paragraph
  - ✓ It is the consensus body’s decision when to stop making new substantive changes, but any substantive change must be fully processed, **including public review, comment resolution, vote, etc.**
  - ✓ Document who makes the decision, how and why a particular decision was made as it can be challenged by a participant via a complaint or appeal, or later identified as a concern in the ANSI audit
1.6 and 2.6 Consideration of Views and Objections

• Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in Standards Action.
  • All relevant comments must be considered, even if you think the comments are not well written, not important, philosophical in nature or do not provide alternative language

➢ Separate webinar on votes and public comments – July 14, 2022 at 2pm Eastern
2.6 Consideration of Views and Objections

• In connection with an objection articulated during a public comment period, or submitted with a vote,
  • an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and
  • each such objector shall be advised in writing (including electronic communications) of the disposition of the objection and the reasons therefor.

• Written notice is required; verbal discussions are not sufficient.
2.6 Consideration of Views and Objections

• If resolution is not achieved, each such objector shall be informed in writing that an appeals process exists within procedures used by the standards developer.
  • Procedural appeal regarding the standards development process is to the standards developer first, then to ANSI in the future after a final action has been taken
  • Appeals notice must be in writing
  • Deadline for filing appeal should be clear
  • Procedures for filing appeal should be clear and provided or easily accessible

• Review appeals guidance document for tips
2.6 Consideration of Views and Objections

• In addition, except in the case of Audited Designators, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved (see definition) must be reported to the ANSI BSR.

• Definitions in Annex A of the ANSI Essential Requirements:
  • **Resolved**: A negative vote cast by a member of the consensus body or a comment submitted as a result of public review where the negative voter agrees to change their vote or the negative commenter accepts the proposed resolution of his/her comment.
  • **Unresolved**: Either (a) a negative vote submitted by a consensus body member or (b) written comments, submitted by a person during public review expressing disagreement with some or all of the proposed standard, that have not been satisfied and/or withdrawn after having been addressed according to the developer’s approved procedures.
2.6 Consideration of Views and Objections - Response to Public Comment

• In connection with an objection submitted via public comment:
  • An ASD should add language to the written disposition letter/E-mail sent to a public commenter that states something like
    • This response provides you with an attempted resolution of your comments. **If you wish to remain on record as an unresolved public commenter [and thus, have the right to file a procedural appeal], please respond to x by xx/yy/zz and state as much. If I do not hear from you by this date, then your comments will be considered resolved.**
  • This type of language however, is **never an option with respect to a vote submitted by an ANS consensus body member.**
    • See clause 2.7 for details (slides to follow)
2.6 Consideration of Views and Objections

• When this process is completed in accordance with the written procedures of the standards developer, the standards developer
  • may consider any comments received subsequent to the closing of the public review and comment period, or
  • shall consider them in the same manner as a new proposal.

• Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be so notified.
  • Timely, relevant comments must be considered in the current cycle
  • Late comments may be considered, but if considered, must be afforded full due process, including appeals
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 ballot
  - Include unresolved objection, 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
  - NOTE: a vote to approve a comment resolution alone does not satisfy the recirculation requirement.
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 ANSI BSR or ANSI ExSC and ANSI Audit

➤ Separate webinar on votes and public comments — July 14, 2022 at 2pm Eastern
Evidence of consensus in accordance with these procedures and the accredited procedures of the standards developer shall be documented.

Consensus is demonstrated, *in part*, by a vote of the consensus body. The developer's procedures shall state specifically how consensus will be determined.

An example of the criteria for consensus includes a requirement that a majority of the consensus body cast a vote (counting abstentions) and at least two-thirds of those voting approve (not counting abstentions).

The developer may submit for approval an alternative methodology for determining consensus.

• ANSI ExSC decision
2.7 Evidence of Consensus and Consensus Body Vote

• Votes for the approval of a document or portion thereof as a candidate ANS may be obtained by letter, fax, recorded votes at a meeting or electronic means.

• All members of the consensus body shall have the opportunity to vote.
  • On a decision to approve a document as an ANS

• When recorded votes are taken at meetings, members who are absent shall be given the opportunity to vote before or after the meeting.
  • This is a vote separate from a recirculation opportunity
2.7 Evidence of Consensus and Consensus Body Vote

- ASDs shall not change a vote unless instructed to do so by the voter.
- If the change of vote was not submitted in writing by the voter, then written confirmation of such a vote change shall be provided to the voter by the developer.
- It is never appropriate for an ASD to inform voters that if they are not heard from, their negative vote will be considered withdrawn and their vote will be recorded as an abstention or an affirmative.
- All negative votes that are not changed at the request of the voter shall be recorded and reported to the BSR as unresolved negatives by any ASD that has not been granted the authority to designate its standards as American National Standards without approval by the BSR.
2.7 Evidence of Consensus and Consensus Body Vote

• ASDs shall record and consider all negative votes accompanied by any comments that are related to the proposal under consideration.

• This includes negative votes accompanied by comments concerning potential conflict or duplication of the draft standard with an existing American National Standard and negative votes accompanied by comments of a procedural or philosophical nature.

• These types of comments shall not be dismissed due to the fact that they do not necessarily provide alternative language or a specific remedy to the negative vote.
2.7 Evidence of Consensus and Consensus Body Vote

- ASDs are not required to consider negative votes accompanied by comments not related to the proposal under consideration, or negative votes without comments.

- The ASD shall indicate conspicuously on the letter ballot that negative votes must be accompanied by comments related to the proposal and that votes unaccompanied by such comments will be recorded as “negative without comments” without further notice to the voter.

- If comments not related to the proposal are submitted with a negative vote, the comments shall be documented and considered in the same manner as submittal of a new proposal.
2.7 Evidence of Consensus and Consensus Body Vote

• If clear instruction is provided on the ballot, **and a negative vote unaccompanied by comments related to the proposal is received notwithstanding**, the vote may be counted as a “negative without comment” for the purposes of establishing a quorum and reporting to ANSI. However, such votes (i.e., negative vote without comment or negative vote accompanied by comments not related to the proposal) shall not be factored into the numerical requirements for consensus, unless the ASD’s procedures state otherwise.

• The ASD is not required to solicit any comments from the negative voter.

• The ASD is **not required to conduct a recirculation** ballot of the negative vote **or notify the negative voter of the right to appeal**.

• The ASD is required to report the “no” vote as a “negative without comment” when making their final submittal to the BSR unless the ASD has been granted the authority to designate its standards as American National Standards without approval by the BSR.
2.7 Evidence of Consensus and Consensus Body Vote

• The ASD shall maintain records of evidence regarding any change of an original vote.

• Except in regard to votes on membership and officer-related issues, each member of a consensus body should vote one of the following positions (or the equivalent):
  a) Affirmative;
  b) Affirmative, with comment;
  c) Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection);
  d) Abstain.
2.7 Evidence of Consensus and Consensus Body Vote

• For votes on membership and officer-related issues, the affirmative/negative/abstain method of voting shall be followed.
  • Votes with regard to these issues need not be accompanied by reasons and need not be resolved or circulated to the consensus body.
  • Be mindful that sometimes voters provide problematic comments related to a candidate that should not, in general, be circulated
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
  • Options re: negative votes unrelated to revision underway
  • Philosophical 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
2.8 Appeals

- 2.8.1 To the Standards Developer
- 2.8.2 To ANSI
  - the ANSI Board of Standards Review (BSR)
  - the ANSI Executive Standards Council (ExSC)
  - the Appeals Board
- Summary explanation of appeals processes is posted on ANSI Online in *ANS Guidance Documents* ([www.ansi.org/asd](http://www.ansi.org/asd))

> Separate webinar on Appeals – July 28, 2022 at 2pm Eastern
Informal Resolution - Listen...

- The procedural requirements discussed today can delay consensus and underpin complaints:
  - ANSI encourages settlement of disputes at any time if the settlement is consistent with the applicable ANSI procedures.
  - Some participants do not understand how standards are developed...help to educate them!
  - Address concerns seriously and quickly – don’t avoid potential problems, they usually do not go away!
  - Any settlement or agreement to which the parties agree will terminate the appeals process.
ANS Development Cycle — Overview

- PINS Announcement; PINS Deliberation
- Public Review; Consensus vote
- Consideration of Views & Objections; Recirculation; Complete SDO Appeals
- ANSI Appeals; Publication
- Approval
- Review of Due Process Requirements
QUESTIONS?
Section 3.0 Normative ANSI Policies
3.0 Normative ANS Policies

Every ANSI-Accredited Standards Developer (ASD) shall comply with the normative policies contained in this section. The ASD may choose to:

1. include the text that follows, as appropriate, in its accredited procedures along with any additional information as required;

or

2. submit to ANSI a written statement of full compliance with these policies in addition to policy statements that satisfy the requirements set-forth in this section.
Normative Policies

- ANSI Patent Policy (3.1) *(Revised 2020)
- Commercial terms and conditions (3.2) *(Revised 2021)
- Antitrust policy (3.3)
- Evidence of compliance (3.4)
- Metrics policy (3.5)
- Interpretations policy (3.6)
3.1 ANSI patent policy

• No objection in principle to drafting an ANS in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

• Participants are encouraged to bring patents with claims believed to be essential to the attention of the ANSI-Accredited Standards Developer (ASD).
3.1 ANSI patent policy - 2

• The ASD shall receive from the patent holder or a party authorized to make assurances, in written or electronic form, either:
  
  a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
  
  b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:

  ➢ under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or

  ➢ without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.
3.1 ANSI patent policy revision

• ASDs are expressly required to submit any negative patent holder letters of assurance along with the relevant BSR-9 or BSR-109 submittal.
  ➢ In such cases, the ASD would be expected to also submit an explanation as to why the ASD believes the proposed ANS meets the ANSI Patent Policy.

• 2022 BSR-9/BSR-109 further requires an ASD to certify the following:

  That we agree to comply with the ANSI Patent Policy and that:
  • Any patent holder’s statements or letters of assurances (LoAs) we receive comply with ANSI's (and our) Patent Policy (See 3.1) and will be made publicly available either on our website or on ANSI’s LOA repository (See 15 above).
  • Any negative LoAs (i.e., those indicating the patent holder is unwilling to license essential patent claims) we receive will, in addition, be (i) provided with this BSR-9 form or, (ii) if received after the BSR-9 form is filed, provided directly to the Secretary of the BSR within 30 days of receipt.
ANSI Patent Policy = IPR Policy for ANS

• ANSI Patent Policy (3.1 of the ANSI Essential Requirements) is a safeguard for users of an ANS and for ANSI-Accredited Standards Developers (ASD) because it lets both know whether a patent holder of essential technology that is referenced in the ANS is available on reasonable and non-discriminatory terms (RAND) to all who wish to implement the ANS
  • the Patent Policy applies only to "essential" patent claims and not to patented technology that may be referenced in the standard, but is not necessary in order to comply with the standard’s requirements
  • early disclosure of the possible existence of any such essential patent claims is encouraged so all are aware and can make informed choices regarding the inclusion of the patented technology
  • the ASD must receive from the patent holder or its designee a written assurance (aka Patent Letter of Assurance - PLOA) that the patent holder either does not hold a patent claim required to implement the standard or that it will license applicants (those seeking to implement the standard) under RAND terms
  • the ANSI Patent Policy requires that when an ASD receives a PLOA for an essential patent, the standard must include a notice that points out to implementers that there may be a patent claim that is essential to the implementation of the standard
ANSI’s Patent Policy

• To learn more, see these other ANSI documents for guidance:
3.2 Commercial terms and conditions

• Sets the guardrails for commercial terms and conditions in an ANS.

• An ANS cannot include terms or conditions that are primarily contractual or commercial in nature, as opposed to technical, engineering or scientific in nature.

• This section precludes an ANS from dictating contractual terms or compelling an implementer to use products/services from a particular source.
3.2 Commercial terms and conditions

• The examples provided in 3.2 are just that – and not an exhaustive list
  • For example, the term “contractual terms” includes contract negotiation terms

• Additional examples, not expressly cited, but that may not be included in an ANS
  • Price-related terms or conditions of sale
  • Extended warranties
  • Named products or service providers, e.g., ABC Product Testing
3.2 Commercial terms and conditions

Except as otherwise permitted by these Essential Requirements, ANS shall not include terms or conditions that are primarily contractual or commercial in nature, as opposed to technical, engineering or scientific in nature.

Thus, for example, an ANS shall not include:

- contractual requirements (3.2.1);
- endorse or require the use of proprietary products or services (3.2.2); or
- endorse or require the use of particular conformity-assessment bodies, testing facilities or training organizations (3.2.3).
3.3 Antitrust Policy

• American National Standards shall be developed in accordance with applicable antitrust and competition laws and meetings amongst competitors to develop American National Standards are to be conducted in accordance with these laws.
  
  • Include this statement
  
  • Submit an alternative statement
  
  • Ensure that as an ASD you understand what this means
    
    • Some organizations have detailed guides for what is and is not appropriate in a meeting of a consensus body
3.4 Evidence of compliance

• ANSI-Accredited Standards Developers shall retain records to demonstrate compliance with all aspects of these and the developer’s accredited procedures. Such records shall be available for audit as directed by the ANSI Executive Standards Council (ExSC).
  • Periodic Maintenance
  • Continuous Maintenance
  • Stabilized Maintenance

➢ Audit & Reaccreditation Webinar – June 23, 2022
3.5 Metric policy

- Each ANSI-Accredited Standards Developer shall have on file at ANSI a metric policy. International System of Units (SI) are the preferred units of measurement in American National Standards.
3.6 Interpretations policy

- All ANSI-Accredited Standards Developers are required to have an interpretations policy on file with ANSI.
  - It is acceptable to have a policy that states that interpretations shall not be provided
  - Suggest policy requires written requests and responses
- ANSI does not, nor may anyone on behalf of ANSI, issue interpretations of American National Standards
  - All such requests are forwarded to the appropriate sponsoring standards developer
Questions?
Section 4.0 Normative ANS
Administrative Procedures

4.1 Accreditation of ANS Developers – June 23rd Webinar
4.2 Approval of actions in connection with ANS – July 21st Webinar (Forms)
4.3 Planning, coordination and public notice
4.4 Designation of ANS
4.5 Publication of ANS
4.6 National Adoptions – June 30th Webinar
4.7 Maintenance of ANS
Re/accreditation Process — General

ASD submits revised procedures in strike-through-underline format with an explanation

Public Review in Standards Action & Response to Comments by ASD

Re-accreditation Approval (Appeal to the ExSC then Appeals Board possible)

Review of Revisions, Responses to comments by ANSI ExSC; Additional comments possible
to appeal. ANSI will not normally hear an appeal of an action or inaction by a standards developer relative to the development of an American National Standard until the appeals procedures provided by the standards developer, which must be implemented promptly and with decisions made expeditiously, have been completed. However, conclusion of the appeals process at the standards developer, is not a precondition for filing an appeal with the Executive Standards Council (ExSC) of an organization’s continuing accreditation status.

Claims of procedural non-compliance raised during the course of an active standards development process are to be addressed in accordance with the standards developer’s appeals process which shall conclude before final submittal of evidence of consensus is made to ANSI in support of the approval of a standard as an American National Standard.

Except in the case of an Audited Designator, an appeal of the approval of a standard as an American National Standard is to be filed in accordance with the Operating Procedures of the ANSI Board of Standards Review (BSR). Complaints concerning ANSI Audited Designators, including the approval of a standard as an American National Standard, are governed by the Operating Procedures of the ANSI Executive Standards Council (ExSC).

Appeals of actions shall be made within reasonable time limits specified in applicable procedures; appeals of inactions may be made at any time. Such appeals shall be directed to ANSI in accordance with the procedures of the appropriate ANSI Committee board or council board or council (e.g., Board of Standards Review, Executive Standards Council).
Maintaining Accreditation: Use of revised procedures

If the ASD decides to implement revised procedures prior to the final approval of the ExSC, they may do so provided that

- records concerning the implementation are maintained and available for use by the ANSI Audit Program; and
- the developer certifies that the changes are in compliance with the *ANSI Essential Requirements*; and
- the developer accepts responsibility for all actions taken with regard to a candidate American National Standard, including resubmittal, if the ExSC does not approve a particular procedural provision

➤ Audit & Reaccreditation Webinar – June 23, 2022
Approval of Actions in Connection with ANSI - Section 4.2

• New ANSI = *New to ANSI*
• Revised=Substantive change (no distinction between “major” and “minor” or number of changes)
• Reaffirm=No Substantive change
• Withdrawn
• Stabilized
4.3 Planning, Coordination and Public Notice

• Refer to PINS Guidance document for further discussion of “good faith efforts”
• PINS Process
• Clear public announcements
• Joint efforts
• Liaisons and the like
• Coordinate with U.S. TAG to ISO, IEC or ISO/IEC JTC1
4.4 Designation of ANS

• Designation must be unique, but is selected by the ASD and not ANSI
• Use of “ANSI” in approved standard’s designation is optional, but ANS must be identified as such
• Reaffirmations must be identified as such
Publication of American National Standards

• May be published either by ANSI (contact ANSI’s Publication Department) or by the developer

• Published within 6 months from the date of approval
  • Extension may be requested – use the Multi-purpose extension form
Publication of American National Standards

- Portions of a published document that were not approved through the full consensus process but contain information that may appear to be requirements necessary for conformance with the approved American National Standard (ANS) shall be
  - (1) clearly identified at the beginning and end of each such portion of the document, or
  - (2) such information shall be overprinted on the cover page. These portions of the document shall be marked with the following, or similar, explanatory language:

  “The information contained in this (portion of a document) is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI’s requirements for an ANS. As such, this (portion of a document) may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the standard.”
4.5 National Adoptions

• See ANSI National Adoption Procedures for eligibility and processing requirements unique to national adoptions of ISO or IEC standards as ANS

  • www.ansi.org/nationaladoption

➤ June 30, 2022 National Adoption Procedures webinar
4.7 Maintenance of American National Standards

- Periodic
- Continuous
- Stabilized
- National Adoptions (separate document)

✓ Remember: each ASD is obliged to track and maintain ANS throughout a document’s lifecycle as an ANS
  ➢ Use online reports as a basis for comparison of your records with ANSI’s
4.7.1 Periodic Maintenance

• Review and action (reaffirmation, revision or withdrawal) completed at least once every five years (based on date of approval as an ANS)
  • Extensions are available upon request – see online form
  • Active PINS or BSR-8 lets the public know the standard will be revised or reaffirmed and so an extension is not required and the standard will not expire on its 5\textsuperscript{th} anniversary of ANS approval
  • Automatic Expiration as an ANS: 10th anniversary of approval date
4.7.2 Continuous Maintenance (CM)

- Standards updated on a continuous basis – entire standard is open
  - On a schedule determined by the standards developer
  - When a request for revision is received it is acted upon
- After the standard is approved as an ANS, then PINS to revise is not required
- Register ASD under CM; use BSR-9 to indicate CM
- If no revisions take place in four years, the standard shall be reaffirmed or withdrawn by its 5th anniversary of approval as an ANS
- In the event that a BSR-8/108 (public review) has not been submitted for an ANS under CM within 5 years of its approval, the ASD may request an extension, but shall then maintain the ANS under periodic maintenance
4.7.3 Stabilized Maintenance

• A standard that is maintained under the stabilized maintenance option shall satisfy the following eligibility criteria:
  • the standard addresses mature technology or practices, and as a result, is not likely to require revision; and
  • the standard is other than safety or health related; and
  • the standard currently holds the status of American National Standard and has been reaffirmed at least once; and
  • at least ten years have passed since the approval or last revision of the standard as an ANSI; and
  • the standard is required for use in connection with existing implementations or for reference purposes.

• Initial decision requires approval by the BSR via BSR-10 form, “The due process and consensus requirements defined herein apply to the decision to maintain an ANSI under the stabilized maintenance option.”
  • Outreach to achieve balance is still required
5.0 Audited Designator

• Applies only to ASDs that hold the status of Audited Designator

• ASHRAE, ASTM, IAPMO, NFPA, NSF, UL
Annexes

• Annex A: Definitions

• Annex B: Procedures for the Development of a Provisional American National Standard (PS)
  • Very limited application
  • Available for use by all ASDs if the criteria are satisfied
  • When all of the following circumstances apply:
    1. When implementation of the Provisional ANS or Provisional Amendment may result in an improvement to the safeguarding of life, and there is a well-established need for the prompt dissemination of information that addresses an emergency situation or other special circumstance;
    2. When the use of the accredited procedures of the ASD would cause an undue delay in the issuance of a related standard; and
    3. When an ASD supports the development of a Provisional ANS or a Provisional Amendment with the intention of initiating the processing as an ANS, of the Provisional ANS or the Provisional Amendment to an ANS, within 45 days of its approval date. Processing of the ANS shall be in accordance with the ASD’s accredited procedures, including ANSI public review in Standards Action and consensus body ballot.
ANSI Essential Requirements: 2003-2022

• Summary of annual changes to the ANSI Essential Requirements since its issuance are contained in the document entitled “Summary of Revisions to the Essential Requirements: 2003-2022”

• Available at www.ansi.org/asd with other guidance documents
Helpful Resources

• ANSI Essential Requirements: www.ansi.org/essentialrequirements

• Standards Action and 2022 publication schedule: www.ansi.org/standardsaction

• Summary of ANSI process steps: www.ansi.org/anskeysteps
  • See another version through the new ANSI-pages

• PINS, BSR-8s, BSR-11, PSA-01 (single and excel):
  • https://www.ansi.org/portal/psawebforms/

• ANSI Value Brochure: www.ansi.org/ansvalue

• ANSI Federation COVID 19 responses:
  • https://www.ansi.org/resource-center/covid-19
  • Send your organization’s updates to: pr@ansi.org

• Standards Boost Business: www.standardsboostbusiness.org

• 2020 United States Standards Strategy: www.ansi.org/usss
ANS Procedures, Interpretation, Guidance and Forms
SAMPLE www.ansi.org/asd

• ANS Forms - slide deck
• Appeals guidance
• Audit – procedures and guidance
• Balance, Outreach & Targeted Outreach guidance (2022)
• PINS Deliberation guidance & sample report (2022)
• Efficiencies in the standards development process
• ExSC interpretations: recirculation, openness
• National Adoptions of ISO, IEC and ISO/IEC JTC 1 as ANS - slide deck of the basics
• and more...
“American Way” webinar series
still to come…

- June 23, 2022 (Thursday at 2pm Eastern): ANSI-Accredited Standards Developer (ASD) ANS Audit & Reaccreditation Processes
  Register in advance for this webinar: https://goansi.webex.com/goansi/onstage/g.php?MTID=eebb485e88ccbd644d76dd51218bd00d9

  Register in advance for this webinar: https://goansi.webex.com/goansi/onstage/g.php?MTID=ee72e2635798c50b75132ad61e06a8f3e

- July 14, 2022 (Thursday at 2pm Eastern): ANS Process: Focus on Votes & Public Comments
  Register in advance for this webinar: https://goansi.webex.com/goansi/onstage/g.php?MTID=e5e4c6e79289c69d7deb45adb98d5299a

- July 21, 2022 (Thursday at 2pm Eastern): ANS Forms
  Register in advance for this webinar: https://goansi.webex.com/goansi/onstage/g.php?MTID=e57cc2d7de066db098e39f4af18ccd380

- July 28, 2022 (Thursday at 2pm Eastern): Procedural Appeals – ASD and ANSI Appeals Processes
  Register in advance for this webinar: https://goansi.webex.com/goansi/onstage/g.php?MTID=e5fefa6472f59d75dffe176fc57e5910d

- September 22, 2022 (Thursday at 2pm Easter): What is an ANS anyway? (Public session)
  Register in advance for this webinar: https://goansi.webex.com/goansi/onstage/g.php?MTID=e22faad22382ce20cadd97c1c07107952
QUESTIONS?
We hope you’ll join us to celebrate World Standards Week 2022: October 10-14, 2022

https://www.ansi.org/events/standards-events/world-standards-week

Thanks for joining us today...
Reference - 2022 revisions follow
ExSC_017_2019

• Let’s look at the text of the revisions
• Key revisions follow on individual slides
• Additional various editorial updates also included in 2022 ANSI Essential Requirements
1.5 Notification of standards development (also 2.5)

Timely and adequate notice Notification of standards development activity shall be announced in suitable media suitable to demonstrate that a meaningful opportunity for participation, debate and deliberation by all directly and materially interested parties in a fair and equitable manner was provided.
2.1 Openness

Timely and adequate notice of any action to create, revise, reaffirm, or withdraw a standard, and the establishment of a new consensus body shall be provided to all known directly and materially interested parties. Notice should include a clear and meaningful description of the purpose of the proposed activity and shall identify a readily available source for further information. In addition, the member’s name (or if membership is by organization, the name of the organization with a point of contact), affiliation and interest category of each member of the consensus body shall be made available to interested parties upon request. The affiliation of a consensus body member refers to the entity that the consensus body member represents, which may or may not be that person’s employer. If the consensus body member is serving in an individual capacity, then the name of the individual, their sponsors (if any) and interest category shall be made available upon request. Contact information is not required.

- A sponsor is defined as an organization that provides funds specifically to support the individual’s participation in the standards activities of the consensus body.
2.3 Balance

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

The interest categories appropriate to the development of consensus in any given standards activity are a function of the nature of the standards being developed. Interest categories shall be discretely defined, cover directly and materially interested parties and differentiate each category from the other categories. Such definitions shall be available upon request.

Consensus body members, including consultants, typically are classified in accordance with the business or other interests of their employers or the sponsors they represent in connection with the standards development activity. In cases where a consensus body member receives funding from the sponsoring ANSI-Accredited Standards Developer (ASD) or other entities, that information shall be disclosed to determine if it will impact the member’s interest classification.

- For purposes of this section, a “consultant” is someone who agrees to provide professional service in exchange for compensation, financial or otherwise.
2.3 Balance (continued)

In determining the interest categories appropriate to a standards development activity, an ASD shall give consideration shall be given to at least the following three categories:

a) producer;
b) user;
c) general interest.

If, after consideration, a “General Interest” category is deemed appropriate, that interest category should include only those whose business or other interests are not covered by another discretely defined interest category.

Where appropriate, additional interest categories should be considered. However, interest categories shall not be created for the purpose of avoiding balance requirements.

Further interest categories that may be used to categorize directly and materially interested parties consist of, but are not limited to, the following: a) Consumer; b) Directly affected public; c) Distributor and retailer; d) Industrial/commercial; e) Insurance; f) Labor; g) Manufacturer; h) Professional society; h) Regulatory agency; i) Testing laboratory; k) Trade association.
2.5.1 Project Initiation Notification System (PINS)

A statement shall be submitted and published as part of the PINS announcement that shall include:

(a) an explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard; and

(b) identification of the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard; and

(c) the interest categories that will or are expected to comprise the consensus body.

If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published.

If a developer receives a written request for additional information or for the opportunity to discuss the proposal from a directly and materially interested outside party or current consensus body member, during the 30-day PINS comment period, the ASD shall respond in writing within 30 days of the comment deadline.
Additional PINS Field on Form

« Identify Stakeholders: List the relevant stakeholders, (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard. (EXISTING)

➤ 2022 Additional question:

« Interest Categories: List the relevant interest categories that will or are expected to comprise the consensus body.

REMINDER: If you use the Excel option for multiple PINS, please download the newly updated file. Please do not use the prior version as it does not have the new field. Thanks!
2.8.2 Right to Appeal: Appeals at ANSI

Parties who are directly and materially interested in and who have been or will be adversely affected by any procedural action or inaction by ANSI or by any ANS-related process have the right to appeal. ANSI will not normally hear an appeal of an action or inaction by a standards developer relative to the development of an American National Standard until the appeals procedures provided by the standards developer have been completed. As required in section 2.8.1, appeals at the ASD shall be addressed promptly and a decision made expeditiously and issued in writing. However, conclusion of the appeals process at the standards developer level is not a precondition for filing an appeal of an organization’s continuing accreditation status with the ANSI Executive Standards Council (ExSC).

Claims of procedural non-compliance raised during the course of an active standards development process are to be addressed in accordance with the standards developer’s appeals process. The standards developer's appeals process shall conclude before final submittal of evidence of consensus is made to ANSI in support of the approval of a standard as an American National Standard.

Except in the case of an Audited Designator, an appeal of the approval of a standard as an American National Standard is to be filed in accordance with the Operating Procedures of the ANSI Board of Standards Review (BSR). Complaints concerning ANSI Audited Designators, including the approval of a standard as an American National Standard, are governed by the Operating Procedures of the ANSI Executive Standards Council (ExSC).

Appeals of actions shall be made within reasonable the time limits specified in applicable procedures; appeals of inactions may be made at any time. Such appeals shall be directed to ANSI in accordance with the procedures of the appropriate ANSI board or council-Committee (e.g., Board of Standards Review, Executive Standards Council).
4.1.2  Application for Accreditation as a Developer of American National Standards

Following the comment period, the ExSC shall consider the information supplied by the applicant and any comments and responses received, including reports on coordination from the appropriate ExSC designee if any, standards advisors, and the BSR. If comments are submitted that challenge support for an applicant’s accreditation, the applicant shall supply documented evidence of such sufficient support for consideration by the commenter and the ExSC. The ExSC shall determine whether accreditation should be approved. The applicant must satisfy the requirements established in the ANSI Essential Requirements before accreditation can be granted. If, during the course of the accreditation process, the developer makes a change to their originally submitted scope or to their originally submitted operating procedures, an additional announcement shall be published in Standards Action. If, however, the developer makes changes to the originally submitted operating procedures at the specific direction of the ExSC or their designee in order to bring their procedures into compliance with the ANSI Essential Requirements, an informational announcement shall be placed in Standards Action without additional public review. Accreditation will not be granted to an applicant whose procedures do not satisfy the requirements set forth herein. In the event that accreditation is not granted, the ExSC shall advise the applicant of the reasons, and the applicant shall have the opportunity to reapply. Upon accreditation, the applicant shall be notified and a notice shall appear in Standards Action.