

American National Standards (ANS) Workshop

*Through the Looking Glass – A Closer Look at
Openness, Balance and Disclosure*

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ANSI

1918 - 2018

Welcome

*Lane Hallenbeck, ANSI VP
Accreditation Services*

Today's Moderator



Welcome to those participating by webex

- During the Workshop all webex attendees will be muted to eliminate background noise
- If you wish to pose a question or make a comment, please use the **Raise Hand** option and you will be unmuted when it is your turn
- We have over 70 attendees by webex, so please be patient and understand that our time for each Panel is limited



Today's agenda

- ◆ Welcoming remarks: ANSI President Joe Bhatia
 - Introduction of moderator, ANSI VP, Accreditation Services, Lane Hallenbeck
- ◆ American National Standards Primer: Chris Dubay and Gaby Davis
- ◆ The Role of ANS: One perspective, given by Commissioner Adler U.S. CPSC
- ◆ *BREAK*
- ◆ Panel 1: Openness and Participation in the ANS Process, Claire Ramspeck
- ◆ Panel 2: Balance and Interest Classification, Gaby Davis
- ◆ *LUNCH*
- ◆ Panel 3: Affiliation, Disclosure and Accurate Accounting of ANS Consensus Body Members, Paula Watkins
- ◆ Panel 4: Should the *ANSI Essential Requirements* be further refined to distinguish among types of ANS?, Claire Ramspeck
- ◆ *BREAK*
- ◆ Moderated Full Group Discussion: Chris Dubay
- ◆ Closing Remarks and Next Steps: ANSI President, Joe Bhatia



Welcoming Remarks
Down the rabbit hole...

ANSI President Joe Bhatia



American National Standards and *ANSI's Essential Requirements*

Gaby Davis, ANSI Board of Standards Review (BSR) Chair

Chris Dubay, ANSI Executive Standards Council (ExSC) Chair

Anne Caldas, ANSI Staff



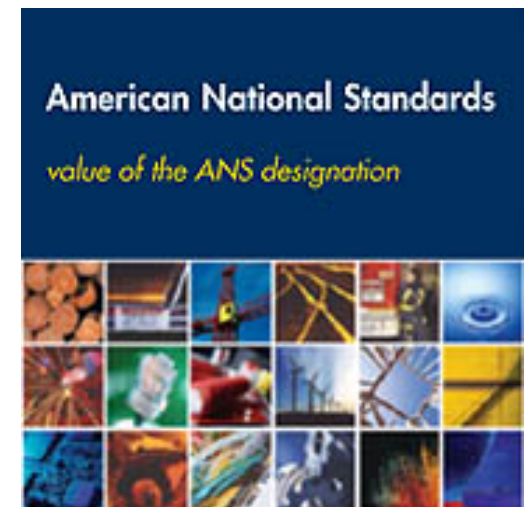
Let's review some ANSI basics...

Anne Caldas



American National Standards (ANS)

- ◆ *ANSI Essential Requirements: Due process requirements for American National Standards (www.ansi.org/essentialrequirements)*
- ◆ Approximately 240 ANSI-accredited standards developers (ASD)
(www.ansi.org/asd)
 - Only ASDs may submit standards for approval as ANS
 - Not all standards developed by these organizations are submitted for consideration as ANS
 - There are approximately 11,500 ANS
 - All ASDs are subject to ANSI's neutral third-party oversight including a routine audit of ANS and an annual compliance review of accredited procedures



Learn more: www.ansi.org/ansvalue

An American National Standard (ANS) is a Voluntary Consensus Standard (VCS)

- ◆ ANS: a VCS developed in accordance with the “*ANSI Essential Requirements*” subject to ANSI’s **unique**:
 - 1) accreditation of consensus procedures;
 - 2) neutral oversight;
 - 3) approval process;
 - 4) appeals process; and
 - 5) procedural audit.
- ◆ ANS are the focus of today’s Workshop

What is ANSI's role in the ANS process?

- ◆ 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



Who makes ANS-related decisions?

- ◆ 3 Program Oversight Committees, populated by ANSI Members, reporting to the ANSI National Policy Committee:
 - ANSI Executive Standards Council (ExSC)
 - ❖ Procedures, accreditation, appeals, audits
 - ANSI Board of Standards Review (BSR)
 - ❖ Approval and withdrawal of ANS*
 - ANSI Appeals Board
 - ❖ Final level of appeal at ANSI
- ◆ All serve as neutral, knowledgeable professionals
- ◆ Oversight role is subject to conflict of interest procedures

What procedures govern the ANS process?

- ◆ All ASDs are bound by the *ANSI Essential Requirements* and their ANSI-Accredited Procedures
 - *ANSI Essential Requirements* is a living document, issued January of each year
 - ANSI does not distinguish between methods – like canvass, committee
 - ANSI ExSC considers each set of procedures individually and in total
 - ◆ 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 distribution lists
 - 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”



*Let's take a quick look at the
"ANSI Essential Requirements: Due process
requirements for American National
Standards"*

www.ansi.org/essentialrequirements



ANSI's Definition: Consensus

- ◆ Consensus means substantial agreement has been reached by directly and materially affected interests.
 - 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.
 - Consensus, in the ANS context, is more than a numerical determination

ANSI's Definition: Consensus body

- ◆ Consensus body: The group that approves the content of a standard and whose vote demonstrates evidence of consensus.
 - Committee, canvass list, Technical Committee, Board, etc.

ANSI's Definition: 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:
 - a) expressing a position and its basis,
 - b) having that position considered, and
 - c) having the right to appeal.
 - Due process allows for equity and fair play.
 - The following constitute the minimum acceptable due process requirements for the development of consensus.
 - See next slide

ANSI Essential Requirements

Criteria for ANS Consensus (read together)

1.1 & 2.1 Openness

1.2 & 2.2 Lack of dominance

1.3 & 2.3 Balance

1.4 & 2.4 Coordination and harmonization

1.5 & 2.5 Notification of standards development

1.6 & 2.6 Consideration of views and objections

1.7 & 2.7 Consensus vote

1.8 & 2.8 Procedural appeals

1.9 Written procedures

1.10 Compliance with normative policies: ANSI patent policy, commercial terms & conditions, antitrust, evidence of compliance, metric, interpretations



Today we'll focus on...

- ◆ Openness
- ◆ Balance
- ◆ Lack of dominance

1.1 & 2.1 Openness

What is required?

- ◆ 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.

1.1 & 2.1 Openness

What is required?

- ◆ 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 affected interests.
- ◆ 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.
 - ASD is not required to provide contact information as part of the roster.

1.1 & 2.1 Openness Related definition

- ◆ **“Affiliation”** 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, that person’s employer, sponsor and interest category should be available.

1.2 & 2.2 Lack of dominance

What is required?

- ◆ 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.*
- ◆ Unless it is **claimed in writing** (including electronic communications) by a directly and materially affected party that a single interest category, individual or organization dominated the standards development process, no test for dominance is required.
 - A written claim of dominance is considered a procedural grievance that should be reviewed by the ASD in a timely manner and is later eligible for review again within the ASD's appeals process and subsequently, at ANSI.

1.3 & 2.3 Balance

What is required?

- ◆ 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, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, *outreach to achieve balance shall be undertaken.*

1.3 & 2.3 Balance

What is required?

- ◆ 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 all materially affected parties and differentiate each category from the other categories.**
 - Such definitions shall be available upon request.
- ◆ In defining the interest categories appropriate to a standards activity, **consideration shall be given to at least** the following:
 - a. Producer
 - b. User
 - c. General interest
 - Where appropriate, additional interest categories should be considered.[2]

[2] **Further interest categories that may be used** to categorize directly and materially affected persons 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; i) Regulatory agency; j) Testing laboratory; k) Trade association.

2.3 Balance

“Historical criteria”

- ◆ 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**...

1.3 & 2.3 Balance – Notes

- ◆ Balance is important and shall be sought
- ◆ Targeted outreach to solicit participation from one or more underrepresented 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
- ◆ Evidence of outreach shall be available to the BSR, the ExSC 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

1.3 & 2.3 Balance – Notes

- ◆ Interest categories must be *appropriate to the nature of the standard*
- ◆ Interest category definitions must be available upon request
- ◆ Typical outreach may include, in addition to *Standards Action*:
 - Targeted outreach as needed in 1 or more interest categories
 - Website announcements: standing and special/targeted
 - Trade press
 - E-mail/letter based solicitations
 - Announcements at meetings and/or meeting reports
 - Personal/telephone solicitations (documented)
 - Other

ANSI's Essential Requirements do NOT require

- ◆ Drafting a proposed ANS from scratch
- ◆ Meetings
- ◆ Use of 3 (or these) Interest Categories: User, Producer, General Interest
- ◆ The consensus body to develop and vote on responses to public comments or comments submitted with a consensus body member's vote
- ◆ Openness, balance, due process, consensus on a working group (or the like), unless a developer's procedures state otherwise

Due process safeguards in the ANS process

- ◆ ANSI is neutral
- ◆ ASDs participate voluntarily
- ◆ ANS-related procedures are living documents, subject to proposed revisions from materially interested parties
- ◆ ASDs must have written and publicly available procedures
- ◆ Public notice and comment consideration is required: standards, procedures
- ◆ ANS maintenance requirements apply – regular review of ANS is required
- ◆ ANSI procedural appeals process: time-tested, credible and fair procedural review (typically requires conclusion of appeals process at ASD)
- ◆ Procedural audit process of ANS, which addresses the integrity and the “plumbing” of the ANS consensus process
- ◆ Opportunity to request the “Withdrawal for Cause” of a standard’s ANS status at any time

Where can I find ANS information?

www.ansi.org/asd

- ◆ List of ANSI-Accredited Standards Developers (ASD) with a scope and contact
- ◆ Lists of proposed ANS and approved ANS
- ◆ Guidance documents, procedures and interpretations

www.ansi.org/StandardsAction

- ◆ PINS (Project Initiation Notifications): notice of proposed ANS
- ◆ Public review: open public comment opportunities on proposed ANS
- ◆ Recently approved ANS
- ◆ Procedural revisions to ANSI's *Essential Requirements*

Questions?

Gaby Davis, ANSI Board of Standards Review (BSR) Chair

Chris Dubay, ANSI Executive Standards Council (ExSC) Chair



The Role of American National Standards: One perspective

Commissioner Robert Adler
U.S. Consumer Product Safety Commission



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Panel 1 – Openness and Participation in the ANS Process

Claire Ramspeck, Moderator



Panel 1 – Openness and Participation in the ANS Process

- ◆ **Moderator: Claire Ramspeck, ASME, ANSI OMF Chair, ANSI ExSC Standards Advisor**
- ◆ Walter Jones, Laborers Health & Safety Fund of North America
- ◆ Len Morrissey, ASTM International
- ◆ Elaine Newton, ORACLE
- ◆ Elise Owen, EPA, ANSI ExSC Member, ANSI Board Member
- ◆ Greg Saunders, DoD, Vice Chair ANSI National Policy Committee (NPC)
- ◆ Rachel Weintraub, Consumer Federation of America, ANSI Board Member

Panel 2 – Balance and Interest Classification of ANS Consensus Body Membership

Gaby Davis, Moderator



Panel 2 – Balance and Interest Classification of ANS Consensus Body Membership

- ◆ **Moderator: Gaby Davis, IAPMO, ANSI BSR Chair**
- ◆ Hany Demian, FDA
- ◆ Linda Golodner, Chair ANSI Consumer Interest Forum (CIF), ANSI Board Member
- ◆ Megan Hayes, Plastics Industry Association
- ◆ Monica Leslie, NSF International, ANSI BSR Member
- ◆ Mary McKiel, American Academy of Forensic Sciences, ANSI Board Vice Chair
- ◆ Christine Niero, Professional Testing Inc.
- ◆ David Pittle, Former CPSC Commissioner, Former Sr. VP Consumer Reports, ANSI Board Member, ASTM F15 Committee on Consumer Products Exec Com, ANSI ExSC Standards Advisor, ANSI CIF Member

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Panel 3 – Affiliation, Disclosure and Accurate Accounting of ANS Consensus Body Members

Paula Watkins, Moderator



Panel 3 – Affiliation, Disclosure and Accurate Accounting of ANS Consensus Body Members

- ◆ Moderator: Paula Watkins, API, ANSI ExSC Member
- ◆ Bob Adler, Commissioner, U.S. CPSC
- ◆ Neil Bogatz, IAPMO, ANSI ExSC Member
- ◆ Cristine Fargo, Industrial Safety Equipment Association, ANSI BSR Member
- ◆ Len Morrissey, ASTM International
- ◆ David Pittle, Former CPSC Commissioner, Former Sr. VP Consumer Reports, ANSI Board Member, ASTM F15 Committee on Consumer Products Exec Com, ANSI ExSC Standards Advisor, ANSI CIF Member
- ◆ Jeff Smith, Phillips Nizer LLP

Panel 4 – Should the *ANSI Essential Requirements* be further refined to distinguish among types of ANS?

Claire Ramspeck, Moderator



Panel 4 – Should the ANSI Essential Requirements be further refined to distinguish among types of ANS?

- ◆ Moderator: Claire Ramspeck, ASME, ANSI OMF Chair, ExSC Standards Advisor
- ◆ Patty Edwards, U.S. CPSC, ANSI ExSC Standards Advisor, ANSI Board Member
- ◆ Tim Fisher, American Society of Safety Engineers
- ◆ Gordon Gillerman, NIST, ICSP Chair, ANSI Board Member
- ◆ Tim Klein, Office of the Assistant Secretary for Research and Technology/DoT, Chair ANSI GMF, ANSI Board Member
- ◆ Christine Niero, Professional Testing Inc.
- ◆ Dan Ryan, UL, ANSI ExSC Vice Chair
- ◆ David Pittle, Former CPSC Commissioner, Former Sr. VP Consumer Reports, ANSI Board Member, ASTM F15 Committee on Consumer Products Exec Com, ANSI ExSC Standards Advisor, ANSI CIF Member

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Moderated Full Group Discussion

Chris Dubay, Moderator



Panel 5 – What have we heard today?

- ◆ Moderator: Chris Dubay, NFPA, ANSI ExSC Chair, ANSI Board Member
- ◆ Bob Adler, Commissioner, U.S. CPSC
- ◆ Gaby Davis, IAPMO, Chair ANSI BSR
- ◆ Linda Golodner, Chair ANSI CIF, ANSI Board Member
- ◆ Tim Klein, Chair ANSI GMF, ANSI Board Member
- ◆ Claire Ramspeck, Chair ANSI OMF, ANSI ExSC Standards Advisor, ANSI Board Member
- ◆ Dan Ryan, Vice Chair ANSI ExSC
- ◆ Greg Saunders, DoD, Vice Chair, ANSI NPC

Closing Remarks & Thank you

ANSI President, Joe Bhatia



For More Information

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