

The Role of American National Standards: One Perspective



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Commissioner, CPSC
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Skepticism About Voluntary Standards

In my view, it's very unlikely that an existing voluntary standard would be appropriately made mandatory.

... First of all, if the standard was developed by a consensus method, its principal feature was that it was acceptable to everybody, not that it reflected the best that was available, even within the existing state of the art. And for us to make such a standard a matter of law seems to me not to be a good practice

**CPSC Commissioner Larry Kushner,
1974 (formerly, Associate Director,
National Bureau of Standards [Now
NIST])**



Recent Developments

- **CPSC and Voluntary Standards Organizations currently work collaboratively and cooperatively – perhaps better than ever.**



CPSC Views on Openness and Due Process



CPSC will participate in voluntary standards activities depending on the openness to all interested parties, and the establishment of procedures which will provide for meaningful participation in the development of such standards by representatives [of various interested stakeholders] having knowledge or expertise in the areas under consideration, and procedures for affording other **due process concerns.**

Source: 16 CFR 1031.5(i)

The Value of ANSI Accreditation According to ANSI*

#2: Increased government reliance

Numerous federal, state, and local authorities rely on ANSI accreditation to demonstrate value and assure competency for important national priorities.

#6: Broad confidence and trust

Industry, consumers, and governments alike recognize the dependability of ANSI accreditation.... [T]he ANSI name brings with it a level of confidence and trust that gives assurance to the outputs of an accredited program.

***Source: ANSI: "The Value of ANSI Accreditation: Top 10 Advantages"**

The Bottom Line: Is it



an industry standard?

an ANSI standard?



ANSI: We Only Do “Due Process”

ANSI does not review or endorse the technical content of an American National Standard. Its approval provides assurance that the standard was developed in compliance with all of ANSI’s *due process-based requirements* and that there was an opportunity for all those who are interested in and affected by a standard to participate in its development.

Source: ANSI Essential Requirements

Due Process Concerns

- Due process does not itself guarantee consumer protection or adequate safety (“let’s kill all left-handed people”)
- Where organization’s primary function is to approve due process, need meticulous scrutiny of such procedures adopted and implemented by SDOs.



Summary of Adler Proposal

- **Limited to Health and Safety Standards**
- **No recommendation to change basic structure of Essential Requirements, just to make them fully realized**
- **Balance Issues/Openness Issues**
- **Full Financial Disclosure to Achieve Balance**

Health and Safety Standards: Proposed Definition

Includes any standard that is intended to protect individual end users, such as consumers or employees, from death, injury or illness.

Presumptive health and safety standards include those from –

- EPA, USDA, NHTSA, CPSC, FDA, OSHA, U.S. Coast Guard (limited to consumer products regulated by Coast Guard), Nuclear Regulatory Commission (e.g., nuclear medicine), FAA (limited to products under FAA's jurisdiction)

Generally excluded from health and safety standards –

- Department of Defense, Department of Homeland Security, Bureau of Alcohol, Tobacco and Firearms, DEA, Nuclear Regulatory Commission (licensing and regulation of nuclear power facilities)

ANSI'S DUE PROCESS CRITERIA

1. **Openness**
2. Lack of dominance
3. **Balance**
4. Coordination and harmonization
5. Notification of standards development
6. Consideration of views and objections
7. Consensus vote
8. Appeals
9. Written procedures

Source: ANSI Essential Requirements



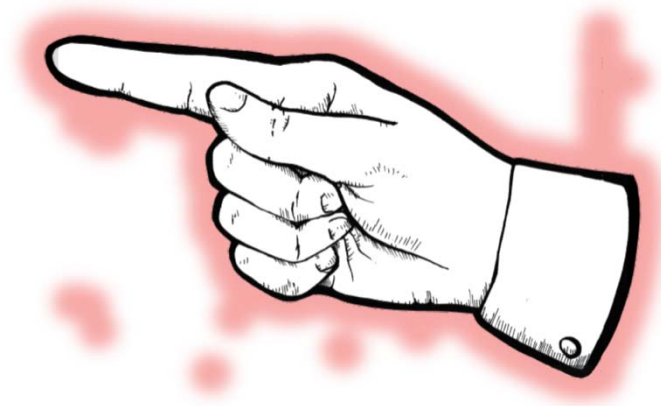
Balance: A Critical Component

- Historically, the criteria for balance are that ... *no single interest category constitutes more than one-third of the membership of a consensus body....*
- Interest categories shall be discretely defined, cover all materially affected parties and differentiate each category from the other categories.

Source: ANSI Essential Requirements

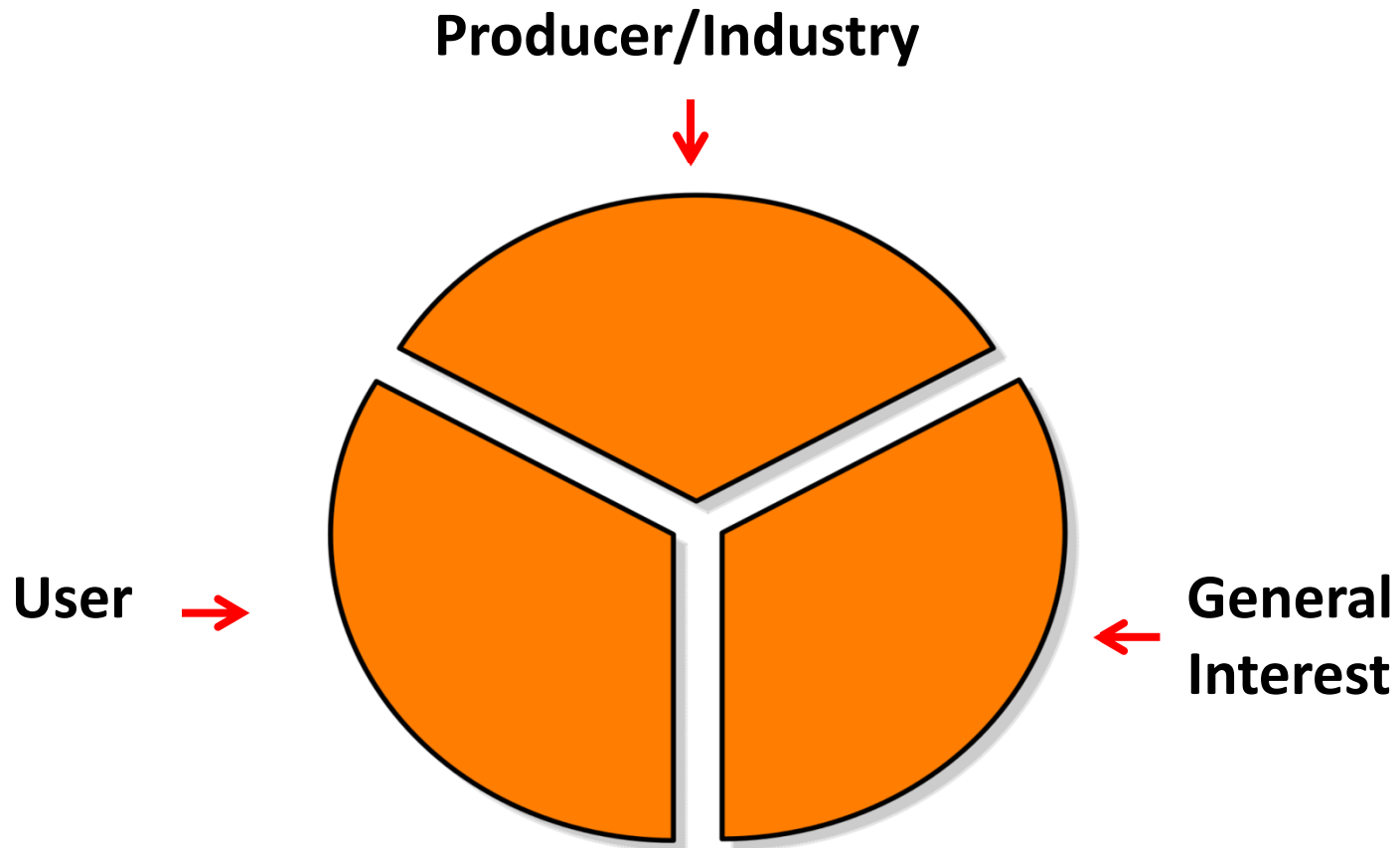
The Three Broad Interest Categories

- **Producer**
- **User**
- **General Interest**



Source: ANSI Essential Requirements

Fair Balance:
No More Than One-Third in Any Category

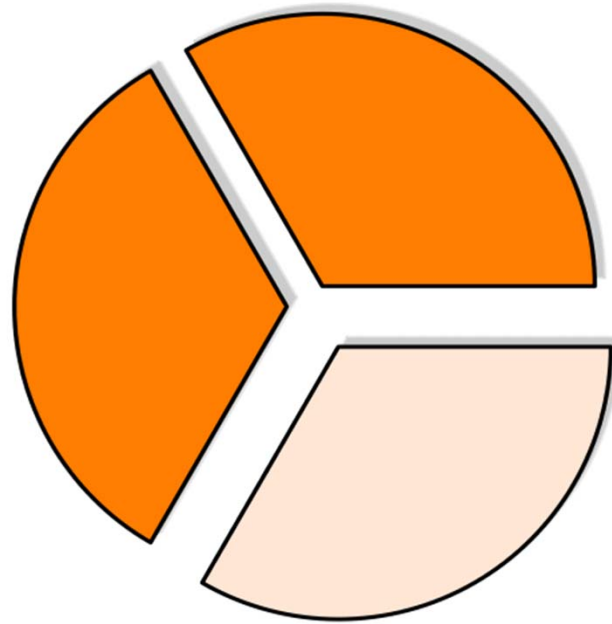


Source: ANSI Essential Requirements

“General Interest” Category: Serious Concerns

- **Individuals with strong financial ties to industry are too often considered “general interest” when they are really industry representatives.**
- **Examples: trade association members, industry consultants, retired industry officials on pensions, expert witnesses, academic grant recipients, family members of industry officials, distributors or retailers of subject products, etc.**
- **No problem with such individuals participating, but strong objection to classifying them as “general interest.”**

What General Interest Should Be: No Financial Ties to Subject Industry

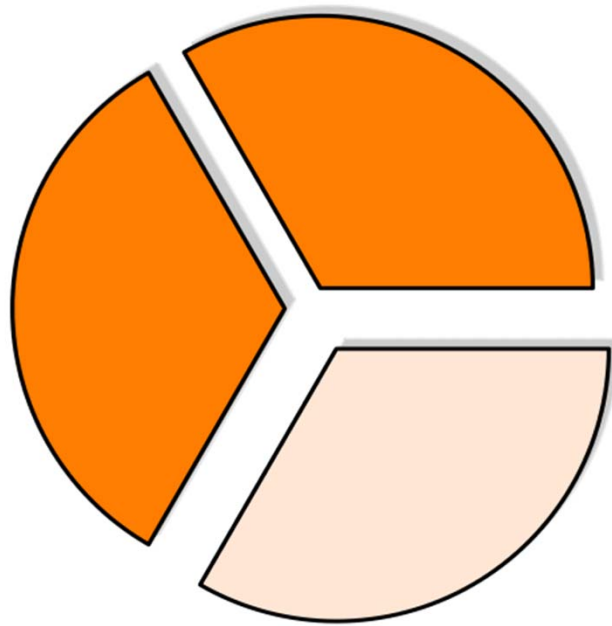


General Interest



- Independent Consultants
- Retired officials (no ties)
- Academics (no ties)
- Testing labs (no ties)
- CPSC staff
- State and local officials
- Etc.

Not General Interest: Financial Ties to Subject Industry



- Trade associations
- Industry Consultants
- Retired industry officials
- Expert witnesses
- Industry grant recipients
- Family members
- Distributors
- Retailers



Gene ~~X~~ Interest

Interest Categories for Health and Safety Standards

BUSINESS	USER	GENERAL
Manufacturers	Individual consumers	Medical professionals
Retailers	Consumer groups	Academics/researchers
Importers	Hobbyists	Professional societies
Distributors	Union representatives	Independent test labs
Trade Associations	Government (all levels)	Government (all levels)
Paid consultants (includes academic consultants)	Representatives of internet sites that evaluate products or services	Independent technical experts
Expert witnesses		Independent consultants
Retired industry employees within past three years (<i>unless receiving industry pension</i>)		Think Tanks
Industry lawyers		Non-industry lawyers

Financial Disclosure: Essential for the Essential Requirements

- **Only way to know whether meeting balance requirements is to know about financial ties**
- **Can't do that without financial disclosure.**



Proposed Disclosure Form [excerpts]

- Name
- Address
- Email
- Phone number
- Employer
- Title
- Standard(s) Applied to Participate in
- Proposed Participation Category (Producer, User, General Interest)*
- Business/Non-business Affiliations reasonably related to subject of standard
- Financial Relationships (Direct or indirect funding sources for time and expenses to participate in standards development)

**Only those stating an intent to be in “user” or “general interest” must fill out the disclosure form. Those who do not fill out the form will be automatically placed in “producer” category.*

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Source: ANSI Essential Requirements



Openness

1.1 Openness

Participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation.



Source: ANSI Essential Requirements

Openness Concerns

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- **Need to provide meaningful opportunities for participants to give input on issues of importance**
 - **Opportunity to engage in dialogue during standards drafting – as opposed to circulation of written drafts without ability to discuss particular provisions (Canvass method)**
 - **Greater advance notice of meetings in distant cities**
 - **Participation via internet/web – better technical hookups needed**

Questions or Comments

