

COMMENTS ON
Proposed revisions to the *ANSI Essential Requirements*
ExSC_017_2019
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I greatly appreciate the opportunity to submit comments on the proposed revisions to the *ANSI Essential Requirements*. I particularly appreciate the opportunity that ANSI has provided me every step of the way to offer suggestions and make comments.

Having read the suggested revisions, I would like to voice my general support for them. I believe that they show a commitment to improving the standards development process in a way that is broadly beneficial to the public. That said, I continue to find the changes falling short of what I believe is truly necessary to ensure that ANSI standards meet ANSI's commitment to due process and full consensus.

My concern stems from my role as a government official with the responsibility to safeguard the public's health and safety. As such, I always look to – and hope for – voluntary standards to play a major role in protecting the public. To the extent that ANSI procedures can help in this role, I strongly support and encourage them. To the extent that they do not meet the public's needs, the government must get involved – a step I always hope is not necessary. This is why I care so strongly about the need for fully adequate ANSI procedures.

With this thought in mind, I offer the following suggested changes² to the current proposal:³

2.2 Lack of dominance

Insert the following after the words “no test for dominance is required” on Line 23 --

Although the particulars of any given standards proceeding that give rise to a party's dominance may vary, the following constitute presumptive dominance –

- a) The refusal to permit or failure to provide the opportunity for a participant's comments to be heard,
- b) The refusal to permit or failure to provide reasonable deliberation and discussion of a participant's views,
- c) The refusal to give or failure to provide adequate notice to any participant of an upcoming meeting,

¹ NB: These comments are submitted exclusively by Commissioner Adler, not on behalf of the Commission.

² In addition to these suggested changes, I have had an opportunity to review former CPSC Commissioner David Pittle's comments to the proposed revisions. I unqualifiedly endorse his comments.

³ My concerns are broader than what I have submitted here. As a reminder, I submitted an extensive proposal for revising the *Essential Requirements* in May 2018. I have attached this proposal to my submission.

- d) The refusal or failure to circulate a draft of a standard without adequate time to read and comment on the draft,
- e) The refusal to permit or failure to provide an open discussion of drafts of a proposed standard,
- f) The establishment of a standard’s consensus body without adequate balance among the interest categories, or
- g) Any other act of failure to act that unfairly gives an advantage to any person or group involved in drafting a standard that will be submitted for acceptance as an American National Standard.

Comment: I realize that there is a reluctance to add provisions to the *Essential Requirements*, as opposed to adding provisions in guidance documents. That said, I have heard enough concerns raised about parties seeking unfairly to dominate the proceedings that I believe the time is ripe for more explicit rules. I am flexible about the precise wording of what constitutes presumptive dominance, but I believe it critical to send a strong signal of ANSI’s disapproval of such behavior.

2.3 Balance

Insert the following at the end of line 71 –

In the special case of *consumer product health and safety standards*,⁴ the following categories shall apply exclusively and additional categories shall not be established:

- a) Producer;
- b) User;
- c) General interest.

Where appropriate, sub-categories of interest categories may be created, but shall not dilute balance requirements that apply to consumer product health and safety-related standards.

Comment: As I have long argued, the *Essential Requirements*, which already have carved out separate requirements for “safety-related” standards,⁵ should have a limited, but

⁴ The term “consumer health and safety standard” includes any product standard that is intended to protect individual end users, such as consumers or employees, from death, injury or illness from use of that product. Any product safety matter that is the subject of official concern by any federal or state health and safety organization shall presumptively be considered a consumer product health and safety standard.

⁵ Section 2.3 (balance) currently states –

Historically, the criteria for balance are that ... no singly interest category constitutes more than one-third of the membership of a consensus body dealing with *safety-related standards*.... (emphasis added).

See also section 4.7.3 of the *Essential Requirements* that also maintains a separate provision for “safety or health related” standards.

important, number of provisions that apply specifically to consumer product health and safety standards. My reasons are as follows –

- Health and safety issues generally occupy a higher level of concern than issues like cost, quality, precision, or aesthetics. These other issues are certainly important, but usually do not directly and immediately affect the lives and limbs of the public.
- Health and safety often require special protections that do not necessarily lend themselves to the type of standards that non-health and safety groups write. For example, a safety standard for a children’s product such as a crib may employ a different cost-benefit approach to account for infants’ vulnerability than a measuring standard for two-by-four wood pieces. Accordingly, different approaches and requirements are necessary.
- As a government regulator who cherishes my involvement with ANSI and other voluntary standards bodies, I must point out that I and other representatives from health and safety agencies have a legislative mandate to scrutinize both the development and substance of safety standards. Voluntary safety standards stand in the place of mandatory standards, so we must be certain that voluntary standards have been developed in a fair and rigorous manner. If CPSC and other health and safety agencies are to continue to work as partners with voluntary standards organizations – as I am committed to do – I believe it essential that such organizations demonstrate sensitivity to the need for extra precautions in developing health and safety standards.
- To the extent that the Task Group insists that any revisions to the *Essential Requirements* must apply to *all* ANSI standards, it effectively stymies any health and safety reforms since such reforms typically add requirements that many SDOs not involved in health and safety issues view as unnecessary and annoying. Anyone who has attended recent ANSI/TASK GROUP meetings can verify this point.

1.5 Notification of standards development

Insert the following at the end of line 77 –

1.5.1 Canvass Method

No health or safety standard may be approved through a non-deliberative canvass method, i.e., an approach in which a draft is circulated for a vote in the absence of reasonable deliberation or discussion among the participants, which may be conducted online or through other reasonable means of communication.

Comment: Since I began as a Commissioner, I have repeatedly heard complaints from consumer groups that various SDOs provide minimal to virtually no meaningful opportunity for deliberation and discussion. I certainly appreciate the addition of the

language in the proposed revisions in sections 1.5 and 2.5 calling for meaningful opportunity for participation, debate and deliberation by all directly and materially affected persons in a fair and equitable manner. That said, I would still like some language in the *Essential Requirements* that explicitly addresses the canvass method to drive home the point.

2.5.1 Project Initiation Notification (PINS)

Delete the word “and” at the end of line 98.

Add the word “and” at the end of line 99 and insert the following –

(d) full financial disclosure of any and all financial connections, direct or indirect, that exist with respect to any Producer interest participating in the development of a health and safety standard.

Comment: I fail to see how compliance with the Balance requirements of section 2.3 can be assured without the parties’ financial disclosure. Many SDOs that participate in ANSI development currently have detailed and elaborate financial disclosure forms that must be filled out in order for parties to participate in their deliberations. I doubt that there is a person involved in standards development work who has not filled out numerous financial disclosure forms, so this should be considered a routine procedure. More importantly, given the many instances of parties with financial ties to the industry that is the subject of a voluntary standard development process participating as General Interest members, I believe it critical to have them properly identified and classified. All are welcome, of course, but not in interest categories to which they have no right to claim membership.

PREVIOUS PROPOSAL

ANSI Essential Requirements: Due process requirements for American National Standards**1. Essential requirements for due process**

These requirements apply to activities related to the development of consensus for approval, revision, reaffirmation, and withdrawal of American National Standards (ANS).⁶

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 standards.

⁶ Please see Section 6.0 for additional requirements for such activities related to health and safety standards.

6.0 Essential requirements for due process for health and safety standards.

In addition to the requirements that apply to activities related to the development of consensus for approval, revision, reaffirmation, and withdrawal of American National Standards (ANS), the following requirements shall apply to standards that address health and safety concerns. A health and safety standard shall include any standard that is intended to protect end users, such as consumers or employees, from death, injury or illness. Any matter that is the subject of official concern by any federal or state health and safety organization shall presumptively be considered a health and safety standard subject to this section in the event that the matter shall be considered for development as an American National Standard.

Due process means that any person (organization, company, government agency, individual, etc.) with an interest in the development of a health and safety standard has a right to participate by: a) expressing a position and its basis, b) by having that position considered, and c) having the right to appeal. Due process allows for equity and fair play. In addition to the requirements set forth in section 1-5 of this document, the following constitute the minimum acceptable due process requirements for the development of consensus for health and safety standards.

6.1 Openness

Participation shall be open to all persons who are interested in the development of a health and safety standard who agree to abide by the essential requirements for due process set forth for the development of American National Standards. There shall be no financial barriers or requirements for participation in the development of a health and safety standard. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor restricted on the basis of technical qualifications or other such requirements.

In order to guarantee openness at every stage of the development of a health and safety standard, the standard developer shall facilitate or host one or more sessions at the outset of the consensus process to allow the consensus body members to discuss the health and safety goals of the proceeding and the available evidence supporting the need for the standard. At this meeting, the members should express their preliminary views regarding how the standard should be developed and what its requirements should be.

In order to promote openness throughout the development process, all meetings of the consensus body shall be open to all members, either in person, by conference call, or interactive webinar. In all instances where meetings are through digital or other media, the standard developer shall ensure that all members are notified in writing at least ten (10) days in advance and provided clear instructions about how to participate in the meetings.

To ensure the openness of the process, the standard developer shall maintain written records of all meetings of the consensus body. Such records shall include that date, time, subject, and

attendees of the meeting. These records shall be available for inspection by any review body within ANSI.

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 the membership is by organization, the name of the organization with a point of contact), affiliation⁷ and interest category of each member of the consensus body shall be made available to interested parties upon request.

No health and safety standard may be approved through the canvass method, i.e., an approach in which a draft is circulated for a vote in the absence of a full discussion among the participants either through a meeting in person, by conference call, or interactive webinar, unless all members of the consensus body agree to such an approach.

6.2 Lack of dominance

The standards development process shall not be dominated by any single interest category, individual or organization, including the standard developer. 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.

Any member of a standards development activity may object at any point in the process by claiming in writing that the process is subject to one or more parties' dominance. In support of this claim, the party objecting should offer specific facts that illustrate that a party has exercised dominance to the exclusion of fair and equitable consideration of other viewpoints.

To prevent dominance, the standards development process shall –

- a) Provide appropriate balance, in accordance with section 6.3, on the standards development consensus body,
- b) Operate the process in accordance with the openness requirements in section 6.1,
- c) Permit any party dissatisfied with the process on the basis of one or more parties exercising dominance to object in writing at any time before or during the process and to respond in writing to the objections.

6.3 Balance: Basic Categories

⁷ "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 shall be available.

Sections 6.3 and 6.4 are intended to replace and supersede section 2.3 of the Essential Requirements.

The criteria for balance on health and safety standards are that no single interest category constitutes more than one-third of the membership of a consensus body dealing with such standards.

Balance in the development of health and safety standards is the greatest need for American National Standards. Without balance, consensus standards will inevitably face dominance by parties who seek to draft standards favorable to their particular concerns rather than standards that favor the public interest. Accordingly, it is vital that careful attention be paid to establishing consensus bodies with balance of interests.

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 other categories. Such definitions shall be available upon request. In defining the interest categories appropriate to a standards activity, the following broad classifications shall apply⁸:

- a) Business interest;
- b) User interest;
- c) General interest.

Where appropriate, additional interest categories should be considered (subject to section 6.4).⁹

Business interest shall include all who, directly or indirectly, receive compensation or financial benefit from the production or sale of a consumer product (or a related product¹⁰) that is the subject of a standards development proceeding. At a minimum, the term includes manufacturers, retailers, importers, distributors, trade association members and staff, paid consultants, industry retirees, and expert witnesses for the consumer product that is the subject of the standards development proceeding.

User interest includes all end users for whom a consumer product is produced. It also includes parents or other caregivers of end users. [**need to expand this**] No one who currently, or in the past, has received (or anticipates receiving) compensation, directly or indirectly, from the

⁸ For a table that summarizes these interest categories, see Appendix 1.

⁹ 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.

¹⁰ For example, one who is affiliated with the production of all-terrain vehicles (ATVs) would be placed in this interest category even if he or she worked exclusively on recreational off-highway vehicles (ROVs).

production or sale of the consumer product that is the subject of the standards development proceeding is eligible to serve as part of a user interest group.

Appropriate representative user views shall be actively sought and fully considered in standards activities. Whenever possible, user participants shall be those with requisite technical knowledge, but other users may also participate. User participation may come from both individuals and representatives of organized groups. There are at least two user categories for health and safety standards:

1. User-consumer: Where the standards activity in question deals with a consumer product, such as lawn mowers or aerosol spray, an appropriate consumer participant's view is considered to be synonymous with that of the individual user – a person using goods and services rather than producing or selling them.
2. User-labor: Where the standards activity in question deals with subjects of special interest to the American worker such as products used in the workplace, an appropriate user participant is a representative of labor.

General interest is a catch-all category for those with an interest in the consumer product that is the subject of a standards development proceeding who do not fit into the Business Interest or User-Interest categories. For example, it includes individuals or groups who provide medical or other services to end-users of the consumer product that is the subject of a standards development proceeding. It also includes university researchers, government experts, professional societies, test laboratories, and independent technical experts. No one who currently, or in the past, has received (or anticipates receiving) compensation, directly or indirectly, from the production or sale of the consumer product that is the subject of the standards development proceeding is eligible to serve as part of a general interest group.

6.4 Balance: Subdivision of Interest Categories

As noted, within the three broad interest categories, it may be appropriate and useful to further subdivide members of the standards development proceeding into smaller interest groups with shared concerns (see footnote 3 for examples). All interested parties are encouraged to participate.

In order to maintain appropriate balance, however, any subdivided interest group will be considered to remain within one of the three main interest group into which it fits. Under no circumstances shall any subdivided groups constitute more than one-third of the broad interest group in which they belong. For example, should users subdivide into user-consumer and user-labor groups, they cannot then claim the right to cast more than one-third of the total votes in the standards development proceeding.¹¹

¹¹ Or to put it another way: each of the three broad interest groups is entitled to cast one-third of the votes regarding the standard – no more, no less.

6.5 Notification of standards development and coordination

Notification of standards activity shall be announced in suitable media as appropriate to demonstrate the opportunity for participation by all interested persons. Developers must particularly document the steps they have taken to extend invitations to participate to relevant consumer groups, public interest groups, and individual consumers.

6.5.1 Project Initiation Notification (PINS)

At the initiation of a project to develop or revise an American National Standard, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*. In the case of health and safety standards, the developer shall reach out beyond an announcement in *Standards Action* to critical stakeholders, especially those of consumers, consumer groups, public interest groups, or labor groups (as appropriate) with a particular interest in the development of the standard. Further, the developer shall document the steps it has taken to notify and solicit participation particularly from these groups.

Any announcement of the initiation of the development or revision of an American National Standard 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., consumer, medical, environmental, labor, etc.) likely to be directly impacted by the standard.

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

6.5.2 Public Review

In all instances of the revision or development of a health and safety standard, there shall be a minimum of a 60-day public comment period. 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*

HEALTH AND SAFETY INTEREST CATEGORIES

BUSINESS INTEREST	USER INTEREST*	GENERAL INTEREST*
Manufacturers	Individual consumers	Medical professionals
Retailers	Consumer groups	Academics/researchers
Importers	Hobbyists	Professional societies
Distributors	Union representatives	Test labs
Trade associations	Government (federal, state, local)	Independent technical experts
Paid consultants (includes academic consultants)		Plaintiff attorneys
Expert witnesses		
Retired industry employees		
Industry attorneys		

*No commercial interest in production or sale of the consumer product that is the subject of the standards proceeding