

PROPOSED REVISIONS TO THE ANSI *ESSENTIAL REQUIREMENTS*

ANSI Standards Action – December 6, 2019

ExSC_017_2019

1) INTRODUCTION

These comments were developed by an informal group interested in consumer issues based on combined experiences with various ANSI standards efforts. We previously submitted comments (ExSC_047_combined_SH proposal) to ANSI in May of 2017 on the need to strengthen the ANSI Essential Requirements (ERs). We focused on a subset of ANSI standards – those addressing consumer and worker safety and health. In response to these and various other comments, ANSI published several proposed revisions to the ERs on December 6, 2019.

The ANSI ERs play an important role in voluntary consensus standard setting because they describe the minimum due process requirements that accredited standard developers (ASDs) must follow when developing American National Standards (ANSs). ANSI is the U.S. national body for the International Standards Organization (ISO) thus ANSI standards have important domestic and global ramifications for consumer and worker end-users. The integrity of ANSI standards reflects the rigor and implementation of the ERs.

We believe that while the proposed changes to the ERs represent welcome improvements, the overall changes do not go far enough. For example, new wording clarifies affiliation of consensus body members (2.1, lines 15-18) and classification of consultants (2.3, lines 35-39). This could help reduce the balance problems that occur when industry consultants are placed into consensus body general interest categories. Further, new language encourages provision of reasonable advance notice and fair and equitable deliberations (1.5, lines 75-77, and 2.5, lines 81-84). Various appeal procedures are also clarified (2.8.2, lines 137-156). ANSI proposes that these changes apply to all standard developers, not just those involved with standards addressing end-user safety and health.

These modest changes fall far short of our goal to remedy persistent and fundamental deficiencies in the ERs. Our previous comments were crafted to enable the ERs to meet these five fundamental benchmarks:

- 1) Standard developer conflict of interest is disclosed, minimized, and mitigated.*
- 2) Rigorous administrative review is performed at the outset and identifies and resolves procedural deficiencies – before the consensus process begins.*
- 3) Standards are developed by diverse and balanced consensus bodies with meaningful opportunities for participation.*

4) Standards development is guided by an evidence-based framework that is transparent, objective, and consistent with safety and health practice.

5) A more comprehensive appeals process provides a necessary check for conformance with the Essential Requirements.¹

We find the proposed changes insufficient to allow the ERs to meet these basic public policy benchmarks for balanced, credible, protective, evidence-based safety and health standards suitable for national and international use.

In addition, the proposed changes fall far short of enabling the ERs to meet ISO recommendations addressing consumer participation in standard setting. This means that ANSI's processes fail to elevate U.S. practices to meet or exceed recommendations published by ISO for use by all national bodies. These fourteen recommendations were published nearly twenty years ago in 2001 and changes to U.S. practices are long overdue. For example, the ISO recommendations include these items (excerpts and partial list):

Recommendation 3. At the national level, consumer interests should be invited to participate in all technical committees executing standards projects affecting the interests of the consumer. The degree of participation should reflect the relative importance to consumer interests of the particular project.

Recommendation 4. If consumers are not able to finance their participation in the standardization process themselves, the national body should enable consumers to participate in priority areas of consumer interest. It should be recalled that consumers form an integral part of the consensus-building process.

Recommendation 10. During the standards-writing process, consumer input should be sought in particular at the following stages:

- when establishing the scope of the standard (e.g. health and safety, fitness for use and environment), listing the characteristics, assigning the tasks to the members of the committee and determining whether research among consumers is necessary;*
- during the technical committee's work, whenever a decision is to be made that affects the established scope and/or the required performance level(s);*
- following the circulation of the draft, when the committee considers all the comments received;*
- at the voting stage.²*

¹ Informal workgroup cover letter to Ann Caldas of ANSI transmitting comments, May 5, 2017

² ISO/IEC Statement on Consumer Participation in Standardization Work. ISO/IEC/GEN 01:2001. https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/copolcoparticipation_2001.pdf

Unfortunately, the proposed changes to the ERs do not provide a framework to support this level of participation – they do not even clearly direct ASDs to include any consumer participation on standards of importance to consumers. In summary, while we support the modest changes proposed for updating of the ERs, they are insufficient to address these key issues.

In addition to the proposed wording changes to the ER document, the ANSI Executive Council (ExSC) Task Group also provided general and specific recommendations for 1) enhancement of existing guidance; 2) development of new guidance; and 3) development of additional guidance and a definition specifically for consumer product safety standards; and 4) suggested pilot project topics to better understand additional approaches for consumer product safety standards.

We urge clarity about how external parties and consumer representatives can participate in these efforts and how these efforts will eventually be used to further strengthen the ERs. Guidance typically is viewed differently than requirements – especially in appeals and challenges, so it is unclear to us how expanded guidance ultimately provides consumers with sufficient protection. For example, how will a much-needed definition for a Consumer-Product-Safety Standard really function if it is guidance and not a requirement?

2) SPECIFIC COMMENTS

a) Section 2.3 Balance

Basis for comments: ANSI uses this section to describe two concepts. The first concept is the “historical” criteria for balance of interests represented by simple proportional limits on the upper numbers of consensus body members allowed in any particular interest category. The second (less clearly described) concept is the need to include all materially affected parties in the consensus body. The obvious concern for consumer representatives is that consensus bodies can meet the first concept apparently without meeting the second concept.

As previously stated in our May 2017 comments, Section 2.3 does not clearly describe ANSI’s intentions on this second concept. Do ASDs need to include consumer participation in standards that affect the interests of consumers? The existing language, even with proposed revisions, continues to provide a contradictory picture.

Lines 31-32 require that “Interest categories **shall** be discretely defined, cover **all** materially affected parties, and **differentiate each category** from the other categories” (emphasis added). This wording implies that consumers need to be identified and included as a materially affected interest category on consensus bodies for standards affecting consumer interests.

However, this apparent requirement is undercut later in the same section. Lines 41-45 require that ASDs consider a minimum of three interest categories: a) producer, b) user, and c) general interest. Line 52 along with footnote 3 then classify consumers as an “additional” interest category that “**should** be considered” (emphasis added). This suggests that inclusion of consumers is discretionary – even for consumer-relevant standards. It conflicts with the previous language requiring all materially affected parties to be covered.

This confusion continues into the final portion of Section 2.3 beginning on line 54. Here, ANSI includes a strong statement that “Appropriate, representative user views **shall** be actively sought and fully considered in standards activities” (line 54) (emphasis added). The ERs then introduces (but does not define) the concept of a “user category”. This suggests that some type of sub-category could be used as a mechanism to include consumers and other groups. “User-consumer” is listed first among four user categories. However, because this concept is not fully developed and because it comes **after** line 52 (which describes consumers as a discretionary “**additional interest category**”) it fails to sufficiently override or reconcile the previous language. In summary, the section in its entirety fails to clearly require consumer participation for standards affecting consumers.

Per our previous comments, we are aware of at least one ANSI appeals case that demonstrates the confusing and contradictory nature of section 2.3. Here again is a general description of that case:³

The standard was relevant for consumer safety. The ASD knew or should have known that some of the regulated products affected consumers. For example, the ASD had met with CPSC and been briefed on an increasing trend in consumer injuries from one of the products. The ASD knew of published research describing over 10,000 reported consumer injuries over a multi-year period. Lastly, it was informed by some of the participants - two consensus body members communicated the need to include consumer participation to the ASD at the outset of the consensus process.

The two consensus body members participated in an ASD-level appeal (per ANSI procedures) of the standard for multiple procedural issues, including lack of balance given the lack of any consumer participation. In response, the ASD respondent took the position that this balance claim was unfounded, because the ANSI ER simply mentions in a footnote that certain other interest categories “may be used” in the standard development process. The ASD further claimed that it was not a mandatory ANSI due process requirement to use those other

³ It is our understanding that ANSI prefers that specific standard developers and details not be provided for due process reasons. ANSI is aware of this case and should possess the reports and decisions documenting the case. We can provide additional case details and references at ANSI’s request.

categories, nor was the use of additional interest groupings a benchmark for compliance with ANSI's ERs.

The appeals panel ruled 2 to 1 upholding the ASD position and denying the appeal. The panel report stated that appellant arguments about an unbalanced consensus body **were more related to perceived inadequacies in the ERs** than on standard developer inactions, and that consumer representation was **not required** (emphasis added).

A minority report by the third panel judge stated that the canvass body was not sufficiently diverse and the lack of consumer participation was a serious flaw. He stated that if ANSI wanted ASDs to only follow minimum criteria for interest categories, why would they include all of the additional discussion in section 2.3? His interpretation, which lost out to the two other panel judge views, was that ANSI wanted all affected groups to be adequately represented.

This case provides a specific example of how scrutiny of section 2.3 by an ASD and two appeals panel judges found that it did not explicitly require consumer participation for a standard that clearly involves consumer interests. It underscores that Section 2.3 does not adequately address the balance concept related to including materially affected parties such as consumers.

The ExSC did propose new language to address consultant misclassification issues, however, none of that language directly reconciles the contradictory provisions described above.

We believe that the revised section 2.3 does not adequately support the ISO recommended position that it is essential for consumer representatives to participate in the standards development process for products and services relevant to consumers.

This means that ANSI, as the U.S. ISO standards body, is deficient in regard to international benchmarks for consumer participation. We also believe this has additional ramifications for use of ANSI voluntary consensus standards by CPSC and other state, local and federal agencies.

Proposed Alternative Language:

The existing section 2.3 requires substantial re-writing to clarify the concept of including all materially affected parties as an essential balance concept. Given the critical nature of this section sub-paragraphs should be included for clarity. We previously submitted language to revise this section and we also found that the Adler and Pittle comments contained worthwhile approaches for ER requirements and guidance. We were unable to finalize alternative language fully incorporating all three approaches for submittal, but do submit the following outline and partial content to show how section 2.3 could be restructured. We also suggest that section 1.3 on balance also be re-stated to be consistent with a new section 2.3.

2.3 Balance *(Proposed revised section)*

2.3.1 Balance Criteria

Standards are to be developed by a consensus body with a balance of interests. Two criteria must be met to demonstrate balance.

- a) No single interest category shall constitute more than a) one-third of the voting membership of a consensus body dealing with safety-related standards or b) one-half of the voting membership of a consensus body dealing with other than safety-related standards, and:
- b) All materially affected groups are identified, discretely defined via interest categories or interest category subgroups, and represented in consensus body voting membership. These groups shall be developed by the ASD as a function of the nature of the standard being developed and the potential and type of impacts on various groups.

2.3.2 Interest categories

All standards shall include at least these three primary interest categories as a minimum.

- a) Business Interest
- b) User Interest
- c) Independent General Interest

Standard developers may use the option of creating additional interest categories in order to meet the criteria to identify, discretely define, and include all materially affected groups.⁴

2.3.3 Interest category subgroups

Standard developers may create subgroups within the three primary interest categories as an alternative approach to meet the requirement to identify, discretely define, and include all materially affected groups.⁵

2.3.4 Classification and other issues

Whenever possible, participants shall be those with the requisite technical knowledge, but others may also participate. Participation should come from both individuals and representatives of organized groups.

⁴ Examples of additional interest categories include but are not limited to 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;

⁵ Examples of interest category subgroups include but are not limited to the following: a) Business Interest category subgroups: producers, distributors and retailers, employers; b) User Interest category subgroups: consumers, labor, directly affected public; c) Independent General interest category subgroups: government agencies, academic and independent researchers, independent technical experts

Interest categories or subgroups shall not be created for the purpose of avoiding balance requirements. Standards developers are responsible for ensuring that consensus body members are assigned to the appropriate interest category or subgroup.⁶

The Independent General Interest category, should include only those whose business or other interests are not covered by a discretely defined interest category or subgroup, or those who represent multiple interest categories.

Consensus body members, including consultants⁷, shall normally be classified in accordance with the business or other interests of their employers or the sponsor they represent in connection with the standards development activity. In cases where a consensus body member receives funding from the sponsoring ASD or other entity, that information shall be disclosed, to determine if it will impact the participant's interest classification.

Published final approved standards shall include a listing of canvass body members and affiliations in the forward to the standard.

We encourage ANSI to look at pragmatic approaches used by other ANSI-accredited standard developers for additional ideas on how to include consumer participation. For example, Section 7.1 of the ASTM Technical Committee Regulations simply calls for consumers to be classified separately as a fourth interest category in addition to producers, users, and general interest.⁸

b) Section 2.8 Appeals

Basis for comments: While the scope of appeals is broad (Line 123 refers to “any procedural action or inaction”) it is also vague. Standard developers only need to show that they met the minimum due process requirements described by the ERs. Lack of clarity is an obstacle to use of appeals procedures by consumer participants, who may have to determine if procedural actions were inappropriate, and then develop and deliver a written appeal all within 30 working days after an ASD action. This reduces the check and balance value of the appeals process given that participants who experience procedural problems may be hesitant about the nature of legitimate appeals topics.

Lines 117 and 118 state that “Procedural appeals include whether a technical issue was afforded due process”. This is a critical concept for safety and health standards yet we can find no ANSI language or guidance to further define this important issue. The

⁶ The May 2018 Adler comments included much information that could also be used for guidance to help ASDs make appropriate classification determinations.

⁷ For purposes of this section, a "consultant" is someone who agrees to provide professional advice or representation in exchange for compensation, financial or otherwise.

⁸ ASTM International. Regulations Governing ASTM Technical Committees. October 2018. Pg. 9
https://www.astm.org/regs_Regulations.pdf

burden of proof in appeals is on the appellant, and lack of clarity is a disincentive to using the appeals process.

In addition, the ERs are silent about appeal panel outcomes. Language is needed to prevent an ASD who loses an appeal on procedural issues such as balance from then turning to the same flawed consensus body for remedies and next steps.

Proposed Alternative Language:

Insert two new sentences in line 118 after "...was afforded due process."

Technical issue due process refers to the treatment of evidence-based comments relevant to the basis and technical content of a draft or final standard. It includes but is not limited to: a) directly addressing technical issue comments; b) providing an objective rationale in cases where technical issue comments are not accepted; c) in cases where technical issue comments are not accepted based on other available evidence, sharing that evidence with commenters; and d) having the content of the standard substantially reflect the weight of the available evidence.

Insert new footnote in line 125 after "...have the right to appeal"

"Examples of specific procedural issues that could be considered include but are not limited to: a) withholding information about consensus body member interest group or subgroup affiliations; b) failure to include all materially affected groups; c) misclassification of consensus body members that reduces balance; d) ASD conflict of interest; e) problematic conduct of meetings or voting in a manner that reduces full participation opportunities.

3) TOPICS NOT ADDRESSED IN PROPOSED ER LANGUAGE

a) Definition of a Safety and Health standard

Basis for comments: The ExSC Summary report general recommendations included a working definition for a "Consumer Product Safety Standard", but did not describe whether this will be added to the ERs or to some type of guidance.

While this definition should be suitable, it would be more useful if included as part of the ERs. In addition, we had previously provided draft ER language on several other safety and health standard considerations that have not been addressed. For example, we provided an explicit goal to make clear that such standards should use the best available scientific and objective information to protect end users to the extent technologically and economically feasible from unreasonable risks of death, injury, cumulative trauma, or ill health effects. This included eliminating or adequately reducing the addressed risks.

We also previously suggested that safety and health standards include a written safety and health goal statement to describe the specific types of injuries and illnesses that the standard is intended to prevent. This statement was to serve as the mission statement for development of the standard.

Lastly, we also suggested text to ensure that consensus bodies developing safety and health standards follow the Hierarchy of Control framework, and/or adopt by reference ISO/IEC Guide 51:2014.⁹ Without such language, the ANSI process does not assure that safety and health standards conform with well-accepted safety and health practices – meaning that standards could for example be developed that rely solely on product warnings instead of available design and engineering improvements. This is not a hypothetical concern – it is a continuing issue for development of ANSI safety standards.

While a definition is an important first step, additional language such as this is needed to put ANSI safety and health standards on an acceptable and credible footing.

b) Avoiding and Mitigating Conflicts of Interest for ANSI-accredited safety and health standard developers

Basis for comments: This is a critical issue, especially for safety and health standards. The only current mention of conflict is in Section 2.4 of the ERs, which addresses conflict among standards. No new ER language was proposed by the ExSC.

We previously provided substantial comments and language to define and address this issue. It included measures to avoid, disclose, and mitigate potential conflict of interest. We provided the example of how a trade association serving as a standard developer for a safety standard could have a secondary and conflicting interest where the association also has a stated mission to advance industry interests such as by influencing safety standards on behalf of industry members. We described an optimal approach of having a different group (this could include but not be limited to groups such as UL or ASTM) serve as ASD. We then described a secondary approach to reduce and mitigate conflict of interest in the case where groups such as industry trade associations do serve as ASDs for such standards.

Please understand that these comments are not intended to criticize the majority of standard developer organizations. However, potential conflict of interest is a legitimate topic, and many other groups and institutions (e.g. scientific journal publishers, financial advisors, law practice) have gone ahead and developed requirements and guidance to clarify and improve practices.

We note that the ANSI ExSC Task Force recommendation 3.1 (Item 6, bullet 7) calls for best practices for conflict of interest assessments be explored. However, it is unclear if this will address the important topic of potential standard developer conflict of interest.

It is a serious and unfortunate omission that the ERs do not address this topic and we strongly believe that ANSI must continue to work to fill this important gap.

⁹ See

https://isotc.iso.org/livelink/livelink/fetch/2000/2122/4230450/8389141/ISO_IEC_Guide_51_2014%28E%29_-_Safety_aspects_-_Guidelines_for_their_inclusion_in_standards.pdf?nodeid=8389248&vernum=-2

c) Outreach

Basis for comments: The ER mentions that “outreach to achieve balance shall be undertaken” if a “consensus body lacks balance” in section 1.3. Yet no other language is provided to describe minimum outreach activities that ASDs need to undertake. This is a subject of critical interest to consumer representatives.

We note that the ANSI ExSC Task force recommendation 3.1, Item 7, and Recommendation 3.2, Item 5 call for guidance on outreach be developed, including guidance for outreach to engage consumer organizations.

We previously provided text for an expanded outreach section, including reporting to ANSI on outreach efforts. Again, this is a key area that deserves requirements and/or strong guidance for relevant cases.

d) Lack of Dominance

Basis for comments: No changes were proposed for the existing ER language for lack of dominance. This is a missed opportunity given that the existing provisions are weak and rely on reporting of problems after the process has concluded – when voting on the standard has already taken place. We previously provided comments and suggested provisions to help prevent dominance. These included provisions to include ASDs, given that they are involved with critical decisions related to participant selection, interest group classifications and other actions that can relate to dominance. We also note that the previously submitted Adler comments also included more extensive text to address lack of dominance. We support the approach taken in these comments and urge the ExSC to strengthen these ER provisions.

We note that the ANSI ExSC Task force recommendation 3.1, Item 5 calls for development of guidance about claims of dominance, including against the ASD.

e) Implementation and conduct of the consensus process

Basis for comments: The ERs discuss ten due process topics but none address the process to be used to develop an evidence-based standard, even though this is a highly relevant due process issue. Basic quality assurance provisions are needed to ensure that for example a record is created for the standard and that an evidence-based framework be used to develop standards. This is a critical issue for safety and health standards. We previously developed and submitted language to address implementation and conduct of the consensus process and these remain valid. We also provided specific text to restrict the use of existing canvass approaches for development of safety and health standards.

We note that the ANSI ExSC Task Force recommendations 3.1, Items 1 and 2 call for development of guidance to address response to comment practices and record development. Recommendation 3.2, Item 4 and 3.3, Item 1 address development of guidance to improve procedures where canvass approaches are used. We note that

ANSI had previously grandfathered the use of the canvass approach for standard development. It is important that the recommended guidance not be used to resurrect previous canvass practices.

f) ANSI Review of Standard Developer procedures

Basis for comments: ANSI performs accreditation reviews and performs and administrative review of ASD procedures at the outset of the standards development cycle. This is an important check and balance on topics such as whether ASDs have included materially affected parties to support balance prior to starting the consensus process. The joint submitters previously described cases where the ANSI review failed to catch problems and suggested ER language to bolster these reviews.

We note that the ANSI ExSC Task Force stated that it did not agree to additional ANSI reviews during the standard development process. No additional guidance or pilot on this topic was described. We believe this is an important oversight that needs reconsideration.

In closing, we thank the ExSC Task Force and ANSI staff for their efforts to improve the Essential Requirements. We look forward to working with you further to meaningfully strengthen the ERs to bring about needed changes to improve the rigor, integrity, and value of ANSI standards.

Sincerely,

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