

May 5, 2017

Ann Caldas, Secretary
ANSI Executive Standards Council
25 West 43rd Street, 4th floor
New York, NY 10036

Dear Ann:

This is a request to please convey the attached proposal to the ANSI Executive Standards Council (ExSC) for their review and consideration for adoption into the ANSI Essential Requirements.

This proposal was developed by an informal workgroup consisting of the undersigned who have experience with various ANSI consensus standard efforts involving consumer and worker safety and health. Our collective experiences have led us to conclude that safety and health standards present special challenges to standards development that existing ANSI Essential Requirements do not meet. As a result, we believe it is necessary to clarify and strengthen the ANSI's Essential Requirements.

Over the past year our workgroup discussed these issues and developed the attached "*Proposal for Adding a New Safety & Health Section to the ANSI Essential Requirements*". It consists of DRAFT language combined with rationale sections to highlight the key issues of concern.

The Essential Requirements play a vital role in the ANSI standard development process. They provide critical direction for standard developers. They exist to ensure that the process is balanced, transparent, and objective. When amended, we believe the ANSI process will more reliably lead to credible, protective, evidence-based standards suitable for national and international use. We believe the current requirements fall short of these aspirations in standards dealing with health and safety. We believe our proposal improves the Essential Requirements and enables them to meet five fundamental public policy 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.*

We hope that consideration of our proposal encourages the ANSI Federation to think more broadly about the practices and procedures needed to involve consumer and worker voices. These participants represent the end-users directly affected by ANSI safety and health standards. Their participation provides needed diversity of opinion that leads to meaningful and protective standards, and will enhance broader acceptance by users in the marketplace.

We want to support ANSI in effectively promoting and implementing the thirteen International Standards Organization (ISO) recommendations included in the 2001 ISO/IEC Statement on Consumer Participation in Standardization Work. Therefore, our proposal includes language to encourage funding of consumer participation and we note that this unmet need was to be addressed in ISO recommendation #4. We request that ANSI review these recommendations as part of their review of our proposal. This may provide additional context and help ANSI identify other consumer-related areas and policies where additional changes may be needed.

In addition, we understand that it is the ANSI ExSC that is the group designated to consider our recommendations. We note that the ExSC operating procedures call for the council to have at least one and preferably two members from ANSI's Consumer Interest Forum. However, it is unclear to us whether that requirement is currently being followed.

We thank you for your past assistance and look forward to working with you and the ExSC to bring about these needed changes to the Essential Requirements.

Sincerely,

Kathleen A. Thuner
Chair, ANSI Consumer Interest Forum (CIF)

Sally Greenberg
ANSI Director-at-Large; Vice Chair, ANSI CIF

R. David Pittle
ANSI Director-at-Large, Member, ANSI CIF

Rachel Weintraub
ANSI Director-at-Large; Member, ANSI CIF

Matt Gillen
Member, ANSI CIF

Brian Stiger
Member, ANSI CIF

PROPOSAL FOR ADDING A NEW SAFETY & HEALTH SECTION TO THE ANSI ESSENTIAL REQUIREMENTS

INTRODUCTION

The ANSI Essential Requirements (ERs) describe the minimum due process requirements that accredited standard developers (ASDs) follow when creating ANSI standards. The integrity of the ANSI standard development process depends on these requirements. We believe, based upon problems experienced on several recent standard efforts involving different ASDs, that the time has come to bolster the ERs that apply for a critical subset of ANSI standards – those that address consumer and worker safety and health (S&H).

The current ERs already recognize that S&H standards sometimes require special considerations. Two provisions are already more stringent for ANSI safety standards. A more stringent balance criterion is required along with a more stringent maintenance schedule.¹ We believe that several other provisions require clarification and new language. The stakes are high because process shortcomings that lead to weak standards pose serious injury or illness consequences for consumer and worker end-users. The ANSI process needs to be robust enough to consistently produce credible, protective, evidence-based safety and health standards suitable for national use. Because ANSI serves as the U.S. national body for the International Standards Organization (ISO), the process needs also to meet or exceed ISO recommendations for consumer participation in standards work.

We developed comprehensive supplemental language to clarify and strengthen the ER requirements specific to developing S&H standards. Each section is provided below in *blue italic font*, followed by a rationale discussion to briefly highlight the need and purpose for the language.

REVIEW OF PROPOSED NEW REQUIREMENTS

New Section 6.0 Safety and Health Standard Requirements

These requirements apply to activities related to the development of ANSI safety and health standards.

Rationale: Adding this new section at the end of the current ERs serves to: 1) put all the needed provisions in one place; and 2) to demarcate that these provisions do NOT apply for non-safety ANSI standards. The intention is for all ANSI ASDs to follow these requirements when developing ANSI S&H standards.

¹ Section 2.3 states that no single interest category can constitute more than one-third of the consensus body membership instead of the one-half criterion used for other standards. Section 4.7.3 states that safety standards are not eligible for the ten-year stabilized maintenance schedule and must be updated every five years.

6.1 Definition of a safety and health standard

Safety and health standards are those intended to protect end users such as consumers and employees from adverse outcomes such as death, injury, cumulative trauma, or ill health effects. Safety and health standards should include a reference to “safety” and/or “health” in either the standard title or the standard abstract and a safety and health goal statement in the standard itself.

Rationale: There are many types of ANSI standards. Most address non-safety topics such as equipment standardization or testing requirements. The current ERs mention but do not define safety standards. A definition is needed to describe the purpose of a S&H standard, to guide standard developers on whether a given standard should be considered a S&H standard, and to provide a mechanism to more clearly identify ANSI S&H standards.

6.2 Safety and health standard goal

The ANSI safety and health standard goal is to employ 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. The goal includes eliminating or adequately reducing the addressed risks. Accredited standards developers shall commit to this goal in the development of ANSI safety and health standards.

Rationale: A goal complements the definition and provides an overarching target that ASDs and consensus body participants will use to guide their efforts.

6.3 Avoiding and Mitigating Conflicts of Interest for ANSI accredited safety and health standard developers

A potential conflict of interest occurs when a standard developer’s ability to meet the ANSI safety and health standard goal (per section 6.2 above) could be compromised by a competing duty to a secondary interest. Secondary interests include but are not limited to a developer’s financial relationship with one or more members of the committee; or interests linked to its own or its member’s organizational commercial interests relating to compliance costs, financial profitability, or concerns related to competition or liability.

The negative effects of a conflict of interest occur when secondary interests unduly influence decision-making or receive greater weight during the standard setting process than the primary safety and health standard goal. For example, this occurs when a trade association or other business organization seeks to serve as an accredited ANSI safety and health standard developer. If the association represents the very same groups (e.g., manufacturers, employers, retailers/distributors) that would be affected by the standard in question, then it has an inherent potential conflict of interest. This is because the association’s mission or charter almost always includes a general responsibility to serve or advance the interests of its members. These secondary interests can potentially conflict with the above-described primary ANSI goal of developing a standard that sufficiently protects end-users.

6.3.1 Optimal approach – Avoid or minimize potential Conflict of Interest

Ideally, potentially conflicted organizations interested in serving as standard developers will take meaningful steps beforehand to reduce real or perceived conflict of interest sources or else will recuse themselves from serving as ASDs if other organizations with fewer potential conflicts are interested in serving instead. Note that this is not intended to prevent or limit the ability of trade associations or similar parties with potential conflicts from participating in the consensus body for the standard in question.

6.3.2 Secondary approach – Disclose and mitigate potential Conflict of Interest

Alternatively, potentially conflicted organizations, or organizations that have reduced but not eliminated real or perceived conflict per section 6.3.1 may serve as standard developers by following the steps and measures below and by conducting efforts according to the highest professional standard.

- A) *Disclosure of potential conflict of interest to ANSI during the accreditation review stage and to prospective consensus body members.*
- B) *Taking appropriate mitigation steps such as but not limited to structuring the consensus body to include one or more co-chairs from interest categories other than that of the standard developer organization, and giving the co-chairs active roles during standard development and response to comments.*
- C) *Retention of all records related to selection of consensus body members, ANSI reviews and dispositions, claims of dominance concerns, unresolved objections, and appeals and determinations for at least three complete standard cycles (15 years) and making this information available to ANSI and consensus body members prior to initiation of standard development.*

ANSI will take additional steps in evaluating procedures and information from potentially conflicted ASDs as follows:

- D) *ANSI will evaluate the disclosure and mitigation steps and measures proposed by the ASD as part of its initial and secondary and additional reviews called for by section 6.8.*
- E) *ANSI will consult with one or more third parties from affected end user interest groups² in performing the initial, secondary, and additional reviews called for by section 6.8. The purpose is to get additional information to increase confidence that materially affected groups have been identified and included.*

² This could include checking with consumer representatives on the ANSI Consumer Interest Forum (CIF), or checking directly with consumer or labor representatives to gain perspectives on affected groups for consideration in consensus bodies.

F) In approving standards developed by potentially conflicted parties, the ANSI Board of Standards Review (BSR) shall evaluate any claims that decisions were unduly influenced by the developer's conflict of interest. A sufficient showing that a conflict of interest played a negative role shall trigger an evaluation for invoking the Withdrawal for Cause under section 4.2.1.3 of the Essential Requirements.

Rationale: The current ERs discuss conflict only from the perspective of conflicting and overlapping standards. There is no other explicit mention of conflict of interest. This is a serious gap for safety and health given the common practice of allowing industry trade associations to serve as ASDs for S&H standards that directly affect their member's products and commercial interests. While we recognize that trade associations can add value to standard development by bringing subject matter expertise, ANSI must recognize the inherent tensions and very real conflicts of interest that can occur. ANSI allows the ASD to select and categorize the consensus body participants and this directly affects resulting balance and dominance. ANSI allows the ASD to write the draft standard and to respond to comments. There are no explicit requirements to reduce the likelihood that a standard developer could be unduly influenced by the interests of members or others over the health and safety interests of affected end users such as consumers and workers.

This new section addresses this vulnerability. It describes the general issue, and it provides an optimal approach to communicate what should be ANSI's preferred approach to this issue to shape efforts to reduce conflicts over the long term. It also provides a secondary approach to accommodate the reality that trade associations and similar conflicted parties will likely be interested in continuing to serve as ASDs in the near term. The provisions in this secondary approach utilize terminology from the ANSI code of ethics, provide ASDs flexibility to develop their own measures, and spell out some meaningful steps to mitigate conflicts. ASDs would update their standard development operating procedures to incorporate these changes.

The new section also describes how ANSI will supplement its reviews of operating procedures when these conditions apply. A consultation provision is included to assist ANSI with questions such as whether a proposed standard will affect end user groups such as consumers or labor. This consultation could be done by groups such as the ANSI CIF. The provisions also call for relevant records to be retained for three five year cycles to: 1) give both ANSI and candidate participants a more complete picture of whether there has been any conflict of interest items raised in previous efforts so they can be monitored; and 2) to clarify and strengthen the current ERs requirement to retain records for "one cycle". One cycle could be interpreted to mean that records developed during the previous standard-setting effort could be discarded once a "new" standard update cycle commences – even though that would be the time when any conflict information from the previous effort would be most informative to ANSI and participants.

Note that the focus of this language is on ASDs. The focus is not on consensus body participants. Lastly, many of the other recommended provisions that follow are also intended to mitigate potential ASD conflict of interest.

6.4 Balance

This language supersedes section 2.3 of the Essential Requirements.

6.4.1 Interest categories and materially affected parties

The criteria for balance for a safety and health standard are that: 1) no single interest category constitute more than one third of the voting membership of a consensus body; and 2) all materially affected parties are identified, discretely defined, and represented in one of the three primary interest categories: Business Interest, End-user Interest, and Independent General Interest.

To make it clear that these requirements have been met, safety and health standard developers shall explicitly list all materially affected parties as individual subgroups within the selected interest categories submitted to ANSI for review. In addition, every safety and health standard shall include the following three primary interest categories AND materially affected party subgroups listed below:

A) *Business Interest category*

Producer subgroup: small and large manufacturers or others in the supply chain involved with producing the item(s) addressed by the safety and health standard. May also include trade associations representing these groups and consultants and expert witnesses with financial links to producers.

Distributor subgroup: wholesale and retail organizations involved with the distribution, importation and sale of the item(s) to downstream employers and other organizational end-users. May also include trade associations representing these groups and consultants and expert witnesses with financial links to distributors.

Employer subgroup: downstream employers using the item(s) covered by the safety and health standard. May also include employer trade associations and consultants and expert witnesses with financial links to employers.

B) *End-user interest category*

Consumer subgroup: consumer organizations interested in the health and well-being of consumers using the item(s) covered by the standard. May also include individual consumers or hobbyists representing consumer organizations. May include experts who have been hired by these groups to help advance an understanding of the issues involved.

Labor subgroup: labor and worker organizations representing employees who use the item(s) covered by the standard. May also include individual employees representing labor and worker organizations. May include experts who have been hired by these

groups to help advance an understanding of the issues involved.

C) *Independent General interest category*

Government Agency subgroup: *federal, state and local agency representatives involved with employee and/or consumer enforcement, consultation, or procurement related to the item(s) covered by the standard.*

Professional safety and health organization subgroup: *organizations or societies representing safety and health experts involved with protecting employees and /or consumers from injuries and illnesses associated with the item(s) covered by the standard.*

Academic and independent researcher subgroup: *individuals who have performed and published safety and health related research relevant to the item(s) covered by the standard and/or the types of injuries and illnesses relevant to the covered item(s). Includes academic researchers, governmental researchers, medical experts, and other independent researchers and technical experts.*

NOTE: *Individuals and groups participating in category C cannot have any monetary connections with interest categories described in sections A and B above. This is intended to include connections such as past consulting, research sponsorship, or paid presentations.*

It is the responsibility of standard developers to suggest additional entities to subgroups as may be appropriate to fill discretely defined subgroups to ensure that ALL materially affected parties are identified, listed, and represented on the consensus body.

6.4.2 Multiple-standard developers

Some standard developer organizations use one consensus body to develop several related standards. This practice is allowable when the conditions below are met:

A) *Mixing ANSI safety and non-safety standards.*

In this case, the standard developer shall ensure that procedures to be used for any new or revised safety and health standards meet Section 6 requirements. This most likely will call for supplementing the membership of the consensus body to be used for the safety standard so as to meet the balance requirements of Section 6.4.

B) *Mixing multiple ANSI safety standards.*

In this case, it is assumed that the procedures will already meet Section 6 requirements. Use of a single consensus body to develop multiple safety standards is allowable where the

topics are similar such that the consensus body membership meets the Section 6.4.1 balance criterion test that “all materially affected parties are identified, discretely defined, and represented in one of the three primary interest categories”. If not, then supplemental changes to the membership of the consensus bodies will be needed.

Rationale: ANSI’s true intentions about balance are unclear in the current ERs section 2.3. On one hand, “shall” language communicates that interest categories be “discretely defined” and “cover all materially affected parties” and “differentiate each category from the other categories”. On the other hand, other language in this same section undercuts these requirements by indicating that they are discretionary. For example, the same section 2.3 also states that additional interest categories “should be” considered “where appropriate”, and lists eleven groups that “may be used” to “categorize directly and materially affected persons”.

This means that the critical requirement for balance is open to interpretation by ASDs and that the ERs language cannot be used to successfully challenge³ the use of consensus bodies that have either no or only token participation by groups most likely to be affected by injury or illness – consumers and workers.

Meaningful balance is a crucial requirement for true consensus and it provides the diverse perspectives needed to forge a meaningful protective standard suitable for national use. Lack of balance undermines the integrity of the ANSI process. It also increases the difficulty in getting consumer and labor representative to participate on consensus bodies: “Why participate if you will be only a token voice greatly outnumbered and ignored by industry representatives?”

Another major problem is that the current ERs minimum interest category requirements (producer, user, and general interest) can work against balance because they easily overlap and allow confounding. For example, the ERs do not make clear that parties with business interests in common with producers cannot participate in the general interest category.

The revision of the balance section clarifies and incrementally strengthens the existing balance requirements. It makes clear the materially affected parties that need to be included to achieve balance. It retains the current ERs requirement for a minimum of three interest categories and that no single interest category constitute more than one third of the membership. It reorganizes the three core interest categories into more fundamental groupings to minimize confounding. The term “subgroup” is used to identify and describe the key participants most relevant for development of S&H standards. These encompass many of the same eleven groups mentioned in ERs footnote 2 of section 2.3.

Language addressing “multiple standard” developers acknowledges that some organizations

³ The question of whether at least one consumer representative should have been included on the consensus body used for developing a consumer product S&H standard was at issue in a recent appeal case at the ANSI standard developer level. The appellant claimed that the consensus body was not balanced because there was no consumer representation and only token labor participation and that the appellant had notified the ASD about this shortcoming beforehand. The appeals panel concluded that the current ERs did not require such representation. The panel report ruled against the appellants, stating that appellant arguments about an unbalanced consensus body were more related to perceived inadequacies in the ERs than on standard developer inactions, thus demonstrating to us that the current language is inadequate and is open to interpretation.

use the same consensus body to develop multiple standards. There is no objection to this practice if these Section 6 requirements are used to govern the development of the safety standard and if the practice does not result in the lack of participation by other “materially affected” parties. This could be resolved by adding additional members to balance the consensus body for the particular standard where the participation was needed.

6.4.2 Participant qualifications and balance

At least one-half of the consensus body members for any safety and health standard shall consist of individuals with safety and health qualifications. Such qualifications can be demonstrated by evidence of education, certification, experience or employment directly relevant to occupational and/or consumer safety and health.

Rationale: The current ERs offer no provisions to ensure that safety and health professionals – the individuals most familiar with the worker and consumer S&H body of knowledge – are included in the consensus bodies established to develop ANSI S&H standards. A new participant qualifications section takes the simple but necessary step of ensuring that safety and health standards are developed by consensus bodies where at least half of the members have safety and health qualifications. The criteria are flexible to address a wide variety of candidates. This will improve the quality of standards while leaving plenty of opportunity for other types of individuals to participate.

6.4.3 Outreach

Standard developers shall actively seek participation from materially affected parties to create a balanced consensus body. Publication in ANSI Standards Action alone is not sufficient. In addition, the initial outreach shall be done by contacting groups likely to be affected by the standard to encourage their participation on the consensus body.

NOTE: *It is appropriate to offer financial support (e.g. modest stipends, travel reimbursement, and other out-of-pocket expenses) to enable end-user, independent interest, and non-profit and governmental individuals and organizations to participate.*

Secondary outreach shall be done by getting input from prospective consensus body candidates. To facilitate this input, standard developers shall provide the prospective consensus body candidates with the following descriptive information: 1) the prospective list of interest categories and discretely defined subgroups; and 2) identification of the prospective consensus body candidates (name, organization, interest category and subgroup classification, safety and health/other qualification). The standard developer shall request the consensus body candidates to identify whether there are any missing materially affected parties, and if so any suggestions for organizations and/or individuals that could broaden or strengthen category

representation. Standard developers shall consider and act on these recommendations as appropriate to finalize the consensus body membership.

Rationale: The current ERs mention that “Appropriate, representative user views shall be actively sought” in section 2.3 and that “outreach shall be undertaken” in section 1.3 when the consensus body lacks balance. The revised Outreach section clarifies the specific minimum active outreach activities required of the standard developer. It also calls for a second round of outreach using input from consensus body participants on whether there is an absence of materially affected parties critically needed for ensuring a diverse and balanced consensus body.

A note explicitly states that basic financial support may be needed to enable certain groups to participate. On one hand, we acknowledge that this needs to be done carefully to avoid creating potential conflict of interest. On the other hand, we believe that this step is needed to address current obstacles to participation for some groups. We note that ISO explicitly recommends that standards bodies such as ANSI develop funding mechanisms to support consumer participation in standards work⁴.

6.5 Lack of Dominance

This section supersedes Section 2.2 of the Essential Requirements

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. Because dominance has a detrimental impact on the standard development process, the emphasis must be on prevention rather than addressing it after the standard development process has ended.

Preventing dominance is addressed by the following requirements:

- A) Use of a balanced consensus body as described in section 6.4;*
- B) Submittal of basic information to ANSI for use in initial and secondary clearance review (see list in 6.5.1 below);*
- C) Implementation of transparency during the consensus process; and*
- D) The ability of consensus body members and materially affected parties to submit written claims about dominance concerns noted during the standard development process.*

Additional information on these requirements is provided below:

6.5.1 Submittal of basic information to ANSI

⁴ See the 2001 ISO recommendations at

https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/copolc participation_2001.pdf

See also page 23 discussion at: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/involving_consumers.pdf

ASDs currently submit standard development operating procedures to ANSI as part of the accreditation process. To enable transparency, standard developers shall provide the following supplemental information to ANSI prior to initiating the consensus process:

- A) Final list of discretely defined subgroups proposed to represent all materially affected parties and their place in the primary interest categories. Organizations developing multiple safety and health standards will submit information to indicate which subgroups and materially affected parties are represented for each standard.*
- B) Consensus body roster information to include: A) name, organization, interest category and subgroup classifications, safety and health/other qualification; B) additional consensus body member linkage information – such as but not limited to membership, consulting, or monetary links to either the standard developer or the members of the Business Interest category⁵.*
- C) Description of initial and secondary outreach efforts and the standard developer disposition of outreach and suggestions.*

6.5.2 Implementing transparency during the consensus process

Standard developers are to practice a high degree of transparency during the entire consensus process. This includes but is not limited to the following steps:

- A) Providing the basic submittal information to all consensus body members*
- B) Reporting changes requested by ANSI in response to the submittal information to all consensus body members.*
- C) Providing transparent voting results and responses to comments (both votes and all written comments) to all consensus body members.*

6.5.3 Written claims about dominance concerns

Standard developers shall provide all consensus body members with this required statement prior to initiating consensus:

“As defined by ANSI, 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. Lack of dominance is critical to development of a meaningful protective safety and health standard. If you have any questions, or believe that dominance is or has occurred, please notify the

⁵ Examples of linkages to report include but are not limited to: 1) paid consulting work for the standard developer or regulated community; 2) membership on a safety relevant committee associated with the standard developer organization or industry group; and 3) representing a trade association that has members in common with the standard developer organization.

standard developer so this can be addressed. You also have the right to notify ANSI in writing during the development process or at the completion of voting if you believe dominance affected the consensus process. All procedures used by standard developers must meet ANSI Essential Requirements which can be found at https://www.ansi.org/standards_activities/domestic_programs/overview ”

Any consensus body participant or other directly and materially affected party who believes that a single interest category, subgroup, individual, or organization (including the standard developer) has dominated the standards development process is encouraged to describe this concern in writing (including electronic communications). Participants should report concerns and supporting information to the standard developer first and, if the issue persists, directly to ANSI. Standard developers shall evaluate the concerns and shall share reports and findings with all consensus body members.

Rationale: The current ERs dominance provisions are weak and rely solely on reporting of problems after the process has concluded - when voting on the standard (which is still likely to go forward) has already taken place. The current ERs do not explicitly address the role of the ASD, which is a crucial gap given that the ASD is the group most clearly positioned to dominate the standard development process.

Ensuring lack of dominance is an important goal and warrants introducing new measures prior to consensus group initiation to help prevent dominance from occurring. The revised provisions call for standard developers to take basic steps and to share information with ANSI so it can perform a meaningful and informed administrative review prior to giving the go ahead for the standard developmental process to start. It also calls for basic steps to improve transparency during the consensus process by giving participants a full view of representation and voting and by informing them that they have the right to notify both the committee and ANSI if they believe there have been dominance problems that have continued unabated.

The current ERs do not state that any procedural changes required by ANSI be communicated. They do call for unresolved objections to be reported to the consensus body, but do not explicitly require that the actual comments submitted by each participant and the response to comments be provided. While the overall voting results (e.g. how many in the affirmative vs negative) are to be reported, the actual voting status for each participant is not explicitly required to be provided. The revised language addresses these shortcomings. Section 6.5.3 includes the written claims measures included in the current ERs (since section 6.5 supersedes 2.2) and expands and clarifies outcomes from those measures. Taken together, we believe the revised measures will shift the emphasis from documenting dominance after the fact to intervening to reduce it up front or before the consensus deliberations are completed.

6.6 Implementation and conduct of the consensus process

6.6.1 Development of a record

Standard developers shall create an electronic record to serve as the repository for all information intended to be considered by committee members. The record shall be easily accessible to all consensus body members and to ANSI and shall be organized into information categories helpful for easy accessibility to members.

Information to be placed in the record includes but is not limited to the following categories:

- A) Studies and reports relevant to the standard, with special emphasis on information that has been published in the scientific literature years since the standard was last revised⁶;*
- B) Relevant or related international or domestic standards that have been updated since the standard was last revised;*
- C) Patent or other technology reports relevant to engineering changes worthy of consideration; and*
- D) Unpublished objective studies and information deemed relevant by the submitter to the standard revision.*
- E) Written statements describing relevant committee evaluations and the underlying objective engineering rationale*

Standard developers shall inform consensus body members about the record and shall add supplemental information suggested by consensus body members that meets the above categories.

At their discretion, standard developers may create an “administrative” section of the record to hold various correspondence, including consensus body notifications.

Rationale: There are ten due process topics included in the current ERs. None address how to go about creating an evidence-based standard, even though this is a due process issue critical to ensuring development of effective national safety and health standards. This new section 6.6 remedies this shortcoming and puts the standard development process on a sound foundation for producing credible protective standards that can meet the test of being in the public interest—economically and technologically feasible—and suitable for national use.

This new section starts by calling for creation of a “record” for the standard. This accomplishes two goals. First, it makes it easier for busy consensus body participants to find and read relevant information in preparation for voting. Second, it eliminates the objectionable but

⁶ For completely new standards, the record shall include all relevant studies regardless of publication date.

currently allowable practice where a standard developer can claim to rebut a comment based upon unshared information.

6.6.2 Safety and health goal statement

Safety and health standards shall include a written statement or paragraph to address the following elements:

- A) *The specific types of injuries, cumulative traumas, or health endpoints that the standard is intended to prevent or reduce;*
- B) *The specific user groups that the standard is intended to protect (e.g. residential construction workers, consumers performing home repairs).*

The draft initial statement is to be shared with consensus body members for additional consideration and input and the final statement is to be included as a section of the completed standard. This statement serves as the committee's mission statement.

Rationale: This new section calls for a safety and health goal statement to be developed. The initial version is to be shared with consensus body members when they join the committee and the final version is to be included in the completed standard. This simple step is important because most ANSI standards do not include any description of the type of injury or illness endpoints or target audiences that the standard is intended to address. Having such a requirement gives consensus body members a way to think constructively about the provisions needed for the standard to be effective. It adds accountability to make it more likely that resulting standards address the highest known risks and target audiences. Lastly, it also makes it easier for users – including consumer and occupational safety and health professionals – to identify standards that could be used to prevent deaths, injuries, or illnesses of concern to them.

6.6.3 Participation process, Information exchange, and drafting of standard

The standard development process shall promote participation and interaction.

- A) *Participation of consensus body members shall be optimized by:*
 - 1) *providing appropriate advance notice of meetings;*
 - 2) *providing access by phone or web service that facilitates audio communication and document sharing; and*
 - 3) *including all consensus body members in all meetings (i.e. meetings that invite certain consensus body members but not others are not permitted).*
- B) *The standard developer shall facilitate or host one or more sessions at the outset of the consensus process to allow consensus body members to discuss the safety and health goal statement; the available objective evidence for the standard; and to exchange*

views about how this evidence relates to the safety and health mission statement. The intent is to promote awareness of the best available evidence relevant to the development of a particular safety and health standard. Following this discussion, the consensus body members will together develop the first draft outline of the proposed standard. The draft is to be developed further using a combination of inputs from consensus body members and the standard developer. This activity can be conducted in person or by conference call or interactive webinar or other methods.

- C) *Use of the existing basic canvass method to develop an ANSI Safety and Health standard is not permitted. This is because it allows standard developers to draft the standard without complete consensus body input, and allows voting to proceed without any prior discussion or exchange of views about new information that has become available since the last revision. A modified canvass method that incorporates the requirements of 6.6.3 can be used if agreed upon by the consensus committee.*

Rationale: This new section addresses fundamental topics related to consensus body participation. It addresses basic irregularities that have come to our attention. It calls for at least one session to be held at the outset to facilitate the exchange of information among consensus body members. This helps ensure that members will be informed about new and relevant information and more likely to produce a credible standard suitable for national use. New language explicitly states that the existing canvass method cannot be used, since that method does not include any measures to assure that consensus body members are aware of updated evidence prior to voting. It also calls for consensus body members to have input to the drafting of the initial version of the standard. This is important because once the standard has been drafted, it tends to frame and constrain the issues for comment. ASD's can still develop their own concepts for a standard outline but will need to let discussion occur first before presenting it as input to the group.

6.6.4 Hierarchy of Controls framework

ANSI safety and health standards committees shall follow the Hierarchy of Control framework. The intent of this risk reduction framework is to preferentially use more reliable engineering solutions that eliminate and control hazards over less reliable solutions that aim to modify end-user behavior via warnings, administrative controls, or use of personal protective equipment. The Hierarchy of Control ranks the basic elements for reducing risks in the following order of decreasing effectiveness:

- A) *Elimination: Physically remove the hazard*
- B) *Substitution: Replace the hazard*
- C) *Engineering Controls: Isolate users from the hazard*
- D) *Administrative Controls: Change use practices via warnings and procedures*
- E) *Personal Protective Equipment: Protect users via safety equipment*

In some cases, where it is not possible to fully eliminate risks, the major risks will be reduced via design and engineering approaches with any remaining residual risks addressed via warnings and procedures. Safety and health standards shall reflect the Hierarchy of Control and shall include a statement that the Hierarchy of Controls was followed.⁷ In keeping with ISO/IEC Guide 51:2014 for including safety aspects into product and system standards, standard developers shall familiarize all consensus body member participants about the Hierarchy of Controls framework.

Rationale: This new section mandates that ANSI S&H standards follow the Hierarchy of Controls. This addresses a major gap in using the ANSI ERs. Without such language, the ANSI process does not assure that S&H standards conform with fundamental and well-accepted safety and health practice benchmarks. An example would be a standard that relies solely on product warnings over available design and engineering improvements. Standards that do not follow the Hierarchy of Controls are more likely to be unfit and unsuitable for national use. Note that the Hierarchy of Controls itself embraces flexibility to allow use of several approaches – but is intended to ensure that those approaches known to be the most reliable for end users are given preference for consideration.

6.6.5 Evidence-based framework

The goal of an ANSI safety and health standard is to use all available scientific and objective information to protect end-users from unreasonable risks of death, injury, cumulative trauma, or ill health effects to the extent feasible. Accordingly, standard developers are to consider the best available evidence as the basis for affording technical issue due process. This means that standard developers shall rely on the weight of the available evidence in the record in responding to technical comments that recommend more than editing changes to the content of the draft standard. Standard developers rebutting such technical comments shall ensure that their written response does the following:

- A) *Directly addresses the comment;*
- B) *Includes a bona fide safety and health-related rationale;⁸ and*
- C) *Is based on objective evidence available to the commenter in the record.*

⁷ Examples of sources of information on the Hierarchy of Controls concept include:

A) ISO/IEC GUIDE 51:2014(E) (see http://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;

B) ANSI/AIHA/ASSE Z10-2012 (see http://www.asse.org/assets/1/7/Z10_Tech_Brief_2012_Revised.pdf);

C) OHSAS-18001 (see <http://www.nsaie/getattachment/Our-Services/Certification/Management-Systems/OHSAS-18001/MD-19-02-Rev-4--OHSAS-18001-Occupational-Health-and-Safety.pdf.aspx>)

D) ISO 12100 – 2010 (see http://www.iso.org/iso/catalogue_detail?csnumber=51528);
or E) the NIOSH topic page (see <http://www.cdc.gov/niosh/topics/hierarchy/default.html>)

⁸ This means for example that a safety related comment could not be responded to by a non-safety rational such as stating that a given piece of equipment is already available on the market.

Rationale: This new section includes language to require the use of an evidence-based framework for responding to consensus body participant comments for changing the standard, especially those accompanied by references to existing objective information. The intent is to remedy the current lack of a definition for what is meant by “whether a technical issue was afforded due process”. The status quo means that ASDs have broad discretion to disregard substantive comments – as long as some type of written response is provided. We believe that ANSI intends for additional voting by consensus body members to serve as a check and balance to possible ASD overreach on response to comments. However, we are not convinced that this functions as a sufficient check and balance for S&H standards given the other problems we are aware of. These include the lack of ASD conflict of interest provisions, consensus body balance deficiencies, lack of measures to inform consensus body participants about the existing body of evidence, and lack of transparency on submitted comments. The new language is intended to ensure that standard developers clearly respond to technical comments using three clear criteria. This will serve to change the comment resolution process from an opaque subjective process to a more objective transparent evidence-based process which will in turn improve the ability of re-voting to serve as a meaningful check and balance.

6.7 Appeals of Safety and Health Standards

This section supplements Section 2.8 of the Essential Requirements.

6.7.1 Subjects for appeal

Safety and health standards shall include additional rights to appeal the following:

- A) *Whether the standard developer met the ANSI safety and health standard goal.*
- B) *Whether the standard developer demonstrated actions or inactions indicating conflict of interest.*
- C) *Whether the standard developer met all requirements for*
 1. *Balance, outreach, and participant qualifications*
 2. *Lack of dominance*
 3. *Implementation and conduct of the consensus process; including development of a record, establishment of and adherence to a safety and health goal statement, facilitation of participation and information exchange, adherence to the Hierarchy of Controls, and adherence to an evidence-based framework for affording technical issue due process.*
 4. *Whether the content of the standard fails to substantially reflect the weight of the available evidence.*
- D) *Whether ANSI performed technically sufficient reviews of the standard developer procedures to ensure they met the ANSI Essential Requirements including the Safety and Health requirements.*

Rationale: The current ERs are vague about what subjects can be appealed. Section 2.8 requires that the minimal topics include “procedural issues” (including “whether a technical issue was afforded due process”). However, no further explanation is provided on what these terms mean. Unclear appeal rights reduce the likelihood that consensus body participants and other materially affected parties use these rights, thus diminishing the check and balance value of appeals.

The new language provides a simple description of germane S&H subjects that can be appealed. As with the current section 2.8, the supplemental items A-C are to be incorporated into standard developer appeal procedures.

Item D addresses ANSI procedures and allows for the first time an appeal when appellants claim that ANSI itself performed a technically deficient review. We believe this is needed because a direct nexus can be made between a deficient ANSI review and erosion of procedural issue appeals rights against the standard developer. For example, we know of one S&H appeals case where ANSI’s tacit approval of the ASD’s procedures was successfully used by the ASD as a defense against the appellant’s claims that the ASD did not comply with the only two ANSI ERs specific to S&H. ANSI’s accreditation review failed to identify that the ASD procedures did not meet these two ANSI ERs requirements and the appeals panel ruled against the appellant. So in this case the deficient ANSI review rendered the appeal moot.

6.7.2 Appeal procedures

Standard developer appeal procedures shall include the following additional provisions above and beyond those currently listed in section 2.8 of the Essential Requirements:

- A) *Selection of judges for panel. At least two of the three judges shall have safety and health qualifications for panels hearing appeals that address the following topics:*
- 1. Adherence to the Hierarchy of Controls;*
 - 2. Adherence to an evidence-based framework for affording technical issue due process, and/or*
 - 3. Whether the content of the standard fails to substantially reflect the weight of the available evidence*
- B) *Appeal panel outcomes. Appeals upheld on claims that the standard developer did not meet requirements for balance, outreach, participant qualifications, lack of dominance, or failure to substantially reflect the best available evidence may not, depending on circumstances, be remanded back to the same consensus body for further actions. It is possible that the process may need to be restarted under different supervision.*

Appeals upheld on claims that ANSI did not perform an adequate review of the standard developer procedures will require additional review by the ANSI Board of Standards Review to determine appropriate corrective actions prior to restarting the process.

Rationale: The purpose of this new section is to address key issues related to appeal procedures. Paragraph A ensures that appeals panels include individuals with S&H qualifications when the appeal will involve determinations about topics related to safety and health subject matter. Paragraph B fills a current gap by describing expected outcomes from appeals decisions. This is important because there is currently no explicit language in the ERs to prevent ASDs who lose appeals on procedural issues such as balance from then turning to these same flawed consensus bodies for certain remedies and next steps. This is a disincentive to filing an appeal which undercuts the check and balance value of appeals.

6.8 ANSI Review of Standard Developer procedures

ANSI shall perform the following reviews for all ANSI safety and health standards.

6.8.1 Initial Review

ANSI shall first review records from the previous standard revision effort to check on any relevant history related to review and appeals that should be taken into consideration. ANSI shall then examine standard developer operating procedures and submitted supplemental information to determine compliance with the following:

- A) Whether the standard description meets the definition of a safety and health standard;*
- B) Whether the standard developer has any organizational conflict of interest; and if so, whether measures and steps taken meet section 6.3.2 requirements;*
- C) Whether a five-year review schedule is being used;*
- D) Whether there is an acceptable initial safety and health goal statement;*
- E) Whether the proposed interest categories and materially affected party subgroups appear adequate and balanced given the scope of the standard and the scope of the initial safety and health goal statement;*
- F) That the record is functionally accessible; and*
- G) That the standard developer procedures meet all other ANSI safety and health standard and general Essential Requirements.*

ANSI shall communicate any shortcomings in writing to the standard developer. The standard developer shall re-submit procedures to address shortcomings. Upon initial review approval, the standard developer shall initiate the process of contacting consensus body members.

Rationale: This final section of the new Section 6 addresses the crucial issue of ANSI review. ANSI currently performs accreditation reviews and an administrative review at the outset of a new standards development cycle to determine that the ASD procedures satisfy the Essential Requirements (including specific accreditation criteria as described in the current ERs section 4). ASDs then proceed with assembling a consensus body and then proceed with initiating the standard effort.

The purpose of this language is to delineate and expand the administrative topics for ANSI to consider during this initial accreditation review for any standard intended to address S&H. As with the existing accreditation topics, the purpose is to ensure that all pre-conditions are met to support a successful standard development process.

6.8.2 Secondary Review

ANSI shall perform a second review once the standard developer has completed outreach and has populated the consensus body. The review will evaluate the following:

- A) Whether the consensus body meets the requirement that more than one half be those with safety and health qualifications per section 6.4.2;*
- B) Whether the final membership lists for the three primary interest categories and discretely defined subgroups meet the required balance criteria;*
- C) That initial and secondary outreach activities, including standard developer disposition of suggestions, was sufficient*
- D) That consensus body identification information is complete and that linkage information does not indicate the potential for dominance to occur in the proposed final consensus body.*

The purpose of the secondary review is for ANSI to review the above information to be submitted by the ASD to make a basic determination that a good faith effort has been made to create a diverse balanced consensus body that includes all materially affected parties that does not have inherent dominance characteristics that could adversely affect the consensus process.

ANSI shall communicate shortcomings in writing to the standard developer and, if necessary, the standard developer shall re-submit procedures to address shortcomings. After secondary review approval, the standard developer shall initiate the consensus process.

Rationale: The initial ANSI administrative review ensures that the ASD's procedures meet the ERs. ANSI does not currently take follow-up steps to check with ASD's on how approved interest categories have been converted into an actual balanced diverse consensus body. The status quo leaves only the appeals process as a check on problems such as balance – but this

occurs after the standard has already been developed using what may have been a fatally flawed consensus body.

The purpose of this new language is to add a second administrative ANSI review. The review would examine information submitted by the ASD about the intended consensus body participants. This check would determine whether balance provisions, such as including sufficient consumer and labor representatives, pass muster. This provides an additional opportunity to catch and fix shortcomings at the front end of the process before consensus deliberations begin. It does not make sense from a public policy perspective to allow unbalanced consensus bodies to proceed to deliberate for a period of years and to then rely upon appeals after the fact from groups who are underrepresented or even unrepresented on the consensus body. The emphasis needs to be up front to incentivize standard developers to develop diverse consensus bodies.

6.8.3 Additional review triggered by written claims about dominance concerns

ANSI shall review all written concerns (including electronic communications) submitted to ANSI by any consensus body participant or other directly and materially affected party who believes that a single interest category, subgroup, individual, or organization (including the standard developer) has inappropriately dominated the standards development process.

Reports filed during the consensus process (prior to final voting on a standard) shall lead to putting a hold on the consensus process to evaluate the claim. ANSI will make a determination on whether remedial changes are needed prior to final voting; or whether the dominance requires that the process be restarted.

Evaluation of reports filed after final voting on the standard has taken place (but prior to final ANSI approval) shall lead to an ANSI determination on whether the dominance requires that the process be repeated.

Rationale:

The ANSI ERs currently allow for written claims about dominance concerns. ANSI is silent on how when and how these written claims are to be evaluated. The purpose of this final section is to complement and support the current ER requirement.