

Ally Kupferberg

From: Anne Caldas
Sent: Thursday, March 18, 2021 4:36 PM
To: Anne Caldas
Subject: Response to public comments - Proposed revisions to the ANSI Essential Requirements - Mr. Bob Adler
Attachments: ExSC_025_2021_ER TG Report from 2019.pdf; ExSC_017_2019_030921.pdf; ExSC_012_2021_balance_outreach.pdf; ExSC_017M_2019_Adler_incl_prev_proposal.pdf; ExSC_013_2021_lack_of_dominance.pdf

Greetings –

We hope that you are well.

Thank you for submitting the attached public comments in response to proposed revisions to the *ANSI Essential Requirements* (www.ansi.org/essentialrequirements) announced in *ANSI Standards Action* in December 2019. Background on the original proposed revision is included in the attached report (ExSC_025_2021). The ExSC has considered all public comments and as a result, edited the original proposed revision, now attached here in its final edited form (ExSC_017). This edited version was approved by the ANSI ExSC in February 2021 and will be submitted to the Executive Committee of the ANSI Board of Directors for final approval in March 2021 for incorporation into the 2022 edition of the *ANSI Essential Requirements*.

Note that the final revision (ExSC_017) includes updates to the following provisions:

- Openness – moved existing “Affiliation” footnote to main text to promote transparency
- Balance:
 - The interest category of a voting member to reflect the business interests of their primary source of support for participation on the consensus body
 - Definition of “sponsor” and “Consultant”
 - Clarification that sub-categories of interest categories should not be used to circumvent balance requirements and a clarification of the use of General Interest
 - Deletion of “Professional society” and “Trade association” from list of optional, sample, interest categories as these are more akin to membership categories than to interest categories, and the source of funding should be reflected in the interest category
- Project Initiation Notification System (PINS):
 - New requirement to list anticipated interest categories expected to comprise the consensus body to promote transparency
 - New requirement for a response from an ASD to a request for further information on a project or to discuss it
- Emphasis on timely and adequate notice of standards development activity
- Appeals: Clarification of ANSI appeals process and reference to applicable procedures based on the type of appeal, e.g., American National Standard (ANS) approval versus accreditation of a standards developer

Please also note that consistent with recommendations in the attached ExSC Task Group Report, ANSI has updated our website to provide easy access to information about the American National Standards (ANS) process and how to participate in it. Please visit the new ANS pages, including these: <https://www.ansi.org/american-national-standards/ans-introduction/overview#introduction> , <https://www.ansi.org/american-national-standards/info-for-the-general-public/general-public> and <https://www.ansi.org/american-national-standards/info-for-standards-developers/standards-developers> .

In addition to the discussion in the attached ExSC_025_2021 report which addresses some of your comments and the edits reflected in the final version of ExSC_017, please see the following responses presented by section of the proposed revision:

Original Lines 20-23: 2.2 Lack of Dominance

- Line 23 – suggest new text giving examples of presumptive dominance. The ExSC did not accept this proposal and has agreed to enhance existing guidance rather than revise this section of the procedures further. Some of the proposed language is already addressed in existing guidance, while other examples may not rise to the level of dominance, i.e., an exercise of undue influence to the exclusion of fair and equitable consideration of other viewpoints. Some of the examples may reflect procedural concerns but not – when assessed in context – the existence of dominance as ANSI defines the term. See attached ExSC_013_2021.

Original Lines 25-71: 2.3 Balance

- Line 71 proposes the addition of text that requires Producer, User, GI for "consumer product health and safety standards". The ExSC has considered this and similar proposals and not accepted it. The ExSC has agreed to create guidance that could include options based on the model presented here and elsewhere. Public input, and Consumer Interest Forum (CIF) input, will be sought on any proposed new or enhanced guidance documents developed. Please see ExSC_025 for further background and ExSC_012 for current guidance on balance.

Original Lines 73-88: 1.5 & 2.5 Notification of Standards Development

- Line 77, prohibit the use of the "canvass method" for health and safety standards. The ExSC has discussed this proposal multiple times and not accepted it. However, the ExSC was supportive of the revisions shown in ExSC_017, which include new, additional requirements at the PINS phase. Current requirements for comment consideration, written response to objections, recirculation of unresolved negative votes and comments and the right to appeal remain accessible to those who participate in the ANS process. Finally, ANSI does not recognize a particular standards development model called the "canvass method" as reference to one was removed in the 2003 edition of the *ANSI Essential Requirements*. Regardless of the procedural model used, ANSI's requirements apply. An ASD may do more, but not less.

Original Lines 81-105: Section 2.5.1 PINS

- Line 99 new addition to PINS section: (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. This proposal was not accepted. The ExSC has discussed this issue and agreed on the updated revisions shown in the attached final version of ExSC_017 as well as the creation of guidance that will share samples of the varied practices, e.g., consensus body application questions, of ASDs in relation to financial disclosure. See also the ExSC TG Report and the revisions that address interest classifications.

Again, thank you for your interest and your comments.

Sincerely,
Anne

Anne Caldas
Secretary, ANSI Executive Standards Council
ANSI
212-642-4914
acaldas@ansi.org
www.ansi.org



www.ansi.org/usss