

Ally Kupferberg

From: Anne Caldas
Sent: Thursday, March 18, 2021 4:51 PM
To: Anne Caldas
Subject: Response to public comments - Proposed revisions to the ANSI Essential Requirements - Consumer Representatives
Attachments: ExSC_025_2021_ER TG Report from 2019.pdf; ExSC_017_2019_030921.pdf; ExSC_017W_2019_Gillen_et_al_joint.pdf; ExSC_012_2021_balance_outreach.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, which includes new language concerning consultants and interest classification, as well as new PINS requirements and other topics, please see the following responses presented by section of the proposed revision:

Original Lines 1-5: Section 1.3 Balance – NOTE: Section 1.3 was not open for comment, but included for reference

- Lines 1 and 25: Comments regarding balance appear to reflect a misunderstanding of some aspects of the *ANSI Essential Requirements*. The current *ANSI Essential Requirements* requires outreach to achieve balance among interest categories appropriate to the development of consensus in any given standards activity, as a function of the nature of the standards being developed. If consumers fit this description then outreach to engage consumers is required. This is not new, nor is it missing from the current edition of the *ANSI Essential Requirements*. For more information about balance and outreach, see the attached guidance document (ExSC_012_2021).

Original Lines 25-71: 2.3 Balance

- Lines 25, 41-45: Balance: ANSI's requirements for balance are that balance shall be sought and outreach to achieve balance is a requirement. The ExSC has already decided that ANSI-Accredited Standards Developers (ASDs) are not required to use only User-Producer-General Interest as flexibility exists and will continue to exist. However, the ExSC also agreed to develop further guidance that may include some of the examples submitted by you and others; draft guidance will be shared with the ANSI CIF when it is available, for comment. Please see updated edits to (ExSC_017) and also see the ExSC TG report (ExSC_025) and the existing ExSC Guidance document on balance and outreach.

Original Lines 107-156: Appeals

- Lines 117 and 118 regarding this text: "Procedural appeals include whether a technical issue is afforded due process." This text does not require revision as it represents a generally understood concept within the ANS process, based on what is and is not required by the *ANSI Essential Requirements* in terms of "procedural" criteria (see section 1.0 and 2.0). See also the ExSC TG report for the ExSC's position on issues like "evidence-based" comments. See also the applicable ASD procedures whose standards development process is involved in any given issue.
- Lines 118 and 125: See the *Operating Procedures of the ANSI Board of Standards Review (BSR)*, *ANSI Executive Standards Council (ExSC)* and *ANSI Appeals Board* which provide ample details about the appeals process. Any alleged non-compliance with the *ANSI Essential Requirements* and an ANSI-Accredited Standards Developer's (ASD's) accredited procedures could form the basis of a procedural appeal; a non-exhaustive list of examples or a series of interpretations is not viewed as helpful.

Various

- Please refer to the ExSC report (ExSC_025), shared with the proposers previously, for background on the ExSC's decisions leading to the proposal shown in ExSC_017. This report addresses issues like the rejection of additional ANSI reviews, special treatment of Trade Associations as ASDs, proposals that go to the technical content of an ANS, applicability of ISO rules to ANS, reference to "hierarchy of controls" and more.
- General correction: the reference to "ANSI" appeals process in your public comments is not correct as the authors' reference appears to be to an appeals panel convened at the ASD level, not ANSI. No appeals have been filed with ANSI through the ANSI Board of Standards Review, ANSI Executive Standards Council or ANSI Appeals Board, by any of the authors of your comments (see page 4, para 3).
- The ExSC disagrees that there are "persistent and fundamental deficiencies in the ER" and notes again, that none of the proposers have availed themselves of ANSI's multi-level appeals process. The commenters have had options to vet grievances before the ANSI BSR, ANSI ExSC and ANSI Appeals Board, but they have chosen not to utilize them.
- Public input, and CIF input, will be sought on any proposed new or enhanced guidance documents developed. Recent consumer-related input obtained during roundtables managed by ANSI's new Consumer Manager will be shared with the ExSC as well.
- ISO's guidance does not govern the American National Standards process.
- Education and appeals: See ANSI's new website, updated with consumers and the general public in mind. An entire new section/path walks the public through all aspects of the ANS process.
- A definition of safety and health standard will not be included in the *ANSI Essential Requirements*. Please see ExSC_025.

Again, thank you for your interest and your comments.

Sincerely,

Anne

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