

## Ally Kupferberg

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**From:** Anne Caldas  
**Sent:** Thursday, March 18, 2021 4:41 PM  
**To:** Anne Caldas  
**Subject:** Response to public comments - Proposed revisions to the ANSI Essential Requirements - Dr. Pittle  
**Attachments:** ExSC\_025\_2021\_ER TG Report from 2019.pdf; ExSC\_017\_2019\_030921.pdf; ExSC\_012\_2021\_balance\_outreach.pdf; ExSC\_017K\_2019\_RDPittle.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](http://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> .

It is noted that you participated in the October 2020 ExSC discussions concerning the proposed revisions and heard the debates. The resulting updated proposal was shared with all meeting attendees and finally balloted to the ExSC. In addition to the meeting discussion and the discussion contained in the attached ExSC\_025\_2021 report which addresses some of your current and prior comments, as well as the edits reflected in the final version of ExSC\_017, which includes new language concerning consultants and interest classification, as well as other topics, please see the following responses presented by section of the proposed revision:

- Line 25 Balance - "without a proper balance, the resultant standard cannot call itself a consensus standard". This proposal was not accepted. The ExSC has debated this over the years. ANSI's requirements for balance are that balance shall be sought and outreach to achieve balance is a requirement. Please also refer to the ExSC TG Report and existing guidance.

- Lines 35-39: Suggests an edit and adds a new example; however, it is noted that not all ASDs would use the "user-consumer" interest category, so the example is not accurate as presented. Please refer to the updated final proposed revision for edits related to interest categories.
- Lines 41-71 regarding interest categories, proposes adding Table 1 (and Table 2) to the Essential Requirements. The ExSC did not accept this proposal, but has already decided that 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 guidance that could include the Tables you suggest, with the examples and accompanying description. Such draft guidance would be announced for public comment and circulated to the CIF to solicit input from the public and ASDs. Please see updated edits to this section in the final proposed revision.
- Lines 47-49 – suggests a further revision to the "General interest" category discussion. Please see edits to this section, which address in part your comments.
- Lines 55-56: Propose the addition of explanatory/clarifying text related to Users. After discussion, the ExSC disagreed with this proposal noting that the current language already allows for users with "requisite technical knowledge" and "other users" from "both individuals and representatives of organized groups". In addition, the current language states that "appropriate, representative user views shall be actively sought and fully considered in standards activities."
- Please refer to the TG report, shared with the proposers previously, for background on the ExSC's decisions leading to the proposal shown in ExSC\_017\_2019. 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.
- 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.

Again, thank you for your interest and your comments.

Sincerely,

Anne

Anne Caldas

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