Ally Kupferberg

From: Anne Caldas
Sent: Wednesday, March 17, 2021 11:40 AM
To: Anne Caldas
Subject: Response to public comments - Proposed revisions to the ANSI Essential Requirements - AAMI
Attachments: ExSC_025_2021_ER TG Report from 2019.pdf; ExSC_017E_2019_AAMI.pdf; ExSC_017_2019_030921.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 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. 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.

Please also note that consistent with recommendations in the attached ExSC TG 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 .

Responses to your comments and suggestions are presented here by section:

Lines 1-5: Section 1.3 Balance – NOTE: Not open for comment, included for reference

- **AAMI (E)** Line 4 - Response: Reference to "historical" is to the terminology used in 2.3 Balance "Historically, the criteria for balance are…"

Lines 7-13: Section 2.1 Openness – NOTE: Not open for comment, included for reference

- **AAMI (E)** Line 8 - Response: "Adequate notice" is a term that is not new in this proposed revision. The "adequacy" of the notice is judged either against the ASD's procedural requirements or the ANS-related context, for example, ANSI's PINS Notice is 30 days, but other procedural requirements vary in terms of the number of days. This allows ASDs flexibility, within the context of preserving due process and promoting participation.

Lines 25-71: 2.3 Balance

- **AAMI (E)** Line 35, 52, 90 – Editorial, footnotes will be updated throughout the document when a final revision is approved.

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

- **AAMI (E)** Line 75, 81 – Reasonable vs. advance notice – Accepted in principle The ExSC agreed to use "Timely and adequate notice". Such terminology will always involve judgement, unless an ASD's procedures specify a time period, in which case that time period applies. The ExSC does not wish to prescribe every timeframe because ASDs' models differ.
- **AAMI (E)** Line 76 – What is "meaningful opportunity"? This terminology allows flexibility within the context of preserving due process and promoting participation – both aspects that are assessed in the particular context. In addition, this language tracks OMB A-119: " Openness: The procedures or processes used are open to interested

parties. Such parties are provided meaningful opportunities to participate in standards development on a non-discriminatory basis. The procedures or processes for participating in standards development and for developing the standard are transparent."

- **AAMI (E)** Lines 75-76, 82 – What is "suitable media"? This is long-standing language that has provided ASDs with flexibility based on the nature of the standard under development, for example, a technical medical journal may not be "suitable media" in which to announce a standard for the development of concrete. Many examples are provided in the ExSC's guidance on Balance and Outreach/ Also, please see the edited version of the proposal, which uses "media suitable".
- **AAMI (E)** Lines 75-84 – Concern about the use of words subject to interpretation. The *ANSI Essential Requirements* intentionally includes a mix of very specific requirements, e.g., 30-day PINS notice, and flexible requirements, e.g., ballot durations, to allow for flexibility among the 240 ANSI-Accredited Standards Developers (ASDs). An ASD's implementation of any of ANSI's procedural requirements will ultimately be judged by the BSR, the ExSC and/or the Appeals Board as the case may be – as well as through an ASD's appeals process. An auditor never has the final say as suggested, and an ASD always has the opportunity to raise concerns during the course of an audit, for specific review by the ExSC. An ASD is absolutely within its rights to prescribe a timeframe for everything in its procedures and the ExSC in turn, would judge whether such timeframes meet ANSI's due process goals.

Lines 81-105: Section 2.5.1 PINS

- **AAMI (E)** Lines 102-105 – Suggested rewording. Please see attached which includes editorial updates.

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