

AAMI Comments on the Proposed Revisions to the Current (2019) ANSI International Procedures
(November 19, 2021 *ANSI Standards Action* [ExSC_095_2021])

Thank you for the opportunity to comment on the proposed revisions to the current ANSI International Procedures. We are pleased with the proposed changes but have a handful of editorial suggestions or requests for clarification.

1. Page 10, (1.5.5.3, item 8) lines 294

Comment: We understand the intent of this provision is to ensure that an external organization managing an ANSI-held Secretariat is “connected” with the TAG and U.S. stakeholders. Many external organizations (like AAMI) manage both ISO Secretariats and the corresponding TAGs. For an organization administering the TAG, there could be a potential conflict of interest in serving as a voting or nonvoting member of the TAG.

Proposed Change: Add text to clarify that the requirement to serve as a member of the TAG does not apply when an organization is the TAG Administrator.

8. Unless the external organization administers the TAG, it has agreed to serve as a voting or non-voting member of the TAG.

RESPONSE: Accept edit to 1.5.5.3 Delegation of a Secretariat to an External Organization.

2. Page 15, (footnote 6)

6 “Affiliation” refers to the entity that the U.S. TAG member represents, (which may or may not be that person’s employer). If the TAG member is serving in an individual capacity, then the name of the individual, that person’s employer (if employed), their sponsors (if any) and interest category shall be made available upon request. Contact information is not required. A sponsor is defined as an organization that provides funds specifically to support the individual's participation in the standards activities of the TAG.

Comment: We are okay with this text but would like confirmation that there is no requirement that an ASD allow an individual to serve on a TAG in a personal capacity instead of as a representative of their employer if the employer has a material interest in the TAG’s work. We would not normally permit this on TAGs that we administer and want to make sure that this text is not interpreted as requiring us to change our practice. Finally, is it appropriate to put a requirement (e.g., “shall”) in a footnote?

RESPONSE: The opportunity to apply for membership on an ANSI-Accredited U.S. TAG has to be available to any applicant that meets ANSI’s definition of U.S. National Interested Party, which includes “a U.S. citizen or permanent legal resident”. There may be a reason to deny membership, but the opportunity for an individual to apply must exist.

Footnote 6 provides further explanation of 2.3.3 (5) and the requirement that a TAG Roster be provided upon request is reflected in both. Since it is a requirement, the use of “shall” is appropriate.

3. Page 23, (footnote 13)

Comment: See comment 3 (on footnote) 6, above.

RESPONSE: See prior response.

4. Page 24, (A.4.1 Role of the TAG), line 850 through 851

Comment: There should be an option to have cochairs.

Proposed Change: Add “(or Cochairs)” after “Chair” in both line 850 and line 851.

RESPONSE: Accept.

5. Page 28, (A6.1 Application), line 1036

We understand the intent of this change is to get away from the use of “substantive change” as defined in the ANSI ERs. It would be helpful to add a definition or guidance on what “material change” means.

RESPONSE: (Correct cite is line 1036 in A7.7.) The following new definition of “material change” will be added as a clarification:

A material change is one that alters or modifies the U.S. position or the intent of the U.S. comments at issue.