ExSC_017_2019 edited – Approved by the ANSI ExSC February 2021 for submission to the ANSI Executive Committee of the Board of Directors for final approval March 9, 2021

Proposed revisions to the ANSI Essential Requirements (www.ansi.org/essentialrequirements)

1.3 Balance

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

2.1 Openness

Timely and adequate notice of any action to create, revise, reaffirm, or withdraw a standard, and the establishment of a new consensus body shall be provided to all known directly and materially interested parties. Notice should include a clear and meaningful description of the purpose of the proposed activity and shall identify a readily available source for further information. In addition, the member's name (or if membership is by organization, the name of the organization with a point of contact), affiliation4 and interest category of each member of the consensus body shall be made available to interested parties upon request. The affiliation of a consensus body member refers to the entity that the consensus body member represents, which may or may not be that person's employer. If the consensus body member is serving in an individual capacity, then the name of the individual, their sponsors¹ (if any) and interest category shall be made available upon request. Contact information is not required.

2.2 Lack of dominance

Unless it is claimed in writing (including electronic communications) by a directly and materially interested party that a single interest category, individual or organization dominated the standards development process, no test for dominance is required.

2.3 Balance

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

The interest categories appropriate to the development of consensus in any given standards activity are a function of the nature of the standards being developed. Interest categories shall be discretely defined, cover <u>directly and</u> all materially interested parties and differentiate each

¹."Affiliation" refers to the entity that the consensus body member represents (which may or may not be that person's employer). If the consensus body member is serving in an individual capacity, then the name of the individual, that person's employer, sponsor and interest category should be available. Contact information is not required.

¹ A sponsor is defined as an organization that provides funds specifically to support the individual's participation in the standards activities of the consensus body.

category from the other categories. Such definitions shall be available upon request.

Consensus body members, including consultants², typically are classified in accordance with the business or other interests of their employers or the sponsors they represent in connection with the standards development activity. In cases where a consensus body member receives funding from the sponsoring ANSI-Accredited Standards Developer (ASD) or other entities, that information shall be disclosed to determine if it will impact the member's interest classification.

In <u>determining defining</u> the interest categories appropriate to a standards <u>development</u> activity, <u>an ASD shall give</u> consideration consideration shall be given to at least the following <u>three categories:</u>

- a) producer;
- b) user;
- c) general interest.

If, after consideration, a "General Interest" category is deemed appropriate, that interest category should include only those whose business or other interests are not covered by another discretely defined interest category.

- Where appropriate, additional interest categories should be considered.³ <u>However, interest categories shall not be created for the purpose of avoiding balance requirements.</u>
- Appropriate, representative user views shall be actively sought and fully considered in standards activities.

Whenever possible, user participants shall be those with the requisite technical knowledge, but other users may also participate. User participation should come from both individuals and representatives of organized groups. There are several user categories:

- 1. User-consumer: Where the standards activity in question deals with a consumer product, such as lawn mowers or aerosol sprays, an appropriate consumer participant's view is considered to be synonymous with that of the individual user a person using goods and services rather than producing or selling them.
- 2. User-industrial: Where the standards activity in question deals with an industrial product, such as steel or insulation used in transformers, an appropriate user participant is the industrial user of the product.
- 3. User-government: Where the standards activity in question is likely to result in a standard that may become the basis for government agency procurement, an appropriate user participant is the representative of that government agency.
- 4. User-labor: Where the standards activity in question deals with subjects of special interest to the American worker, such as products used in the workplace, an appropriate user participant is a representative of labor.

² For purposes of this section, a "consultant" is someone who agrees to provide professional service in exchange for compensation, financial or otherwise.

³ Further interest categories that may be used to categorize directly and materially interested parties consist of, but are not limited to, the following: a) Consumer; b) Directly affected public; c) Distributor and retailer; d) Industrial/commercial; e) Insurance; f) Labor; g) Manufacturer; h) Professional society; In) Regulatory agency; ij) Testing laboratory; k) Trade association.

1.5 Notification of standards development

<u>Timely and adequate notice notification</u> of standards <u>development</u> activity shall be announced in media suitable to demonstrate <u>that a meaningful</u> opportunity for participation, <u>debate and deliberation</u> by all directly and materially interested parties <u>in a fair and equitable manner was provided</u>.

2.5 Notification of standards development and coordination

<u>Timely and adequate notice</u> of standards <u>development</u> activity, <u>including formation of a consensus body or a consensus body meeting</u>, shall be announced in media suitable to demonstrate that <u>a meaningful</u> opportunity for participation by all directly and materially interested parties in a fair and equitable manner was provided.

Developers are encouraged to consult any relevant international or regional guides that may impact the proposed standard and shall advise the relevant ANSI-Accredited U.S. TAG(s) if the standard is intended to be submitted for consideration as an ISO, IEC or ISO/IEC JTC-1 standard.

2.5.1 Project Initiation Notification System (PINS)

At the initiation of a project to develop or revise an American National Standard⁴, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*. Comments received in connection with a PINS announcement shall be handled in accordance with these procedures.

A statement shall be submitted and published as part of the PINS announcement that shall include:

- (a) an explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard;
- (b) identification of the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard: and
- (c) the interest categories that will or are expected to comprise the consensus body.

If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published.

If a developer receives a written request for additional information or for the opportunity to discuss the proposal from a directly and materially interested outside party or current consensus body member, during the 30-day PINS comment period, the ASD shall respond in writing within 30 days of the comment deadline.

2.8 Appeals

The provision for appeals is an important element of due process. This section gives general criteria regarding the right to appeal, to whom appeals are made and what may be appealed.

2.8.1 Right to Appeal: Appeals at the standards developer level

The written procedures of an ANSI-Accredited Standards Developer (ASD) shall contain an identifiable, realistic, and readily available mechanism for the impartial handling of

⁴ Including the national adoption of ISO and IEC standards as American National Standards, but excluding actions setforth in 2.5.1.1.

procedural appeals regarding any action or inaction. Appeals shall be addressed promptly and a decision made expeditiously <u>and issued in writing</u>. A standards developer may choose to offer an appeals process to address appeals on other than procedural issues. Procedural appeals include whether a technical issue was afforded due process. Appeals procedures shall provide for participation by all parties concerned without imposing an undue burden on them. Consideration of appeals shall be fair and unbiased and shall fully address the concerns expressed.

Parties who are directly and materially interested in and who have been or will be adversely affected by any procedural action or inaction by a standards developer with regard to the development of a proposed American National Standard or the revision, reaffirmation, or withdrawal of an existing American National Standard, have the right to appeal. The burden of proof to show adverse effect shall be on the appellant. Appeals of actions shall be made within reasonable time limits; appeals of inactions may be made at any time. Appeals shall be directed to the standards developer responsible for the action or inaction in accordance with the appeals procedures of the standards developer. If a fee for a procedural appeal is charged, then it shall be predetermined, fixed and reasonable. A procedure for requesting a fee waiver or fee reduction shall be available.

2.8.2 Right to Appeal: Appeals at ANSI

Parties who are directly and materially interested in and who have been or will be adversely affected by any procedural action or inaction by ANSI or by any ANS-related process have the right to appeal. ANSI will not normally hear an appeal of an action or inaction by a standards developer relative to the development of an American National Standard until the appeals procedures provided by the standards developer have been completed. As required in paragraph 2.8.1, appeals at the ASD shall be addressed promptly and a decision made expeditiously and issued in writing. However, conclusion of the appeals process at the standards developer level is not a precondition for filing an appeal of an organization's continuing accreditation status with the ANSI Executive Standards Council (ExSC).

Claims of procedural non-compliance raised during the course of an active standards development process are to be addressed in accordance with the standards developer's appeals process. The standards developer's appeals process shall conclude before final submittal of evidence of consensus is made to ANSI in support of the approval of a standard as an American National Standard.

Except in the case of an Audited Designator, an appeal of the approval of a standard as an American National Standard is to be filed in accordance with the *Operating Procedures* of the ANSI Board of Standards Review (BSR). Complaints concerning ANSI Audited Designators, including the approval of a standard as an American National Standard, are governed by the *Operating Procedures of the ANSI Executive Standards Council* (ExSC).

Appeals of actions shall be made within reasonable—the time limits specified in applicable procedures; appeals of inactions may be made at any time. Such appeals shall be directed to ANSI in accordance with the procedures of the appropriate ANSI Committee board or council (e.g., Board of Standards Review, Executive Standards Council).