

1 **ANSI Essential Requirements: Due process requirements for American National Standards**

2 **1. Essential requirements for due process**

3 These requirements apply to activities related to the development of consensus for approval,
4 revision, reaffirmation, and withdrawal of American National Standards (ANS).¹

5 Due process means that any person (organization, company, government agency, individual,
6 etc.) with a direct and material interest has a right to participate by: a) expressing a position
7 and its basis, b) having that position considered, and c) having the right to appeal. Due process
8 allows for equity and fair play. The following constitute the minimum acceptable due process
9 requirements for the development of standards.

10 *Comment: The only change here is the footnote indicating that section 6.0 pertaining to*
11 *health and safety standards has been added.*

12

¹ Please see Sections 6.0-6.4 for additional requirements for such activities related to health and safety standards.

1 **6.0 Essential requirements for due process for health and safety standards.**

2 In addition to the requirements that apply to activities related to the development of consensus
3 for approval, revision, reaffirmation, and withdrawal of American National Standards (ANS), the
4 following requirements shall apply to standards that address health and safety concerns. For
5 purposes of Section 6, ~~a~~A health and safety standard shall include any product standard that is
6 intended to protect individual end users, such as consumers or employees, from death, injury
7 or illness from use of that product. Any product safety matter that is the subject of official
8 concern by any federal or state health and safety organization shall presumptively be
9 considered a health and safety standard subject to this section in the event that the matter
10 should be considered for development as an American National Standard.²

11 Matters that do not pertain ~~to~~ to the health and safety of the product's end user are not
12 covered by this section. For example, a standard that addresses quality, fairness, sustainability,
13 deception, discrimination, or similar societal issues may be extremely important, but will not
14 fall within this section.

15 Due process means that any person (organization, company, government agency, individual,
16 etc.) with an interest in the development of a health and safety product standard has a right to
17 participate by: a) expressing a position and its basis, b) by having that position considered, and
18 c) having the right to appeal. Due process allows for equity and fair play. In addition to the
19 requirements set forth in sections 1-5 of this document, the following constitute the minimum
20 acceptable due process requirements for the development of consensus health and safety
21 product standards. Where there are no changes to sections 1-5 of this document, the
22 procedures currently applicable shall continue to apply

23 *Comment: This section makes clear that the suggested changes will apply only to health
24 and safety product standards. This is an expansion of the current scope of section 2.3 of
25 the Essential Requirements which applies only to "safety standards." This section
26 recognizes that health issues are as critical to protecting the public as much as safety
27 issues. This also recognizes that most agencies that address safety issues also address
28 health issues. To that end, this section defines the term "health and safety standard."
29 Essentially, it uses a common-sense approach by covering those standards that address
30 issues relating to death, injury, or illness from products by end users. A good rule of
31 thumb would be to look to whether a health and safety agency like FDA, CPSC, EPA,
32 OSHA, USDA would exercise jurisdiction over the product. If so, the standard should
33 generally be considered a health and safety standard. ~~For the most part~~ Although some*

² Nothing in this section is intended to change any copyright rights currently in existence.

1 *agencies' jurisdiction extends beyond product issues, this section for the moment*
2 *addresses is limited to products used by consumers or workers. In a limited number of*
3 *instances, a concern broader than products may also be considered. For example, OSHA*
4 *relies on standards that are designed to protect workers from falls, excessive cold or*
5 *heat, or noise.*

6 6.1 Openness

7 Participation shall be open to all persons who are directly and materially affected by the
8 activity in question with respect to the development of a health and safety standard who agree
9 to abide by the essential requirements for due process. ~~There~~ Other than a nominal fee for the
10 purchase of a voluntary standard under consideration, there shall be no ~~undue~~ financial
11 ~~barriers or~~ requirements for participation in the development of a health and safety product
12 standard. Voting membership on the consensus body shall not be conditional upon
13 membership in any organization, nor unreasonably restricted on the basis of technical
14 qualifications or other such requirements.

15 In order to promote openness at every stage of the development of a health and safety
16 product standard, the standard developer shall facilitate or host one or more sessions, which
17 may be conducted online, at the outset of the consensus process to allow the consensus body
18 members to discuss the health and safety goals of the proceeding and the available evidence
19 supporting the need for the standard.

20 In order to promote openness throughout the development process, all official meetings of the
21 standards developer shall be open to all members, either in person, by conference call, or
22 interactive webinar. Unofficial discussions among members of different interest groups to
23 develop particular positions on issues are permitted and need not be open to all members.
24 However, such discussions may not substitute for a full discussion of critical issues in open
25 sessions that permit all voting members to participate.

26 In all instances where meetings are through digital or other media, the standard developer shall
27 ensure that all members or other known interested parties are directly notified in writing (by
28 mail or electronic means) at least ten (10) days in advance and provided clear instructions
29 about how to participate in the meetings. It shall be the responsibility of the standard
30 developer to ensure that electronic means for conducting meetings are readily available to all
31 participants.

32 To ensure the openness of the process, the standards developer shall maintain written records
33 of all meetings of the consensus body. Such records shall include a summary of the topics

1 discussed and the date, time, subject, and attendees of the meeting. These records shall be
2 available for inspection by all members of the consensus body and any review body within
3 ANSI.

4 Timely and adequate notice of any proposed action to create, revise, reaffirm, or withdraw a
5 health and safety standard, and the establishment of a new consensus body shall be provided
6 to all known ~~directly and materially affected interests~~ interested parties. Notice should include
7 a clear and meaningful description of the purpose of the proposed activity and shall identify a
8 readily available source for further information. In addition, the affiliation³ and interest
9 category of the proposer shall be noted on the proposal. If the proposal was submitted by an
10 organization, the name of the organization with a point of contact shall be included with the
11 proposal. In addition, the affiliation and interest category of each member of the standards
12 developer shall be made available to interested parties upon request.

13 **6.1.1 Canvass Method**

14 No health or safety standard may be approved through a non-deliberative canvass
15 method, i.e., an approach in which a draft is circulated for a vote in the absence of
16 deliberation or discussion among the participants, which may be conducted online. All
17 standards shall include deliberation and discussion of the provisions of a draft standard
18 either in person, by conference call, or interactive webinar, *unless* all members of the
19 consensus body agree to such an approach.

20 *Comment: This section on Openness generally tracks the language of the Essential*
21 *Requirements with one major exception. There have been a number of complaints about*
22 *ballots being distributed by the standards developer with little to no opportunity for*
23 *discussion or deliberation regarding the substance of draft standards, historically*
24 *referred to as the "Canvass Method". A consensus process should not limit participants*
25 *only to ballots and written comments. Given the ~~explosion in forms of widespread~~*
26 *availability of interactive media, this section does not prescribe any particular form of*
27 *discussion or deliberation; it merely requires that a meaningful dialogue be conducted*
28 *among the participants. The section does not prohibit the canvass method; but it does*
29 *set minimum requirements for discussion and balloting ~~through~~ when the canvass*
30 *method is employed.*

³ "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 shall be available.

1 **6.2 Lack of dominance**

2 The standards development process shall not be dominated by any single interest category,
3 individual or organization, including the standards developer. Dominance means a position or
4 exercise of dominant authority, leadership, or influence by reason of superior leverage,
5 strength, or representation to the exclusion of fair and equitable consideration of other
6 viewpoints.

7 Any member of a standards development activity may object at any point in the process by
8 claiming in writing that the process is subject to one or more parties' dominance. In support of
9 this claim, the party objecting should offer specific facts that illustrate that a party has
10 exercised dominance to the exclusion of fair and equitable consideration of other viewpoints.

11 Members who object to a standards development in writing and with adequate documentation
12 may file an immediate appeal to [the Board of Standards Review??] and seek a stay in the
13 proceeding until dominance issues have been resolved. Although the particulars of any given
14 standards proceeding that give rise to a party's dominance may vary, the following constitute
15 presumptive dominance –

- 16 a) The refusal to permit or failure to provide the opportunity for a participant's comments
17 to be heard,
18 b) The refusal to permit or failure to provide reasonable deliberation and discussion of a
19 participant's views,
20 c) The refusal to give or failure to provide adequate notice to any participant of an
21 upcoming meeting,
22 d) The refusal or failure to circulate drafts of a standard without adequate time to read and
23 comment on each draft,
24 e) The refusal to permit or failure to provide a discussion in open session of drafts of a
25 proposed standard,
26 f) The establishment of a standard's consensus body without adequate balance among the
27 interest categories, or
28 g) Any other act or refusal to act that unfairly gives an advantage to any person or group
29 involved in drafting a standard that will be submitted for acceptance as an American
30 National Standard.

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31 To prevent dominance in the development of health and safety standards, the standards
32 development process shall –

- 33 a) Provide appropriate balance, in accordance with section 6.3, on the standards
34 development consensus body,

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- 1 b) Operate the process in accordance with the openness requirements in section 6.1,
- 2 c) Permit any party dissatisfied with the process on the basis of one or more parties
- 3 exercising dominance to object in writing at any time before or during the process.

4 *Comment: This section generally tracks the language of the current version of the Essential*
5 *Requirements except for the reference to openness requirements in section 6.1 and*
6 *providing balance in the next section, 6.3. It also provides the right to an immediate appeal*
7 *on the grounds of undue dominance of any party in a standard's development so long as the*
8 *party filing an appeal has documented the charges of dominance in writing. Should [the*
9 *Board of Standards Review] determine that such an appeal has merit, it may stay an SDO's*
10 *proceeding until the dominance issues have been resolved. To provide more clarity in the*
11 *determination of dominance, the section provides examples that would warrant a finding of*
12 *dominance.*

13 **6.3 Balance: Basic Principles**

14 The criteria for balance on health and safety standards are that no single interest category
15 constitutes more than one-third of the voting members of a consensus body dealing with such
16 standards. All of the requirements set forth in this section and in section 6.4 shall apply to
17 official voting members of any voluntary health and safety standard developed under these
18 procedures and requirements.

19 [Alternative: In the event that a standards developer wishes to use interest categories other
20 than Business, User, and General Interest, as set forth below, the developer may do so, but in
21 no circumstance shall give more than fifty percent of the voting power to any single business
22 group or combination of business groups. To prevent providing greater voting weight to
23 Business Interests, the developer shall adjust voting weights needed to maintain proper
24 balance as set forth in this section.]

25 Balance of participation in the development of health and safety standards, as defined in
26 Section 6.3.1, is the greatest need for American National Standards. Without balance,
27 consensus standards will inevitably face dominance by parties who seek to draft standards
28 favorable to their particular concerns rather than standards that favor the broad public interest.
29 Accordingly, it is vital that careful attention be paid to establishing consensus bodies with a
30 balance of interests and take steps to ensure that such balanced interests are included in every
31 step of the process.

1 Any member of a standards development activity may object at any point in the process by
2 claiming in writing that the process lacks proper balance. In support of this claim, the party
3 objecting should offer specific facts that illustrate that imbalance has occurred.

4 The failure of a standards developer to achieve balance throughout the development of such a
5 standard shall bar the standard from approval as an American National Standard.

6 *Comment: One of the fundamental principles of American National Standard*
7 *development is the need for balance in the development of standards. Because ANSI*
8 *approval is limited only to whether a standard development body meets minimum due*
9 *process requirements and because balance is perhaps the most important component of*
10 *due process, no standard that is drafted by a consensus body that lacks balance shall be*
11 *approved as an American National Standard. Section 6.3.1 provides measures that a*
12 *standard development body may use to ~~address imbalance issues~~ achieve balance.*

13

14 **6.3.1 Balance: Basic Categories**

15 There are three basic interest categories appropriate to the development of consensus in any
16 health and safety product ~~given~~ standards activity. Each basic category may be comprised of an
17 array of subcategories that are a function of the nature of the standards being developed.
18 Interest categories shall be discretely defined, cover all materially affected parties and
19 differentiate each category from other categories. Such definitions shall be available upon
20 request. In defining the interest categories appropriate to a health and safety product
21 standards activity, the following broad classifications shall apply⁴:

- 22 a) Business interest;
- 23 b) User interest;
- 24 c) General interest.

25 Each subcategory must ~~fit~~ be placed uniquely into one of the three basic categories. Where
26 appropriate, additional subcategories ~~interest categories~~ may be considered (subject to section
27 6.4).⁵

⁴ For a table that summarizes these interest categories, see Appendix 1.

⁵ Further interest categories that may be used to categorize directly and materially affected persons 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, i) regulatory agency, j) testing laboratory, k) trade association.

1 Business interest shall include all who, directly or indirectly, receive compensation,
2 reimbursement, or financial benefit⁶ from the production or sale of a product (or a related
3 product⁷) that is the subject of a standards development proceeding. At a minimum, the term
4 includes manufacturers, retailers, importers, distributors, trade association members and staff,
5 paid consultants, industry retirees, and expert witnesses hired by a business interest for the
6 product that is the subject of the standards development proceeding. Independent third-party
7 testing laboratory personnel with a broad interest in the testing protocol of a standard shall not
8 be included in the business interest category unless they have been specifically hired to
9 participate in the development of a standard by a business client or clients.

10 User interest includes all end users for whom a product is produced. It also includes parents or
11 other caregivers of end users. No one who in the past three years has received or currently
12 receives (or has contracted to receive) compensation or reimbursement, directly or indirectly,
13 from the production or sale of the product that is the subject of the standards development
14 proceeding is eligible to serve as a participant in a user interest group.⁸

15 Appropriate representative user views shall be actively sought and fully considered in standards
16 activities. Whenever possible, user participants shall be those with requisite technical
17 knowledge, but other users may also participate. User participation may come from both
18 individuals and representatives of organized groups. There are several user categories for
19 health and safety standards:

- 20 1. User-consumer: Where the standards activity in question deals with a consumer
21 product, such as lawn mowers or aerosol spray, an appropriate consumer participant's
22 view is considered to be synonymous with that of the individual user – a person using
23 goods and services rather than producing or selling them.
- 24 2. User-labor: Where the standards activity in question deals with subjects of special
25 interest to the American worker such as products used in the workplace, an appropriate
26 user participant is a representative of labor.
- 27 3. User-government: Where the standards activity in question is likely to result in a
28 standard that may become the basis for government agency procurement, an
29 appropriate user participant is the representative of that government agency.

⁶ Participants need not list the precise amount of any such compensation, reimbursement, or financial benefit. As used in this section, the term "reimbursement" includes reimbursement for travel or other expenses.

⁷ For example, one who is affiliated with the production of all-terrain vehicles (ATVs) would be placed in this interest category even if he or she worked exclusively on recreational off-highway vehicles (ROVs). In all instances in which the term "product" is used, it shall include the concept of "related product" as well.

⁸ Anyone receiving a pension from a producer or business that is the subject of the standard under development shall not be eligible to serve in the user interest category.

1 4. User-industrial: Where the standards activity in question deals with a product that is
2 used by an industrial entity exclusively as an end user, an appropriate user participant is
3 the industrial user of the product.

4 General interest is a catch-all category for those with an interest in the consumer product that
5 is the subject of a standards development proceeding who do not fit into the Business Interest
6 or User-Interest categories. For example, it includes individuals or groups who provide medical
7 or other services to end-users of the consumer product that is the subject of a standards
8 development proceeding. It also includes university researchers, government employees,
9 professional societies, test laboratories, and independent technical experts. No one who in the
10 past three years has received or currently receives (or has contracted to receive) compensation
11 or reimbursement, directly or indirectly, from the production or sale of the product that is the
12 subject of the standards development proceeding is eligible to serve as a participant in a
13 General Interest group.⁹

14 If the standards developer lacks the balance outlined in Sections 6.3 and 6.4, the standards
15 developer shall conduct significant outreach efforts to bring the membership of the standards
16 development process into balance. Included in outreach efforts should be documented
17 solicitation of participation by consumer groups such as Consumers Union, Consumer
18 Federation of America, National Consumers League, technical departments of universities,
19 academic societies, retired business executives, retired teachers, and appropriate
20 governmental agencies. In instances where initial outreach efforts have proven unsuccessful,
21 the standards developer shall document whether it has offered to fund the participation of any
22 unrepresented or underrepresented interest. If the outreach efforts fail to achieve balance, the
23 ~~consensus body~~ votes of the consensus body shall be adjusted or apportioned to ensure
24 balance of no more than one-third per interest group. Within this basic rule, adjustments may
25 be made at the discretion of the standard developer. For example --

26 1. Membership of an interest group that is overrepresented may be adjusted
27 downward by removing the number of voting participants necessary to achieve
28 proper balance. For example, if one interest group has ten members and
29 another interest group has only five, the number of eligible voters of the larger
30 group shall be adjusted down to five. Such adjustments shall be done by fair and
31 reasonable methods to determine which members shall be eligible to vote.

⁹ Anyone receiving a pension from a producer or business that is the subject of the standard under development shall not be eligible to serve in the General Interest category.

2. Membership of an interest group that is overrepresented may be adjusted downward by splitting the vote into fractions of a vote until proper vote balance is achieved. For example, if one interest group has twice the number of eligible voters as another, the overrepresented interest group participants shall be allotted only half a vote in order to match the underrepresented group of voting participants;
3. Membership of an interest group that is underrepresented may be adjusted upward by multiplying the power of votes for ~~any voting member~~ those voting members until balance is achieved. For example, if one interest group has half the number of eligible voters as another, the underrepresented interest group participants shall be allotted twice the number of votes in order to match the overrepresented group of voting participants; or
4. Any other reasonable means of adjustment that ensures a balance of no more than one-third voting rights per interest group.

6.3.2 Full Disclosure of Financial And Other Important Interests

In order to participate as a voting member in a standards development proceeding, each participant shall provide, at a minimum, the following information which shall be available to all members of the consensus body and to ANSI staff:

- a. Any and all financial connections, direct or indirect,¹⁰ of the participant (or any immediate family member) to a Business Interest (including a trade association) that produces a product that is the subject of the standards development proceeding;
- b. Any compensation or reimbursement, direct or indirect, by the participant (or any immediate family member) for participating in the standards development proceeding as a consultant, expert witness, or otherwise; and
- c. Any and all relevant memberships or volunteer relationships (e.g., professional organizations, trade associations, public interest or civic groups) that include a direct interest in the product that is the subject of the standards development proceeding.
- d. Any change in circumstances that would change the member's status from one of the interest ~~categories~~ groups to another (which must be reported prior to any further participation in standards development activity).

¹⁰ This includes retirees of a producer, trade association, or other organization that is involved in producing the product that is the subject of a standard development proceeding.

1 *Comment: This section provides more detail regarding the requirements for balance. It*
2 *leaves unchanged the rule that no single interest category may constitute more than*
3 *one-third of the official voting membership of a standards developer . This section does*
4 *several things:*

- 5 • *It more precisely defines the three interest categories. In essence, it states*
6 *that anyone who has received compensation or reimbursement from a*
7 *business interest involved in producing the product that is the subject of a*
8 *standard development must be placed in the category of Business Interest.*
- 9 • *The section also makes clear that participants who previously might have*
10 *been considered General Interest members (such as industry retirees, expert*
11 *witnesses for the industry, academic consultants with financial ties to the*
12 *industry, consultants for the industry) cannot be considered General Interest.*
13 *They are welcome to participate, but must do so as members of the Business*
14 *Interest category.*
- 15 • *The section addresses a common concern arising from those instances in*
16 *which, despite the best outreach effort of a standard developer, insufficient*
17 *members of an interest group participate to permit balance in terms of*
18 *numbers of votes. In such cases, the standard developer must document its*
19 *outreach efforts, which may include offering funding for participation. Where*
20 *outreach efforts still fail, the standard developer may choose among several*
21 *alternatives: (i) to remove some voters from an overrepresented interest*
22 *group, (ii) to subdivide the votes of the overrepresented group, (iii) to expand*
23 *the votes of each member of an underrepresented group, or (iv) any other*
24 *reasonable means of adjustment that preserves the balance of interest*
25 *categories.*
- 26 • *In order to ensure that participants get properly classified into the interest*
27 *category to which they should belong, this section sets minimum*
28 *requirements for disclosure of financial and other interests in the product*
29 *under standards development. Such disclosures must be available to*
30 *consensus body members and to ANSI staff in order to ensure the integrity of*
31 *the process and should guide the classification of participants in the standard*
32 *development process.*

33 **6.4 Balance: Subdivision of Interest Categories**

34 As noted, within any of the three broad interest categories, it may be appropriate and useful to
35 further subdivide ~~participants members of the standards development proceeding~~ into smaller

1 interest ~~groups subcategories~~ with shared concerns (see footnote 3 for examples). All
2 interested parties are encouraged to participate.

3 In order to maintain appropriate balance, however, any subdivided interest ~~category group~~ will
4 be considered to remain within ~~one of the three~~ main interest ~~category group~~ into which it fits.
5 Under no circumstances shall the ~~sum of the~~ official voters of any subdivided ~~categories groups~~
6 have the right to cast more votes than ~~the~~ one-third number of the ~~total broad interest group~~
7 ~~in which they belong~~. For example, should ~~the users-users category~~ subdivide into user-
8 consumer and user-labor groups, they cannot then claim the right to cast more than one-third
9 of the total official votes in the standards development proceeding.¹¹

10 *Comment: This section addresses the issue of subdividing interest categories. It permits*
11 *such categories to be subdivided in order to make the standard development process*
12 *more substantive and efficient. However, it makes clear that subdividing the three*
13 *interest categories does not create a different voting protocol. Each ~~subdivision~~*
14 *~~subcategory~~ must still vote as part within of its one-third broader interest category.*

16 **EFFECTIVE DATE**

17 This amendment shall become effective one year after final approval by ANSI.

¹¹ Or to put it another way: each of the three broad interest groups is entitled to cast one-third of the votes regarding the standard – no more, no less.

1 **INTEREST CATEGORIES FOR HEALTH AND SAFETY PRODUCT STANDARDS**

BUSINESS INTEREST	USER INTEREST*	GENERAL INTEREST*
Manufacturers	Individual consumers	Medical professionals
Retailers & <u>internet sellers</u>	Consumer groups	Academics/researchers
Importers	Hobbyists	Professional societies
Distributors	Union representatives	Independent Test labs
Trade associations <u>related to the product</u>	Government (federal, state, local)**	Government (federal, state, local)**
Paid consultants (includes academic consultants)	Internet sites that evaluate products/services	Non-industry attorneys
Expert witnesses	Consumer columnists	Independent technical experts
Retired industry employees within the past three years***		Independent consultants
Industry attorneys		

2

3 *No commercial interest in production or sale of the product that is the subject of the
 4 standards proceeding

5 ** Depending on its interest in a standards proceeding, government may either represent its
 6 interests as a user/purchaser of the product or its interests as a representative of the public.

7 *** Retired industry employees who receive a pension from an industry member that produces
 8 the product that is subject of the voluntary standard under development shall be considered to
 9 fall within the Business Interest group irrespective of how many years they have been retired.