

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).<sup>1</sup>

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.*

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<sup>1</sup> 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. A  
5 health and safety standard shall include any standard that is intended to protect end users,  
6 such as consumers or employees, from death, injury or illness. Any matter that is the subject of  
7 official concern by any federal or state health and safety organization shall presumptively be  
8 considered a health and safety standard subject to this section in the event that the matter  
9 should be considered for development as an American National Standard.<sup>2</sup>

10 Matters that do not pertain to health and safety are not covered by this section. For example, a  
11 standard that addresses quality, fairness, sustainability, deception, discrimination, or similar  
12 societal issues may be extremely important, but will not fall within this section.

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

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

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<sup>2</sup> Nothing in this section is intended to change any copyright rights currently in existence.

1            *products may also be considered. For example, OSHA relies on standards that are*  
2            *designed to protect workers from falls, excessive cold or heat, or noise.*

### 3    **6.1 Openness**

4    Participation shall be open to all persons who are directly and materially affected by the  
5    activity in question with respect to the development of a health and safety standard who agree  
6    to abide by the essential requirements for due process. There shall be no undue financial  
7    barriers or requirements for participation in the development of a health and safety standard.  
8    Voting membership on the consensus body shall not be conditional upon membership in any  
9    organization, nor unreasonably restricted on the basis of technical qualifications or other such  
10   requirements.

11   In order to promote openness at every stage of the development of a health and safety  
12   standard, the standard developer shall facilitate or host one or more sessions at the outset of  
13   the consensus process to allow the consensus body members to discuss the health and safety  
14   goals of the proceeding and the available evidence supporting the need for the standard.

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

21   In all instances where meetings are through digital or other media, the standard developer shall  
22   ensure that all members or other known interested parties are directly notified in writing (by  
23   mail or electronic means) at least ten (10) days in advance and provided clear instructions  
24   about how to participate in the meetings.

25   To ensure the openness of the process, the standards developer shall maintain written records  
26   of all meetings of the consensus body. Such records shall include a summary of the topics  
27   discussed and the date, time, subject, and attendees of the meeting. These records shall be  
28   available for inspection by all members of the consensus body and any review body within  
29   ANSI.

30   Timely and adequate notice of any proposed action to create, revise, reaffirm, or withdraw a  
31   health and safety standard, and the establishment of a new consensus body shall be provided  
32   to all known directly and materially affected interests. Notice should include a clear and  
33   meaningful description of the purpose of the proposed activity and shall identify a readily

1 available source for further information. In addition, the affiliation<sup>3</sup> and interest category of  
2 the proposer shall be noted on the proposal. If the proposal was submitted by an organization,  
3 the name of the organization with a point of contact shall be included with the proposal. In  
4 addition, the affiliation and interest category of each member of the standards developer shall  
5 be made available to interested parties upon request.

### 6 **6.1.1 Canvass Method**

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

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

### 23 **6.2 Lack of dominance**

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

29 Any member of a standards development activity may object at any point in the process by  
30 claiming in writing that the process is subject to one or more parties' dominance. In support of

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<sup>3</sup> "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 this claim, the party objecting should offer specific facts that illustrate that a party has  
2 exercised dominance to the exclusion of fair and equitable consideration of other viewpoints.

3 To prevent dominance in the development of health and safety standards, the standards  
4 development process shall –

- 5 a) Provide appropriate balance, in accordance with section 6.3, on the standards
- 6 development consensus body,
- 7 b) Operate the process in accordance with the openness requirements in section 6.1,
- 8 c) Permit any party dissatisfied with the process on the basis of one or more parties
- 9 exercising dominance to object in writing at any time before or during the process.

10 *Comment: This section generally tracks the language of the Essential Requirements except*  
11 *for the reference to openness requirements in section 6.1 and providing balance in the next*  
12 *section, 6.3.*

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

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

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

31 *Comment: One of the fundamental principles of American National Standard*  
32 *development is the need for balance in the development of standards. Because ANSI*

1           *approval is limited only to whether a standard development body meets minimum due*  
2           *process requirements and because balance is perhaps the most important component of*  
3           *due process, no standard that is drafted by a consensus body that lacks balance shall be*  
4           *approved as an American National Standard. Section 6.3.1 provides measures that a*  
5           *standard development body may use to address imbalance issues.*

### 6   **6.3.1 Balance: Basic Categories**

7   There are three basic interest categories appropriate to the development of consensus in any  
8   given standards activity. Each basic category may be comprised of an array of subcategories  
9   that are a function of the nature of the standards being developed. Interest categories shall be  
10   discretely defined, cover all materially affected parties and differentiate each category from  
11   other categories. Such definitions shall be available upon request. In defining the interest  
12   categories appropriate to a standards activity, the following broad classifications shall apply<sup>4</sup>:

- 13       a) Business interest;
- 14       b) User interest;
- 15       c) General interest.

16   Each subcategory must fit uniquely into one of the three basic categories. Where appropriate,  
17   additional interest categories may be considered (subject to section 6.4).<sup>5</sup>

18   Business interest shall include all who, directly or indirectly, receive compensation,  
19   reimbursement, or financial benefit<sup>6</sup> from the production or sale of a product (or a related  
20   product<sup>7</sup>) that is the subject of a standards development proceeding. At a minimum, the term  
21   includes manufacturers, retailers, importers, distributors, trade association members and staff,  
22   paid consultants, industry retirees, and expert witnesses hired by a business interest for the  
23   product that is the subject of the standards development proceeding. Independent third-party  
24   testing laboratory personnel with a broad interest in the testing protocol of a standard shall not  
25   be included in the business interest category unless they have been specifically hired to  
26   participate in the development of a standard by a business client or clients.

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<sup>4</sup> For a table that summarizes these interest categories, see Appendix 1.

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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.

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

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

- 11 1. User-consumer: Where the standards activity in question deals with a consumer  
12 product, such as lawn mowers or aerosol spray, an appropriate consumer participant's  
13 view is considered to be synonymous with that of the individual user – a person using  
14 goods and services rather than producing or selling them.
- 15 2. User-labor: Where the standards activity in question deals with subjects of special  
16 interest to the American worker such as products used in the workplace, an appropriate  
17 user participant is a representative of labor.
- 18 3. User-government: Where the standards activity in question is likely to result in a  
19 standard that may become the basis for government agency procurement, an  
20 appropriate user participant is the representative of that government agency.
- 21 4. User-industrial: Where the standards activity in question deals with a product that is  
22 used by an industrial entity exclusively as an end user, an appropriate user participant is  
23 the industrial user of the product.

24 General interest is a catch-all category for those with an interest in the consumer product that  
25 is the subject of a standards development proceeding who do not fit into the Business Interest  
26 or User-Interest categories. For example, it includes individuals or groups who provide medical  
27 or other services to end-users of the consumer product that is the subject of a standards  
28 development proceeding. It also includes university researchers, government employees,  
29 professional societies, test laboratories, and independent technical experts. No one who in the  
30 past three years has received or currently receives (or has contracted to receive) compensation  
31 or reimbursement, directly or indirectly, from the production or sale of the product that is the

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<sup>8</sup> 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 subject of the standards development proceeding is eligible to serve as a participant in a  
2 General Interest group.<sup>9</sup>

3 If the standards developer lacks the balance outlined in Sections 6.3 and 6.4, the standards  
4 developer shall conduct outreach efforts to bring the membership of the standards  
5 development process into balance. Included in outreach efforts should be documented  
6 solicitation of participation by consumer groups such as Consumers Union, Consumer  
7 Federation of America, National Consumers League, technical departments of universities,  
8 academic societies, retired business executives, and appropriate governmental agencies. In  
9 instances where initial outreach efforts have proven unsuccessful, the standards developer  
10 shall document whether it has offered to fund the participation of any unrepresented or  
11 underrepresented interest. If the outreach efforts fail, the consensus body votes shall be  
12 adjusted or apportioned to ensure balance of no more than one-third per interest group.  
13 Within this basic rule, adjustments may be made at the discretion of the standard developer.  
14 For example --

- 15 1. Membership of an interest group that is overrepresented may be adjusted  
16 downward by removing the number of voting participants necessary to achieve  
17 proper balance. For example, if one interest group has ten members and  
18 another interest group has only five, the number of eligible voters of the larger  
19 group shall be adjusted down to five. Such adjustments shall be done by fair and  
20 reasonable methods to determine which members shall be eligible to vote.
- 21 2. Membership of an interest group that is overrepresented may be adjusted  
22 downward by splitting the vote into fractions of a vote until proper balance is  
23 achieved. For example, if one interest group has twice the number of eligible  
24 voters as another, the overrepresented interest group participants shall be  
25 allotted only half a vote in order to match the underrepresented group of voting  
26 participants;
- 27 3. Membership of an interest group that is underrepresented may be adjusted  
28 upward by multiplying the power of votes for any voting member until balance is  
29 achieved. For example, if one interest group has half the number of eligible  
30 voters as another, the underrepresented interest group participants shall be  
31 allotted twice the number of votes in order to match the overrepresented group  
32 of voting participants; or

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<sup>9</sup> 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.



- 1           4. Any other reasonable means of adjustment that ensures a balance of no more  
2           than one-third voting rights per interest group.

3   **6.3.2 Full Disclosure of Financial And Other Important Interests**

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

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

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

- 25                 • *It more precisely defines the three interest categories. In essence, it states*  
26                 *that anyone who has received compensation or reimbursement from a*  
27                 *business interest involved in producing the product that is the subject of a*  
28                 *standard development must be placed in the category of Business Interest.*  
29                 • *The section also makes clear that participants who previously might have*  
30                 *been considered General Interest members (such as industry retirees, expert*  
31                 *witnesses for the industry, academic consultants with financial ties to the*  
32                 *industry, consultants for the industry) cannot be considered General Interest.*

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<sup>10</sup> 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                    *They are welcome to participate, but must do so as members of the Business*  
2                    *Interest category.*
- 3                    • *The section addresses a common concern arising from those instances in*  
4                    *which, despite the best outreach effort of a standard developer, insufficient*  
5                    *members of an interest group participate to permit balance in terms of*  
6                    *numbers of votes. In such cases, the standard developer must document its*  
7                    *outreach efforts, which may include offering funding for participation. Where*  
8                    *outreach efforts still fail, the standard developer may choose among several*  
9                    *alternatives: (i) to remove some voters from an overrepresented interest*  
10                   *group, (ii) to subdivide the votes of the overrepresented group, (iii) to expand*  
11                   *the votes of each member of an underrepresented group, or (iv) any other*  
12                   *reasonable means of adjustment that preserves the balance of interest*  
13                   *categories.*
  - 14                   • *In order to ensure that participants get properly classified into the interest*  
15                   *category to which they should belong, this section sets minimum*  
16                   *requirements for disclosure of financial and other interests in the product*  
17                   *under standards development. Such disclosures must be available to*  
18                   *consensus body members and to ANSI staff in order to ensure the integrity of*  
19                   *the process and should guide the classification of participants in the standard*  
20                   *development process.*

#### 21    **6.4 Balance: Subdivision of Interest Categories**

22    As noted, within the three broad interest categories, it may be appropriate and useful to  
23    further subdivide members of the standards development proceeding into smaller interest  
24    groups with shared concerns (see footnote 3 for examples). All interested parties are  
25    encouraged to participate.

26    In order to maintain appropriate balance, however, any subdivided interest group will be  
27    considered to remain within one of the three main interest group into which it fits. Under no  
28    circumstances shall the official voters of any subdivided groups have the right to cast more  
29    votes than the one-third number of the broad interest group in which they belong. For  
30    example, should users subdivide into user-consumer and user-labor groups, they cannot then  
31    claim the right to cast more than one-third of the total official votes in the standards  
32    development proceeding.<sup>11</sup>

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<sup>11</sup> 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            *Comment: This section addresses the issue of subdividing interest categories. It permits*  
2            *such categories to be subdivided in order to make the standard development process*  
3            *more substantive and efficient. However, it makes clear that subdividing the three*  
4            *interest categories does not create a different voting protocol. Each subdivision must*  
5            *still vote within its one-third broader interest category.*

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7    **EFFECTIVE DATE**

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

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**INTEREST CATEGORIES FOR HEALTH AND SAFETY STANDARDS**

<b>BUSINESS INTEREST</b>	<b>USER INTEREST*</b>	<b>GENERAL INTEREST*</b>
Manufacturers	Individual consumers	Medical professionals
Retailers	Consumer groups	Academics/researchers
Importers	Hobbyists	Professional societies
Distributors	Union representatives	Independent Test labs
Trade associations	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		

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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.