

9 Qualifications (requests for Voting Membership, only):

- a) Do you/the organization you represent have a direct and material interest in the work of the committee?
 - Yes (briefly describe, e.g., "my company manufactures products that are subject to the committee's standards" or "I use the devices standardized by the committee in my medical practice")
 - No
- b) Please briefly describe your other qualifications for membership on the committee, including relevant education and experience, and/or attach an up-to-date curriculum vitae.

10 Conflict of Interest (requests for Voting Membership, only): Item 2 requested that you identify the company or organization that you plan to represent on the committee using the attached "Committee Member Disclosure Form." If you have any relationships that could be perceived as a conflict of interest with any OTHER companies (i.e., companies that are not identified in item 1 of the attached Disclosure Form), identify the companies and briefly describe the nature of the relationship/potential conflict of interest here. (Such relationships do not necessarily disqualify an applicant from an independent voting membership on a committee.) *If none, please so state.*

11 Parent/Subsidiary Relationships (industry representatives only): If applicable, please identify the parent corporation of your firm and any subsidiaries of your firm.

Parent _____

Subsidiaries: _____

12.

SIGNATURE _____ **DATE** _____

For Office Use Only	
Date Received: _____	19 _____
Date to cochaurs: _____	19 _____
For Action by: _____	19 _____
Response _____	
Follow-up to applicant made on: _____	19 _____

Annex A.1 -- Committee Membership Disclosure Form

Complete one form per committee and attach to Committee Membership Application Form
(See attached sheet for more information on completing this form)
PLEASE TYPE or PRINT IN BLOCK LETTERS

Name: _____

Committee: _____

1. Do/will you represent one or more manufacturers or institutions on the above committee? (See 2.3.2.1)

Yes. Identify the manufacturer(s) and/or institution(s) and their AAMI membership status below.
(Committee liaisons should identify the sponsoring institution here and full committee name in #2b)

No. Go to #2.

		AAMI mbr/fee payer ¹	
		<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	Parent Company (if applicable)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	Parent Company (if applicable)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	Parent Company (if applicable)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

2. If you do not represent manufacturers or institutions, who do you represent:

a. Myself (Independent Expert)

b. Other _____

(Fill in complete name; do not use acronyms. Committee liaisons: Please include alphanumeric designation(s), if any, and committee name(s); you can represent more than one committee to the AAMI committee)

Signature _____ Date: _____

BY COMPLETING THIS FORM, YOU ASSUME THE RESPONSIBILITY
FOR THE ACCURACY OF THIS INFORMATION.

¹ Representatives of nonmembers (regardless of fee payment status) cannot be permitted to assume leadership positions or serve on adjudicative bodies.

Disclosure Form

Item 1:

Instructions:

- If you represent more than 3 companies and/or institutions, attach sheet with additional names.
- If you are uncertain of corporate or institutional membership/fee status, contact AAMI Vice President of Membership at 703-525-4890 ext. 232 or lfreeman@aami.org.
- Representatives of subsidiary companies: List both the company you represent and its parent, and check "yes" in the membership column if either company is an AAMI corporate member or fee payer. If the parent is a subsidiary of a third company, indicate both parents in the parent section and check "yes" in the membership/fee column if any of the three companies is an AAMI corporate member or fee payer.

Example:

		AAMI mbr/fee payer	
Company x	Company y, a subsid of Company z	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Mfr or Inst represented	Parent Company (if applicable)		

Important Additional Information:

- 1.1 The manufacturer(s) and institutions(s) must verify this information. If representing company or institution other than employer (or employer's parent company), include letter from the company or institution with your application nominating you as their representative to the committee. (Liaisons from one AAMI committee to another AAMI committee are exempt from this requirement.)

If verified, you are eligible for committee participation, assuming you are the only representative of the organization(s) listed above and the organization(s) are either corporate or institutional members, or pay the non-member company or institution participation fee, as applicable. If employed by a parent or "sister" company, you are not eligible to represent the AAMI corporate member or fee payer unless your company's sales were included along with those of the subsidiary or "sister" company in calculating dues or the fee. Even if they join AAMI or pay non-member fees separately, two affiliated companies (e.g., "sister" companies or a parent and subsidiary) may have only one vote per committee. If you are applying to a committee for the first time or have made any change in representation since you last completed this form, you must also complete a committee membership application form which will be processed in accordance with the *AAMI Standards Program Policies and Procedures Manual* (see clause 2.3 and related subclauses of the *Manual* for more information).

- 1.2 If you represent companies or institutions that are not corporate or institutional members or fee payers, you need to review the non-member company technical committee participation policy or the non-member institution technical committee participation policy, as applicable. Non-member companies and institutions may participate on committees but need to review their options. Briefly, nonmembers must pay corporate or institutional dues or non-member committee fees in order to be eligible for voting or liaison representation, however, there are other options for participation.
- 1.3 Please note that this information will be made known to other committee members. You are responsible for meeting AAMI requirements for each nonmember you represent. Representatives of nonmembers (regardless of fee payment status) cannot be permitted to assume leadership positions or serve on adjudicative bodies.

Item 2: See 2.3.2.2 of the *AAMI Standards Program Policies and Procedures Manual*. If you represent more than 2 committees, attach sheet with additional names.

Excerpts from AAMI Standards Program Policies and Procedures Manual (2007)

2.3 Committee membership

2.3.1 Committee size

There is no restriction on the size of committees that have primary authority for developing consensus on one or more technical documents. However, committees that have evolved over time to serve as a coordinating body for several working groups may be limited in size provided that the committee has no direct responsibility for development of a technical document. (See also 2.3.6)

2.3.2 Voting members

2.3.2.1 Representative members and alternates

A representative member is anyone who meets one or more of the following criteria:

- the individual receives remuneration or expense reimbursement in any form from a company or institution (hereafter referred to collectively as "organization") for his/her committee participation
- the individual is expected to vote for or speak on behalf of an organization with respect to standards under development by the committee
- the individual is compensated to be an information source for an organization with respect to the activity of the committee.

Organizations are permitted only one representative member per committee. (A parent corporation and its divisions or subsidiaries are considered one corporate entity, or "organization," for purposes of voting representation.)

Representative members may appoint one alternate of record, if desired. An alternate's vote is counted only if the principal representative fails to vote.

NOTE: An alternate of record receives all committee correspondence, appears on committee rosters, etc. Temporary alternates (see 2.3.14.3) are also allowed if necessary to cover a specific meeting that the member and alternate of record, if any, are unable to attend.

Representative members and alternates must be confirmed by the organization(s) represented.

Generally, no representative shall have more than one vote. However, if two or more organizations appoint the same individual to represent each of them, that individual may cast a separate vote for each organization represented. The organizations shall confirm in writing² to the AAMI Vice President of Standards Development or AAMI Vice President of Standards Policy and Programs (hereafter collectively referred to as "AAMI Standards vice presidents") that they are aware of and will accept the results. Additionally, representation of more than one organization by the same individual shall require approval by a majority of the committee, excluding the vote of that individual.

2.3.2.2 Independent expert members

Individuals who do not meet the criteria of 2.3.2.1 may serve on committees and vote on committee matters as independent expert members.

² Unless a specific means of transmittal is indicated, all requirements in this manual to submit or distribute items "in writing" or "by letter" is intended to broadly cover written communications that are transmitted electronically (via e-mail, facsimile, or the AAMI website) or by surface mail.

2.3.3 Lack of dominance

The standards development process shall not be dominated by any single interest category, individual or organization.

Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

Unless a directly and materially affected person claims in writing that a single interest category, individual or organization dominated the standards development process, no test for dominance is required. If such a claim is made, the person or organization must show how they have been adversely and substantially affected as a direct result of the alleged dominance, and should propose specific corrective action.

2.3.4 Openness and diversity (“balance”)

Reasonable representation of experts from each interest category that is directly and materially affected by the work of the committee will improve the quality of the work as well as reduce the possibility that claims of dominance will be made against the committee. Therefore, participants from all relevant interest categories shall be sought with the objective of achieving balance. Evidence of outreach efforts shall be documented.

Voting membership shall consist of representatives from at least two (and preferably all three) interest categories, and no applicant shall be denied membership solely on the basis of his/her category of interest. (I.e., there shall be no specific exclusion of an interest category from voting membership, however a committee is allowed to operate with only two interest categories if representation from the third cannot be obtained. Under no circumstances shall committees be allowed to operate with representation from only one interest category.)

Historically referred to as “balance,” this is something of a misnomer in that it connotes an equal number of participants from all three interest categories recognized by AAMI. However, such an arbitrary requirement fails to recognize that the interest categories appropriate to the development of consensus are a function of the nature of the standard(s) being developed by the committee. Combined with the voluntary nature of standards participation, it may not always be possible to achieve representation from all three interest categories. A requirement for equal participation from those interest categories that are represented can be equally difficult to achieve, and even if this is accomplished upon the initial formation of the committee, maintaining such “balance” is virtually impossible since it is typical for some members to resign from the committee in the midst of a project, and/or to receive new applications for membership from organizations or individuals with a direct and material interest in the standards being developed by the committee.

Therefore, while “balance” is a laudable goal to strive for, it should not be achieved at the expense of an open process that encourages participation, and that achieves the greatest diversity of interests possible.

2.3.5 Interest categories

AAMI recognizes three interest categories. At least two, and preferably three, should be represented on each technical committee. (see also 2.3.3 and 2.3.4)

2.3.5.1 Producer

A member who represents an organization that produces or sells materials, products, systems, or services covered in the scope of the document(s) developed by the committee shall be classified as a producer.

2.3.5.2 User

A member, or a member who represents an organization, who in the context of his/her profession purchases or uses materials, products, systems, or services covered in the scope of the document(s) developed by the committee shall be classified as a user provided that the member could not also be classified as a producer.

2.3.5.3 General interest

A member who does not fit into any of the preceding categories, for example: Government agency representatives; representatives of consumer (patient) groups; pure research experts; representatives of testing and certification bodies (unless the committee is developing test method standards); or experts who, through career change or retirement, are no longer "active" producers or users of materials, products, systems, or services within the scope of the committee.

2.3.5.4 Categorization of membership associations

A membership association (e.g., trade association, professional society) shall be categorized according to the interest category of its members. Membership associations representing both producers and users shall be placed in the "general interest" category.

NOTE: The complete *AAMI Standards Program Policies and Procedures Manual* is available as follows:

WORD 97 version <http://www.aami.org/standards/downloadables/aamiproc.doc>

Acrobat (pdf) version: <http://www.aami.org/standards/downloadables/aamiproc.pdf>
