

AAMI Order Code: AAMIProc

AAMI STANDARDS PROGRAM National and International (U.S. TAG) Policies and Procedures Manuals

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AAMI STANDARDS PROGRAM POLICIES AND PROCEDURES MANUAL

ANSI Accredited
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Objectives of this manual

The objectives of this manual are to:

1. Review the scope, major purposes, and organization of the AAMI standards and technical publications program;
2. Explain the basic policies and procedures by which AAMI standards, recommended practices, and technical publications are developed and approved, and by which U.S. TAG positions on international documents are developed and approved.
3. Identify the various approaches that committees can use in formulating and disseminating technical information;
4. Provide format guidelines for writing standards, recommended practices, and other technical publications;
5. Expedite the development and acceptance of standards, recommended practices, and technical publications to assure cost-effective use of membership resources and timely dissemination of information that is intended to help improve patient care.

A final and very important objective of this manual is to keep AAMI members, committee participants, and other interested parties abreast of new AAMI policies that affect the standards and technical publications program. Consequently, this manual may require frequent change.

Notes on changes to the June 2007 edition

This edition of the AAMI procedures includes the following modifications to the June 2007 edition:

Clauses 3.3.1, 3.3.4, 3.5.7.2.6, 3.6.1, 3.6.2.1 a), 3.6.2.1 e), 3.6.2.4, 3.6.3.1 and 3.6.3.2 have been modified to clarify that the appeals mechanisms outlined in the manual are available for the impartial handling of procedural complaints regarding substantive actions or inactions. Procedural complaints can include whether a technical issue raised in compliance with these procedures was afforded due process.

Annex H, AAMI Antitrust Statement, was added. This statement was approved by the AAMI Board of Directors in late 2007 and applies to all committees of the association, up to and including the Board of Directors. The statement is therefore added for easy reference by members of the AAMI Committee on Standards Strategy, the AAMI Standards Board, members and liaisons of AAMI technical committees and technical advisory groups (including subcommittees, advisory groups, task groups, working groups, etc.), as well as guests at any meetings of these committees.

AAMI Standards Program Policies and Procedures Manual

1. Program scope and organization

This section of the manual covers the scope, objectives, and basic organization of the AAMI standards and technical publications program.

1.1 Program scope

The Association for the Advancement of Medical Instrumentation (AAMI) is recognized as one of the foremost voluntary standards-setting organizations in the United States. The AAMI standards program is accredited by the American National Standards Institute (ANSI) — the organization that coordinates the development and promotion of all U.S. voluntary standards and that officially represents the United States in international standards-setting — under the following scope.

Standards for medical devices and for healthcare products and services.

At the heart of the program are AAMI's technical committees, made up of persons who are knowledgeable about the subject matter within the scope of the committee's work through technical, medical, industrial, or other experience in the field and falling into one of three interest categories — medical device producers, users, or general interests. Collectively, these experts form a true interdisciplinary group that develops standards and other technical documents toward the aim of improving safety of medical instrumentation and advancing medical technology. Perhaps best known for the development of American National Standards for electromedical devices and recommended practices in the area of sterilization technology, AAMI standards committees also develop technical information reports, technology conference reports, and position statements on a wide range of issues of concern to the health care community, including quality systems and corresponding general aspects of medical devices, cardiovascular implants, active implantable medical devices, and biological evaluation of medical devices.

Another major aspect of the program is the administration of international technical committees, which write international standards, and of U.S. technical advisory groups (TAGs), which develop the comments on behalf of the United States and vote on international documents. These aspects of the AAMI standards program are governed in many respects by the policies and procedures of the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the American National Standards Institute (the official U.S. member to these bodies). In addition, AAMI has developed a separate policies and procedures manual which (a) explains in greater detail the AAMI International Standards Program, and (b) sets forth policies and procedures unique to AAMI in its administration of U.S. technical advisory groups.

In short, with over 100 national and international technical committees and advisory groups under its administration, AAMI plays a significant role in the development of medical device standards with worldwide application.

NOTE — Hereafter, information provided in this manual refers only to the AAMI National Standards Program, unless otherwise specified.

1.2 Program objective

The purpose of the AAMI standards program is to assist the health care professions and industry in the U.S. and abroad with the use, acceptance, and advancement of medical technology. This is accomplished by AAMI technical committees, which develop consensus recommendations on medical device safety, performance, and use. As adjuncts to these

recommendations, AAMI also establishes referee test methods, conducts technical conferences and educational programs, and issues expert opinion statements on technical issues of concern to the AAMI membership and the health care community. The end result of these activities is publication of voluntary standards, recommended practices, technical information reports, and conference reports, all of which contribute toward advancing medical technology and the quality of patient care.

1.3 Program benefits

AAMI standards, recommended practices, and other technical documents reflect the combined knowledge of medical device producers, users, general interests and specific technology experts, and are voluntarily conceived and used. Their application is solely at the discretion and judgment of the user of the document. Consequently, the AAMI standards program benefits the industry and the health care professions in a number of ways, without restricting technological advancement.

1.4 Types of technical committee documents

1.4.1 General

AAMI technical publications are classified according to their objectives, the consensus that is desired or can be achieved, the audience to be served, and the technology that is the subject of the document. Different types of documents may be appropriate for the same technology at different times because the needs of the professions, the needs of the industry, and the maturity of the technology itself evolve over time. The types of technical publications described in the following paragraphs are given only as examples and are not intended to restrict committees from developing other responses to specific technical issues.

1.4.2 Medical device standards

A medical device standard recommends to the manufacturer the information that should be included with the product, basic safety and performance criteria, and measurement techniques that can be used to determine whether the product meets the safety and performance criteria. While a standard is primarily directed towards the device manufacturer, it may also be of value to the potential user of the device as a reference for device evaluation.

1.4.3 Recommended practices

A recommended practice provides guidelines for the use, care, evaluation, or processing of medical devices. A recommended practice is addressed primarily to the health care or industrial *personnel* involved in using, maintaining, evaluating, or processing a device; it does not directly establish safety and performance criteria for the device itself. Like standards, recommended practices require national consensus.

1.4.4 American national standards

When a standard or recommended practice is designated an "American National Standard," it means that all of ANSI's requirements for consensus, due process, public review, and ANSI review have been met. The major differences between AAMI standards (or recommended practices) and American National Standards are that the latter have been subjected to the additional review procedures of ANSI, are recognized as national standards, and may be submitted (with AAMI's written consent) directly as U.S. positions for international acceptance.

1.4.5 Technical information reports

A technical information report (TIR) is a review of important technical issues relevant to a particular technology and a statement of expert opinion released by a technical committee. The AAMI Standards Board must approve release of a TIR; however, the reports are not subject to

public review. A TIR, which allows discussion of several sides of an issue, may be issued when there are not enough data to develop a standard or when consensus cannot be achieved. TIR's may also be issued when a committee believes that the procedures for developing a standard or recommended practice would unduly delay the promulgation of information needed by the industry and/or the health care professions. Some TIR's serve as interim statements by committees working to develop standards or recommended practices.

1.4.6 Technology conference reports

Technology conference reports are partial or complete proceedings of AAMI technical conferences, seminars, or other educational programs. AAMI sponsors such programs to provide a public forum for addressing topical public health questions, reporting new technological research, and/or discussing issues related to standards or recommended practices. A technology conference report reflects the expert opinion of the conference faculty but is not necessarily a national consensus or even a consensus among the members of the sponsoring committee.

1.4.7 Other technical publications

The AAMI standards program provides a vehicle for the development of technical communications tailored to the specific needs of its membership and the health care community at large. AAMI committees are not limited to the categories of technical publications described in the foregoing paragraphs, but rather are encouraged to devise innovative approaches to education and technology assessment.

1.5 Technical document format

1.5.1 General

AAMI uses *ISO/IEC Directives, Part 2, Rules for the structure and drafting of International Standards* as the style guidelines for AAMI standards and recommended practices, with the following exceptions:

- U.S. English may be used in place of U.K. English
- a rationale for the requirements of an AAMI standard or recommended practice and for national deviations contained in AAMI adoptions of ISO and IEC standards is mandatory (in the ISO/IEC directives, rationales are voluntary)
- a period may be used in fractions in place of a comma (e.g., 0.1 instead of 0,1)
- a comma may be used to separate numbers into thousands instead of a space, and no separator is needed to the right of a decimal point (e.g., 1,000,000 instead of 1 000 000; 0.3456 instead of 0.345 6).

1.5.2 Metric Policy

The International System of Units (SI) shall be used in all AAMI consensus documents. The following exceptions are allowed if deemed necessary by the committee for the understanding of a document:

- if the SI unit is not commonly used in the U.S., but is commonly used outside of the U.S., the value in SI units should be used, however the value in other units may be included parenthetically after the SI value
- if the value in SI units is not commonly used in or outside of the U.S., another unit may be used in place of the SI unit (the committee should select the most widely known unit; if this is

The above exceptions, when used, should be applied to specific values rather than to the document as a whole.

1.5.3 Patent policy

The committee shall follow the ANSI patent policy in effect at the time the document is balloted. See [G.3.1 ANSI patent policy - Inclusion of Patents in American National Standards](#).

1.5.4 Commercial terms and conditions

The committee shall follow the ANSI policy for commercial terms and conditions in effect at the time the document is balloted. See [G.3.2 Commercial terms and conditions](#).

1.6 Program organization

1.6.1 General

The AAMI national standards program consists of approximately 100 technical committees and working groups that are assisted by staff and supervised by the AAMI Standards Board.

1.6.2 Technical committees

Technical committees provide the technical resources for developing, approving, interpreting, and revising standards and recommended practices. They also develop and/or review technical information reports, propose and/or design some of the educational programs from which ensue AAMI technology conference reports, and originate various types of technical communication. Each committee must have a balanced representation of user, producer, and general interest experts and must afford the opportunity for participation by all interests affected by the committee's work. Section 2 of this manual describes committee operations in detail.

1.6.3 AAMI Standards Board

1.6.3.1 General

The Standards Board directs and supervises all AAMI technical committee activities relating to the national standards program. In conjunction with the AAMI Committee on Standards Strategy, the Standards Board also has some responsibility for oversight of international standards activity. (Information contained in this manual, for example "Responsibilities" below, applies only to AAMI's national standards program. For similar information on Standards Board and/or AAMI technical committee involvement and conduct in the international program, see the *AAMI International Standards Program Policy and Procedures Manual*.)

1.6.3.2 Membership

The members of the Standards Board are the President of AAMI, AAMI's Vice President of Standards Policy and Programs (non-voting), three or more committee (co)chairs appointed by the President, and four or more additional experts appointed at the discretion of the President. The membership of the Standards Board must reflect balanced representation of user, producer, and general interests. A representative of user or general interests and a representative of producer interests cochair the Standards Board.

1.6.3.3 Terms

The cochairs of the Standards Board serve three-year terms, renewable at the discretion of the President. Members serve three-year renewable terms.

1.6.3.4 Responsibilities

The Standards Board determines whether AAMI policies and procedures have been followed in the development of standards and recommended practices and in the promulgation of other technical publications. The Standards Board also advises the President of AAMI on the appointment of committee (co)chairs, reviews the progress of committee work, authorizes the initiation and termination of committee activities, recommends resource allocations, develops new or revised policies as necessary for approval by the Board of Directors, and hears appeals of committee decisions. Only the Standards Board can authorize new committees and new projects, certify that AAMI standards, recommended practices, and technical information reports were developed in accordance with these procedures and can be published as final AAMI documents and/or can be submitted to ANSI for final approval as American National Standards.

1.6.4 AAMI Board of Directors

The Board of Directors establishes or revises the *AAMI Standards Program Policies and Procedures* and serves as the final AAMI appellate body for disputes concerning standards and recommended practices.

1.6.5 AAMI staff

The AAMI staff manages the program on a day-to-day basis, advising committees on AAMI policies and procedures, scheduling meetings, maintaining records, preparing committee documentation, revising technical documents on the basis of committee deliberations, implementing the balloting and public review processes, and generally coordinating committee and Standards Board activities. Substantive staff support for specific committee projects generally begins when a standard or recommended practice reaches the balloting stage or when a complete draft of a technical information report has been prepared. At this stage, the staff assumes primary responsibility for preparing meeting minutes and documenting the committee's responses to comments; the staff also edits ensuing drafts of the standard, recommended practice, or technical information report and handles the production of the final text.

1.6.6 AAMI Committee on Standards Strategy

The AAMI Committee on Standards Strategy advises the Board and staff on strategy and funding of the AAMI Standards Program, including AAMI positions on proposed policies of other national, international, or regional standards bodies (ANSI, ISO, IEC, CEN, CENELEC, etc.) In addition, the committee serves as a sounding board for other AAMI programs that use or are otherwise related to standards and regulations. The Chairman and members of the committee serve at the discretion of the AAMI President for two-year, renewable terms. While the committee is not involved, *per se*, in procedural matters governing the development and promulgation of standards, since strategy can affect procedures and vice versa, the cochair of the Standards Board serve *ex officio* as "Committee Liaisons" to the Committee on Standards Strategy and, in the reverse, the committee is invited to comment on any changes to AAMI standards or TAG procedures that are proposed by the Standards Board.

2. Committee structure and operations

2.1 Purpose and scope of AAMI technical committees

Committees of volunteer technical experts are the heart of the AAMI standards program. Each AAMI technical committee has a defined scope of work and operates under established policies and procedures. An AAMI committee determines the need for standards, recommended practices, other technical publications and educational programs within its area of competency and expertise; develops technical documents in accordance with AAMI policies and procedures;

interprets final AAMI standards and recommended practices; reviews and revises final AAMI standards and recommended practices within five years of their approval; assists the staff in developing educational programs in the committee's area of work; and advises AAMI on responses to government initiatives and other public policy matters within the committee's area of work.

2.2 Committee (co)chairs

2.2.1 General

Most AAMI technical committees are cochaired by a producer and either a user or general interest representative who share the responsibilities of managing the committee. If suitable candidates from these interest categories cannot be found, it is acceptable

- for the cochairs to be from the same interest category provided that they have strong complementary differentiation (e.g., a manufacturer of sterilized products and a representative of a contract sterilization facility would offer distinctly different experience to the work of an industrial sterilization working group) or
- for a committee to be chaired by a single individual.

NOTE —Where "(co)chairs" are specified in this manual, if the committee has two (or more) chairs, the procedure applies equally to all.

2.2.2 Selection

The President of AAMI appoints committee (co) chairs in consultation with the AAMI Standards Board and any existing chairs of the committee. Committee members may submit nominations for consideration; a candidate may be chosen and the committee offered the opportunity to comment or submit additional nominations; or the committee may be asked for nominations from whom the (co)chair nominee(s) will be selected. Based on this input, together with any comments from existing chairs of the committee (if applicable), the Standards Board then makes a recommendation to the President. In the event that a committee has no chair owing to resignation or other reasons and there is pressing business before the committee and/or an impending meeting, the President may appoint an acting chair without consulting the committee or the Standards Board to serve while the above process is being conducted to fill the vacancy(ies).

2.2.3 Terms

The term of appointment or reappointment is two years, with the total term not to exceed six consecutive years in ordinary circumstances. This term may, however, be extended at the discretion of the President in consultation with the Standards Board.

2.2.4 Qualifications

Committee (co)chairs must be recognized experts in the technological area(s) within the purview of the committee and must have substantial technical, medical, industrial or other experience in the field. It is also desirable that they have prior experience in AAMI or other standards-setting activities, or have actively participated in AAMI programs generally. A committee (co)chair should have sufficient time and resources to fulfill the responsibilities of committee leadership. Ideally, a committee (co)chair should have had prior experience in managing committee activities, as might be gained through the leadership of hospital policy committees; of medical, hospital, or trade association committees; or of technical committees of a standards-setting organization. The producer (co)chair of a committee must be a representative of an AAMI corporate member, unless special circumstances dictate that this requirement be waived by the Standards Board and President. For non-producer (co)chairs,

preference is given to individual members of AAMI and representatives of AAMI institutional members; non-producer (co)chairs from the user interest category are generally given preference over those from the general interest category.

2.2.5 Responsibilities

Committee (co)chairs are responsible for the general administration of committee activities, with advice and support provided by AAMI staff. Specifically, (co)chairs are responsible for:

- a) Implementing the policies, objectives, and priorities of the Association, as established by the AAMI Standards Board and the AAMI Board of Directors;
- b) Efficiently managing committee activities to ensure timely completion of technical work and other committee business in accordance with established timetables (see also 2.11);
- c) Periodically reviewing committee membership for balanced representation, active participation by all members, and a manageable working size, and advising staff, as necessary, regarding additional organizations or independent experts who could be invited to join the committee in order to improve balance, proposed terminations of non-active members, and formation of executive boards, task groups, etc. to improve efficiency. (This is a shared responsibility of the (co)chairs and AAMI staff.)
- d) Approving or advising staff on approval of new members and on removal of members for cause (see also 2.3.9 and 2.3.13);
- e) Appointing other committee officers, as necessary, (e.g., a recording secretary, working group (co)chairs, project leader);
- f) Advising staff on technical and administrative matters relevant to the committee's work;
- g) Conducting committee meetings;
- h) Documenting committee meetings in the absence of the AAMI staff;
- i) Representing the committee, as necessary and upon request of the AAMI President, at meetings of ANSI or AAMI policy bodies, at public hearings involving matters of importance to the AAMI membership, and the like.

Unless delegated the authority by the AAMI Standards Board, Board of Directors, or President, committee (co)chairs may not speak officially for the Association.

2.2.6 Termination of appointments

Effective leadership is the single most important ingredient of committee productivity. Therefore, a (co)chair appointment may be terminated at any time by the President, in consultation with the Standards Board, should it become evident that the (co)chair has insufficient time and resources to adequately fulfill his/her responsibilities or that the (co)chair is not properly executing AAMI's policies and procedures. In such a case, the (co)chair will receive written notification of the proposed termination of his/her appointment and will be offered the opportunity to respond.

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 writing¹ 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.

2.3.3 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

¹ 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.

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.

2.3.6 Selection

Members of a committee that has primary authority for developing consensus on one or more technical documents are selected by application (see 2.3.9) and by invitation. Members of a committee that has evolved over time to serve as a coordinating body for several working groups and has no direct responsibility for development of a technical document may be selected by invitation, only. (See also 2.3.8)

2.3.7 Term

There is no set term for committee membership, except as specified in 2.3.8.

2.3.8 Qualifications

A committee member should either have a direct and material interest in the device(s) and/or process(es) covered by the technical documents assigned to that committee, or be employed or represent an organization with a direct and material interest in the device(s) and/or process(es) covered by the technical documents assigned to that committee. Members who do not have, or represent an organization that doesn't have, a direct and material interest may also serve as voting members, subject to (co)chair approval, provided that they are knowledgeable about the subject matter within the scope of the committee's work through technical, medical, industrial, or other experience in the field, and/or provide specialized knowledge or expertise needed by the committee. A committee member must also have sufficient time and resources to fulfill the responsibilities of membership, particularly the review and critique of documents in progress.

Committee members need not be individual members of AAMI, nor must they represent institutional or corporate members of AAMI; however, the Standards Board may impose cost reimbursement fees on for-profit corporations that are not corporate members of AAMI, and/or on not-for-profit institutions (including associations, societies, government agencies and the like) that are not institutional members of AAMI.

Some technical committees may, over time, evolve into management and coordinating bodies as the scope of the parent committee grows and a number of working groups are formed to develop technical documents. For committees serving primarily a management and coordinating function:

- further qualifications for membership may be imposed, and
- membership is for two-year renewable terms by invitation of the (co)chairs in consultation with the AAMI President.

2.3.9 Application process

Any person wishing to be appointed to an AAMI technical committee must apply to the AAMI national office. An application form (see *Annex A*) should be sent to one of the Standards vice presidents and include a Representation Disclosure Form for each committee applied to. An on-line application is also available at http://www.aami.org/standards/tc_join.html. The application should include a brief statement regarding the direct and material interest of the applicant (or organization represented by the application) in the work of the committee. The application also should include a brief summary of qualifications or be accompanied by an up-to-date curriculum vitae. Prospective producer members must disclose any corporate parent/subsidiary relationships. Prospective user or general-interest members must disclose any potential conflicts of interest; e.g., consulting arrangements with manufacturers or service on a corporate medical board.

NOTES:

1. A conflict of interest does not necessarily disqualify an applicant from independent voting status on a committee.
2. The blank committee membership application form included at annex (Annex A) may be used to apply to TAGs and sub-TAGs, as well as to AAMI Technical Committees.

If the applicant (or the organization represented by the applicant) clearly has a direct and material interest in the device(s) and/or process(es) covered in documents under development by the committee, the application may be approved by one of the Standards vice presidents. If the applicant's direct and material interest is unclear to staff or staff believes the application should be denied based on 2.3.10 or some other section of these procedures, the application will be sent to the appropriate committee (co)chairs for a decision. Unanimous agreement of the (co)chairs is required for the application to be approved.

Upon reaching a decision, staff will send the applicant one of the following:

- a letter of appointment,
- a letter that the appointment was approved but cannot be confirmed until specified administrative requirements are met (and including a deadline for meeting same after which a new application also would be required), followed by a letter of appointment if administrative requirements are met, or
- a letter that the application was denied by the (co)chairs for specified reason(s).

The (co)chairs of the committee shall be copied on all confirmations and denials of new appointments.

2.3.10 Refusal of membership

Committee membership may be refused for one or more of the following reasons:

- (a) the applicant (or organization to be represented by the applicant) does not have a direct and material interest in the device(s) and/or process(es) covered by the committee²,
- (b) the work of the committee is nearing completion,
- (c) members of the particular committee being applied to are selected by invitation and not by application³,

² This is not intended to imply that such applications must be refused. As stated in 2.3.8, participation from experts who do not have, or represent an organization that does not have, a direct and material interest can be appointed, however approval of such applications is solely at the discretion of the committee (co)chairs.

- (d) approval of the application would result in two primary voting members from the same organization, either by virtue of representation, employment, or a combination of the two
- (e) in the case of user or general interest representatives, the applicant has such a substantial relationship with a producer that he/she cannot be granted independent voting status;
- (f) in the case of producer or institutional representatives, the sponsoring firm is neither a corporate/institutional member of AAMI nor willing to pay a cost reimbursement fee;
- (g) the applicant refuses to complete a Representative Disclosure Form.

An applicant has the right to appeal if membership is denied.

2.3.11 Responsibilities

Committee members must actively participate in all committee business. In particular, they must respond to all committee ballots and official canvasses. Regular attendance at meetings is desirable, but is not a requirement of membership. However, committee membership still includes the responsibility of providing input throughout the standard-development process, if not orally at a meeting, then through submission of written comments prior to a meeting, and of keeping informed of committee decisions through timely review of minutes and other committee documentation. In this way, meetings can focus on new business and documents can progress more rapidly.

In addition, committee members are responsible for notifying AAMI of changes in address, and corporations or institutions represented on committees are responsible for advising AAMI of desired changes in representative.

2.3.12 Full disclosure

To ensure lack of dominance and due process, it is important that AAMI be kept up-to-date on the organizations that are represented by committee members. Therefore, members shall be required to periodically (as determined by the Vice President of Standards Policy and Programs, and not to exceed annually) complete a Representative Disclosure Form (or equivalent) for each active committee they serve on.

2.3.13 Termination of membership

Committee membership is a privilege extended and continued based on interest, participation, and knowledge; it is not a right. All interested individuals, institutions, and corporations have the rights of participation accorded by due process, but these rights do not automatically extend to voting committee membership. Many substantive opportunities for participation are available through the public review process (see Section 3). Consequently, committee (co)chairs or the AAMI Standards Board may terminate a committee membership for reason of lack of participation or interest, *in particular, failure to record a vote or abstention on two consecutive letter ballots dealing with committee business of any type that are distributed after the member is appointed to the committee. This applies to all requests, whether addressed to the full committee or just to those members who have not yet voted, and whether involving two ballots of unrelated matters, two ballots related to a single issue or project (e.g., consecutive drafts issued for vote), one ballot of a single issue or draft (e.g., a member has not recorded a vote after receiving both the initial request to the committee and a follow-up request to members who did not meet the initial deadline, or any combination thereof).* Substantive violation of AAMI policies is also cause for termination of membership. Persons, institutions, or corporations

³ This only applies to committees that (a) have evolved over time to serve as a coordinating body for several working groups and (b) have no direct responsibility for development of technical documents.

whose voting representation on a committee has been terminated will be so notified in writing by one of the Standards vice presidents (unless termination is the result of non-deliverable mail) and will retain the rights afforded them by due process (see 3.3), including the right to participate in committee meetings, comment on documents in progress, receive written responses to their comments, and appeal substantive actions and inactions. See also 2.3.14.2.

2.3.14 Changes in corporate/ institutional representation

2.3.14.1 Change of representative

Requests for changes in corporate or institutional representation must be made in writing to one of the Standards vice presidents by the primary representative of the company or institution to AAMI, his/her designee, or some other appropriate corporate or institutional officer. This written notification should include the effective date of the change and the full name, title, address, phone, fax and email of the new representative.

Note: This applies to changing the person filling an existing seat held by the organization. Requests for new voting membership shall be submitted via a committee membership application form.

2.3.14.2 Change in affiliation

A corporate or institutional representative who changes employment and wishes to remain a member of the committee must reapply. The corporation or institution formerly represented by said individual must, if continued representation is desired, make a request for change of representation in accordance with 2.3.14.1.

Members who were originally appointed as independent experts must reapply if they are no longer eligible for independent expert status and are now representing a company or institution on AAMI committees.

2.3.14.3 Temporary designation of alternate

A committee member who is unable to attend a forthcoming meeting and wishes to designate an alternate to attend and vote on his/her behalf for that meeting, only, must notify one of the Standards vice presidents in advance and in writing. Representative members may also appoint an alternate of record (see 2.3.2.1).

NOTE: Members are responsible for providing temporary alternates with any background material necessary to cover the meeting he/she is attending on behalf of the member and alternate of record (if any).

2.3.15 Liaisons

Liaisons to technical committees are representatives who are marked in the AAMI committee database to receive all committee documentation except ballots. Liaisons are not a part of the committee membership and do not have a vote. Rather, the purpose of the liaison category is to facilitate communication about a committee to eligible representatives.

AAMI recognizes two types of liaisons:

- Committee liaisons, who represent one committee to another committee, and
- Corporate or Institutional Member liaisons, who represent an AAMI corporate or institutional member to a committee.

In general, liaison status will not be granted to an organization that also has a Representative Member on a committee (though exceptions will be considered on a case-by-case basis), and will be limited to one liaison representative per organization per committee. However, since this category is an administrative convenience and has no official standing, these guidelines are

subject to change, and AAMI can deny, discontinue, or otherwise limit the number of liaisons allowed to a committee, to all committees under the program, the number of liaison representatives allowed per organization, etc. if needed for program efficiency or to keep program expenses in line with budget.

To request liaison status on an AAMI technical committee, send a completed application form (see *Annex A*) to one of the Standards vice presidents and include a Representation Disclosure Form for each committee applied to.

2.4 Transaction of committee business

2.4.1 General

Committee business is conducted both by correspondence and at scheduled meetings. A letter ballot or query of the full committee membership must ratify substantive actions on consensus documents. (See also section 3.) Most active AAMI committees meet two or three times each year, but at least annually. Ideally, meetings are scheduled in conjunction either with the AAMI Annual Meeting and/or with an appropriate medical/health care seminar or convention. Meetings also can be conducted by teleconference. Meeting announcements and agenda materials as well as other types of committee documentation are generally prepared and distributed by the AAMI staff, after appropriate consultation with the committee leadership.

Committee documentation is distributed exclusively via the internet in combination with e-mail communications to the committee regarding business at hand and/or announcing that new documents are available at the AAMI website. Therefore, in order to participate effectively, members must have access to the internet and a functioning e-mail address.

Committee members and liaisons shall comply with the most current terms and conditions for submitting documents to AAMI for distribution to a committee, and for redistribution of committee documentation to persons not on the committee. These terms and conditions are publicly available via the “Committee Central” section of the AAMI website (www.aami.org/committeecentral). A copy will be mailed on request to persons without access to the internet.

2.4.2 Announcement of meetings

All committee meetings must be preceded by written notice, at least thirty calendar days in advance for face-to-face meetings, and twenty-one calendar days in advance for meetings held by teleconference. This notice must specify the time, date, and location of the meeting (or dial-up information for meetings held by teleconference) and must clearly describe the nature of the business to be conducted. When possible, a detailed agenda and any necessary agenda materials should be distributed to committee members and their alternates in advance of the meeting.

2.4.3 Conduct of meetings

Committee meetings are conducted by the (co)chairs or their designee. A quorum consists of 50 percent of voting membership of the committee; for official conduct of business, it is desirable, but not required, that a quorum of the members be present. If a quorum is not present, any substantive action must be held for the next meeting at which a quorum is present, or must be ratified by letter ballot of the full committee.

Meetings are conducted in general accordance with parliamentary procedures, with substantive committee decisions made by motion and vote. Only voting members of the committee, or a member's duly appointed alternate (but not both), may vote at a meeting. Less consequential matters may be decided less formally. (For example, during a meeting devoted to the

refinement of a document in progress, every revision need not be subjected to a motion and vote).

NOTE — Just as members of a working group may not vote at a meeting of the parent committee (unless they are also members of the parent), membership on a parent committee does not confer any special privileges to individuals attending a working group or other subgroup meeting. That is, only a voting member of the committee that is convened may vote at a meeting.

2.4.4 Public participation in meetings

2.4.4.1 Technical committee meetings

All AAMI committee meetings are open to the public; however, only committee members are permitted to vote. Also, at the discretion of the (co)chairs, it is permissible to limit comment to members. The same policies apply to meetings of standing working groups.

2.4.4.2 Closed meetings

Only executive boards and task groups may conduct meetings in closed session. Any minutes or other documentation ensuing from such meetings, however, must be publicly available. Meetings of standing committees and working groups shall *not* be held in closed session.

NOTES:

1. (Co)chairs or project leaders must be explicit when requesting AAMI staff to arrange space for closed meetings (so that announcement is not inadvertently made to the general public) and must provide staff a list of invitees, in writing, if staff is also requested to send out the invitations for the meeting.
2. The meeting secretary (usually a (co)chair) is responsible for providing one of the Standards vice presidents with a copy of the minutes (and any documents ensuing from the meeting) for the file and to fill any requests for same.

2.4.5 Documentation of meetings

All committee meetings must be documented by minutes. For meetings at which ballot results or public comments on consensus documents are considered, AAMI staff ordinarily prepares the minutes. For other meetings, it may be necessary for the (co)chairs or a designated committee member to take the minutes. The minutes must document the members and guests present and all substantive actions taken by the committee. Formally voted motions should be recorded verbatim, with a report of the action taken -- approved (or disapproved) unanimously, or approved (or disapproved) with the number of affirmatives, negatives, and abstentions. If determined by the committee, the time and place of the next meeting should also be included in the minutes.

2.4.6 Distribution of documents

Meeting minutes, documents in progress, and other committee materials are generally distributed from the AAMI national office. Only materials distributed from the AAMI national office are part of the official record. All original materials submitted to AAMI for a committee or prepared and distributed by AAMI staff are AAMI copyrighted property and shall not be reproduced or stored in an electronic retrieval system absent prior written authorization by AAMI.

2.4.7 Decisions subject to Standards Board approval

Committee decisions to commence new work, terminate existing work, or finalize a standard, recommended practice, or technical information report are all subject to Standards Board review and approval.

2.5 Executive boards

Committees may have executive boards that assist the (co)chairs in developing and directing the committee's program of work. The committee (co)chairs appoint the members of an executive board in consultation with the Standards Board for two-year renewable terms. An executive board should consist of no more than seven members, and there must be balanced representation that includes all interest categories represented on the parent committee. Those members representing user or general interests must be either individual members of AAMI or representatives of AAMI institutional members; those representing industrial interests must be representatives of AAMI corporate members. Executive boards may assume any responsibility for directing or expediting committee work that does not adversely affect due process. In this regard, the terms of reference shall be documented by the Executive Board and submitted in writing to the AAMI Vice President, Standards Policy and Programs within three months of the Board's formation, and any substantive change to the original terms of reference shall be submitted within three months of the change.

2.6 Working groups and task groups

2.6.1 Scope of work

Working groups may be appointed to undertake specialized technical work under the auspices of the main committee. Standing working groups may be established to perform ongoing work in particular technological areas within the general scope of the parent committee. Task groups may be appointed to address very specific technical issues, research particular technical questions, or perform the initial organizational or drafting work for new committee projects. Upon completion of their task, these groups are usually disbanded. Another acceptable approach to writing the first draft is for the committee (co)chairs to appoint a project leader. See 2.7.

2.6.2 Working groups

The same policies and procedures outlined for technical committees in 2.1 through 2.4 apply to working groups except that the (co)chairs of the parent committee are responsible for the appointment and rotation/termination of working group (co)chairs rather than the President, and these decisions are made without Standards Board consultation.

Note: Some of the sections cited above contain alternate procedures depending on whether a technical committee has, or does not have, direct responsibility for development of a technical document. Since all working groups have direct responsibility for one or more technical documents, none of these alternate procedures apply to working groups.

2.6.3 Task groups

The chair(s) of a task group is (are) selected by the (co)chairs of its parent body (committee, working group). The members may be chosen from the members of its parent body, and/or outside experts may be asked to participate. Task groups operate informally under the general supervision of their parent bodies. As noted earlier (2.4.4.2), closed meetings are permissible. Upon completion of their work, task groups may be either discontinued or upgraded to working group status.

2.7 Project leaders

2.7.1 Appointment

As an alternative to a task group or working group, a project leader may be appointed to develop a standard, recommended practice, or technical information report. This appointment may be made either by one of the Standards vice presidents, in consultation with the (co)chairs of the responsible committee or working group (hereafter "responsible committee"); or by

decision of the responsible committee. The project leader should have access to appropriate resources for carrying out the development of a document up to the ballot stage with little or no support from AAMI. Project leaders are usually, but not limited to, one of the (co)chairs of the responsible committee.

2.7.2 Project leader development of the draft document

A project leader may invite expert assistance from among the membership of the responsible committee when he/she deems necessary, and is responsible for convening, chairing, and documenting (or arranging for a recording secretary to document) any meetings of task groups formed by him/her to complete the development of a document. (AAMI staff will arrange for meeting rooms if desired. *AAMI will bear the cost of meeting room rental only upon prior approval of one of the Standards vice presidents.*) Preparation of the initial draft document and subsequent revisions, up to the ballot document, is the responsibility of the project leader; documents should be written following the format specified in 1.5.1). When the project leader, in consultation with the (co)chairs of the responsible committee, deems the document ready for review by the responsible committee, at least one of the Standards vice presidents is notified and an original copy is provided for distribution to the responsible committee for comment.

2.7.3 Project leader responsibility through comment period

Prior to committee ballot, the document should be distributed for preliminary comment from the AAMI national office under a cover letter prepared by staff, in consultation with the project leader. The project leader should provide staff with the following details: Whether comments should be submitted to the project leader in writing, or if a meeting will be held to hear and review comments; if a meeting is desired, the preferred date and location (AAMI will make meeting arrangements and bear the cost of meeting room rental). The project leader is responsible for chairing and documenting the meeting (or arranging to have the meeting documented by a recording secretary), and for supplying at least one of the Standards vice presidents with a copy of the minutes and any documentation ensuing from the meeting within sixty calendar days of the meeting's completion. This review and comment stage may be repeated, as necessary, until the project leader and responsible committee (co)chairs feel that the document is ready for ballot. At that point, the project leader sends an original copy of the document (preferably in revisable electronic format) to one of the Standards vice presidents with note(s) from the (co)chairs agreeing that the document is ready to be balloted. AAMI staff will then assume primary responsibility for overseeing the further disposition of the document through ballot, public review, final approval and publication.

2.7.4 Other project leader responsibilities

Project leaders should be prepared to act as consultants regarding technical matters arising at any stage of developing the document, including during balloting, public review, or the final editing of the document for publication. Most importantly, project leaders are responsible for meeting interim deadlines so that the document will be completed on schedule (see 2.11.2).

2.8 Termination of committees

The Standards Board may decide to dissolve a technical committee or working group (collectively, "committee") and terminate its program of work, based on lack of progress, apparent lack of interest, or other cause. In such a case, all voting members, alternates, and parties known to be interested in the committee's work must receive a written notice of the Standards Board's intent and must be allowed at least thirty calendar days in which to file comments or objection. A notice must also be placed in *Standards Monitor Online* and/or the "Standards Monitor" section of *AAMI News*. The Standards Board must give due consideration

to any comments or objections filed before making a final decision on the dissolution of the committee.

2.9 Inactive status of committees

Committees that have completed a program of work and do not have immediate plans for new work are not dissolved because they must remain ready to consider proposed amendments of their work, issue interpretations, and, in the case of standards and recommended practices, reconvene for the purpose of review and revision in accordance with AAMI procedures. No meetings are scheduled during a period of inactive status, but membership records are kept up to date and certain types of business may be conducted by correspondence.

2.10 New technical work

2.10.1 Evaluation and approval of new work

Since AAMI's resources and the resources of its committees are limited, proposed new technical projects must be evaluated with great care to ensure that the project is responsive to high-priority clinical needs; is the best approach to addressing these needs, and is technically feasible. Authorization must be obtained from the Standards Board before a new committee can be chartered or an existing AAMI committee can undertake substantive new work.

2.10.2 Criteria for establishing new committees or initiating new work

The Standards Board has identified the following criteria as essential to evaluating the need for establishing a new committee and/or initiating new programs of work under the auspices of an existing committee:

- a) The standard, recommended practice, or other technical publication has been determined to be high priority based on clinical/health care needs.
- b) There is not a more appropriate technical organization willing and able to do the work.
- c) The proposed work program has sufficient financial support, through membership revenue, cost reimbursement, voluntary contributions, government contracts/grants, generation of revenue (for example, document sales after completion), or other sources of funding.
- d) The project contemplated is within the scope of the committee or within AAMI's general scope of work and does not duplicate work undertaken elsewhere.
- e) There are a substantial number of individual, institutional, and corporate members of AAMI willing to participate in the proposed new committee or program of work.

2.10.3 Initiating and obtaining authorization for establishing new committees or new work

The process for establishing a new committee or approving new work is initiated by submitting a New Work Item Proposal (see *Annex B*) to one of the AAMI Standards vice presidents. Proposals will be sent to the appropriate AAMI committee for review and recommendation to the Standards Board, or if the proposed new work is outside the scope of AAMI's current program and a new committee would have to be established, the proposal will be submitted directly to the Standards Board. The individual or committee submitting the proposal for new work shall be advised in writing of the Standards Board decision within six months of receipt of the new work item. See also 2.11.2.

2.10.4 Waivers

For established committees, the Standards Board may choose to waive formal written proposals for new work and rely on informal consultation with staff and the committee leadership.

2.11 Annual review and evaluation

2.11.1 General

The objectives and program of work of each technical committee are reviewed annually by the Standards Board to ensure that the work is progressing on schedule. If this is not the case, means of assisting the (co)chairs and committee in meeting planned objectives are explored. The amount of time required for a committee to complete a standard, recommended practice, or technical information report varies with the scope of the committee's work and the complexity of the documents under development.

2.11.2 Time limits for completion of new standards, recommended practices, and technical information reports

All active projects must have on file a scheduled date of completion (month and year), which has been approved by the Standards Board. The amount of time from approval of new work to scheduled date of completion shall not exceed five years for standards, four years for recommended practices, or eighteen months for technical information reports, unless authorized by the Standards Board at the proposal stage or shortly thereafter. (Co)chairs, on behalf of a committee, may "negotiate" an extended schedule with the Standards Board by providing a written request in care of the AAMI Vice President of Standards Policy and Programs explaining why an exception is necessary, and how much additional time is needed. While projects that come in under the maximum years to completion are preferred to those that come in over, committees should be realistic at the outset in committing to a scheduled date of completion. Occasionally, lack of progress is so severe that termination of the project is deemed the best course of action; progress, or lack thereof, is judged against the schedule proposed at project initiation.

Once a scheduled date of completion has been agreed upon and recorded, the (co)chairs are responsible for seeing that the time limit set for their project is met or bettered. Based on experience, the following chart shows the maximum period of time that can be taken to complete certain "milestones" in a document's progress and still finish a project on time⁴. It is always better to be ahead, rather than behind, at any given stage to allow extra time for any special problems or unforeseen delays.

⁴ When requesting an extended schedule for completion, milestone periods should be adjusted accordingly.