

AAMI Order Code: AAMIProc

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

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Published by the

Association for the Advancement of Medical Instrumentation
4301 N Fairfax Drive
Suite 301
Arlington, VA 22203-1633

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AAMI DPM5; December 2007
(Corrected April 2008; Updated April 2009 and July 2011)

AAMI STANDARDS PROGRAM POLICIES AND PROCEDURES MANUAL

ANSI Accredited
(reaccreditation under these procedures, as amended December 2007 and July 2011,
approved effective 19 July 2011)

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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:

December 2007 changes

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. *[NOTE: Annex H is now Annex G as a result of July 2011 changes – see below.]*

April 2008 changes

Annex G, ANSI patent and commercial terms policies – clauses 3.1.1.bi), 3.1.2 and 3.1.4 were revised to incorporate corrections issued by ANSI on 13 March 2008. *[NOTE: These changes superseded by removal of Annex G as a result of July 2011 changes – see below.]*

April 2009 changes

Annex G, ANSI patent and commercial terms policies – clauses 3.1.1.bi), 3.1.2 and 3.1.4 were revised to incorporate corrections issued by ANSI on 13 March 2008. *[NOTE: These changes superseded by removal of Annex G as a result of July 2011 changes – see below.]*

July 2011 changes

Added “current” before “ANSI ...policy” to 1.5.3 and 1.5.4 and deleted “in effect at the time the document is balloted” from first sentence. Also deleted second sentence of both clauses referring to Annex G.

Added “in writing” to clauses 3.3.6, sentence 2, and 3.5.6.6, paragraph 1, sentence 1 to clarify that responses to comments and objections must be provided in writing.

Deleted Annex G, “ANSI Patent and Commercial Terms Policies.” Renumbered Annex H, “AAMI Antitrust Statement” as Annex G and modified references to same in body of procedures.

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

not commonly used in the U.S., a value in other units may be included parenthetically after the more widely known unit).

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 current ANSI patent policy.

1.5.4 Commercial terms and conditions

The committee shall follow the current ANSI policy for 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 cochairs 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 whose voting representation on a committee has been terminated will be so notified in writing by

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.

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.

Stage of Development	Maximum number of months from approval of new work for:		
	Standard*	Recommended Practice*	Technical Information Report
Preliminary draft completed	18 months	18 months	12 months
Initiation of Committee Draft stage (with or without vote) - Optional	36 months	24 months	N/A
Initiation of Proposed Draft stage (committee ballot and, if applicable, public review)	42 months	36 months	15 months
Final Proposed Draft stage	60 months	48 months	18 months
*Schedule is for new documents; see 2.11.4 for revisions of approved documents.			

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

2.11.3 Time limits for other projects

Other types of work are scheduled on a case-by-case basis.

2.11.4 Periodic review of existing standards and recommended practices

2.11.4.1 Documents maintained on a periodic basis

AAMI standards and recommended practices shall be reaffirmed, revised or withdrawn within five to six years of their last approval. This period is not extended by the approval of an amendment; i.e., the time since the “last approval” is based on the date that AAMI (or ANSI, when applicable) last approved the full document or reaffirmation of the full document. Since revisions of medical device standards can take as long as the original document’s development, the reaffirmation/withdrawal process shall proceed if necessary to meet the five to six year rule, even if a revision project is underway. See also 3.10.

2.11.4.2 AAMI-authored documents maintained on a continuous basis

Large standards with well-defined parts can be maintained on a continuous basis (e.g., annually) with the approval of the Standards Board. See also 3.10.2.

2.11.5 Periodic review of technical information reports

Technical information reports, usually issued as interim documents, should be reviewed every three years to determine whether the document is still current and/or whether a full consensus document should be developed to replace the report or a revised report should be developed.

2.11.6 Withdrawal for cause

The Standards Board can withdraw any AAMI standard, recommended practice, or technical information report upon a sufficient showing that one or more of the following conditions applies:

- a) a significant conflict with another AAMI standard or recommended practice is identified and cannot be otherwise resolved;
- b) AAMI’s requirements for designation, publication, and maintenance were violated;

2.12 Committee funding

2.12.1 General

In general, AAMI cannot reimburse travel expenses or provide honoraria for committee service. AAMI does underwrite direct expenses associated with committee activities (e.g., meeting room rentals, reproduction and postage costs associated with the distribution of documents). A primary source of funding for the standards program is general AAMI membership revenues; this is why committee (co)chairs are encouraged to assist the staff with membership recruitment and why committee members are encouraged, though not required, to become individual, corporate, or institutional members of AAMI. Secondary sources of funding include cost reimbursement revenues and revenues from the sale of technical publications and from other AAMI publications, programs, and services. Financial allocations are *not* made to individual committees, even those whose work generates income for the association, but rather to the standards program as a whole.

2.12.2 User travel funds

Some committees have created travel funds (from contributions provided by corporations represented on the committee) to help ensure the participation of user committee members who could not otherwise attend committee meetings. If a committee decides to establish such a fund, the (co)chairs assist staff in encouraging contributions. The fund is administered from the

AAMI office, but the committee (co)chairs authorize expenditures and periodically review the account.

2.12.3 Special projects

On several occasions, committees have established funds for special projects, such as scientific research programs. AAMI acts as administrator of these funds, in consultation with the committee (co)chairs.

3. Consensus and due process: Policies and procedures for the development of standards and recommended practices

3.1 Development and due process

AAMI standards and recommended practices are developed by consensus, in accordance with policies and procedures that are designed to ensure due process while promoting committee efficiency and productivity.

3.2 Consensus

Consensus is achieved when individuals and organizations having a direct and tangible concern with a standard or recommended practice achieve substantial agreement according to the judgment of the AAMI Standards Board, the AAMI Board of Directors, and/or the ANSI Board of Standards Review. Consensus is more than a simple majority, but does not require (and rarely achieves) unanimity. Establishing a consensus on a standard or recommended practice entails:

- a) substantial agreement⁵, by written ballot, among the members of the responsible committee (and parent committee[s], if any),
- b) appropriate public review,
- c) resolution of comments, and
- d) concurrence with the consensus, according to defined criteria, by the AAMI Standards Board, the AAMI Board of Directors, and/or the ANSI Board of Standards Review.

Consensus requires that all views and objections be considered and responded to, and that a concerted and documented effort be made towards their resolution; consensus does *not* require that all objections be withdrawn.

3.3 Due process

3.3.1 Definition of due process

Due process means that anyone with a direct and material interest has a right to express a position and its basis, have that position considered, and to appeal substantive actions or inactions at points in the process where his or her rights may be materially affected. Due process provides for equity and fair play. The concepts described in the following paragraphs constitute the minimum due process requirements for establishing consensus on an AAMI standard or recommended practice.

⁵ "Substantial agreement" is defined as approval by at least a majority of the committee membership and at least two-thirds of those voting, excluding abstentions. However, this definition, which was borrowed from ISO/IEC, does not take into account the need to look at the voting record of each interest category and in some cases, subsets of those categories, as well as the committee membership as a whole. It also does not obviate the requirement for a two-thirds return of ballot, including abstentions, in order for the ballot to be considered valid.

3.3.2 Openness

Participation must be open to all persons (organization, company, government agency, individual, etc.) who are directly and materially affected by the document. There must be no unreasonable financial or procedural barriers to participation. Timely and adequate notice of major steps in the consensus process and how to obtain more information must be provided. In addition, the affiliation and interest category of each member of the consensus body must be made available to interested parties upon request. Openness is essential to due process, and experience has shown that openness leads to more rapid acceptance of a document.

3.3.3 Written procedures

The policies and procedures contained in this manual, together with any amendments thereto, govern the methods used for consensus development and must be available to any interested party.

3.3.4 Appeals

Appeals mechanisms must be available for the impartial handling of procedural complaints regarding substantive actions or inactions. Procedural appeals include whether a technical issue raised in compliance with these procedures was afforded due process.

3.3.5 Notice

Any planned substantive action relative to the development and promulgation of a consensus document must be widely publicized to provide a reasonable opportunity for response.

3.3.6 Consideration of views and objections

Prompt consideration must be given to the written views and objections of all participants. A concerted effort must be made to resolve all expressed objections, and each objector must be advised in writing of the disposition of the objection, the reasons for the action taken, and, if applicable, the opportunities for further comment or appeal. Unresolved objections must be made known to the AAMI Standards Board and, if applicable, the ANSI Board of Standards Review.

3.3.7 Records

Substantive and relevant records of the development and approval history of a consensus document must be prepared, maintained, and made accessible to those having a direct and material interest (under reasonable conditions of time, cost, location, and convenience to all concerned).

Records concerning new, revised, or reaffirmed consensus documents that are maintained on a periodic basis shall be retained for one complete standards cycle, or until the document is revised.

Records concerning actions on consensus documents, or a part(s) of a consensus document, maintained under the continuous maintenance option (see 2.11.4.2) shall be retained for a minimum of five years or until approval of the subsequent revision or reaffirmation of the complete standard.

Records concerning withdrawn consensus documents shall be retained for at least five years from the date of withdrawal.

3.4 Key concepts underlying AAMI standards and recommended practices

3.4.1 Fundamental concepts

During the development of any standard or recommended practice, a committee must keep in mind several fundamental concepts:

- a) to the extent possible, the document should establish minimum performance or functional criteria, not design specifications;
- b) every requirement or recommendation should be supported by rationale;
- c) compliance with requirements or recommendations should be verifiable.

3.4.2 Performance criteria

The device requirements of AAMI standards and the guidelines for device use, processing, or maintenance provided in AAMI recommended practices should set forth performance goals, leaving to the device designer's ingenuity and the device user's judgment the exact means of achieving them. Only when judged essential to safety and effectiveness should design specifications be considered; the need for such specifications must be weighed carefully against the potential impact on technological innovation and cost. Likewise, committees should avoid "convenience" or "nice to have" issues that do not directly relate to assurance of safety and effectiveness. AAMI consensus documents are not blueprints or "cookbooks," but rather statements of expert opinion as to what constitutes, for any given device or process, minimum necessary safety and performance criteria.

3.4.3 Rationale

The rationale statements included in AAMI standards and recommended practices are important for many reasons. A rationale statement explains and justifies a requirement or recommendation in terms of the clinical or other risks being addressed, the scientific underpinnings of the requirement or recommendation, and its contribution to the overall assurance of safety and effectiveness. Not only do users of AAMI consensus documents have a right to know the reasons for recommendations that may affect their current practices, but rationale statements also encourage compliance. In addition, a committee may, if it feels it necessary, include a minority opinion on a controversial point in the rationale, provided that minority views are clearly identified as such and the reasons for not accepting them are given. In this way, rationale statements can facilitate the development process by focusing the committee's attention on those issues that are truly important to safety and effectiveness, by making known the committee's reasoning to nonmember commenters, and by providing a vehicle for judging the persuasiveness of comments and objections.

Finally, rationale statements provide a means for responsible interpretation and revision of standards and recommended practices. Technology changes with experience and with new scientific data. While every effort is made to ensure that AAMI standards and recommended practices are flexible and accommodating of new design approaches and processing techniques, any document of this nature is necessarily a "snapshot" of a technology. Some recommendations may become less relevant or significant with the passage of time, and some may not apply at all to individual circumstances or unforeseen technological advances. Consequently, it is essential that device manufacturers and users understand the original basis for a recommendation so that they can make reasonable judgments about the need for compliance.

3.4.4 Verification of compliance

It serves no purpose to establish a performance requirement if there is no means for the device manufacturer, device user, or other interested party to determine compliance. In medical device standards, in particular, it is important that a verified referee test method be provided for every safety and performance requirement. Otherwise, the manufacturer has no real basis for evaluating a device against the standard or for making and defending label claims; the device user does not have a reliable basis for interpreting or trying to replicate the manufacturer's data; and there are no ready means for resolving questions or disputes about compliance. In addition, vague, unverifiable recommendations simply confuse matters and may even give false assurance of safety and effectiveness.

3.5 The development process for standards and recommended practices

3.5.1 General

Developing and promulgating any consensus document entails the same basic steps. The following paragraphs describe each of these steps, and Figure 1 (page 34) summarizes the overall process.

3.5.2 Announcement of new committee or new work project

Upon Standards Board approval of the establishment of a new committee or the initiation of a new work project⁶ by an existing committee, an announcement must be made in *Standards Monitor Online* and/or the "Standards Monitor" section of the *AAMI News*. This announcement must describe the scope of the work and indicate how interested parties can obtain further information (for example, a copy of the new work proposal) or apply to participate, and a roster of the committee or working group members who will be undertaking the work must be prepared or updated.

⁶ A "new work project" includes a project to develop a new technical document, to revise an existing technical document, or to amend an existing technical document.

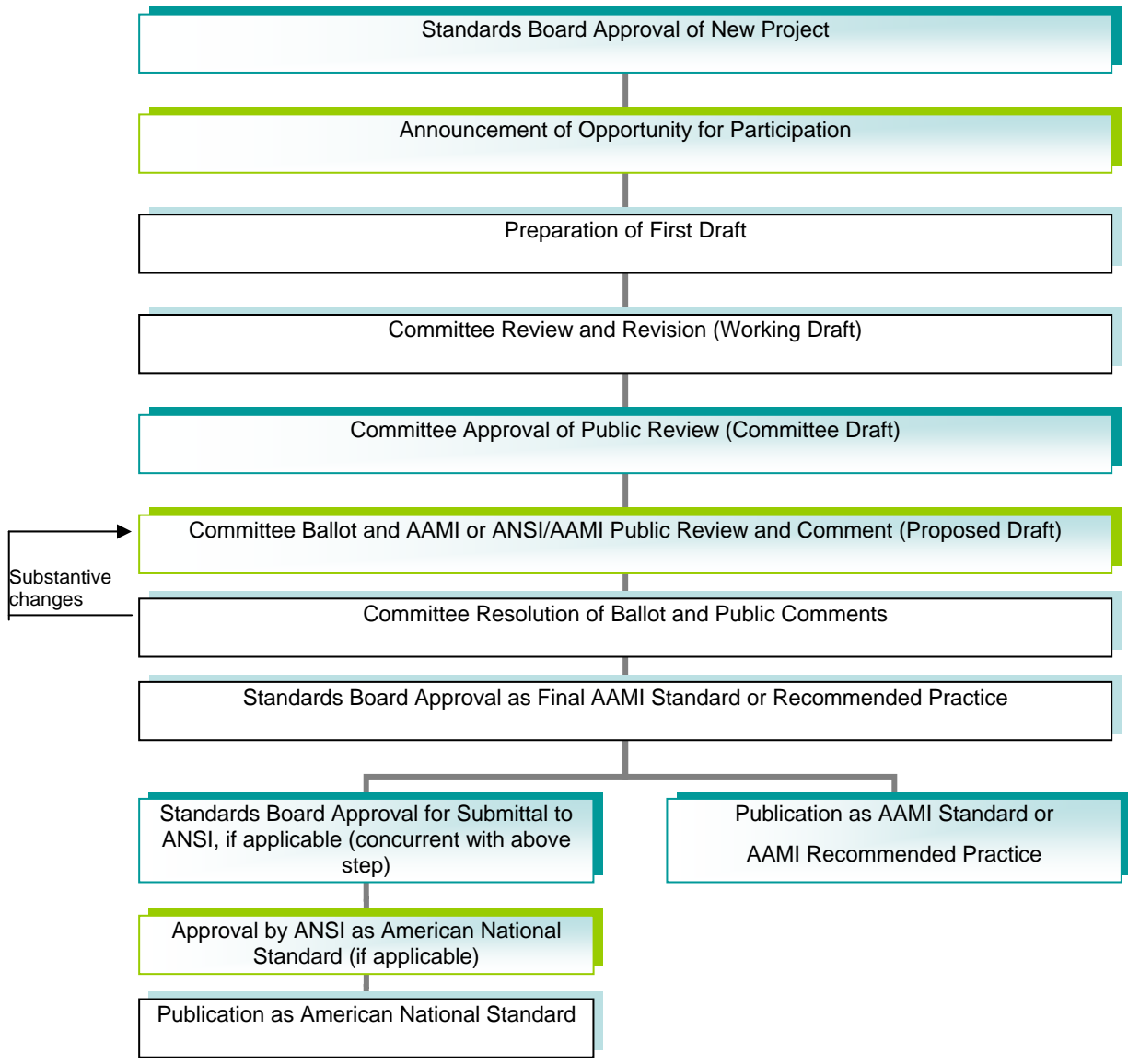


Figure 1. Steps in the development and approval of an AAMI standard or recommended practice.

3.5.3 Initiation of work

The new work item or equivalent document detailing the scope and outline for the project as well as the planned schedule for its completion shall be made available to all committee members and the (co)chairs of the parent committee, if applicable. If a new committee is formed to undertake the work, members should be reminded of how to obtain a copy of this manual. In the case of a revision, any comments submitted to AAMI on the final document that is being revised which were deferred to the next revision also shall be distributed to the committee.

NOTES

1. The approved new work item proposal or equivalent should be placed in the committee's working document area on the AAMI website as a "public document" so that other interested parties have access to the information, and should remain there until the committee finishes the work so that members can readily refer to the approved scope and schedule for the project(s) they are working on.
2. For ANSI projects, staff also must submit to ANSI a Project Initiation Notification Submission (PINS) form shortly after the project is initially approved.

A small task group, chaired by a project leader, may be appointed to undertake the initial drafting work.

3.5.4 Drafting stages

3.5.4.1 Preparing the first draft

The project leader, task group, or committee should begin by reviewing the policy and format guidelines for AAMI standards and recommended practices found in this manual. (AAMI follows ISO/IEC format for its standards and recommended practices; copies are available to (co)chairs and project leaders from AAMI.) Other resources that can help in developing the initial outline or draft are "The Objectives and Uses of AAMI Technical Documents," which is published in all final AAMI standards or available from staff on request; the "AAMI Standards Philosophy" (see [Annex D - AAMI Standards Philosophy and Strategy — Key Elements](#)); other AAMI technical documents of the same type as the committee is developing; ANSI/AAMI/ISO 14971, *Medical devices – Application of risk management to medical devices*; and ANSI/AAMI/ISO TIR16142, *Medical devices—Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*. In addition, depending on the scope of the project, one or more of the following international guides may be helpful: ISO Guide 51, *Guidelines for the inclusion of safety aspects in standards*; ISO Guide 63, *Guidance on the development of International Standards in the field of health care technology*; ISO Guide 64, *Guide for the inclusion of environmental aspects in product standards*; and IEC 60513, *Fundamental aspects of safety standards for medical electrical equipment*.

To accomplish the actual writing, one typical approach is to assign sections of the document to committee or task group members, collate the work assignments, and then distribute a preliminary draft to the participants for review and refinement. Experience has shown that it is important to get *something* on paper early in the process, even in the recognition that the document is very far from acceptance. This limited review and comment process continues until the committee (co)chairs feel that the document should be formally designated a first working draft, which is then made available to the full committee membership.

The development of the preliminary and first working drafts are key steps. Exhaustive debate of issues in abstract terms is not generally productive. It is only when an actual document begins to take shape that there is a basis for orderly progress.

3.5.4.2 Committee review of the draft (Working Draft stage)

Several drafts and informal review-and-comment cycles may be necessary before the committee or working group is satisfied that the document is ready for formal ballot and public review. This is still an informal stage in the development of a consensus document, where working documents can include "placeholders" for sections still to be submitted, comments from committee members and invited experts can be given verbally at a meeting or in writing, and comments can be considered by the full committee at a meeting or referred to a project leader or task group for resolution. Written responses are not required to any of the comments submitted at this point, although the committee, project leader or task group may wish to explain

rejection of certain comments in minutes of a meeting or a report to the committee in an effort to resolve the matter prior to formal ballot and public review stages. If AAMI staff receives comments on a draft document from someone outside of the committee, staff shall advise the submitter (1) that the draft is not on public review, (2) that only comments submitted on public review drafts receive written responses from AAMI or an AAMI committee, and (3) that staff is forwarding their comments to the responsible committee, project leader, or task group for their consideration in developing the next draft.

3.5.5 Committee refinement of the draft (Committee Draft)

A complete draft (i.e., a draft that does not contain any “placeholders” for text still to be written) is designated a “Committee Draft” if it is distributed to the committee for purposes of determining whether it should proceed to formal ballot and public review. Official canvass of a Committee Draft can be approved by the (co)chairs or by simple majority of voting members present at a meeting, however initiation of same is subject to concurrence by the AAMI Vice President of Standards Policy and Programs that the draft is “complete” as defined above. This is an optional stage that can be skipped if three-fourths of the members present at a meeting vote to proceed directly to formal ballot and public review (Proposed Draft stage).

If the Committee Draft stage is not skipped, the Committee Draft shall be distributed to all committee members and invited reviewers with an invitation to submit written comments to be taken into consideration before entering the next (Proposed Draft) stage. The cover memorandum also shall include notice regarding how the comments will be reviewed and resolved and the decision to circulate another Committee Draft or to instead proceed to formal ballot and public review (Proposed Draft) stage will be made – at a committee meeting (with date specified) or by letter ballot. If by letter ballot, a ballot form and voting roster shall also be provided. The deadline for submitting comments and/or ballots shall be at least thirty calendar days from distribution of the material.

Written responses to comments on a Committee Draft are recommended but not required unless the committee is working by correspondence rather than resolving comments at a meeting. If the extent of comments or ballot results make it clear that another Committee Draft will have to be circulated, for example, the committee may decide to refer the comments to a task group as the basis for preparing a new Committee Draft. Or if all of the members who submitted comments are at the meeting where the comments are being reviewed, the (co)chairs may propose at the outset that in the interest of time, the committee only document accepted changes to the text and suggestions for comments to be resubmitted with additional rationale or proposed wording if a comment seems reasonable, but does not provide enough information for the committee to make a change to the text. If written responses are prepared to the comments, they shall be distributed to the full committee as part of the background documentation for the next action. In any case, it shall be made clear when distributing the first Proposed Draft for formal ballot (and public review) that members are responsible for submitting all comments that they wish to become part of the formal record, regardless of whether it is a new comment or a comment that they raised either verbally or in writing on previous Working Drafts or Committee Drafts.

If AAMI staff receives comments on a Committee Draft from someone outside of the committee, staff shall advise the submitter (1) that the draft is not on public review, (2) that only comments submitted on public review drafts receive written responses from AAMI or an AAMI committee, and (3) that staff is forwarding their comments to the committee for its consideration in developing the next draft.

The committee can proceed to the next (Proposed Draft) stage if three-fourths of the members voting by letter ballot on a Committee Draft approve proceeding to the next stage, or if three-

fourths of the members present at a meeting approve moving to the next stage. Even if the minimum requirement for moving to the next stage is approved by letter ballot, the committee can overturn that decision if three-fourths of the members present at a meeting vote to circulate another Committee Draft in light of the extent or nature of changes made in response to comments. The committee cannot, however, overturn rejection by letter ballot and must repeat Committee Draft stage if less than three-fourths of the members voting by letter ballot approved proceeding to the next stage.

3.5.6 Formal Consensus Development (Proposed Draft stage)

3.5.6.1 General

The decision to proceed to Proposed Draft stage is made at a committee meeting or by letter ballot of a Committee Draft. Proposed drafts shall be circulated for formal committee ballot and public review concurrently.

3.5.6.2 Deadlines falling on a holiday or weekend

Unless otherwise specified in the original communication specifying a deadline for response, any deadlines that fall on a U.S. Federal holiday or on a weekend are automatically extended to the next business day. This applies to committee deadlines as well as public review deadlines.

3.5.6.3 Formal committee ballot

For documents authored by a working group, the ballot may consist of the authoring working group, only, or a joint ballot may be conducted consisting of the authoring working group and its parent committee. The following paragraphs describe the AAMI policies and procedures applicable to formal committee ballots conducted to determine consensus on a Proposed Draft.

3.5.6.3.1 Ballot types

- a) Full ballot: A ballot of a complete Proposed Draft, where the entire draft is subject to comment, and that requires all members to record a vote or an abstention. A copy of the Proposed Draft and current voting roster must be provided when conducting a full ballot. At least one full ballot must take place before a continuation ballot can be conducted.
- b) Continuation ballot: A ballot to determine if members wish to modify their vote from what was recorded on the last full ballot, where only changes since the last Proposed Draft (if any) are subject to comment, and where members are only required to respond if they failed to vote or abstain on the last full ballot or wish to change their vote. A copy of the last Proposed Draft, a separate document indicating all changes since that draft and now subject to comment (limit 3 pages), if any, a detailed summary of voting results from the last full ballot including comments and their resolutions, as well as a current voting roster (if different from the detailed summary of voting results) must be provided when conducting a continuation ballot.

3.5.6.3.2 Decision concerning joint ballots

Committees with one or more working groups shall decide, by letter ballot, whether documents authored by its working groups will be balloted jointly by the parent committee and the authoring working group, or just by the authoring working group. The proposal to include or exclude members of a parent committee from working group ballots of documents is passed if two-thirds of the voting members of the committee agree to the proposal. The committee's decision shall apply to all working groups of the committee, and shall remain in effect until a proposal to change the committee's practice is acted upon by letter ballot. Proposals to reballet the

question can be agreed to by the committee at a meeting or can be made in writing by a (co)chair or voting member of the committee. While proposals to reballot the question of joint ballots may be submitted at any time, there shall be a minimum period of twelve months between ballots to change a committee's joint ballot practice.

3.5.6.3.3 Distribution of ballots

The AAMI staff prepares the letter ballot, which shall clearly indicate whether it is a full ballot or continuation ballot, and that negatives without comments will be recorded as such with no further notice to the voter. The document, ballot, voting results from the last ballot of a Proposed Draft (if applicable), current ballot roster (if different from the detailed voting results or if this is the first ballot of a Proposed Draft), and any other relevant background information are distributed to voting committee members and alternates, and to invited reviewers (if any) selected by the committee (co)chairs. For continuation ballots, the changes from the previous Proposed Draft shall also be included (limit 3 pages) with clear indication that only those changes are subject to comment. The same draft placed on full public review must also be submitted to full ballot and vice versa. The same changes placed on partial public review must also be submitted to continuation ballot and vice versa.

3.5.6.3.4 Ballot period

The ballot period for a full ballot is generally six weeks. The ballot period for a continuation ballot is generally four weeks. No ballot shall be less than three weeks.

3.5.6.3.5 Ballot disclosure requirements and multiple votes

When responding to a letter ballot, members must identify their category of interest in the document and, if applicable, correct any out-of-date information concerning the organization they represent on the committee (see 2.3.2.1). Members also must disclose any potential conflict of interest, that is, a current substantial financial relationship with a company that they do not 'represent' (see 2.3.2.1) on the committee if the company produces the product or service covered by the document under ballot, regardless of whether said company is represented by a voting member of the committee or not. As per 2.3.2.1, organizations are permitted only one representative member per committee, and an alternate's vote is counted only if the principal representative fails to vote.

In the case of a potential conflict of interest (see above), staff shall provide any such information to the (co)chairs of the committee that is responsible for reviewing and resolving ballot comments, and depending on the nature of the relationship and the issue at ballot, it may be necessary for the member who has the potential conflict of interest to vote and comment in conjunction with the producer with whom a current substantial financial relationship has been identified. Such matters are adjudicated on a case-by-case basis by the committee (co)chairs and the Standards Board.

In the case of joint ballots (see 3.5.6.3.2), if an organization is represented on more than one committee included in the ballot and multiple ballots are returned, the following hierarchical order shall be used to determine the 'principal representative' whose vote will be counted, if cast:

1. voting member of committee responsible for reviewing and resolving ballot comments ('review committee')
2. alternate member of 'review committee'
3. voting member of parent committee to 'review committee'

4. alternate member of parent committee to 'review committee'
5. voting member of any other committee included in ballot
6. alternate member of any other committee included in ballot

3.5.6.3.6 Voting

Committee members may vote "Affirmative" (with or without comments), "Negative," or "Abstain." A committee member should vote "Affirmative" if he/she endorses the document exactly as presented, or if his/her comments are of an editorial nature or can be resolved without substantive technical changes⁷ in the text, or if the committee member supports the document regardless of whether or not his/her comments (technical or other) are accepted. A committee member should vote "Negative" if substantive technical changes would be necessary to resolve at least one of the comments submitted with the negative vote.

NOTE — It is not necessary to vote negative in order to assure committee consideration of comments. Committees are obliged to seriously consider and respond to *all* comments, whether accompanying affirmative or negative ballots, except as qualified below or elsewhere in this manual.

Negative votes *must* be accompanied by comments; otherwise, they shall be recorded as "negative without comments" without further notice to the voter. This applies to a negative vote on a full ballot, and on changes to negative from affirmative, abstain or not voting on a continuation ballot. This does not apply to members who maintain a negative vote from one ballot to a subsequent continuation ballot provided that the member submitted comments with the original negative vote.

Note: While members who voted negative with comments on the last full ballot can maintain their negative on one or more subsequent continuation ballots without resubmitting comments or submitting new comments, the committee is not required to reconsider comments from a previous ballot that were rejected or partly rejected absent additional written justification from the person who originally submitted the comment, or submission of the same or a similar comment on a subsequent ballot from another member of the committee or from a public reviewer.

Abstentions must be accompanied by an explanation.

All comments and objections, whether accompanying affirmative or negative ballots, must be *specific* and include the following information: the number of the paragraph containing the offending text; the reasons why the individual objects to the text; suggested alternative text that would resolve the individual's objection; and, in the case of substantive technical objections, a refutation of the existing rationale. Comments shall not be submitted as marginal notations on a copy of the document; comments in the form of a question should be avoided.

AAMI reserves the right to return for re-submission any comments that are illegible or that reference a specific company, product or product line other than the member's product, unless the comment refers to a section of a Proposed Draft that cites a specific company, product or product line.

3.5.6.3.7 Ballot return

For a ballot to be valid, at least two-thirds of the committee members must record a vote or an abstention. This is one reason why a committee member's failure to respond to two consecutive ballots (or to have a vote or abstention on record if one of the last two consecutive ballots is a continuation ballot) is grounds for termination of his/her appointment (see 2.3.13).

⁷ A "substantive change" is one that directly and materially affects the use of the document. Examples from the American National Standards Institute of substantive changes include changes from "shall" to "should" or vice versa; addition, deletion or [technical] revision of a requirement, regardless of the number of changes; and addition of mandatory compliance with referenced standards.

3.5.6.4 Public review

3.5.6.4.1 Definition

Public review is a process by which AAMI consensus documents are made available by AAMI and, in most cases, ANSI, for review by interested parties.

3.5.6.4.2 General notification of public review

Public comment is solicited by notice in *Standards Monitor Online* and/or the "Standards Monitor" section of *AAMI News*, and in *ANSI Standards Action* if applicable. This notice describes the scope of the proposed standard or recommended practice, states its availability for review and comment, explains how a copy of the document can be obtained, and indicates the deadline for receipt of comments. On recommendation of the committee or its (co)chairs, either of the AAMI Standards vice presidents may also send complimentary copies of the proposal to recognized experts and/or organizations having competence and interest in the subject matter of the document for their review and critique.

3.5.6.4.3 Public review period

The public review period shall be as follows:

- A minimum of thirty calendar days if the full text of the revision(s)⁸ can be published in the AAMI (and ANSI, if applicable) periodical(s) used for announcing public review;
- A minimum of forty-five calendar days if the document is available in an electronic format, deliverable within one working day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided in the public review announcement; or
- A minimum of sixty calendar days, if neither of the aforementioned options is applicable.

These periods may be extended at the discretion of the staff.

3.5.6.5 Handling of late comments and comments unrelated to the proposal

The committee is not required to consider late ballot or late public review comments in deciding whether to proceed to the next action on the project. However, late comments that are not considered as part of the review and resolution of the current Proposed Draft shall be documented and considered in one of the following ways, and the submitter(s) of the late comments shall be so notified:

- If another ballot and public review cycle is warranted by the nature or extent of the changes made in response to timely comments, late comments from the previous Proposed Draft shall be treated as though they had been submitted on the subsequent Proposed Draft (full ballot) or portions of the draft subject to comment (continuation ballot).
- If another ballot and public review cycle is not warranted, late comments shall be treated as a new proposal. Within six months of final approval of the document, the committee shall decide whether the late comments warrant an amendment, errata or immediate revision, should be deferred to the next scheduled periodic review, or should be rejected with explanation. The

⁸ This typically would not apply to the first public review, but can be used if only substantive changes from the previous Proposed Ballot are being put out for continuation ballot and public review

compilation of late comments together with the committee's resolutions shall be distributed to all late commenters as well as to the members of the committee.

The committee is also not required to consider comments that are not related to the proposal currently on public review, however such comments shall be documented and considered in the same manner as submittal of a new proposal, and the submitter of the comments so notified.

See [Annex E - Responding to ballot and public review comments](#) for additional guidance.

3.5.6.5.1 Return of comments

AAMI reserves the right to return for re-submission any comments that are illegible or that reference a specific company, product or product line other than the public reviewer's product, unless the comment refers to a section of a Proposed Draft that cites a specific company, product or product line.

3.5.6.6 Response to ballot and public comments

For technical comments that are rejected or that are not accepted in their entirety, the committee shall provide an explanation for the rejection in writing. This applies whether the comment proposed a substantive change, a technical clarification, or a technical correction. Provided that the comment is specific and/or a rationale for the comment is included, the explanation shall provide a technical basis for rejecting the comment. Reference to a rationale statement published in the Proposed Draft is acceptable provided that it is responsive to the justification provided with the comment suggesting modification of the Proposed Draft. It is also acceptable to refer to a detailed explanation already drafted in response to another comment provided that the explanations are the same for both. The committee's explanation for rejecting other types of comments can be of a more general nature.

Committees shall not provide official interpretations of drafts. Therefore, replies to questions submitted with ballot or public review comments should only be provided to the extent that an actual comment can be implied by the question (e.g., "Based on this question, it appears the requirement/test/rationale needs to be revised to clarify intent and the committee has reworded x.x.x as follows.....").

The committee is not required to respond to comments that are withdrawn by the submitter. "Comment withdrawn" shall only be entered into the resolution column at the request of the person who submitted the comment (or, in the case of a representative member of the committee, by either the voting member or alternate of record) and documentation of the withdrawal must identify by name the person who withdrew the comment and how it was withdrawn (e.g., "orally at the meeting" or "by email, copy attached").

Occasionally, while reviewing comments for purposes of resolution, the committee will identify additional changes that are needed. These additional changes shall be included in the table of comments and resolutions.

The compilation of comments and their resolutions shall be distributed to all committee members with the next ballot and to all other commenters announcing concurrent public review, or if no substantive changes were made, with a proposal to submit the document to the AAMI Standards Board (and ANSI, with the Board's approval) for final approval.

Late comments that were not reviewed by the committee and comments not related to the proposal shall be compiled into separate tables or otherwise clearly identified as such.

NOTE—In the case of a parallel ballot of an international document under consideration for U.S. adoption, the above applies to AAMI committee decisions concerning which comments to submit, either as written or with modification, or reject for submission as part of the U.S. consensus position. The above also applies to any U.S. comments that are

officially submitted to ISO or IEC and subsequently withdrawn by a U.S. expert member of the international working group that is charged with resolving international comments on a draft. In addition, the committee shall be provided with the ISO or IEC documentation indicating how other U.S. comments and any non-U.S. comments were resolved.

Whenever resolutions of comments are distributed, committee members with a negative vote on record are asked to identify any comments from their previous ballot(s) that they are willing to withdraw if they decide to maintain their negative vote, and public reviewers are informed that public review comments are considered “resolved” absent written objection to the documented resolution within thirty calendar days.

See also [Annex E](#) and [Annex F](#).

3.5.6.6.1 Decision regarding further action

If disposition of comments on a Proposed Draft result in substantive technical changes, a full or continuation ballot and public review shall be conducted. The decision between conducting another full ballot/public review, or a continuation ballot should be made by the committee when it resolves comments on the current Proposed Draft and requires approval by three-fourths of the members present at the meeting. If the committee decides to conduct a continuation ballot, that decision is contingent upon the ability to publish all changes to the previous Proposed Draft in 3 pages or less; otherwise, another full ballot and public review must be conducted. If there are no comments or if the committee agrees no substantive changes were made as a result of the last ballot/public review, the committee can decide to submit the document for final approval. In the absence of a meeting, the (co)chairs can propose that the document proceed to another full or continuation ballot/public review, or to final approval stage. This proposal is transmitted in writing to the committee and members are given thirty calendar days to object to the proposal.

3.5.7 Final approval

3.5.7.1 Notice to committee and public reviewers

The proposal to submit the document to the AAMI Standards Board and, if applicable, to the American National Standards Institute shall be made in writing to all members of the committee and to any public reviewers with outstanding objections on record together with the final voting results, resolutions of all comments submitted on the last full ballot/public review and all subsequent continuation ballots/public reviews, copies of outstanding objections (if any) from public reviewers to the committee’s resolution of their comment(s), together with a copy of the Final Proposed Draft incorporating all changes approved from continuation ballots, and any other relevant documentation. Recipients shall be given at least fifteen calendar days in which to change their vote, challenge categorization of a change made in response to comments on the most recent Proposed Draft or from a continuation ballot/public review as “not substantive” or to file objection to final approval of the document for other specified reasons.

3.5.7.2 Standards Board approval of final documents

3.5.7.2.1 General

Only the Standards Board can approve publication of a consensus document as a final AAMI standard or recommended practice; or approve its submittal to the ANSI Board of Standards Review for approval as an American National Standard.

3.5.7.2.2 Procedural review

The Board decides on the finalization of a standard or recommended practice based on whether or not it believes that a consensus has been established in accordance with AAMI policies and

procedures and that all committee and public comments have been resolved. Comments are considered to have been resolved when a committee renders a responsive judgment that appears, to the satisfaction of the Standards Board, to be based on substantial committee agreement and good scientific data and rationale. The Board does not conduct a technical review *per se*, nor does it evaluate comments or objections from a technical point of view.

3.5.7.2.3 Documentation

In its decision-making process, the Board reviews the following documentation: copies of all committee and public comments on the last full ballot/public review and any subsequent continuation ballots/public review; the committee's responses to those comments; any further comments from persons objecting to the disposition of their comments; objections to the finalization of the document, and any other documentation that staff deems relevant. The Standards Board also reviews the consensus document itself to ensure that it conforms to AAMI policies.

3.5.7.2.4 Standards Board action

The Standards Board may take final action on a consensus document at a meeting. When, however, a consensus document is ready for final action and there is no Standards Board meeting scheduled in the near future, the Standards Board may take final action by letter ballot. In this case, the following procedure applies:

- a) All relevant documentation is circulated to the members of the Standards Board, along with a letter ballot. The initial voting period is ten working days, subject to extension if insufficient response is received.
- b) The letter ballot offers each member the opportunity to vote for final approval, abstain, or to vote, with an explanation, for holding the matter for discussion at the next meeting. Any vote to hold the decision for the next meeting is honored.
- c) Three-fourths of the membership of the Standards Board must return ballots.

3.5.7.2.5 Denial of approval

If the Standards Board denies approval, the document is returned to the responsible committee with appropriate instructions. The principal reason for denying approval at this stage is a failure of the committee to adequately document that it has considered and resolved all comments.

3.5.7.2.6 Appeals

A Standards Board decision to approve a consensus document as a final AAMI standard or recommended practice and, when applicable, to submit the document to ANSI for approval as an American National Standard is subject to appeal on procedural grounds. If the Standards Board approves a document when formal objection to its final approval is on the record, objectors shall be notified in writing of the Board's decision and offered the opportunity to file an appeal.

3.5.7.3 ANSI approval of final document

Most AAMI standards and recommended practices are submitted to ANSI for approval as American National Standards. The review conducted by the ANSI Board of Standards Review is similar to that conducted by the AAMI Standards Board. It is a procedural review based on the evidence of consensus and due process provided by the ballot and public review documentation.

3.6 Appeals

3.6.1 General

There is a formal appeal mechanism for the impartial handling of procedural complaints regarding substantive actions or inactions on AAMI standards and recommended practices. Procedural appeals include whether a technical issue raised in compliance with these procedures was afforded due process.

3.6.2 Actions and inactions subject to appeal

Persons who have directly and materially affected interests and who have been or will be adversely affected by a standard, or by the lack thereof, shall have the right to appeal the following:

3.6.2.1 Standards Board actions

The following Standards Board actions may be appealed following the procedures outlined in 3.6.3:

- a) approval or denial of approval of a document as a final or reaffirmed standard or recommended practice;
- b) authorization or denial of authorization of submittal of a document to ANSI for approval as an American National Standard;
- c) withdrawal of a published AAMI standard, AAMI recommended practice, or American National Standard;
- d) authorization or denial of authorization for the establishment of a new committee or the initiation of a new project under an existing committee;
- e) approval or denial of approval of an interpretation of a standard or recommended practice.

3.6.2.2 Committee actions

All substantive committee actions can be appealed to the Standards Board following the procedures outlined in 3.6.3. Other committee actions are subject to appeal by decision of the Standards Board.

3.6.2.3 Committee (co)chair actions

Denial of committee membership can be appealed to the Standards Board following the procedures outlined in 3.6.3.

3.6.2.4 Inactions

Substantive inactions of the Standards Board, committee, committee cochair or committee staff that are not covered in 3.6.2.1, 3.6.2.2, or 3.6.2.3 can be appealed to the Standards Board.

3.6.3 Appeal procedure

3.6.3.1 General

An appeal of a Standards Board action or inaction (see 3.6.2.1 for actions subject to appeal) must first be made to the Standards Board. A further appeal may be made to the AAMI Board of Directors.

An appeal of a committee or committee (co)chair action or inaction must be made to the Standards Board. The Standards Board decision is final.

All appeals must be based on procedural complaints regarding substantive actions or inactions. Procedural appeals include whether a technical issue raised in compliance with AAMI procedures was afforded due process.

3.6.3.2 Filing of an appeal

An appeal must be filed in writing to the AAMI office within fifteen working days after notification by AAMI of an action of the Standards Board, committee, or committee (co)chairs. An appeal of an inaction that is related to an active project or new work item proposal must be filed prior to final approval of the project or formal acceptance/rejection of the new work item. An appeal of an inaction that is related to a final document (e.g., failure to initiate periodic review) must be filed prior to that document being superseded or withdrawn.

The appeal shall state the nature of the objection(s) including any adverse effects, the clause(s) of these procedures that is at issue, the actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted. Appeals based on whether a technical issue was afforded due process must also include documented evidence that the comment was submitted in compliance with AAMI procedures. Upon the filing of a properly executed appeal, the responsible committee (if applicable) and Standards Board are notified and the original action is suspended until such time as the appeal can be adjudicated.

3.6.3.3 Hearing of an appeal

The Standards Board must hear the appeal in a meeting or conference call within ninety calendar days after the date of the filing of the appeal or on a date mutually agreeable to all parties. The appellant and the responsible committee must be invited, in writing, to be represented at the hearing with at least fifteen working days advance notice. Any committee member or other interested party may attend the public portion of the appeal hearing if he/she contacts the Vice President of Standards Policy and Programs in advance. Upon hearing all arguments, the Standards Board will decide the matter in closed session. A two-thirds vote of the Standards Board members present is required to modify its original action.

3.6.3.4 Notification of appellant and committee

Standards Board decisions on appeals are rendered *only* in writing. The appellant and the responsible committee must receive written notification of the Standards Board's decision and reason(s) therefore within fifteen working days of the appeal hearing.

3.6.3.5 Filing of an appeal to the Board of Directors

An appeal to the AAMI Board of Directors must be filed in writing within fifteen working days of notification of the Standards Board decision and must explain why the Standards Board decision should be modified. A decision by the Board of Directors to hear an appeal requires approval by a majority of the Board at a meeting at which a quorum is present. The complete Standards Board case file must be made available to the Board of Directors for consideration in reaching a decision on whether or not to hear the appeal. When the Board of Directors reaches a decision, the appellant and the responsible committee are notified in writing.

3.6.3.6 Hearing of an appeal by the Board of Directors

If the Board of Directors decides to hear an appeal, the appellant and the responsible committee are invited, with notice of at least fifteen working days, to be represented at the hearing. The cochairs of the Standards Board participate in the Board's deliberations, but without vote. Any committee member or other interested party may attend the public portion of the appeal hearing if he/she contacts the Vice President of Standards Policy and Programs in advance. Upon hearing all arguments, the Board of Directors will decide the matter in closed session. The Board of Directors may reverse the decision of the Standards Board by a majority vote; if fewer than a majority of the Directors voting are in favor of a reversal, then the Standards Board decision is sustained.

3.6.3.7 Notification of Board decision

Board decisions on appeals are rendered *only* in writing. The appellant, the responsible committee, and the Standards Board must receive written notification of the Board of Directors' decision within fifteen working days of the appeal hearing.

3.6.3.8 Appeal of ANSI decisions on American National Standards

Persons who maintain negative votes on and/or objections to proposed American National Standards also have rights of appeal under ANSI's procedures.

3.7 Publication

Consensus documents shall be published and made available as soon as possible.

NOTE —In the case of American National Standards, documents shall be published no later than six months after ANSI approval. Failing this, AAMI may request an extension from ANSI.

3.8 Interpretations of standards and recommended practices

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Vice President of Standards Policy and Programs. An official interpretation must be approved by letter ballot of the responsible committee, made available for public review, and approved by the Standards Board. An interpretation becomes official and a representation of the Association only upon exhaustion of any appeals and upon publication of a notice of interpretation in the "Standards Monitor" section of *AAMI News*. AAMI disclaims responsibility for any characterization or explanation of a standard or recommended practice that has not been developed and communicated in accordance with the foregoing procedure.

3.9 Amendments of standards and recommended practices

Amendments of published AAMI standards and recommended practices can be proposed at any time. Requests for amendments must be made in writing to the Vice President of Standards Policy and Programs, must offer *specific* text changes, and must include rationale for the recommended changes. An amendment must be denied or approved by letter ballot of the responsible committee and the committee's decision made available for public review and comment. The same balloting, public review, and final approval procedures apply to amendments as to original standards and recommended practices. An approved amendment or information on how to obtain a copy must be published in the "Standards Monitor" section of *AAMI News*.

NOTE — The amendment process is typically reserved for substantive technical changes for which there is a pressing need. Proposed changes of an editorial nature and technical changes of less urgency are compiled over time until the standard or recommended practice is due for general review and revision. Outright errors in the text are corrected by means of an errata sheet, upon review by the responsible committee.

3.10 Periodic review of standards and recommended practices

3.10.1 Documents maintained on a periodic basis

3.10.1.1 Decision to reaffirm or withdraw

Within five years of last approval for AAMI-authored documents that have not been superseded by a later edition, and six years for adoptions of international standards, proposed reaffirmation or withdrawal of an AAMI standard or recommended practice shall be placed on public review. To meet this deadline, a committee ballot to determine consensus on the proposed reaffirmation or withdrawal should be initiated six months to a year before the deadline for initiating public review. The proposal (reaffirm or withdraw) on the ballot form can be based on a decision of the committee taken at a meeting, or in the absence of a meeting, can utilize the default proposal of “reaffirm.” Information concerning any related revision projects or plans to initiate any related revision projects shall be provided with the ballot material, however contingency votes (e.g., reaffirm as long as the committee starts working on a revision) are not allowed. Ballot forms shall include the following choices: Affirmative, Negative with comments; Abstain.

NOTE: A decision to reaffirm or withdraw a standard does not have any impact on existing revision projects, which shall continue until completed or until the committee agrees by separate decision, following usual consensus procedures, to discontinue the work. However for American National Standards staff will need to submit a revised PINS to ANSI after the reaffirmation or withdrawal is approved to correspond with the new designation of the reaffirmed standard, or to change the project from a revision to a new standard in the event the original document is withdrawn.

The periodic review ballot shall also be accompanied by the ballot roster and information on how committee members can obtain a copy of the document under review if they do not already have a copy.

After resolving ballot and public review comments (if any), the committee and any public reviewers shall be provided in writing the final voting results, a compilation of ballot and public review comments (if any) and their resolutions, and the current status of related revision projects (including decisions by the committee not to undertake any revision work at the present time). Recipients are given thirty calendar days to object in writing to final submission, absent which the proposal to reaffirm or withdraw the document shall be submitted to the Standards Board (and ANSI, when applicable) for final approval. Final submission shall be initiated within six months of the close of public review. This period can be extended by up to six months by the Vice President of Standards Policy and Programs based on a determination that an active revision project is sufficiently advanced that it will supersede the document within that period.

3.10.1.2 Decision to revise

Committees can decide to start working on a revision, amendment or errata at any point after a document is published. The purpose of this section of the procedures is to ensure that the committee considers whether a revision project should be started at least once every five years. Therefore, if work to revise a document is not already underway when the committee ballot to reaffirm or withdraw a document is initiated, the committee shall be concurrently surveyed to determine whether or not to begin work on a revision. The survey form will usually ask members to choose between “Revise (with comments supporting the proposal),” “Do not revise,” and “Abstain” and background for the survey shall include any outstanding comments on the previous edition. For adoptions of international documents, this process preferably will occur in

parallel with determining the U.S. position on an international systematic review, and other or additional questions may be needed on the survey form.

If there are no comments in support of a revision, staff in consultation with the cochairs can simply inform members that based on the results of the survey, there are no plans to initiate a revision, noting that the document will be reviewed again in four to five years (or sooner, if comments are received in the interim) and provide a copy of the results of the survey. In the case of international adoptions, the results of the international systematic review also shall be provided.

If there are comments, results of the survey and a complete collection of comments are circulated to the committee and the committee arrives at a consensus, either at a meeting or via correspondence, on whether or not to start work on a revision. In the case of an international adoption, this may be an interim decision and the basis of the U.S. vote, with the final decision deferred until the committee also has the results of the international systematic review. If taken at a meeting, the decision shall be confirmed in writing to the full committee as well as to any outstanding commenters.

If the committee determines that no revision, amendment or errata is needed and there are outstanding comments on the previous edition or committee member comments from the survey, it effectively has rejected the comments suggesting changes or revision and must provide a written compilation of comments and responses to all committee members and any other commenters when the decision is transmitted. Recipients should also be advised of their right to appeal the decision to the Standards Board.

If the decision is to start work on a revision, comments submitted by members of the committee should be taken into consideration in developing the first draft of the revision, but no formal responses are needed. When notifying outstanding commenters (if any) from outside the committee of the new work item, the commenters also shall be provided information on how to join the committee as well as detailed written responses to his/her comments or information on the process that will be used to consider and respond to those comments during the revision project. In addition, staff shall register and announce the project publicly following the same procedures as for a new standard.

Using the above process, the committee should decide whether or not to start working on a revision within the same time period as 3.10.1.1 so that this information can be provided as part of the background for the concurrent reaffirmation or withdrawal of the current standard.

NOTE —In the case of an American National Standard, in the event the document is not reaffirmed, revised, or withdrawn within five years after its approval, AAMI must request an extension of time to reaffirm or revise the standard, or is required to withdraw the standard. The request must be submitted to ANSI within thirty calendar days following five years after the approval date and must demonstrate that work is under way that will lead to revision, reaffirmation, or withdrawal.

If the extension is granted and the American National Standard is not reaffirmed, revised, or withdrawn within the extension period, AAMI may request a second extension. However, regardless of whether an extension is granted, ANSI will withdraw any American National Standard that has not been revised or reaffirmed within ten years from the date of its last approval. For this and other reasons, in 2006 AAMI modified its procedures to require that committees formally reaffirm or withdraw standards every five years regardless of whether a revision project is underway or planned to begin shortly.

If an adopted international document is reaffirmed or withdrawn at the international level, or a revision or amendment is approved internationally, ANSI procedures require that similar action shall be considered by the responsible U.S. committee no later than six months after the international action is completed.

3.10.2 AAMI-authored documents maintained on a continuous basis

Large standards with well-defined parts can be maintained on a continuous basis with the approval of the Standards Board. The responsible committee shall prepare a documented

program for periodic publication of revisions and procedures for timely, documented consensus action on each request for change that is submitted. No portion of the standard shall be excluded from the revision process, and the maintenance procedures must be in full compliance with AAMI policies and procedures for consensus and due process. The program for periodic publication and related maintenance procedures, as well as any subsequent revisions of the program and procedures, shall be reviewed and approved by the AAMI Standards Board.

After the program and procedures are approved by the Standards Board, a clear statement of the intent to consider requests for change and information on the submittal of such requests shall be published in the foreword of the standard or, if the standard is already published, shall be issued as an erratum to the standard. In the event that no revisions are issued for a period of four years, action to reaffirm or withdraw the document shall be taken in accordance with 3.10.1.1.

3.11 Withdrawal for Cause

Normal proposals from the responsible committee to withdraw a standard or recommended practice are covered in 3.10.1.1.

Requests for withdrawal of an AAMI standard or recommended practice by other parties shall be approved by the Standards Board only upon a sufficient showing that one or more of the conditions listed in 2.11.6 applies.

An application for withdrawal for cause of an AAMI standard or recommended practice may be submitted to the Standards Board by any materially interested party including an AAMI technical committee, the AAMI Committee on Standards Strategy, or the AAMI Board of Directors. The application shall be submitted in writing to AAMI offices (attention Vice President, Standards Policy and Programs) and include, at a minimum, the name of the applicant, affiliation (when applicable), address, phone, fax and email, a statement indicating which document should be withdrawn and on what basis (see 2.11.6, a to b), and evidence to support the request for withdrawal.

In such cases:

- a) staff shall refer the request for withdrawal to the responsible committee within fifteen calendar days to review and respond within thirty calendar days.
- b) if the committee concurs with the proposed withdrawal:
 1. public notice shall be given in the next available issue of *AAMI Standards Monitor* and the document shall be withdrawn in accordance with normal procedures;
 2. on or before the date that public review of the proposed withdrawal begins, staff shall provide direct, written notification to the requester and the committee of the public review dates (initiation and deadline);
- c) if the committee does not concur with the proposed withdrawal, within thirty calendar days of confirming this decision, in writing, with the committee, staff shall inform the requester in writing of the committee's reasons and indicate that in the absence of a response (see #1 below), AAMI will assume that the commenter's concerns are resolved and will close the request for withdrawal;
 1. the requester shall advise the Vice President, Standards Policy and Programs whether he/she wishes the withdrawal process to continue or not within thirty calendar days of receipt of the committee's response;
 2. if continuance of the withdrawal process is requested, the matter shall be referred to the Standards Board within 15 calendar days via letter ballot,

including all supporting documentation, for decision on subsequent action. The Standards Board may request additional evidence, including public review, to support a proposed withdrawal before making its decision.

Extensions of time to submit documentation related to a withdrawal for cause may be granted at the discretion of the Vice President, Standards Policy and Programs. Extensions shall be requested prior to the deadline date and shall include a justification therefore.

3. If the Standards Board determines, based on the weight of the evidence presented, that one or more of the criteria listed in 2.11.6 have been satisfied, approval of the document as an AAMI standard or recommended practice shall be withdrawn. If the Standards Board determines, based on the weight of the evidence presented, that none of the criteria listed in 2.11.6 have been met, then approval of the standard or recommended practice shall be maintained.
4. In either case, within 30 calendar days, the requester and the committee shall be notified directly and in writing of the Standards Board's decision. If the Standards Board decides to withdraw a document, within five working days staff shall also remove the item from inventory and notify ANSI of the withdrawal. In addition, public notice that the document has been withdrawn shall be placed in the next available issue of *AAMI Standards Monitor*.

The decision of the Standards Board to either maintain or withdraw the approval of an AAMI Standard or Recommended Practice may be appealed. (See 3.6.2.1 and 3.6.3.)

4. Technical information reports and other technical publications

In addition to standards and recommended practices, AAMI publishes "technical information reports" (TIR's) and other technical publications designed to respond to specific needs of the AAMI membership and the health care community.

4.1 Technical information reports

4.1.1 Definition

A technical information report provides an overview of a particular medical technology or of certain issues pertaining to a particular technology. While a TIR is usually developed under the auspices of an AAMI technical committee, it does not offer consensus recommendations in the fashion of a standard or recommended practice and it is not subject to all of the policies and procedures governing consensus documents.

4.1.2 Origins of technical information reports

A technical information report may be developed because it is more responsive to the needs of the health care community than a standard or recommended practice; because it is needed as an interim, data-gathering step in the establishment of a standard or recommended practice; or because achievement of the consensus required for a standard or recommended practice is difficult or appears unlikely. Sometimes, in the case of a new, rapidly developing technology, there is insufficient data upon which to base a standard, or a standard would impose unjustifiable constraints on the evolution of a technology. When the technology in question has matured or when requisite data has been accumulated, a TIR can serve as a point-of-departure document for a new standard now under development.

4.1.3 Content and format of technical information reports

The objectives and subject matter of TIR's vary widely, so few policy and format guidelines apply. In general, the text should be of a descriptive nature, characterizing the subject technology in the fashion of a technical paper or monograph. While the authors may wish to

offer general recommendations concerning the performance attributes or use of the subject technology, specific performance or use criteria should be avoided. The format of TIR's is flexible, with the main goals being logical organization and clarity of presentation. Published TIR's may be consulted for general guidance.

4.1.4 Development and approval of TIR's

4.1.4.1 Timeliness

One of the desired attributes of a TIR is timeliness. Such a document is intended to respond quickly to the need for information in the field, not to reflect a formal committee consensus. Consequently, the procedures for developing and approving TIR's are not as comprehensive and rigorous as those that apply to standards and recommended practices.

4.1.4.2 Initiating work

The development of a TIR may be proposed by the AAMI Standards Board to the relevant technical committee(s) or vice versa. In the latter case, the committee must apply for Standards Board approval in accordance with the provisions of section 2.

4.1.4.3 Drafting the technical information report

Upon approval of the project, the Standards Board or leadership of the relevant technical committee assigns the actual drafting of the text to a small group of individuals. These individuals are usually, but need not necessarily be, members of an AAMI committee. In some cases, especially when the subject of the TIR transcends the scope of any one technical committee, the Standards Board may establish an *ad hoc* group to write the text.

4.1.4.4 Reviewing and refining the technical information report

When the authors are satisfied with the text, the document is circulated for review and comment to the members of the relevant technical committee(s). Any comments are returned to the authors for consideration. It is not necessary for the authors to formally resolve all comments. Comments may be rejected, incorporated into the text, or presented as "minority opinions," at the discretion of the authors and the committee leadership.

4.1.4.5 Approving the technical information report for publication

When the authors and the committee leadership are satisfied with the TIR, the document is balloted by the committee for the purpose of deciding whether or not to release it for public distribution. Committee approval of release for public distribution will be based upon (a) a two-thirds return of ballot, including abstentions, and (b) approval of at least a majority of the membership and at least two-thirds of those voting, excluding abstentions. The TIR is then presented to the Standards Board for approval, along with an explanation of the disposition of any comments. The Standards Board decides whether to authorize the TIR for publication or to return it to the authors and committee for further work. If approved by the Standards Board, the TIR is issued. The final publication must contain a clear explanation of the objectives of the document and a statement to the effect that it does *not* represent a committee or national consensus. The authors of the document are acknowledged, along with the participating technical committee(s) and any other persons who have made significant contributions.

4.1.5 Updating or expanding the technical information report

Technical information reports should be reviewed every three years to determine whether they are still current. If technology changes have been such that the responsible committee believes

a full consensus document can be developed to replace the report, a new work proposal must be submitted and, if approved, the expanded document would be developed in accordance with the policies and procedures outlined in section 3. Generally, TIR's remain available through AAMI until replaced by (or incorporated into) a standard or recommended practice, although a committee could recommend to the Standards Board that a report be withdrawn because it was dated or for some other reason, or that a revised TIR should be developed.

4.2 Technology conference reports

Technology conference reports are partial or complete proceedings of AAMI technical conferences. The deliberations of AAMI technical committees often suggest the need for a public forum where issues that have arisen relative to a standard or recommended practice may be explored. AAMI also sponsors conferences, seminars, or educational programs to address broad public health issues or specialized topics. To ensure the wide dissemination of the information presented, AAMI frequently publishes conference proceedings. Formerly, these proceedings were termed "Technology Assessment Reports" or "Technology Updates." To avoid confusion with other AAMI technical publications promulgated by AAMI, these terms have been replaced with the general rubric, "Technology Conference Reports." While proceedings reflect the expert opinion of conference faculty and while committee participants often assist in the technical editing, technology conference reports are not consensus documents.

4.3 Other technical publications

The AAMI standards program is designed with the objective of providing technical responses tailored to the specific needs of the health care community. Standards and recommended practices provide technical recommendations having the weight of national consensus. Technical information reports provide timely overviews of the state of the art of particular technologies. Health care professionals are kept up to date on technological advances and research through technology conference reports.

These types of documents, however, are not the only avenues of technical communication available to AAMI members and technical committees. AAMI responds as an organization with comments and public testimony on proposed new government regulations affecting the health care professions and industry. AAMI technical committees provide statements of expert opinion on contemporary technological issues, occasionally issue advisories to the health care community, and are free to apply their ingenuity and expertise to devising new types of technical publications to serve the needs of the health care community.

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

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION
 4301 N Fairfax Drive, Suite 301, Arlington, VA 22203-1633
 Phone: 703/525-4890 FAX: 703/276-0793 Web: www.aami.org email: standards@aami.org
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	
Mfr or Inst represented	Parent Company (if applicable)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Mfr or Inst represented	Parent Company (if applicable)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Mfr or Inst represented	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	
		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Company x	Company y, a subsid of Company z	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.

6. Why AAMI?

Please explain why AAMI is the appropriate organization to undertake the project. Identify any other organizations that could reasonably be expected to have an interest in the proposed project and/or that already have relevant work in progress.

7. Committee

If the project is proposed to be undertaken by an existing AAMI committee, please identify the committee and indicate whether or not the existing membership has adequate relevant expertise; if not, identify those experts and/or organizations that should be invited to join the committee. If the proposed project does not fall within the scope of an existing committee, attach a list of potential members of the committee, consisting of roughly equal members of industry, user, and general-interest representatives, and a list of hospital, medical, or trade groups that support and would participate in the project.

8. Plan of Work

In the case of a standard, recommended practice, or other technical publication, please describe the prospective readership and attach to this proposal a draft outline of the document. In the case of a proposal to undertake the sponsorship of an educational program, describe the recommended format and prospective audience and attach to this proposal a program outline identifying some or all of the prospective faculty.

10. Financial Resources

Please describe any extraordinary resources that will likely be needed for the proposed project and how these resources can be obtained; for example, if a user travel fund is planned, explain how it will be established and maintained. Also identify any potential sources of funding, such as government grants, corporate contributions, and the like.

11. Person(s) to Contact for Further Information

11a. Submitted by (Please provide your name, address, phone number and email address here)

11b. On behalf of (Please indicate the company, committee, association, etc. that has officially asked you to submit this proposal on their behalf, if applicable. If not applicable, leave blank or indicate "self.")

11c. Other persons to contact for further information. If applicable, please provide the names, addresses, phone numbers and email addresses of other individuals who can be contacted about the proposed project should AAMI staff or the Standards Board have questions or need additional data.

For Office Use Only
Date Received _____
Date to SB _____
Action Taken _____
If Approved, Scheduled Completion Date: _____

Annex C -- Public Reviewer Response Form

INSTRUCTIONS: Please complete all 4 parts of the form on this page as well as providing your comments on the form that begins on the next page. Note in particular that:

Comments must be received by the comment deadline on the cover of the public review draft. Late comments may be deferred to the next revision of the document (usually five years from final approval date).

Failure to provide a rationale and suggested alternative text for a comment may result in the committee finding the comment non-persuasive.

When developing the US consensus position on international approval of an ISO or IEC draft, the committee is only required to consider comments from individuals or companies that are domiciled in the United States. (Individuals and companies domiciled outside of the US should contact their official member body to ISO or IEC to determine opportunities for commenting.)

When developing consensus on AAMI standards and recommended practices, the committee will consider comments from all interested and affected parties.

1. DOCUMENT: (Enter designation and title from cover page of draft)

2. YOUR INTEREST CATEGORY:

User Producer/Industry Government/Regulatory General Interest

3. NAME/DATE/SIGNATURE:

Name (print/type)

Date

Signature (required if returning ballot by surface mail or by fax)

4. CONTACT INFORMATION:

Company

Street Address

City/State/Zip

Country (if not US)

Phone #

Email Address

Fax #

RETURN TO: Standards Department

Email standards@aami.org

Fax 703-276-0793

Mail AAMI, 4301 N Fairfax Drive, Ste 301, Arlington, VA 22203-1633

General instructions on voting/commenting are available at the AAMI website at:

<http://www.aami.org/standards/downloadables/balinstr.pdf>

PLEASE KEEP A FILE COPY OF YOUR COMMENTS

To add more rows to the following chart, go to the last cell (bottom row, "Comments" column) and hit your Tab key.

Name:			
Clause ¹	Item ²	Comment Type ³	Comment ⁴
			Comment/Objection: Rationale: Alternative Text:
			Comment/Objection: Rationale: Alternative Text:
			Comment/Objection: Rationale: Alternative Text:
			Comment/Objection: Rationale: Alternative Text:
			Comment/Objection: Rationale: Alternative Text:
			Comment/Objection: Rationale: Alternative Text:

¹ **Clause:** Enter clause numbers only in this field, e.g., 3.4.5 or A3.4.5. Use the "Item" column for unnumbered sections (e.g., Introduction). To specify an item within a numbered clause such as a table, paragraph, etc., fill in both the clause and item columns.

² **Item:** Enter non-numeric section headings (e.g., Introduction) or items within a numbered clause (e.g., paragraph 1; line 3; Table 2; Figure 5; or item c).

³ **Comment Type:** Enter "T" for Technical, "E" for Editorial, or "G" for General (including reason for abstaining on ballot)

⁴ **Comment:** Comments consist of up to three elements.

Comment/Objection: Try to state your comment or objection briefly and clearly, using the other sections for additional explanation and to provide alternate text. Avoid writing comments in the form of a question.

Rationale: Provide a detailed statement in support of your comment. Hints: Include references to published data (if any) that support your position. Refute the document's rationale (if any) in your statement. Skip for editorial comments.

Alternative Text: Enter suggested text for the draft that, if included, will resolve your comment.

Annex D - AAMI Standards Philosophy and Strategy — Key Elements

(Informative)

The Association for the Advancement of Medical Instrumentation (AAMI) is a unique alliance of professionals and organizations dedicated to the understanding and beneficial use of medical device technology. AAMI members include health care institutions, research and teaching facilities, government agencies, manufacturers, test houses, trade associations and individual health care professionals.

AAMI and its members have assumed an important leadership responsibility in medical device standards worldwide. Over more than 35 years of developing medical device standards, the following have evolved as the guiding principles of the AAMI Standards Program:

1. Requirements should be performance-based; design standards should be avoided as they can limit innovation and restrict competition. Requirements should include a corresponding rationale to assist standards users in understanding the requirement, and to help avoid gratuitous requirements. Standards should allow for technology changes/innovation. As appropriate, proven test methods should be provided that standards users can follow to determine compliance with the requirements.
2. There should be “at most one globally applied standard and one globally accepted test, with conformity assessment processes appropriate to the needs of the parties, for each characteristic of a product, process or service.”¹
3. National standards developing organizations (SDO) should not purport to be consensus international standards bodies. All interests should work through accepted international bodies such as ISO, IEC and ITU whenever possible to avoid duplication of effort and standards.
4. Standards are not the basis of competition; they are the basis of “good practices” in terms of patient safety and the basis of harmonizing marketplace, regulatory and other requirements to enhance the use of technology for the welfare of patients. Standards should enhance competition, commerce and the availability of devices and not be barriers to trade.
5. Standards planning and development should be managed on a sectoral basis. In the health care field, standards projects and priorities should reflect the combined needs of government and health care providers as well as industry that is expected to support development of the standard and ultimately to meet the standard. Otherwise, the project will not have the needed technical support from volunteer committee members and/or the final document will be underutilized. Most if not all technical planning efforts should be bottom up, not top down. Standards, when needed and relevant, are an important way for industry, through collaboration and consensus, to serve its “customers:” health care professionals, regulatory bodies and patients.
6. Standards should be based on current technology and consensus; they should not generally lead the state of technology, although exceptions may be necessary e.g. in cases where a standard is needed in order to introduce a system-wide technological innovation. To the extent possible, standards requirements should be based on published, peer-reviewed studies combined with practical experience from the user community.
7. Standards should be developed only where there is a clear need – validated e.g. by a risk assessment – and should address only essential requirements. Resources are limited and must be used wisely. A corollary of this statement is that standards are an important reference to responsible decision-making, but should never replace responsible decision-making by medical device manufacturers and users.

8. Governments should participate with other stakeholders in the setting of priorities for standards, in standards development and in funding standards activities. Governments should utilize voluntary standards in the regulatory process, but government should not be the exclusive or dominant agent in developing standards unless there are compelling circumstances.
9. Governments rarely have the resources to effectively and efficiently develop standards and keep them up to date (which is critical in a regulatory context). To be effective, such standards require strong input from industry and the professions, i.e., the developers and the users of technology. For these reasons, the voluntary consensus standards system should be seen by governments as a viable alternative to developing their own technical standards. A corollary of this statement is that SDOs have a major responsibility to assure that their standards are relevant to the current state of technology.
10. As standards in the health care field, regardless of how they are developed, rarely lead technology, their adoption as regulation may inappropriately preclude cutting edge technology, and become a barrier to innovation. Such barriers do not serve the best interest of patients, manufacturers or governments. Therefore, governments should view voluntary consensus standards as a way, but only one way, to demonstrate compliance with relevant regulatory requirements. However, when public health concerns mandate the adoption of standards, they should be incorporated by reference in regulation.
11. Duplication of effort should be avoided at both the national and international level. The concept of giving “choices” of conflicting standards to users of standards is a burdensome concept in a regulatory context. In addition, unnecessary duplication adds cost to the system and dilutes the consensus process by encouraging “forum shopping.”
12. A fundamental premise underlying effective voluntary standards in the health care technology field is that the user of the standard is a trained and experienced professional who knows when and how a standard should be used and understands the limitations, in general, of voluntary standards.
13. There are many instances where a standard is not the appropriate solution for a safety or performance issue and, in these instances, other means of resolution should be employed.
14. Technical reports are useful when there is insufficient basis or consensus for a standard. Documents that do not allow for full participation and consensus development (e.g., workshop agreements, fast-track adoptions, consortia documents), while of possible use to some industries, should be avoided in the medical area given the safety, regulatory and trade issues involved that require a high level of public due process and consensus.

Approved by the AAMI Board of Directors, June 2007

Reference

1. National Standards Strategy for the United States; 2000, ANSI.

Annex E - Responding to ballot and public review comments

(Informative)

Guidance on documenting resolutions to comments

While not part of the official AAMI procedures, the following guidance on documenting resolutions to comments is intended to assist committees in expediting final approval of their documents by providing resolutions that meet AAMI (and ANSI) requirements. Relevant text from AAMI procedures (clause 3.5.6.6) are excerpted below as additional background. Questions not covered by this paper should be directed to the committee's¹ staff contact.

1. Resolutions should begin with a clear, brief statement regarding acceptance or rejection of the comment (e.g., "Accept," "Reject" (or "Not Accepted"), "Accepted in Part," "Accepted with Modification," "Withdrawn by [name] at meeting," "Outside the scope of the current project; treat as new work item proposal," or in the case of a non-specific comment, "Noted").
2. Unless the comment is accepted in its entirety, the brief statement noted in #1 must be followed by a rationale for rejecting, in whole or in part, a comment. For technical comments, the rationale must provide a technical reason for rejecting the comment (e.g., "The committee disagrees" is not a sufficient response because it does not indicate why the committee disagrees). For editorial comments, "Rejected, editorial" is sufficient.

Note: If the committee disagrees with the self-characterization of a comment as "editorial," "technical," etc., the change by the committee should be clearly indicated and the response based on the committee's characterization. Changes from "technical" to "editorial" should be avoided.

3. If a comment is accepted in part or with modification, the resolution should clearly indicate what part of the comment is accepted and what part is rejected or modified, in addition to providing a rationale for rejecting part of the comment. If the committee accepts a comment but changes the text proposed by the commenter to resolve the concern, a rationale probably is not needed however the specific text agreed to by the committee must be included in the resolution.

Other suggestions

4. If the committee accepts a technical change to a requirement, the committee (or a task group formed for this purpose) should review any related test methods or rationale statements for consistency prior to moving the document to the next stage. Additional changes from this review, if any, must be documented in the resolutions to comments.

Note: Commenters should suggest any such related changes as part of their original comments, so most related changes will already be documented. The above just clarifies that any additional changes that are discovered when checking the revised draft for consistency also should be documented so members have a complete list of changes they are being asked to approve.

5. If the committee assigns the task of resolving some of the comments to the cochairs or some other task group (e.g., if there are too many comments to get through at a meeting), these resolutions must be documented in the resolutions to comments. (I.e., the resolution is not "defer to task group," but is the specific response of the task group in keeping with items #1 through #3 above.)
6. To expedite review, the committee can respond to strictly editorial comments (i.e., acceptance or rejection will not alter the meaning of the text in any way) by stating "Editorial; defer to staff." The

¹ Throughout this paper, "committee" is used generically to include any AAMI standing committee, technical advisory group, working group or technical advisory sub-group with primary responsibility for developing consensus on an AAMI document or U.S. consensus on an international document.

actual decision of staff editors to accept or reject the editorial comment need not be documented in the resolutions to comments.

7. Occasionally, committee discussion of one comment leads to a new comment. While the committee is not required to consider new, verbal comments, if they agree to modify a draft as a result of such a comment, the comment and its resolution must be added to the compilation. If the comment clearly originated with a single individual, it should be identified with that person. Otherwise the commenter is listed as "xx committee."
8. If the committee believes it has a good reason to defer making a decision on a comment to some future activity, it should indicate that the comment is rejected for incorporation into the document currently under development, provide a rationale for that decision, and note its intent to reconsider the comment and when (e.g., committee will submit as a new work item for a separate document by [date]; committee will submit as a new work item for an amendment by [date]; committee will reconsider during next revision (approx five years) or during next periodic review (approx five years). In general, the committee should avoid this kind of "half-way" response to comments so there is no inference that the committee has accepted a comment for incorporation into a future document, since that cannot be guaranteed given the voting/public review process that a future document will have to undergo, approval process for new work items, etc. [Note to staff: For the same reasons, we cannot accept conditional changes in vote from negative voters.]

3.5.6.6 Response to ballot and public review comments (excerpted from *AAMI Standards Program Policies and Procedures Manual*)

For technical comments that are rejected or that are not accepted in their entirety, the committee shall provide an explanation for the rejection. This applies whether the comment proposed a substantive change, a technical clarification, or a technical correction. Provided that the comment is specific and/or a rationale for the comment is included, the explanation shall provide a technical basis for rejecting the comment. Reference to a rationale statement published in the Proposed Draft is acceptable provided that it is responsive to the justification provided with the comment suggesting modification of the Proposed Draft. It is also acceptable to refer to a detailed explanation already drafted in response to another comment provided that the explanations are the same for both. The committee's explanation for rejecting other types of comments can be of a more general nature.

Committees shall not provide official interpretations of drafts. Therefore, replies to questions submitted with ballot or public review comments should only be provided to the extent that an actual comment can be implied by the question (e.g., "Based on this question, it appears the requirement/test/rationale needs to be revised to clarify intent and the committee has reworded x.x.x as follows.....").

The committee is not required to respond to comments that are withdrawn by the submitter. "Comment withdrawn" shall only be entered into the resolution column at the request of the person who submitted the comment (or, in the case of a representative member of the committee, by either the voting member or alternate of record) and documentation of the withdrawal must identify by name the person who withdrew the comment and how it was withdrawn (e.g., "orally at the meeting" or "by email, copy attached").

Occasionally, while reviewing comments for purposes of resolution, the committee will identify additional changes that are needed. These additional changes shall be included in the table of comments and resolutions.

The compilation of comments and their resolutions shall be distributed to all committee members with the next ballot and to all other commenters announcing concurrent public review, or if no substantive changes were made, with a proposal to submit the document to the AAMI Standards Board (and ANSI, with the Board's approval) for final approval.

Late comments that were not reviewed by the committee and comments not related to the proposal shall be compiled into separate tables or otherwise clearly identified as such.

NOTE—In the case of a parallel ballot of an international document under consideration for U.S. adoption, the above applies to AAMI committee decisions concerning which comments to submit, either as written or with modification, or reject for submission as part of the U.S. consensus position. The above also applies to any U.S. comments that are officially submitted to ISO or IEC and subsequently withdrawn by a U.S. expert member of the international working group that is charged with resolving international comments on a draft. In addition, the committee shall be provided with the ISO or IEC documentation indicating how other U.S. comments and any non-U.S. comments were resolved.

Whenever resolutions of comments are distributed, committee members with a negative vote on record are asked to identify any comments from their previous ballot(s) that they are willing to withdraw if they decide to maintain their negative vote, and public reviewers are informed that public review comments are considered “resolved” absent written objection to the documented resolution within thirty calendar days.

Last Revised: 10 March 2005

Annex F - Protocol for tracking and handling pending comments

(Informative)

1. Purpose

1.1 This protocol covers the recording, handling, and tracking of formally submitted comments on a proposed or final consensus document that have not been fully considered and responded to by the responsible committee¹ during ballot or public review, or comments for which consideration and resolution have been deferred by committee decision (collectively, “pending comments”).

2. Initial handling

2.1 Send any formally-submitted comment on a draft or final technical document received outside of committee ballot or public review to the committee leadership for review and consult with them on how to proceed.² Copy senior standards staff on all such correspondence.

2.2 While a last-minute delay to address late or new comments can be frustrating, the committee leadership should be asked to use its best judgment in deciding whether or not to delay final submission of an AAMI document (including national adoptions) based on the urgency of the concerns raised by the comment.

Comments that raise issues having to do with a potential substantive hazard to safety, health or the environment, or unreasonable restraint of trade, should be considered and resolved by the committee as part of the current action. If for some reason the committee cannot address the comment by changes to the requirements of the draft (e.g., because there is insufficient information to base a requirement on), the committee should consider other alternatives such as adding an exclusion section to the scope of the document with a corresponding rationale statement explaining the need for the exclusion and that the committee hopes to be able to address the issue more fully in an amendment or revision of the standard.

For international standards (IS), the AAMI committee is not empowered to suspend finalization of the IS, but should consider the comments relative to how it votes at FDIS stage, the possible submission of a U.S. new work item proposal to amend the IS, an appeal to ISO or IEC on final approval of the IS (due w/in two months of the FDIS voting report), etc.

2.3 If the comment(s) or concern(s) are judged not to be of an urgent nature (as described in sub-clause 2.2, above), or are received after the document has been submitted for final approval and/or published, then correspondence should be sent to the commenting party noting that the comment(s) will be retained and considered as part of a specified, future action³. The commenting party should also be informed of any actions he/she could undertake to expedite the process.⁴

¹ The responsible committee is the AAMI committee, working group, technical advisory group or technical advisory sub-group with primary responsibility for developing consensus on an AAMI document or U.S. consensus on an international document.

² For comments submitted on drafts, this assumes the comment is so late, and/or the document so far along, that the comment cannot be dealt with following normal procedures.

³ Amendment, errata, new work item, next periodic review, etc.

⁴ In the case of comments received before final submission to the Standards Board, this is not an alternative to formal procedures. The committee must also be made aware of the comments, the commenter and committee must be informed of the plan to defer the comment to a later project and of their rights to appeal, and all related documentation must be included in the final submission to the Standards Board.

The comment is retained for future consideration in accordance with clause 3.

3. Recording and tracking pending comments

3.1 Any pending comment(s) will be entered into a collated compilation of all pending comments (CPC). The CPC will be given a Committee document number and will be posted to the web-page of the responsible committee. All pending comments on a single document (and any of its final amendments) will be contained in a single compilation. The CPC may be revised or replaced as necessary, but will remain posted until the final document it relates to is superseded or withdrawn.

3.2 A field in the AAMI Standards Project Record for the final document is used to track the existence of pending comments. The field will be filled-in with the committee document number of the CPC and updated whenever the compilation is revised or replaced. The field will be left empty when there are no pending comments.

4. Final consideration and response

4.1 Pending comments may be considered at any point following final approval of a technical document. A comment is not to be removed from the CPC until it has been responded to in accordance with 4.2 and that response fully documented as part of one of the following actions:

- a) a new work item proposal based on the comment has been circulated for formal consideration.
- b) an erratum based on the pending comment has been issued.
- c) periodic review, reaffirmation and/or revision of the document has been initiated and the comment has been considered and responded to as part of this periodic review, reaffirmation and/or revision.
- d) the comment no longer applies because the document has been withdrawn.
- e) the commenting party has withdrawn the comment, in writing.

Alternatively, comments can remain on the CPC with a notation indicating which have been addressed and as part of what action.

4.2 Staff shall make a good faith effort to notify the author of a pending comment whenever any formal action related to that comment occurs (e.g., a draft amendment is put on public review based on the comment, or a proposal to withdraw the document that the comment refers to is on public review). For 4.1, items a) to c), in accordance with usual procedures, a detailed written response will be documented as part of the record for the project and that response will be sent to the last known mail and or e-mail address of the author of the comment and include information on how to appeal the decision of the committee, when applicable. For 4.1, item e), the committee should be informed that a comment has been withdrawn and is going to be removed from the CPC on that basis, and given thirty calendar days to object to the comment's removal from the CPC.

Additional guidance

It is important that the department keep track of all "pending" comments on a final document so that the responsible committee will review or reconsider these comments at the appropriate time(s) and ultimately address and respond to them in keeping with *AAMI Standards Program Policies and*

Procedures. This protocol, while mandatory for staff, is not part of the formal procedures and if any conflicts are discovered between the two, the formal procedures always take precedence.¹

What is a “pending comment”

Pending comments can include:

1. Timely comments marked for reconsideration: Comments submitted during development of a document as part of ballot or public review, where the committee response was to reject for incorporation into the document currently under development, with rationale, but also noting the committee wishes to reconsider the comment. Between final submission and final approval, any such comments and information from the original resolution regarding when the committee intends to reconsider the comment should be copied to a CPC.
2. Late comments: Ballot or public review comments submitted during development of a document after the specified deadline (AAMI and TAG projects), but before initiation of final notice to committee and public reviewers of intent to submit the document to the AAMI Standards Board for final approval (AAMI projects² only). Unlike the above, the committee is not required to provide a detailed response for its decision to reject a comment for inclusion in the current project. The committee can instead indicate that it is deferring consideration on the sole basis that the comment was late and a final response and rationale will be provided in the context of some future activity. As noted in 2.2, the committee should decide whether or not to defer consideration of a late comment based on the urgency of the issues raised. Beyond that, committees should be encouraged to review and resolve late comments whenever that is feasible and will not unduly delay finalization of a document. Depending on the circumstances, it may take less time (both committee and staff) to deal with late comments in the context of the original project than deferring them to a future action.
3. New comments: Comments submitted during the notification period of committee and public reviewers of intent to submit the document to the AAMI Standards Board for final approval that raise new issues (i.e., not related to a change, or rejection of a change, based on the resolution of ballot and/or public review comments); comments that are submitted between the close of the notification period and publication of the document; and comments that are submitted on the document after it is published.

Pending comments do not include:

1. Comments already fully addressed (i.e., either accepted and incorporated into the document prior to its publication, or where a written explanation developed by consensus of the committee for rejecting the comment has been provided to the commenter, and the response does not include an indication that the committee has also agreed to reconsider the comment as part of some future action).
2. Verbal comments (the only exception is committee comments identified at a meeting during the resolution process and documented as part of the minutes/compilation of comments and resolutions from the meeting)

Questions about a final document, including formal questions that require consideration by the committee of issuing an “Official Interpretation” as well as informal questions about a document, whether received verbally or in writing.

¹ Please bring any conflicts between this document and the official procedures to the immediate attention of senior standards staff for resolution.

² “AAMI projects” include documents developed by an AAMI committee as well as international documents being adopted by an AAMI committee.

Annex G – AAMI Antitrust Statement

(informative)

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

Antitrust Statement

The Association for the Advancement of Medical Instrumentation ("AAMI") and its Board of Directors are committed to the activities of the Association, including meetings held for the purpose of:

1. Promoting the common interests of its members and the general welfare of the healthcare and patient communities through lawful activities.
2. Performing, in a lawful manner, such civic, commercial, industrial, professional and social events and activities to promote or foster the advancement of medical technology.
3. Preparing and disseminating among its members and others accurate and reliable information concerning the medical technology community, including standards, other publications, education and other services.
4. Participating in international, foreign and national standards activities to promote the welfare of the business, professional and patient care community.
5. Participating in scientific, consensus and educational activities and other lawful endeavors for the advancement of the public's and members' interests.

However, AAMI recognizes that in the process of these lawful activities, opportunities may arise that could result in violations of antitrust laws. Violations of antitrust laws are serious, criminal and civil violations, which are punishable by jail terms, fines and treble damage penalties. Therefore, all AAMI members and guests are reminded that AAMI meetings cannot be used, in violation of antitrust laws, to:

1. Discuss pricing, pricing policies, or any marketing policy with an indirect effect on pricing.
2. Confer about division or allocation of sales territories or customers.
3. Establish blacklists or boycotts of suppliers, purchasers, or competitors.
4. Coerce members or others to implement particular programs or policies.
5. Resolve problems in an arbitrary or unreasonable manner or based solely on the needs of a single party or a small, select group.

If you believe a potential antitrust problem has arisen or is occurring during this meeting, please immediately contact the person(s) chairing the meeting or an AAMI staff person.

**Approved November 30, 2007
by the AAMI Board of Directors**

AAMI INTERNATIONAL STANDARDS PROGRAM POLICIES AND PROCEDURES MANUAL

Association for the Advancement of Medical Instrumentation

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Introduction

The Association for the Advancement of Medical Instrumentation (AAMI) is perhaps the single-most active developer of national and international standards for medical devices in the world. Consisting of over 100 technical committees, the AAMI standards program is completing a growing number of national *and* international standards each year, many of which are now identical or technically equivalent to one another.

The objectives of this manual are to review the scope of the AAMI international standards program, and to specify the basic policies and procedures by which U.S. Technical Advisory Groups under that program operate. A separate manual has been developed by AAMI to cover the policies and procedures of its national standards program.

AAMI International Standards Activities

AAMI is "at the hub" of virtually all major areas of international standards for medical devices, serving as the administrator of several important U.S. Technical Advisory Groups, and in many instances, the corresponding international technical committee. At present, AAMI's international standards activities cover the following ISO and IEC committees:

International Organization for Standardization (ISO):

ISO/TC 194	Biological evaluation of medical devices (U.S. TAG)
ISO/TC 194/SC 1	Tissue product safety (U.S. TAG)
ISO/TC 198	Sterilization of healthcare products (U.S. TAG and ISO Secretariat)
ISO/TC 210	Quality management and corresponding general aspects for medical devices (U.S. TAG and ISO Secretariat)
ISO/TC 76	Transfusion, infusion and injection equipment for medical or pharmaceutical use (U.S. TAG)
ISO/TC 84	Devices for administration of medicinal products and intravascular catheters (U.S. TAG)
ISO/TC 150/SC 2	Cardiovascular implants and extracorporeal systems (U.S. TAG and ISO Secretariat)
ISO/TC 150/SC 6	Active implants (U.S. TAG and ISO Secretariat)
ISO/TC 173/SC 3	Aids for ostomy and incontinence (U.S. TAG)

International Electrotechnical Commission (IEC):

IEC/SC 62A	Common aspects of electrical equipment used in medical practice (IEC Secretariat)
IEC/SC 62D	Electromedical equipment (U.S. TAG and IEC Secretariat)

In addition to its standards-development activities, AAMI also holds an annual conference on international standards to help industry, regulators, and others stay current on activities in ISO, IEC, and other major standards organizations such as CEN/CENELEC in Europe. The conference also addresses regulatory and conformity assessment issues, as they relate to voluntary international standards.

AAMI International Standards Program Policies and Procedures Manual

1. General

These procedures for US technical advisory groups (TAG) meet the requirements for due process and coordination in the development of US positions for ISO and IEC activities as given in ANSI "Criteria for the Development and Coordination of US Positions in the International Standardization Activities of the ISO and IEC." A TAG consists of its members and its TAG administrator. A particular TAG is related to a particular ISO or IEC technical committee or subcommittee (e.g. "US TAG for ISO/TC xx.").

A sub-TAG consists of its members. A particular sub-TAG is related to a particular ISO or IEC working group (e.g., "US sub-TAG for ISO/TC 198/WG 1") or to an international standards project (e.g., "US sub-TAG for IEC/SC 62D/WG 1, Cardiac monitors). Occasionally, a sub-TAG is made up of two or more "AAMI Committees" (AAMI technical committees, subcommittees or working groups that develop national standards in addition to serving as a US sub-TAG), if the international standard being developed spans the scope of multiple AAMI Committees.

NOTE—As used in these procedures, "ANSI" refers to the American National Standards Institute, which is the official US member to ISO, or to the ANSI-affiliated United States National Committee (USNC), which is the US member to IEC; and "TAG Administrator" refers to the Association for the Advancement of Medical Instrumentation (AAMI).

2. Functions and responsibilities

The functions and responsibilities of the TAG and/or its sub-TAGs are:

1. Recommend registration of ANSI as a Participating (P-) or Observer (O-) member of an ISO or IEC subcommittee or recommend a change in ANSI membership status on an ISO or IEC technical committee or subcommittee
2. Initiate and approve US proposals for new work items for consideration by an ISO or IEC technical committee or subcommittee
3. Initiate and approve US working drafts for submittal to ISO or IEC technical committee, subcommittee (and, where appropriate, working groups) for consideration as committee drafts
4. Determine the US position on an ISO or IEC draft international standard, draft technical report, committee drafts, ISO or IEC questionnaires, draft reports of meetings, etc.
5. Provide adequate US representation to ISO or IEC technical committee or subcommittee meetings, designate heads of delegations and members of delegations, and ensure compliance with the ANSI "Guide for US Delegates to IEC/ISO Meetings"
6. Determine US positions on agenda items of ISO or IEC technical committee or subcommittee meetings and advise the US delegation of any flexibility it may have on these positions
7. Recommend to the TAG Administrator US technical experts¹ to serve on ISO or IEC working groups
8. Provide assistance to US secretariats of ISO or IEC technical committees or subcommittees, upon request, including resolving comments on draft international standards, draft technical reports, and committee drafts
9. Identify and establish close liaison with other US technical advisory groups in related fields, or identify ISO or IEC activities that may overlap the TAG's scope
10. Recommend to ANSI the acceptance of secretariats for ISO or IEC technical committees or subcommittees
11. Recommend that ANSI invite the ISO or IEC technical committees or subcommittees to meet in the United States

12. Recommend to the TAG Administrator US candidates for the chair of ISO or IEC technical committees or subcommittees and US conveners of ISO or IEC working groups

3. TAG Administrator

The TAG administrator shall be designated by the ANSI Executive Standards Council (ExSC) or its designated standards board², or by the USNC, as appropriate, and shall accept, in writing, the responsibilities described below:

1. Organize the US technical advisory group (including sub-TAGs, as needed) and apply to ANSI for TAG accreditation
2. Submit the US technical advisory group membership (inclusive of sub-TAGs, when applicable) list to ANSI on an annual basis for review by the ExSC or its designated standards board²
3. Determine that the members of the technical advisory group (and sub-TAGs) participate actively
4. Provide for administrative services, including arrangements for meetings, timely preparation and distribution of documents related to the work of the US technical advisory group (and sub-TAGs), and maintenance of appropriate records, including minutes of meetings and results of letter ballots
5. Transmit US proposals and US positions, as developed and approved by the US technical advisory group and/or sub-TAG, to ANSI
6. Nominate US technical experts to serve on ISO or IEC working groups
7. Recommend to ANSI US candidates for the chair of ISO or IEC technical committees or subcommittees and US conveners of ISO or IEC working groups
8. Establish a procedure to hear appeals of actions or inactions of the US technical advisory group (or sub-TAGs)
9. Comply with the requirements associated with ANSI oversight and supervision of activities of the technical advisory group (inclusive of sub-TAGs, when applicable) and its administration
10. Ensure compliance with applicable ANSI and ISO or IEC procedures

4. Officers

There shall be a chairman of the TAG (or, at the discretion of the TAG Administrator, cochairmen), and other officers if required, appointed by the TAG Administrator. Ordinarily, chairmen are selected by the TAG administrator from the individual members of the TAG, however AAMI staff can chair ISO TAGs if the TAG is not also serving as a sub-TAG. IEC TAGs are chaired by the designated Technical Advisor, which can be an AAMI staff member or other expert appointed to this post by the USNC.

There shall be a chairman of each sub-TAG (or, at the discretion of the TAG Administrator, cochairmen), and other officers if required, appointed by the TAG Administrator in consultation the TAG chair(s).

The TAG administrator shall appoint a staff liaison to serve as secretary for each TAG and sub-TAG. In the absence of the staff liaison at a meeting, a chairman or an individual designated by the chair(s) shall serve as the meeting secretary.

5. Membership

Section 2.3 of the *AAMI Standards Program Policies and Procedures Manual*, inclusive of all subsections, shall apply with the following modifications:

2.3.6

Replace entire clause with:

The TAG Administrator appoints members of a TAG or sub-TAG, either by invitation or upon review of an application.

2.3.8

Add the following sentences to paragraph 1:

Members on a TAG or sub-TAG shall be US national persons (organizations, companies, government agencies, individuals, etc.). In the case of TAGs or sub-TAGs that also serve as AAMI Technical Committees, non-US persons who are members of the technical committee may vote on national standards matters, only.

Replace paragraph 2 with:

Most TAGs function as administrative and coordinating bodies, with the primary responsibility for developing US comments and votes on technical matters occurring at the sub-TAG level. TAG membership (provided that the TAG is not also acting as a sub-TAG) may be by invitation (not application) and/or restricted to representatives of broad-based membership organizations, user societies, government agencies, and the like.

5.1 Membership roster

The administrator shall submit the initial list of US technical advisory group members (inclusive of sub-TAGs, when applicable) and the organizations they represent (preferably prior to the initiation of work) to the ExSC or its designated standards board², or to the USNC, as appropriate, for approval.

The roster shall include the following:

1. Title and designation of the TAG.
2. Scope of the TAG.
3. TAG administrator (name of organization, name of secretary, address(es), telephone number).
4. TAG officers (chairman/men and other officers).
5. Members:
 - * Name of the individuals and alternate (as applicable) and their business affiliations including name of the organization they are representing on the TAG.
 - * Name of any self-employed member and business affiliation. Retired persons and independent consultants shall be considered as self-employed.

6. Meetings

Meetings of the TAG or sub-TAG and meetings of the US delegates to international meetings should be scheduled to respond to international activities. TAG and sub-TAG meetings shall be held, as determined by the chair(s)/TAG administrator or by petition of a majority of the members.

6.1 Open meetings

Meetings of the TAG and sub-TAG shall be open to all members and others having direct and material interest. At least thirty calendar days notice of regularly scheduled meetings shall be given by the administrator in the "Standards Monitor" section of *AAMI News*. This notice shall

identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to members and to others expressing interest.

7. Voting

7.1 Vote

Each member shall vote one of the following positions:

1. Affirmative.
2. Affirmative with comments.
3. Negative with reasons. (The reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection.)
4. Abstain with reason.

All instructions provided with the ballot form regarding the presentation of comments shall be adhered to.

7.2 Vote of alternate

An alternate's vote is counted only if the principal representative fails to vote.

7.3 Voting period

The voting period for letter ballots shall be established to allow for timely response to international time limits. An extension may be granted at the option of the chair(s) or administrator when warranted (e.g. when the requirements for approval or disapproval specified by 7.5 or 7.6 are not achieved.)

7.4 Authorization of letter ballots

A letter ballot may be authorized by:

1. Majority vote of those present at a TAG or sub-TAG meeting
2. A chairman
3. The TAG administrator

7.5 Actions requiring written notification

The following actions shall be preceded by thirty calendar day written notification of the TAG and/or sub-TAG, with invitation to comment or object. The actions shall also be announced in the "Standards Monitor" section of *AAMI News*.

1. Appointment of officers by the Administrator
2. Formation of a sub-TAG, including its procedures, scope, and duties
3. Disbandment of a sub-TAG
4. Adoption of TAG procedures, categories of interests, or revisions thereof
5. Change(s) to the TAG scope
6. Termination of the TAG

7.6 Actions requiring approval by two-thirds of those voting

The following actions must be approved by at least two-thirds of those voting by letter ballot, excluding abstentions, or if at a meeting, by two-thirds of those present, excluding abstentions, provided that a majority of the total voting membership of the TAG is present. If a majority is not present, the vote shall be confirmed by letter ballot:

1. Approval of US position on new work item proposal

2. Approval of US position on a Committee Draft with vote
3. Approval of US position on a draft International Standard

7.7 Consideration of views and objections on letter

The administrator of the TAG shall forward the views and objections received to the chair(s) of the sub-TAG³, or his/their designee. The chair(s) shall determine whether the expressed views and objections shall be considered by telephone, correspondence, or at a meeting.

Prompt consideration shall be given to the expressed views and objections of all participants including those commenting on the Committee Draft (CD) or the draft International Standard (DIS) listing in ANSI *Standards Action* or AAMI *Standards Monitor*. A concerted effort to resolve all expressed objections shall be made, and each objector shall be advised of the disposition of the objection and the reasons therefore.

Substantive changes required to resolve objections, and unresolved objections, shall be reported to the sub-TAG³ members to afford all members an opportunity to respond, to reaffirm, or to change their position within appropriate time limits.

7.8 Report of final result

The final result of the voting shall be reported to the TAG and sub-TAG.

7.9 Submittal of US position

Upon completion of the procedures for voting, consideration of views and objections, and appeals, the TAG administrator shall submit the US position to ANSI.

7.10 Information submitted

The information supplied to ANSI shall include:

1. Title and designation of the document
2. Indication of the type of action requested (that is, approval of a new draft international standard or reaffirmation, revision, or withdrawal of an existing draft international standard, questionnaire, etc.)
3. Status of any appeal action related to approval of the proposed US position
4. A summary of the voting and TAG or sub-TAG, as appropriate, member responses
5. Identification of all unresolved views and objections, names of the objector(s), and a report of attempts toward resolution.

8. Termination of TAG

A proposal to terminate a TAG may be made by directly and materially affected interests. The proposal shall be submitted in writing to ANSI and to the TAG administrator and shall include the reasons why the TAG should be terminated. Action shall be taken by the TAG in accordance with 7.5.

9. Communications

Correspondence of TAG or sub-TAG officers and the administrator should preferably be on "TAG correspondence" letterhead. If not, correspondence should clearly show in the title/subject that it concerns TAG matters.

External communications such as inquiries relating to the TAG should be directed to the TAG administrator, and members should so inform individuals who raise such questions. All replies to inquiries shall be made through the TAG administrator.

10. Appeals

Directly and materially affected US national persons who believe they have been or will be adversely affected by an action or inaction of the TAG, sub-TAG, or their administrator shall have the right to appeal.

10.1 Complaint

The appellant shall file a written complaint with the TAG administrator within thirty calendar days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objection(s) including any adverse effects, the section(s) of these procedures or the specific actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

10.2 Response

Within thirty calendar days after receipt of the complaint, the respondent shall respond in writing to the appellant, specifically addressing each allegation of fact in the complaint to the extent of the respondent's knowledge.

10.3 Hearing

If the appellant and the respondent are unable to resolve the written complaint informally in a manner consistent with these procedures, the TAG administrator shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving at least ten working days notice.

10.4 Appeals panel

The appeals panel shall be appointed by the TAG administrator, and shall consist of three individuals who have not been directly involved in the matter in dispute, and who will not be materially or directly affected by any decision made or to be made in the dispute. At least two members shall be acceptable to the appellant and at least two shall be acceptable to the respondent.

10.5 Conduct of the hearing

The appellant has the burden of demonstrating adverse effects, improper actions, or inactions and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the committee and the TAG administrator took all actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may adduce other pertinent arguments, and members of the appeals panel may address questions to individuals. *Robert's Rules of Order* (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

10.6 Decision

The appeals panel shall render its decision in writing within thirty calendar days, stating findings of fact and conclusions, with reasons therefore, based on a preponderance of the evidence. Consideration may be given to the following positions, among others, in formulating the decision:

1. Finding for the appellant and remanding the action to the TAG, sub-TAG, or the TAG administrator with a specific statement of the issues and facts in regard to which fair and equitable action was not taken
2. Finding for the respondent with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections
3. Finding that new, substantive evidence has been introduced and remanding the entire action to the TAG, sub-TAG, or the TAG administrator for appropriate reconsideration

10.7 Further appeal

If the appellant gives notice that further appeal to ANSI is intended a full record of the complaint, response, hearing, and decision shall be submitted by the TAG administrator to the ExSC or to the USNC Secretary, whichever is appropriate.

11. Parliamentary procedures

On questions of parliamentary procedures not covered in these procedures, *Robert's Rules of Order* (latest edition) may be used to expedite due process.

Endnotes

¹ Membership on an international working group (IWG) is a “leadership position.” Therefore, in addition to having the support of the relevant U.S. TAG and/or sub-TAG, in order to be considered for nomination or, once appointed, to be retained as a US expert to an IWG, an individual must meet eligibility requirements and fulfill responsibilities similar to those set for an AAMI Technical Committee cochair. These include but are not necessarily limited to being an active voting member and regular participant at meetings of the U.S. sub-TAG prior to seeking nomination and once appointed to the corresponding IWG; and once appointed, attending IWG meetings regularly, reporting to the U.S. sub-TAG (via timely written reports to staff) after each IWG meeting, and responding to questions from staff, members of the U.S. TAG or other interested U.S. parties on request concerning the status of the international work.

² Where no standards board exists in the area of interest, the ExSC may designate a standards planning panel or special committee

³ In the absence of a sub-TAG, the TAG shall perform this function

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Annex A -- Application for Committee Membership or Liaison Status

Use [Annex A – Application for Committee Membership or Liaison Status](#) (and Annex A.1) from national procedures manual

Annex B -- Criteria for approval of U.S. positions on international standards activities

(Informative)

Excerpted from *Criteria for the development and coordination of U.S. Positions in the International Standardization Activities of the ISO and IEC*, by the American National Standards Institute

B6 Guidelines for determining a U.S. voting position

The development of a U.S. position with regard to voting on international documents is a matter of great complexity. Firm rules for casting affirmative votes, negative votes, or abstentions would be presumptuous and unworkable in many cases. However, efforts should be made to achieve consistency in the perceived conduct of the United States as a participant in international, non-treaty standards development. Toward that end, guidelines for determining a voting position are included herein in order to provide direction toward a consistent voting policy. These guidelines cannot cover all of the factors that must be considered in determining the U.S. vote. They do, however, represent generally accepted principles that should be applied to normal situations.

B6.1 If there is an existing U.S. national standard (i.e. an American National Standard or, in the absence of an American National Standard, another standard generally accepted within the United States) and —

1. If the national standard can be considered equivalent¹ to the requirements in the international document, vote affirmative.
2. If the international document includes different, additional, or more stringent requirements than are in the national standard and the U.S. consensus indicates that such requirements:
 - a. acceptable and should be considered for inclusion in the national standard, vote affirmative, or
 - b. not acceptable, vote negative.
3. If the national standard includes different, additional, or more stringent requirements than are in the international document and the U.S. consensus indicates that such requirements are:
 - a. should be modified in accordance with the international document, vote affirmative, or
 - b. must be maintained, vote negative, or
 - c. must be maintained, but the proposed document is considered to represent the best agreement which can be reached at the present time from an international point of view, vote Abstain with a statement that the U.S. cannot modify its national standard for stated reasons.

B6.2 If no national standard exists and —

1. If U.S. consensus establishes that the international document is:
 - a. technically acceptable and could be used as a basis for the development of a national standard, vote affirmative, or
 - b. not technically acceptable, vote negative.
2. If the international document is of little or no interest to the U.S., abstain.

3. If the international document unnecessarily creates a barrier to domestic or international trade or impedes innovation or technical progress, vote negative.

B6.3 Regardless of whether or not a national standard exists —

If no U.S. consensus has been established, abstain.

B6.4 The U.S. vote, if negative, must be accompanied by reasons and supporting information such as technical data and logical argument. Also, any known exceptions and/or additions that will be required to conform with U.S. safety practices or regulations shall be noted.

B6.5 Exceptions. Exceptions to the above stated voting guidelines should be carefully considered.

¹The word "equivalent" is intended to convey the thought that any product or procedure that meets the requirements of the national standard will also meet the requirements of the international standard and vice versa when tested for conformance by accepted means