AAMI STANDARDS PROGRAM

Policies and Procedures

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AAMI Standards Program National Procedures Manual

1. Program scope and objective

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. AAMI's accredited scope is as follows:

"Standards for health technology products, processes and associated services."

AAMI's standards and technical reports are developed by technical committees or working groups operating as consensus bodies with membership drawn from a variety of backgrounds—clinicians, patient advocates, academicians, engineers, medical device manufacturers, regulators, etc. Collectively, these interdisciplinary groups develop standards and other technical documents intended to advance health technology and patient safety.

AAMI administers U.S. technical advisory groups (TAGs) that participate in the development of international standards on behalf of the U.S. The international aspects of the AAMI standards program are governed by the policies and procedures of the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and ANSI. AAMI has developed separate manuals that sets forth policies for AAMI's administration of U.S. TAGs. Other AAMI committees or working groups may serve as expert advisory groups and provide input to those U.S. TAGs.

Through its national and international technical committees and advisory groups, AAMI plays a significant global role in the development of standards for health technology products, processes and associated services. Procedures and polices provided in this document—the *AAMI Standards Program Policies and Procedures*[1]—refer only to the AAMI National Standards Program, unless otherwise specified.

1.2 Program objective

The AAMI standards program works to assist the healthcare community globally in the use, acceptance, and advancement of health technology.

1.3 Program benefits

AAMI standards and other technical documents reflect the combined knowledge of medical device producers, users, regulators, and specific technology experts. They are intended to be voluntary and to be applied at the discretion and judgment of the reader. Consequently, the AAMI standards program benefits industry and healthcare professions without restricting technological advancement.

[1]Hereafter "*Policies and Procedures".*

1.4 Types of technical committee documents/publications

1.4.1 General

AAMI technical publications are classified according to their objectives or the level of consensus they reflect. The types of technical publications described below are only examples; AAMI committees may develop other types of documents in response to specific technical issues.

1.4.2 Standards

A standard may recommend to a manufacturer the information that should be included with a product, basic safety and performance criteria, and conformance measures that can be used to assess compliance. The inclusion of design specifications in a standard is permitted when circumstances warrant, but design specifications usually are avoided as they can hinder the advancement of technology.

A standard may provide clinical users with guidelines for the use, care, evaluation, or processing of health technology.

AAMI's standards require national consensus.

1.4.3 American National Standards

An AAMI standard designated as an "American National Standard" has been developed in accordance with ANSI's requirements for consensus, due process, public review, and ANSI review.

AAMI may choose to develop consensus standards without submitting them for ANSI approval as American National Standards.

1.4.4 Technical information reports

A technical information report (TIR) is a review of technical issues relevant to a particular technology and a statement of expert opinion. A TIR may include discussion of different sides of an issue or may be issued when a committee believes that the procedures for developing a standard would unduly delay the promulgation of needed information. A TIR may serve as an interim statement by a committee working to develop standards. A TIR also may provide additional guidance to an AAMI or American National Standard or advice on how a standard *might* be implemented.

A TIR represents committee consensus but is not subject to public review.

1.4.5 Other technical publications

The AAMI standards program develops technical communications tailored to the specific needs of its membership and the healthcare community at large. AAMI committees are not limited to the categories of technical publications described in the foregoing paragraphs but may choose to devise innovative approaches to education and technology assessment.

1.5 Metric policy

The use of International System of Units (SI) is preferred in all AAMI consensus documents. For situations where the SI unit is not commonly used or where the SI unit is not the term of art, the

more commonly used measurement or term of art may be used. The value in SI units, however, also may be included parenthetically.

2. Due process

2.1 Due process in the development of standards

Due process means that any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by expressing a position and its basis, having that position considered, and having the right to appeal. Due process allows for equity and fair play.

AAMI standards are developed by consensus, in accordance with policies and procedures designed to ensure due process. AAMI shall abide by all applicable requirements for due process provided in the *ANSI Essential Requirements: Due process requirements for American National Standards*.[2]

2.2 Consensus

Consensus means substantial agreement has been reached by directly and materially affected interests. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution. Consensus is achieved when individuals and organizations having a direct and material interest in a standard achieve substantial agreement according to the judgment of the AAMI Standards Board. Consensus does *not* require that all objections be withdrawn.

Establishing a consensus on a standard or TIRs entails the following:

a) substantial agreement by ballot among the members of the responsible consensus body;

b) appropriate public review (for American National Standards);

c) resolution of comments; and

d) concurrence that consensus has been achieved in the judgment of the AAMI Standards Board.

"Substantial agreement" is defined as minimum approval of at least two-thirds of those voting (excluding abstentions), with at least two-thirds of eligible voters returning ballots (including abstentions). However, the voting record of each interest category also may be considered.

2.3 Openness

Participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

2.4 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,

[2]Hererafter "*ANSI Essential Requirements*".

leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

2.5 Balance

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance, outreach to achieve balance shall be undertaken.

2.6 Coordination and harmonization

Good faith efforts shall be made to resolve potential conflicts between AAMI standards and existing standards promulgated by other standards developers.

2.7 Notification of standards development

Notification of the development of AAMI standards and TIRs shall be announced in suitable media as appropriate to afford an opportunity for participation by directly and materially affected persons.

2.8 Consideration of views and objections

Prompt consideration shall be given to the written views and objections of all participants, including those commenting during public review.

2.9 Consensus vote

Evidence of consensus in accordance with these requirements and, where appropriate, the *ANSI Essential Requirements*, shall be documented.

2.10 Written procedures

These *Policies and Procedures* shall be available upon request to any interested party.

3. Program organization

3.1 General

AAMI national standards and technical documents are developed by a consensus body (a technical committee or working group) assisted by staff and overseen by the AAMI Standards Board.

3.2 Technical Committees/Consensus bodies

Committees and working groups composed of volunteer technical experts are the heart of the AAMI standards program. Each AAMI committee has a defined scope of work and operates under established policies and procedures. An AAMI committee evaluates the need for standards and other technical publications within its area of competency. An AAMI committee also may assist staff in developing educational programs or may advise AAMI on responses to government initiatives and other public policy matters.

A committee may establish working groups to address particular technological areas within the scope of the parent committee.

AAMI standards are developed by a committee or working group acting as a consensus body. Consensus bodies provide the technical resources for developing, approving, and revising standards and TIRs.

Some committees, working groups, or subgroups not only serve as consensus bodies but also may act in an advisory, organizational, or oversight capacity in the standards process. The provisions given in this document governing organization, membership, participation, and operations of consensus bodies do not apply to groups when not acting as consensus bodies.

3.3 AAMI Standards Board

3.3.1 General

The Standards Board approves any revisions to the *AAMI Standards Program Policies and Procedures* and directs and supervises AAMI consensus body activities relating to the national standards program.

3.3.2 Membership

The members of the Standards Board are AAMI's Standards Program Head of Department (HOD) (nonvoting), and eight or more additional experts appointed at the discretion of the Standards Program HOD. The membership of the Standards Board should reflect balanced representation of interest groups and individuals should have preferably served at least one term as a consensus body cochair. Two individuals, preferably representing different interests, co-chair the Standards Board.

3.3.3 Terms

The chairs of the Standards Board serve three-year terms that are renewable at the discretion of the Standards Program HOD. Members serve three-year renewable terms. Under normal circumstances, members should serve on the Standards Board for no more than two consecutive terms, although additional terms may be approved by the Standards Program HOD.

Standards Board member and chair appointments may be terminated at any time by the Standards Program HOD should it become evident that the individual has insufficient time or resources to fulfill the responsibilities of the position, is not properly executing AAMI's policies and procedures, or is not abiding by AAMI policies. In such a case, the individual will receive written notification that the appointment has been terminated.

3.3.4 Responsibilities

The Standards Board determines whether AAMI policies and procedures have been followed in the development of standards and TIRs. The Standards Board’s responsibilities also include the following:

a) advising the AAMI Standards Program HOD on the appointment of consensus body chairs;

b) reviewing the progress of consensus body work;

c) authorizing new projects

d) authorizing the initiation and termination of consensus bodies and consensus body activities;

e) endorsing new or revised policies related to standards work (but are other than the AAMI Standards Policies and Procedures) for approval by the Board of Directors; and

f) hearing appeals of consensus body decisions.

3.3.5 Conduct of meetings

SB meetings are run by the chairs or standards staff. A quorum of 50% of voting members is required for a meeting. Voting members who are not able to attend a meeting for final action on a consensus document but wish to communicate an abstention or objection can do so in accordance with 6.7.4.

Meetings are conducted in accordance with general parliamentary principles and procedures, with some decisions made by motion and vote.

3.4 AAMI Board of Directors

The Board of Directors serves as the final AAMI appellate body for disputes concerning membership, procedures, standards or TIRs.

3.5 AAMI staff

AAMI staff manages the program on a day-to-day basis, advising consensus bodies on AAMI policies and procedures, scheduling meetings, maintaining records, preparing documentation, editing technical documents, administering ballots, overseeing public review, and coordinating consensus body and Standards Board activities.

3.6 AAMI Committee on Standards Strategy

The Committee on Standards Strategy (CSS) is a strategic committee whose primary goal is the development of safe and effective healthcare technology products, processes, and services. Membership is invitation only and limited to corporate members of AAMI. Other AAMI members may be appointed at AAMI's discretion. The chair of the Standards Board may be invited to participate as a non-voting member. There is no term limit for membership.

The CSS chair is selected by the Standards Program HOD from among the committee membership and serves a three-year term, which may be renewed once.

CSS member and chair appointments may be terminated at any time by the Standards Program HOD should it become evident that the individual has insufficient time or resources to fulfill the responsibilities of the position, is not properly executing AAMI's policies and procedures, or is not abiding by AAMI policies. In such a case, the individual will receive written notification that the appointment has been terminated.

4. Consensus body membership and structure

4.1 Definition of consensus body

A consensus body is a "group that approves the content of a standard and whose vote demonstrates evidence of consensus" (*ANSI Essential Requirements*).

When a committee or working group is actively developing and approving AAMI standards or TIRs, that group is acting as a consensus body.

4.2 Consensus body leadership (chairs)

4.2.1 General

Most AAMI consensus bodies have two chairs—one representing industry (see 4.5.2.1) interests and one representing non-industry interests (user, regulatory, general, or other interests). If suitable candidates from disparate interests cannot be found, two chairs from the same interest category may serve or the consensus body may be chaired by a single member.

4.2.2 Selection of chairs

The Standards Program HOD appoints consensus body chairs with appropriate consultation with the AAMI Standards Board and AAMI staff.

In the event that a consensus body has no chair and there is pressing business before the group, the Standards Program HOD may appoint an interim chair.

If a chair is not able to attend a meeting, an acting chair may be appointed by staff to lead the meeting.

4.2.3 Terms of chairs

The term of a consensus body chair appointment is for three years, renewable for a second three-year term. Additional terms may be approved by the Standards Program HOD in consultation with the Standards Board. All terms end either June 30 or December 31, whichever date occurs first following three years from start of term.

4.2.4 Qualifications of chairs

Consensus body chairs should be experts in the technology covered in the scope of the group. The industry chair of a consensus body shall be a representative of an AAMI corporate member, unless this requirement is waived by the Standards Program HOD. For non-industry chairs, preference is given to individual AAMI members and representatives of AAMI institutional members.

4.2.5 Responsibilities of chairs

Specifically, chairs are responsible for:

a) conducting committee meetings;

b) implementing the policies, objectives, and priorities of AAMI;

c) efficiently managing consensus body activities to ensure timely completion of work;

d) advising staff, when requested, on membership matters;

e) appointing task group members or other consensus body officers;

f) advising staff on technical and administrative matters relevant to the consensus body's work;

g) documenting consensus body meetings in the absence of AAMI staff; and

h) representing the consensus body at public meetings or hearings when requested by AAMI or appropriate standards department staff.

Unless authorized by appropriate standards department staff, consensus body chairs may not speak officially for AAMI.

4.2.6 Termination of chair appointments

A chair appointment may be terminated at any time by the Standards Program HOD should it become evident that the chair has insufficient time or resources to fulfill the responsibilities of the position, is not properly executing AAMI's policies and procedures, or is not abiding by AAMI policies. In such a case, the chair will receive written notification that the appointment has been terminated.

4.3 Consensus body size

There is no restriction on the size of consensus bodies.

4.4 Members of consensus bodies

4.4.1 Member qualifications

A consensus body member should have a direct and material interest in the work of the consensus body, either as an individual or through association with an organization. Members who do not have a direct and material interest also may serve as voting members, subject to AAMI approval, provided that they are knowledgeable about the subject of the consensus body's work or possess needed expertise. A consensus body member also must have sufficient time and resources to fulfill the responsibilities of membership and is required to review and vote on all balloted documents or proposals.

Consensus body members need not be individual members of AAMI or represent institutional or corporate members of AAMI; however, AAMI may impose cost-reimbursement fees on for-profit companies that are not corporate members of AAMI or on not-for-profit institutions (including associations, societies, government agencies and the like) that are not institutional members of AAMI.

Consensus body members also must provide adequate contact information. Because consensus body communications and documents are normally distributed electronically, members must have access to the Internet and a functioning e-mail address.

4.4.2 Representative members and alternates

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

a) The individual receives remuneration or expense reimbursement from an organization (a company or institution) to support, or in exchange for, participation in an AAMI consensus body.

b) The individual is expected to vote for or speak for an organization with respect to standards under development by the consensus body.

c) The individual is compensated to be an information source for an organization with respect to the activity of a consensus body.

A representative membership in a consensus body is held by the organization represented rather than the individual serving as a representative.

Organizations may appoint one voting representative per consensus body.

NOTE 1 A parent corporation and its divisions or subsidiaries are usually considered one organization for purposes of voting representation.

Organizations may appoint one alternate representative. An alternate's vote is counted only if the principal representative fails to vote.

Organizations also may appoint up to six non-voting representatives to a consensus body who can participate in the consensus body's work but do not have voting rights.

NOTE 2 With appropriate standards staff approval, additional non-voting representatives from a single organization may be permitted.

An organization or its representative can appoint a temporary alternate as a proxy representative to participate in specific meetings if the organization's primary and alternate representatives are unable to attend.

A single individual participating in AAMI consensus standards development may only represent a single organization.

4.4.3 Independent expert members

Qualified individuals who do not meet the criteria of representative members may serve on consensus bodies and vote on matters as independent expert members.

4.4.4 AAMI Consensus Body Member Code of Conduct

All participants in AAMI consensus bodies shall comply with the AAMI Consensus Body Member Code of Conduct (Annex A).

4.5 Interest categories (stakeholders)

4.5.1 General information

4.5.1.1 Classification scheme

Every consensus body member (stakeholder) shall be classified by interest category. AAMI recognizes five different interest categories: Industry, User, General, Regulatory, and Other. Consensus bodies should strive for participation from all affected interest categories. Members are classified by their overall interest (or the overall interest of the organization they represent) in the AAMI Standards Program's body of work rather than by their interest relative to the work of a specific consensus body or document.

4.5.1.2 Declaration of interest and disclosure of potential conflicts of interests

Consensus body members must declare the interest they represent on AAMI standards committees and must disclose all potential conflicts of interests. Consensus body members also shall comply with any applicable conflict of interest policies set by the AAMI Standards Board or the AAMI Board of Directors.

4.5.2 Stakeholder category definitions

4.5.2.1 Industry Interest category

A member of a consensus body who, as an individual or organizational representative, is involved in the commercial production, promotion, sale, use or distribution of materials, products, systems, or services covered in the scope of technical documents developed by AAMI shall be classified as an Industry Interest stakeholder. Individuals in this interest category include manufacturers, those involved in supply chains, employees of test labs or commercial labs, industry consultants, etc.

4.5.2.2 User Interest category

A member of a consensus body who, as an individual or organizational representative, purchases, utilizes or receives the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare shall be classified as a User Interest stakeholder. Individuals in this interest category include clinicians, employees or representatives of Healthcare Delivery Organizations, clinical consultants, patients, etc.

4.5.2.3 Regulatory Interest category

A member of a consensus body who, as an individual or organizational representative, is involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI shall be classified as a Regulatory Interest stakeholder. Individuals in this interest category would include those representing federal, state, local, foreign, or other government entities.

4.5.2.4 General Interest category

A member of a consensus body who, as an individual or organizational representative, has a general material interest in the materials, products, systems, or services covered in the scope of the technical documents developed by AAMI and who does not fit into any of the preceding categories shall be classified as a General Interest stakeholder. Individuals in this category would include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.

4.5.2.5 Other Interest category

A member who does not fit into any of the preceding interest categories but who still has an identifiable material interest in, or specialized knowledge of the materials, products, systems, or services covered in the scope of technical documents developed by AAMI in the delivery of healthcare shall be classified as an Other Interest stakeholder. The particular interest shall be declared and documented.

4.5.3 Categorization of membership associations

A membership association (e.g., trade association, professional society) shall be categorized according to the appropriate interest category of its members.

4.6 Selection of consensus body members

4.6.1 General

Members of a consensus body are selected by application or by invitation.

4.6.2 Terms

There is no set term for consensus body membership.

4.6.3 Application process

Any person wishing to join an AAMI consensus body must apply for consensus body membership. A completed application should be submitted to the AAMI Standards Department for review and approval by staff. Industry stakeholders shall disclose any corporate parent/subsidiary relationships and any financial relationships with concerned commercial entities. User, General, Regulatory, or Other Interest stakeholders shall disclose any potential conflicts of interest (e.g., consulting arrangements with manufacturers, service on a corporate board).

A potential conflict of interest does not necessarily disqualify an applicant from independent voting status on a consensus body.

If an applicant (or the organization represented by the applicant) clearly has a direct and material interest in the health technology products, processes and/or associated services covered in documents under development by the consensus body, the application may be approved by authorized AAMI staff.

4.6.4 Refusal of membership

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

a) The applicant (or organization represented) does not have a direct and material interest in the health technology products, processes and/or associated services covered by the consensus body.

b) The work of the consensus body is nearing completion.

c) The organization the applicant would represent already is fully represented on the consensus body.

d) For User, General, Regulatory, or Other Interest stakeholders, the applicant has a substantial relationship or conflict of interest that precludes granting independent voting status.

e) For Industry Interest representatives, the sponsoring firm is neither a corporate nor an institutional member of AAMI and is not willing to pay any required cost reimbursement fee.

f) The applicant refuses to complete the application fully or to disclose relevant financial relationships or possible conflicts of interest or provides incomplete or erroneous information in the application.

g) The applicant is not in compliance with or has previously violated the terms of the AAMI Consensus Body Member Code of Conduct, the AAMI Antitrust Policy, or the AAMI Patent Policy, these procedures, or other AAMI policies.

An applicant has the right to appeal if membership is denied. All the correspondences shall be directed to Standards Program HOD.

4.6.5 Responsibilities

Consensus body members shall actively participate in all consensus body business. In particular, they shall respond to all consensus body ballots in a timely manner. Regular attendance at meetings is desirable but is not required.

Consensus body members are responsible for notifying AAMI of changes in e-mail address or affiliation, and organizations represented on consensus bodies are responsible for advising AAMI of desired changes in representation.

4.6.6 Change of interest category or representation

To ensure lack of dominance, balance, and due process, the membership of any individual on a consensus body terminates when that individual's interest category or representation changes. Such a change shall be disclosed, and continued participation in the consensus body by that individual requires that the individual reapply in his or her new capacity.

4.6.7 Temporary designation of alternate

A consensus body member who cannot attend a meeting may designate a proxy for that meeting by notifying AAMI in writing in advance.

4.6.8 Non-voting representatives

Non-voting representatives to technical committees are representatives of an organization who receive all committee documentation but who cannot vote.

Standards staff approve Non-voting representatives and can deny or discontinue their membership for cause.

4.7 Termination of consensus body membership for cause

AAMI staff or the AAMI Standards Board may terminate an individual's or an organization's consensus body membership for lack of participation or interest, *especially for failure to record a vote or abstention on two consecutive letter ballots*. Substantive violation of AAMI policies, including violation of the AAMI Consensus Body Member Code of Conduct, the AAMI Antitrust Policy, or the ANSI Patent Policy, also is cause for termination of membership.

Failure to disclose a change in interest category or representation or to disclose a conflict of interest is grounds for termination of membership.

Membership in a consensus body also may be terminated if it is determined that the individual or company's continued membership or actions may be detrimental to the work of the consensus body, to the interests of AAMI, or to the public good.

Persons, institutions, or corporations whose voting representation on a committee has been terminated for any of the above reasons will be notified in writing and will retain all other rights afforded them by due process.

If AAMI is not able to contact a member or if a member cannot provide a working e-mail address, that individual's membership may be terminated without further notice.

5. Consensus body policies and operations

5.1 Patent policy

AAMI shall comply with the current ANSI patent policy.

5.2 Commercial terms and conditions

AAMI shall comply with the current ANSI policy for commercial terms and conditions.

5.3 Antitrust policy

AAMI shall comply with AAMI's Antitrust Policy (Annex B).

5.4 Intellectual Property policy

AAMI shall comply with AAMI's Intellectual Property policy (Annex C).

5.5 Transaction of consensus body business

Consensus body business is conducted via electronic correspondence, conference calls, web meetings, and face-to-face meetings.

5.6 Announcement of meetings

All consensus body meetings will be announced as early as possible but at least 30 calendar days in advance for face-to-face meetings. Teleconference or web meetings should also be announced as early as possible but not less than 15 calendar days in advance, except in unusual and urgent circumstances. An agenda and any necessary agenda materials should be distributed in advance of the meeting.

5.7 Conduct of meetings

Consensus body meetings are run by the chairs, standards staff, or a designee. There is no quorum requirement to hold the meeting, but absent consensus body members shall be given the opportunity to object to any final substantive actions relating to the disposition of a proposed document.

Meetings are conducted in accordance with general parliamentary principles and procedures, with some consensus body decisions made by motion and vote. Only voting members of the consensus body or a member's appointed alternate or proxy may vote at a meeting. Less consequential matters may be decided less formally.

Formal votes on consensus body approval of a candidate document as a standard or TIR shall take place electronically (not at meetings), and all consensus body members shall be afforded the opportunity to vote

5.8 Public participation in meetings

All AAMI consensus body meetings are open to the public; however, at the discretion of the chairs, it is permissible to limit comments to members.

5.9 Closed meetings

Meetings of standing consensus bodies shall *not* be held in closed session on matters related to standards or TIRs. Committee advisory groups or task groups may, however, conduct meetings in closed session.

5.10 Documentation of meetings

All consensus body meetings, including substantive actions taken by the consensus body, shall be documented by minutes or a brief report.

5.11 Distribution of documents

Meeting minutes, documents in progress, and other consensus body materials are normally distributed by AAMI staff. Only materials distributed by or with the explicit permission of AAMI staff are part of the official record.

Only meeting agendas and public review draft documents are publicly available. Other documentation from consensus body meetings may be shared outside of the consensus body membership on a case-by-case basis only after the explicit permission of AAMI staff.

5.12 Committee advisory groups

Consensus bodies may create committee advisory groups to advise the chairs in developing and directing the consensus body's program of work. The consensus body chairs appoint the members of a committee advisory group in consultation with AAMI staff or the Standards Board. Such boards should have balanced representation from significant interest categories and adhere to AAMI's policies for participation in AAMI Standards Program activities.

5.13 Task groups and project leaders

Task groups may be appointed by the consensus body chairs to address specific technical issues, research technical questions, organize work, or prepare early drafts. Assigning a project leader to write the first draft of a document or revise a working draft in response to consensus body input also is acceptable.

6. Development of consensus standards and TIRs

6.1 New Work Proposal

6.1.1 Initiating new work

AAMI shall make available a new work proposal form detailing information necessary to consider developing a new standard or TIR. To propose new work, a completed form shall be submitted to the AAMI Standards Department. Any individual or organization having a material interest may propose new work, but the work must be within the standards program's approved scope.

Whenever possible, a detailed outline or first draft of the proposed document should accompany the proposal.

AAMI staff will review all new work item proposals for completeness, clarity, and to ensure such work is not already in AAMI's program of work or that of another standards developing organization. Where appropriate, staff may request that proposals be amended to correct deficiencies, provide clarity, or respond to questions.

6.1.2 Evaluation and approval of new work

Proposals may be sent to appropriate parties within AAMI for review. Where appropriate, input may be sought from outside stakeholders with regard to the need and feasibility of the proposed work, as well as to determine whether AAMI is the appropriate organization to develop the work. Such review may include distribution to related AAMI committees, working groups, or other experts for evaluation.

6.1.3 Approval of new work

After completion of the evaluation, staff shall submit the new work proposal for consideration by the AAMI Standards Board with all received input from review and any observations by staff.

The Standards Board shall consider the need for the new work, the priority of the work for AAMI, the feasibility of completing the work, whether the work is in AAMI's scope, and whether AAMI has sufficient resources—including stakeholder participation and current consensus body workload—to undertake the new work. In addition, the Standards Board should consider whether a more appropriate technical organization should undertake the work.

The Standards Board approves the initiation of new work or the formation of a consensus body at an in-person meeting, conference call or web meeting. In order to be approved, at least two-thirds of those members participating in the meeting must support the proposal.

6.1.4 Conversion of a published TIR to an American National Standard

In the event that a consensus body agrees that a published TIR should be revised and converted to a standard, a new work item proposal form shall be completed and the approval process for a standard followed.

6.1.5 Creation and termination of consensus bodies

If the work does not fall under the scope of any existing AAMI consensus body, the AAMI Standards Board may authorize the formation a new consensus body to develop the proposed standard or TIR.

The Standards Board also may dissolve a consensus body and terminate its program of work, based on lack of progress, apparent lack of interest, or other cause.

The decision to dissolve a consensus body can be appealed.

6.1.6 Announcement of new consensus body or new work project

Upon Standards Board approval, new work items shall be publicly announced in AAMI publications, on the AAMI website, or by other appropriate means. For documents proposed as American National Standards, announcements shall comply with the *ANSI Essential Requirements*. Announcements of new work on prospective standards shall comply with the requirements for openness. Any comments resulting from these announcements will be addressed in accordance with 2.5 of the *ANSI Essential Requirements*.

6.1.7 Outreach

Standards staff shall perform and document outreach to materially affected parties to promote participation of affected stakeholders and a balance of interests on the consensus body.

6.2 Working Draft stage

The consensus body shall prepare the initial Working Draft in accordance with AAMI practices, procedures, and editorial style.

After the initial Working Draft has been prepared, the document is circulated to the responsible consensus body for review and comment. Written responses are not required to comments submitted at the Working Draft stage. The consensus body is not obligated to consider comments submitted after the comment deadline.

Comments from individuals outside of the consensus body (e.g., from another related AAMI consensus body) are not normally accepted at this stage but can be, at the discretion of the co-chairs. However, AAMI is not obligated to notify the commenter of their resolution.

Several iterations may be required at the Working Draft stage before advancing a TIR for ballot or a proposed standard for concurrent ballot and public review.

6.3 Committee ballot and public review (Committee Draft for Vote (CDV))

6.3.1 Decision to initiate ballot and public review

After a decision has been made that a document is ready for formal consensus body ballot and, for a standard, proposed public review, it is designated a CDV. The decision to issue a CDV can be made by the co-chairs or by a consensus of voting members present at a meeting (subject to approval by AAMI staff).

6.3.2 Formal consensus body ballot

Proposed standards or TIRs are voted on by the responsible consensus body only. Other consensus bodies may be offered the opportunity to comment on the draft document but may not vote on the documents.

All formal consensus body voting on the approval of a draft document as a standard or TIR shall be conducted electronically, and all members of the consensus body shall have the opportunity to vote.

AAMI staff conduct all approval ballots. A copy of the draft document with all necessary background information shall be distributed to voting consensus body members with instructions.

6.3.3 Ballot period

The ballot period for an approval ballot generally is six weeks. Shorter ballot periods are discouraged. No standard or TIR CDV approval ballot shall be less than three weeks.

6.3.4 Voting

Consensus body members may vote in the affirmative (e.g., “affirmative,” “yes,” or “approve”), in the negative (e.g., “negative," “no,” or “disapprove”) or may abstain. A consensus body member should vote in the affirmative if the member endorses the document whether or not his or her comments are accepted. A consensus body member should vote in the negative if substantive technical changes are necessary to resolve one or more of the member’s comments.

Negative votes shall be accompanied by comments; otherwise, they shall be recorded as “negative without comments” without further notice to the voter. Affirmative votes may include

comments; however, a vote of approval cannot be contingent upon acceptance of those comments.

Abstentions should be accompanied by an explanation.

All comments and objections, whether accompanying affirmative or negative ballots, shall be specific and include, at a minimum, the following information:

a) the clause, subclause, figure, or table containing the content in question;

b) the rationale for the objection;

c) alternative text that would resolve the objection; and

d) an indication as to whether the comment is technical, editorial, or general in nature.

If a comment does not contain a proposal that would resolve the objection, the consensus body must respond to the comment but is not obligated to resolve the objection.

6.3.5 Ballot return and approval requirements

For a ballot to be valid, at least two-thirds of the consensus body members shall record a vote or an abstention. For a document to be considered as approved, at least two-thirds of those voting (excluding abstentions) must return an affirmative vote (with or without comments).

6.3.6 Public review

Public review is a process by which proposed standards are made available for review by interested parties.

AAMI TIRs are not subject to public review.

Public comment is solicited by notice in appropriate AAMI publications or on the AAMI website and, for standards intended as American National Standards, by announcement in accordance with the requirements set forth in the *ANSI Essential Requirements*. This notice shall announce the proposed standard, state its availability for review and comment, explain how to obtain a copy of the document, and provide a deadline for submitting comments.

The public review period shall be in accordance with the provisions of the *ANSI Essential Requirements*.

AAMI public review periods may be extended at the discretion of the staff.

6.4 Consideration of and responding to comments

6.4.1 Return of comments

AAMI reserves the right to return for resubmission any ballot or public review comments that are not provided through a specified format or that reference a specific company, product, or product line other than the commenter's company or product, unless the comment refers to a section of a proposed draft that cites the specific company, product, or product line.

6.4.2 Response to ballot and public comments

6.4.2.1 Rationale for not accepting a comment

For any technical comment that is not accepted, the consensus body shall provide an explanation for the rejection in writing. If the comment is understandable, specific, and offers a rationale, the explanation shall explain a technical basis for rejecting the comment. The response may refer to an explanation provided in response to another comment. The consensus body's explanation for rejecting other types of comments may be of a more general nature.

6.4.2.2 Withdrawn comments

The consensus body 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 commenting member or alternate.

6.4.2.3 Late comments

The consensus body is not required to consider or respond to comments received after committee ballot or public review closure, when deciding whether to advance the document. Consensus body members that submit late comments shall be notified if their comments will not be considered and, if the document is to be reballoted, the late commenter shall be informed in that same communication that there will be another opportunity to provide input.

Late public review commenters shall be notified that they did not meet the deadline, but they may submit comments if there will be a subsequent public review.

6.4.2.4 Comments not related to the proposal undergoing ballot

The consensus body also is not required to consider comments that are not related to the proposal; however, such comments shall be documented with the resolution stating that the comment is not germane to the proposal under consideration. and the commenter invited to submit a proposal for new work.

6.4.2.5 Negative votes without comment

Negative votes without comments shall be treated in accordance with the provisions set forth in the *ANSI Essential Requirements*.

6.4.2.6 Unresolved objections

Unresolved objections exist when a negative vote is sustained by a member of the consensus body or when written comments submitted during public review have not been resolved in accordance with the provisions set forth in the *ANSI Essential Requirements*.

6.4.2.7 Distribution of responses

The compilation of comments and their resolutions shall be distributed electronically to all consensus body members. Each public review comment considered by the consensus body and its resolution shall be provided to the public review commenter.

6.5 Decision regarding further action

Following the resolution of comments, the consensus body may decide to either reballot the document or to move the document to the final approval stage. If the decision is made to reballot, the procedures in 6.3 and 6.4 shall be followed.

If the decision is made to move the document into the final approval stage, any substantive technical changes made to a draft standard as a result of the resolution of comments shall undergo public review. This provision does not apply to draft TIRs.

NOTE For the purposes of these procedures, ANSI's definition of "substantive change" from Annex A of the ANSI Essential Requirements applies.

If there have been substantive changes or there are outstanding objections to approval, submission for final approval is subject to final consensus body 15-day review (recirculation), following completion of subsequent public review(s), before submission to the AAMI Standards Board (see 6.6).

6.6 Final consensus body review and notice to public reviewers (final 15-day review)

NOTE For the purposes of this document, the term "final 15-day review" is equivalent to ANSI's term "recirculation" which is used in the *ANSI Essential Requirements*.

Members of the consensus body and any public reviewers with outstanding objections shall be informed of the decision to submit the document to the Standards Board and, if applicable, to ANSI. All consensus body members shall be provided with documentation of the voting results, resolutions of all comments from or subsequent to the last approval ballot and public review, and copies of any outstanding objections to the resolution of comments or final approval. Each public review comment considered by the consensus body and resolution shall be provided to the public review commenter.

Recipients shall be given a minimum of 15 calendar days in which to object to final approval of the document or (for members of the consensus body) to respond, reaffirm, or change their votes. New technical comments are not invited at this time, only objections based on the resolution of comments.

NOTE If someone did not vote during the ballot, that individual may cast a vote during final 15-day review as delineated by "respond" in the above statement.

The voting results at the end of final consensus body review/recirculation still must support consensus for the proposed document to be submitted to the AAMI Standards Board.

New, revised, or reaffirmed AAMI-authored TIRs with no negative votes and no substantive technical changes are not subject to this requirement.

6.7 Standards Board approval of final documents

6.7.1 General

Only the Standards Board can certify that AAMI standards or TIRs were developed in accordance with these *Policies and Procedures*, and authorize publication as final AAMI documents, or, if applicable, can authorize the submission of a document to ANSI for final approval as an American National Standard.

6.7.2 Procedural review

The Standards Board decision to approve a standard or TIR requires that consensus has been established in accordance with the *Policies and Procedures* and all ballot and public comments have received fair consideration and response. The Standards Board is not expected to conduct a technical review or technical evaluation of comments or objections, but they are expected to review the documentation to ensure that it conforms with AAMI polices.

6.7.3 Documentation

In its decision making, the Standards Board reviews the following documentation:

a) copies of all consensus body and public comments on the last approval ballot and public review;

b) the consensus body's responses to those comments;

c) any further comments from persons objecting to the disposition of their comments; and

d) objections to the finalization of the document and any other documentation that staff deems relevant.

6.7.4 Standards Board action

The Standards Board may take final action on a consensus document at a meeting or by electronic ballot. For electronic ballot, the following procedure applies:

a) All relevant documentation shall be circulated to the members of the Standards Board with the electronic ballot. The initial voting period is a minimum of 14 calendar days and subject to extension if insufficient response is received.

b) The ballot offers each member the opportunity to vote for final approval, to abstain, or to vote, with an explanation, for holding the matter for deliberation via a meeting or conference call/web meeting. Any vote to hold the decision for deliberation is honored.

c) Two-thirds (67%) of the voting membership of the Standards Board must return ballots in order for a vote to have a valid return.

When the SB takes a final action on a consensus document at a meeting, the following procedure applies:

a) All relevant documentation should be circulated to the members of the Standards Board a minimum of two weeks in advance of the meeting.

b) Decisions on final actions at a meeting shall be made by motion and votes of those voting members who are present.

c) Voting members who are not able to attend a meeting and wish to record a formal abstention or objection to approval of a final action shall communicate their position in writing to the AAMI staff no less than three business days in advance of the meeting, and must provide the rationale for such position. Voting members who are unable to attend the meeting and do not submit an objection or abstention with rationale by the deadline shall be considered as consenting to approval of a final action.

d) At least two-thirds of those voting in the meeting (excluding abstentions) shall vote to approve the final action in order for the motion to carry.

6.7.5 Denial of approval

If the Standards Board denies approval, the document is returned to the responsible consensus body along with explanation for the disapproval.

6.7.6 Notification to objectors

Any consensus body member or public reviewer maintaining an objection to approval of the standard or TIR shall be informed in writing or by email of the Standards Board decision to approve a document and, if appropriate, advance for ANSI approval. Those parties also shall be informed in writing or by email that appeal rights exist under these *Policies and Procedures* and that they may file an appeal in accordance with those procedures.

6.8 Publication

Consensus documents shall be published and made available as soon as possible upon final approval or reaffirmation. Publication of standards approved as American National Standards shall comply with the requirements given in the *ANSI Essential Requirements*. AAMI retains the right to withdraw any AAMI standard or TIR for any reason at any time, without further level of review.

6.9 Records

All records of the development and approval of any consensus document shall be maintained for a minimum of five years or until approval of the subsequent revision or reaffirmation of the document, whichever is longer.

Substantive and relevant records concerning withdrawn consensus documents shall be retained for at least five years from the date of withdrawal.

Substantive records of any American National Standard shall be kept in accordance with the requirements of the *ANSI Essential Requirements*.

6.10 Discontinuation of a standards project

AAMI may decide to abandon or discontinue the processing of a proposed new or revised standard or TIR or portion thereof at its own discretion and without a vote of the relevant consensus body.

For candidate American National Standards or technical information reports, the AAMI Standards Board shall be notified.

For candidate American National Standards, AAMI shall notify ANSI immediately of any such decision.

7. Additional procedures for development and maintenance

7.1 Interpretations of standards

The AAMI standards program does not provide non-consensus interpretations of its standards or TIRs. Any verbal or written interpretations provided by committee members, chairs, or other

authorities are their personal interpretations and not the official position of AAMI or of the responsible consensus body.

If clarification of a standard is necessary, the consensus body shall revise or amend the standard to provide this clarification. Any amendment or revision shall be developed following AAMI's full consensus procedures. Where deemed necessary, AAMI can develop a TIR to provide guidance on the application of a standard.

This provision does not prohibit the publication of corrigenda (errata) to correct clear and unambiguous errors in AAMI standards or TIRs.

7.2 Amendments of standards and TIRs

Amendments of published AAMI standards and TIRs may be proposed at any time. Requests for amendments shall be made in writing to the Standards department, shall offer specific text changes, and shall include rationale for the recommended changes. If the proposed amendment expands the scope of the original document, a new work item proposal shall be prepared and submitted to the Standards Board in accordance with 6.1.3.If the amendment does not modify the scope, the approval process shall be the same as for a standard or a TIR, whichever the base document is.

7.3 Periodic maintenance of standards

Within five years of the last approval of a current AAMI or American National Standard, the standard shall be balloted for reaffirmation to the responsible consensus.

For identical adoptions of an ISO or IEC standard, the procedures in clause 4.0 of the *ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards* apply.

If a consensus body proposes to withdraw a document at any time, this proposal will be balloted and placed on public review.

Ballot forms for periodic maintenance of AAMI documents shall include the following choices:

- Reaffirm the American National Standard;
- Reaffirm the American National Standard and start a Revision;
- Withdraw;
- Abstain.

Ballot forms for periodic maintenance of ISO or IEC adoptions shall include the following choices:

- Reaffirm the American National Standard and Confirm the international standard;
- Reaffirm the American National Standard and Revise the international standard;
- Withdraw both the American National Standard and the international standard;
- Abstain.

Contingency votes are not allowed. Comments shall be required when voting to reaffirm and revise or to withdraw.

The approval process for a reaffirmation or withdrawal of a standard follows that for the approval of a new standard except that reaffirmations without outstanding objections are not subject to Standards Board approval.

If any votes to withdraw are received, the recirculation process in 6.6 shall be followed.

7.4 Periodic review of TIRs

TIRs should be reviewed every three years to determine if the document should be maintained, withdrawn, revised, or advanced to become a standard.

Ballot forms for periodic maintenance of AAMI TIRs shall include the following choices:

- Reaffirm the Technical Information Report;
- Reaffirm the Technical Information Report and start a Revision;
- Reaffirm the Technical Information Report and initiate conversion to a standard;
- Withdraw;
- Abstain.

Contingency votes are not allowed. Comments shall be required when voting to reaffirm and revise or to withdraw. If any votes to withdraw are received, the recirculation process in 6.6 shall be followed.

7.5 Withdrawal for cause (administrative withdrawal)

The AAMI Standards Program HOD or the Standards Board can withdraw any AAMI standard or TIR upon showing objective evidence that one or more of the following conditions applies:

a) A significant conflict with another AAMI standard or TIR is identified and cannot be resolved.
b) ANSI's requirements for designation, publication, and maintenance were violated.
c) Supporting the document is contrary to the interests of the public or of AAMI.
d) The document contains unfair provisions or that due process requirements were violated in the document's development or maintenance.

Administrative withdrawal of any American National Standard shall comply with applicable provisions for administrative withdrawal set forth in the *ANSI Essential Requirements*.

7.6 Revisions

A proposal to revise a standard or TIR does not require a new work proposal form. The proposal to begin a revision of a standard or TIR shall be made to the consensus body that authored the document. If the proposed revision expands the scope of the original document, a new work item proposal shall be prepared and submitted to the Standards Board in accordance with section 6.1.3. The proposal to revise a standard or TIR, outside of the provisions of sections 7.3 and 7.4,

shall be discussed at a meeting (either in-person or remote), approved, and documented in a meeting report.

The initiation of a revision does not obviate the requirement for timely periodic review.

A revision of a standard or TIR otherwise follows the procedures detailed in section 6 of these *Policies and Procedures*.

The revision of any American National Standard shall comply with 2.5 of the *ANSI Essential Requirements* with regard to the submission of PINS form and announcement in ANSI Standards Action.

7.7 Continuous maintenance

Appropriate standards or TIRs may be maintained on a continuous basis with approval of the Standards Board. A consensus body proposing continuous maintenance for one of its documents shall prepare a documented program for periodic publication of revisions and timely consideration of each formally submitted request for change. Standards Board approval of the proposal and the program is required.

Continuous maintenance shall comply with all the applicable provisions of these *Policies and Procedures* and, for any American National Standard, with the applicable provisions of the *ANSI Essential Requirements*.

7.8 Provisional standards

AAMI may develop provisional American National Standards following the provisions set forth in Annex B of the *ANSI Essential Requirements*.

7.9 Adoption of international documents by AAMI

7.9.1 Adoption of international standards

For adoptions of ISO or IEC standards, the requirements set forth in the *ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards* and the applicable provisions from these *Policies and Procedures* apply with the following exceptions:

a) A new work proposal form is not required to adopt an International Standard produced by an ISO or IEC Technical Committee or Subcommittee for which AAMI holds the U.S. TAG, nor is Standards Board approval required. The appropriate consensus body may propose and initiate adoption.

b) Staff approval is required to adopt any document produced by an ISO or IEC Technical Committee or Subcommittee for which AAMI does not hold the U.S. TAG. Any such adoption shall comply with the *ANSI Policy Regarding Rights to Nationally Adopt ISO Standards or Otherwise Use IEC and ISO Material*.

c) The expedited procedures set forth in the *ANSI Procedures for the National Adoption of ISO or IEC standards as American National Standards* should be employed.

d) For parallel adoption, the consideration of comments concerns only which comments to submit (either as written or with modification) or reject for submission as part of the U.S. consensus position; however, the consensus body can decide

to accept a comment rejected internationally and publish the adoption with deviations.

e) For parallel adoption, the responses of the U.S. consensus body shall be provided along with the ISO or IEC documentation indicating how all comments (U.S. and non-U.S. comments) were resolved.

f) For parallel adoption of International Standards, the AAMI Committee Draft for Vote ballot and public review occur at the international Enquiry stage (Draft International Standard for ISO and Committee Draft for Vote for IEC).

g) Periodic maintenance shall follow the provisions for adoptions of International Standards set forth in the *ANSI Essential Requirements*.

AAMI also may adopt ISO or IEC Technical Reports or Technical Specifications as AAMI TIRs in accordance with the applicable procedures and provisions given above, but the adoptions shall be registered in accordance with the *Procedures for the Registration of Technical Reports with ANSI*.

8. Appeals

8.1 General

This section sets forth formal appeal mechanisms for the impartial handling of complaints regarding substantive procedural actions or inactions related to AAMI standards and TIRs. Procedural appeals cannot be based on simple error or omission but require substantive error, action, or inaction in the development process.

To appeal an action or inaction, an appellant shall demonstrate that his or her due process rights were compromised and shall have a direct and material interest that is or may be adversely affected.

8.2 Actions and inactions subject to appeal

The following actions may be appealed:

a) approval or denial of a new work proposal;

b) approval or disapproval of a document as a final or reaffirmed standard or TIR;

c) authorization or refusal to submit a document to ANSI for approval as an American National Standard;

d) withdrawal of a published AAMI standard or TIR;

e) establishment of a new consensus body or initiation of new work on a standard or TIR;

f) termination of a consensus body or cessation of work on a standard or TIR;

g) refusal or termination of membership on a consensus body;

h) termination of membership on SB or CSS;

i) dismissal of a consensus body, SB or CSS chair;

j) other substantive uncorrected committee actions that deny due process rights;

k) substantive procedural inactions, not covered above, that violate the due process rights of the adversely affected party.

8.2.1 Fee

The fee for an appeal with the Standards Board is $1,500 (U.S.) payable by the appellant. The fee for a subsequent appeal with the Board of Directors is an additional $1,500 (U.S.).

Fees are payable by the appellant within seven calendar days of notification of the decision by the appeal body (the Standards Board or the AAMI Board of Directors) to hear an appeal.

An appellant may request that AAMI reduce, waive, or refund these fees and shall provide a rationale for this request (e.g., demonstrable financial hardship). The decision to reduce, waive or refund any appeal fee will be made by the AAMI Standards Program HOD after review of the request and rationale.

8.3 Appeal procedure

8.3.1 Appeal to the AAMI Standards Board

8.3.1.1 Filing of an appeal

An appeal of a covered action shall be filed within 15 calendar days of notification of the action.

There is no deadline for appealing a procedural inaction.

The appeal shall state the nature of the objection, including the details of the denial of due process rights, the real or potential adverse effects upon the appellant, the actions or inactions at issue, and the specific remedial action that would satisfy the appellant's concerns. Previous efforts to resolve the objection and the outcome shall be reported. Upon the filing of a properly executed appeal, the responsible consensus body and Standards Board are notified, and the original action is suspended until the appeal can be resolved or considered.

8.3.1.2 Initial staff review of the appeal (informal resolution phase)

Within 30 calendar days of the filing of an appeal, AAMI staff shall make a preliminary determination as to whether a substantive error or omission occurred that violated the appellant's due process rights. If staff determines that a procedural error or omission appears to have occurred but is correctable by further consideration or action of the consensus body, staff will consult with the Standards Board and chairs of the consensus body to determine what action can be taken to cure any real or potential adverse effect.

If, in staff's estimation, a remedy cannot be agreed upon by the parties or if staff cannot establish that a procedural omission or error occurred, the appeal shall be submitted to the Standards Board with all relevant documentation.

8.3.2 Standards Board consideration of the appeal

The Standards Board will be asked to review the appeal to determine if significant evidence exists of a substantive procedural error or omission that violated the due process rights of the appellant and that created potential or actual harm to the appellant. A decision by the Standards Board to hear an appeal requires approval by a majority of the Standards Board by ballot or at a meeting. When the Standards Board reaches a decision, the appellant and the responsible committee are notified in writing within 60 calendar days of the filing of the appeal.

If the Standard Board decides not to hear the appeal, the appellant may submit his or her appeal to the AAMI Board of Directors as detailed below.

If the Standards Board agrees to hear the appeal, a hearing will be scheduled in accordance with the following provisions.

8.3.2.1 Standards Board hearing

The Standards Board shall set a time to hear the appeal via a face-to-face meeting, web meeting, or conference call within six months of the date on which the appeal was filed (or on a date mutually agreeable to all parties). The appellant and the responsible committee shall be invited to be represented at the hearing with at least 30 calendar days' notice. Any committee member or other materially interested party may attend the public portion of the appeal hearing, provided advance notice of attendance is given. Upon hearing all arguments, the Standards Board will decide the matter in closed session. A two-thirds vote of eligible Standards Board members is required to modify an original action or position.

8.3.3 Notification of Standards Board decision

Standards Board decisions on appeals are rendered *only* in writing. The appellant and the responsible committee shall receive written notification of the Standards Board decision and reason(s) thereof within 15 calendar days of the decision.

8.4 Appeal to the AAMI Board of Directors

8.4.1.1 Filing of an appeal to the Board of Directors

An appeal to the AAMI Board of Directors shall be filed in writing within 15 calendar days of notification of the results of an appeal to the Standards Board 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 of Director by ballot or at an electronic or in-person meeting. The complete Standards Board case file shall be made available to the Board of Directors for consideration in reaching a decision on whether to hear the appeal. When the Board of Directors reaches a decision, the appellant and the responsible committee shall be notified in writing.

8.4.1.2 Board of Directors hearing

If the Board of Directors agrees to hear an appeal, the appellant and the responsible committee are invited, with at least 15 calendar days’ notice, to be represented at the hearing. The hearing may be held in person or via a web meeting or conference call. The chairs of the Standards Board participate in the Board's deliberations without vote. Any consensus body member or other interested party may attend the public portion of the appeal hearing with advance notice to the Standards Program HOD. Upon hearing all arguments, the Board of Directors will decide the matter in closed session. To reverse a Standards Board decision, a majority vote of all eligible voting members of the Board of Directors is required.

8.4.1.3 Notification of Board decision

Board decisions on appeals are rendered *only* in writing. The appellant, the responsible committee, and the Standards Board shall receive written notification of the Board of Directors' decision within 30 calendar days of the appeal hearing.

8.5 Appeal of ANSI decisions on American National Standards

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

Annex A – AAMI Consensus Body Member Code of Conduct

This AAMI Consensus Body Member Code of Conduct (Code) is adapted from the *ISO Code of Conduct for the technical work*.

The goal of this Code is to facilitate AAMI's standards development work—work that is carried out in a multi-stakeholder environment. The Code also is intended to ensure that consensus body deliberations are conducted in a respectful and professional manner by all parties.

It applies to anyone who chooses to participate on an AAMI consensus body. The Code is an obligation for participation.

As participants in AAMI's standards program, we acknowledge the responsibility and value of participating in the development of standards and TIRs. We therefore adhere to this Code in accordance with the terms below.

Work for the net benefit of the healthcare community	We recognize that the development of standards is for the net benefit of the healthcare community, over and above the interests of any individual or organization. We are committed to advancing standards within their agreed scope, and we will not hinder their development. We support AAMI's goal of advancing patient safety and health technology.
Uphold consensus and governance	We will uphold the key principles of AAMI's standardization: consensus, due process, honesty, openness, transparency, fairness, effectiveness, relevance, and coherence.
Agree to a clear purpose and scope	We are committed to having a clear purpose, scope, objectives, and will work to ensure the timely development of standards and technical documents.
Participate actively and manage effective representation	We agree to actively participate in standards development projects. We will make our contributions to the work according to the *AAMI Standards Department Policies and Procedures*.
Escalate and resolve disputes	We will identify and escalate disputes in a timely manner to ensure rapid resolution. We will uphold the agreed dispute resolution processes.
Behave ethically	We will act in good faith and with due care and diligence. We will avoid collusive or anticompetitive behavior. We will promote a culture of fair and ethical behavior.
Respect others	We are committed to respecting all others engaged in the development of AAMI standards and technical documents and the professional culture of standards development by: • conducting ourselves in a professional manner; • respecting others and their perspectives; • accepting group decisions and consensus; and • ensuring that the views of all are heard and understood.

Annex B – AAMI Antitrust Policy

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 health technology.
3) Preparing and disseminating among its members and others accurate and reliable information concerning the health 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 June 2021
By the AAMI Board of Directors

Annex C – Policy on Use of AAMI Intellectual Property

This document defines AAMI's policy on certain permitted uses of AAMI-owned or controlled intellectual property (IP) and specifies the means by which AAMI may protect its IP rights. AAMI's IP includes its trademarks and copyrights found in publications such as the standards developed and adopted by AAMI as National Adoptions of international Standards (AAMI Standards), technical information reports, practical information, support and guidance offered by AAMI and may be in physical or electronic forms such as books, periodicals, newsletters, courses and continuing education seminars and materials (collectively, AAMI IP). AAMI's IP is a valuable resource that AAMI offers to its members and to the health technology industry and that must be protected to ensure its longevity and availability. It is the responsibility of AAMI's Board of Directors, staff, members, and other industry stakeholders to protect this resource and ensure that it is used in accordance with this policy.

AAMI GUIDANCE ON THE USE OF IP

1. Notwithstanding the limitations of this policy, licensees may use the content of AAMI Standards and other AAMI IP in accordance with the written license agreement entered into between them and AAMI when they purchased or otherwise licensed that IP.

2. Individuals and entities may freely cite to or reference AAMI IP and are encouraged to do so.

3. In no event may any individual or entity duplicate, publish, quote, print or otherwise communicate the entire content or substantially all of the relevant portions of any AAMI IP without prior written permission from AAMI , with the exception that an AAMI Standard may be submitted to a regulatory body solely for the purposes of meeting specific regulatory requirements and/or for the internal use of the regulatory body. This should be considered a limited license solely for the purpose of assuring that regulators and the regulated receive the full benefit of AAMI Standards during a regulatory process. When submitted to a regulatory body under this section an AAMI Standard must maintain any and all copyright notices and other notices identifying the standard as a National Adoption together with an indication of the origin of the text.

4. An individual or entity may quote, print, or otherwise communicate a portion of the content of an AAMI Standard necessary and relevant to the use without prior written permission from AAMI if the following conditions are met. AAMI reserves the right to evaluate in its sole discretion whether all conditions are satisfied. AAMI further reserves the right to revoke or modify the permissions granted under this section at any time.

    4.1. The use is not for a commercial or for-profit purpose which may or does deprive AAMI of income.

    4.2. The use cannot state or imply AAMI endorsement of any products or services.

    4.3. The use cannot state or imply that AAMI, in any way, represents that any products or services meet or exceed AAMI Standards or recommendations, nor can the use imply

any form of AAMI endorsement of anyone's expertise pertaining to AAMI IP, its products or services.

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Revised and Approved by the AAMI Board of Directors
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