AAMI
Guide for New Committee Members

What members need to know

May 2019

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Contents

Welcome to AAMI

Congratulations on being appointed as a member of an AAMI technical committee.

The purpose of this guide is to help you to participate effectively in AAMI's technical work.

Section A of the document provides information about AAMI and the standards development process. Section B outlines the expectations of you as a participant in the AAMI standards process. Section C is a list of resources that are available to you.

This guide is an overview and subject to update at any point. The most important information for your AAMI committee work is covered in Section B. If you are already familiar with AAMI and the standards development process, feel free to skip the background in Section A.

A. Introduction to AAMI

A.1 Mission Statement

AAMI provides global leadership to support the healthcare community in the development, management, and use of safe and effective healthcare technology.

The Board of Directors recently approved a Strategic Plan for FY 2018-2020 that sets the direction of the organization through the development of the vision, mission, goals, and objectives.

A.2 What is AAMI?

The Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization founded in 1967. It is a diverse community of over 7,000 professionals united by one important mission—the development, management, and use of safe and effective health technology. AAMI is a considered a professional society, not a trade association.

AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals. AAMI is a consensus-building forum rather than an advocacy organization.

AAMI helps members:

- contain costs;
- stay on top of new technology and policy developments;
- add value in healthcare organizations;
- improve professional skills;
- enhance patient care.

AAMI provides a unique and critical forum for a variety of professionals including clinical and biomedical engineers and technicians, physicians, nurses, hospital administrators, educators, scientists, manufacturers, distributors, government regulators, and others with an interest in healthcare technology. AAMI fulfills its mission through:

- Courses, conferences, and continuing education, including certification programs.
- Collaborative initiatives, including summits with the FDA
- A rich array of resources, including peer-reviewed journals, technical documents, books, videos, podcasts, and other products.

A.3 Who is AAMI?

The more than 7,000 members of AAMI are individual members or representatives of health care delivery organizations, medical device industry, test houses, academic institutions, and government agencies.

AAMI committees are made up of:

- nurses, doctors, and biomedical engineers,
- regulatory affairs professionals and research and development engineers,
- quality systems and risk analysis professionals,
- academic and government researchers,
- FDA representatives,
- test house empolyees,
- consultants.

A.4 AAMI Organizational Structure

A.4.1 Board of Directors

AAMI's organization structure consists of a hierarchal structure led by the AAMI president and governed by an elected AAMI Board of Directors. The Board of Directors establishes and revises the AAMI Standard Program Policy and Procedures and serves as the final appellate body for AAMI to resolve disputes related to standards. These are voluntary positions and Board of Director members serve for three-year renewable terms.

A.4.2 Committee on Standards Strategy

The Committee on Standards Strategy (CSS) serves as the conduit through which the AAMI Corporate Member community provides insight and guidance into the current and future strategic priorities for AAMI's domestic and international standards program, thus ensuring the lasting success of the standards program.

Membership on the CSS is by invitation only. There is no limit on the number of companies that can be represented at the CSS however, the company must be an AAMI corporate member (or be willing to join AAMI). There are no limits on the length of time a company or its designated representatives, can hold a position on the CSS so long as the company is an AAMI member in good standing.

A.4.3 Standards Board

The AAMI Standards Board directs and supervises responsibility of all AAMI Technical Committees. AAMI Standards Board members serve three-year renewable terms and are appointed by the Senior Vice President (SVP) of Standards Program and Policy. The Standards Board advises the SVP on cochair appointments, reviews progress of committee work, authorizes the initiation of new work item proposals or the termination of activities, and hears appeals of committee decisions. The Standards Board is the only group that can authorize new committees or new work item projects and provide the final approval of completed documents. These are voluntary positions.

A.4.4 AAMI Staff

The AAMI staff manages the day-to-day aspects of AAMI programs, including advising committees on AAMI policy and procedures, scheduling meetings, maintaining records, preparing committee documentation, revising draft documents based on committee comment resolutions, and implementing the balloting and public review process in addition to generally coordinating committee and Standards Board activities.

AAMI staff also serves as the interface (where appropriate) with the process relating to ISO and IEC documents and relationships. AAMI staff assumes most of the responsibility for communicating with committee members when assigning and collecting committee work tasks.

A.5 AAMI Standards Committees

A.5.1 Overview

AAMI currently has approximately 150 committees and working groups that develop technical documents in a wide array of areas. Device standards address safety and performance of specific devices (e.g., infusion pumps, patient monitors, etc.). Horizontal standards apply across device types (e.g., sterilization, biological evaluation, electrical safety, etc.).

Many of the AAMI committee have international counterparts in IEC or ISO. U.S. participation on the international committee is managed through each AAMI committee.

AAMI committees and working groups are considered consensus bodies in the standards development process.

A.5.2 Cochairs

The AAMI committee cochair position is a voluntary position with individuals nominated by AAMI staff or selected by a call for nominees, approved by the AAMI Standards Board and finally appointed by the President of AAMI. AAMI cochair positions are filled by a wide range of individuals who typically represent one of the following AAMI stakeholder categories: a user facility, individual or group; a medical device producer/manufacturer; or a general interest or regulatory member with expertise in the area of the designated committee. The term of appointment of a cochair is three years, with a reappointment option for a total term not to exceed two consecutive terms in ordinary circumstances.

A.5.3 Committee Membership

Committee members either apply for membership to a standards committee or are appointed by their company representative to AAMI. Members should have a direct interest in the work that the committee is responsible for, as well as the time and resources needed to participate in the work of the committee.

Committee members fall into one of the following five stakeholder categories:

Industry: an individual or organizational representative who is involved in commercial activities related to the technical documents developed by AAMI (includes test houses and commercial labs).

User: an individual or institutional representative who uses the materials, products, systems, or services covered by the technical documents developed by AAMI.

General interest: an individual who has a general/noncommercial interest in the materials, products, systems, or services covered by the technical documents developed by AAMI.

Regulatory: an individual who is involved in the regulation of the materials, products, systems, or services covered by the technical documents developed by AAMI.

Other: an individual who does not fit into the other categories but still has an identifiable material interest or specialized knowledge of the materials, products, systems, or services covered by the technical documents developed by AAMI.

A.5.4 Committee Member Roles

There are three possible positions for a committee member to be in:

- Primary voting
- Alternate voting
- Organizational member liaison

Primary voters are those people who are responsible for submitting a company position and comments on any ballot that has been initiated. Alternates may submit a company position and comments if the primary is not available. Each company is limited to one vote but comments may be collected from other subject matter experts within the organization and submitted under the voting member's name.

Organizational member liaisons receive access to the committee documents but are not eligible to vote.

Individuals in the user or general interest category typically serve on the committee as independent experts.

A.6 Overview of the Development Process

A.6.1 Types of Documents

A.6.1.1 Standards

The purpose of a medical device standard is to assist the healthcare professions and industry with the performance, use, acceptance, and advancement of medical technology. The guiding philosophy is, "One product, one standard, one test worldwide." The fundamental tenet of a standard is to contribute to the quality of patient care. Medical device standards describe performance and test requirements for devices. User-oriented standards are intended to promote safe use, application, and maintenance of medical instrumentation in a health care delivery setting. These types of standards primarily rely on device manufacturers' instructions for use and are not intended to supersede existing clinical practice guidelines. These types of documents are generally considered normative.

A.6.1.2 Technical Information Reports

Technical Information Reports (TIRs) are informative documents, not normative standards. These documents may be used as support for a standard, as a "pre-standard," or to address a particular aspect of medical technology or new technology. Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it. A TIR is not subject to the same formal approval and review process as a

standard. However, a TIR is approved for distribution by an AAMI technical committee and the AAMI Standards Board. A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

A.6.2 Document Development Stages

A.6.2.1 General information

A basic principle of all standards work is openness and transparency with due process afforded to all stakeholders and interested parties. Besides specific areas of expertise represented by committee members, discussions and deliberations leading to a consensus decision should be guided by available objective, evidence-based published literature or other standards. The collected evidence base may also include databases maintained by regulatory or professional organizations. Other types of information may contribute to the documents, including additional published literature, manufacturer's data, and "round robin" testing.

A.6.2.2 New Work Item Proposals

A proposal to create a new standard or TIR starts with filling out an AAMI New Work Item Proposal (NWIP) form. A NWIP can originate from within a committee or can be submitted by an outside party. NWIPs should contain supplementary information such as a rough draft or outline. Committees should discuss the proposal and address any comments or concerns before informing AAMI staff that the package is ready to submit it to the AAMI Standards Board for approval. All proposals for new work must be approved by the AAMI Standards Board before work can proceed.

A.6.2.3 Working Draft

After approval of a NWIP, the first task is to develop a Working Draft (WD) of the document proposed in the NWIP. Typically, the WD is generated by a task group that includes a project leader and one or more committee members chosen for their expertise in a specific area. Once drafted, the WD is circulated to all members of the committee for additional input. Working drafts are not formally balloted.

Comments are submitted on the comment template form, which includes columns for the member's name or member body providing input, specific reference to the part of the WD for which the input is intended, type of comment (general, substantive, or editorial), the comment itself, and the proposed change. A link to the comment form is included with the circulation notice. The comment then meets (face-to-face or electronically) to discuss the comments and accept or not accept them. Accepted comments are incorporated in to the draft document.

A.6.2.4 Committee Draft

Once the committee agrees that the document is ready for vote, the revised draft is circulated to the committee as a Committee Draft (CD) for formal review. The formal review can be either a call for comments or a formal ballot. There are two levels of a committee draft: a committee draft that is circulated for comment only (CD), and a committee draft for vote (CDV).

Documents are typically circulated for review/vote for six weeks, however the period can be shorter or longer at staff discretion. A standard that is out for CDV ballot and intended to be processed as an American National Standard is also submitted to ANSI for notification of public review and comment (notification published in the ANSI Standards Action).

All comments are collected by AAMI staff, collated, and provided to committee members. The committee then considers all comments at a meeting (face-to-face or electronic) to resolve the comments, consider the voting results (if a CDV), and advance the draft to the Final Draft stage if appropriate. If significant substantive technical comments on a balloted document are accepted by the committee, another ballot is required.

A.6.2.5 Final Draft

After the committee considers all comments, the changes are incorporated into the draft document which is now considered a Final Draft (FD). The FD is circulated for a final 15-day committee review. Final committee review gives members the opportunity to verify that all resolutions to comments have been incorporated into the document as agreed and to identify typographical errors. No new comments are accepted at this stage. The FD is then submitted to the AAMI Standards Board for its approval as an AAMI standard or TIR. Following approval, standards are submitted to ANSI for approval as an American National Standard. The document is then published by AAMI as soon as possible. See Figure 1 and Table 1.

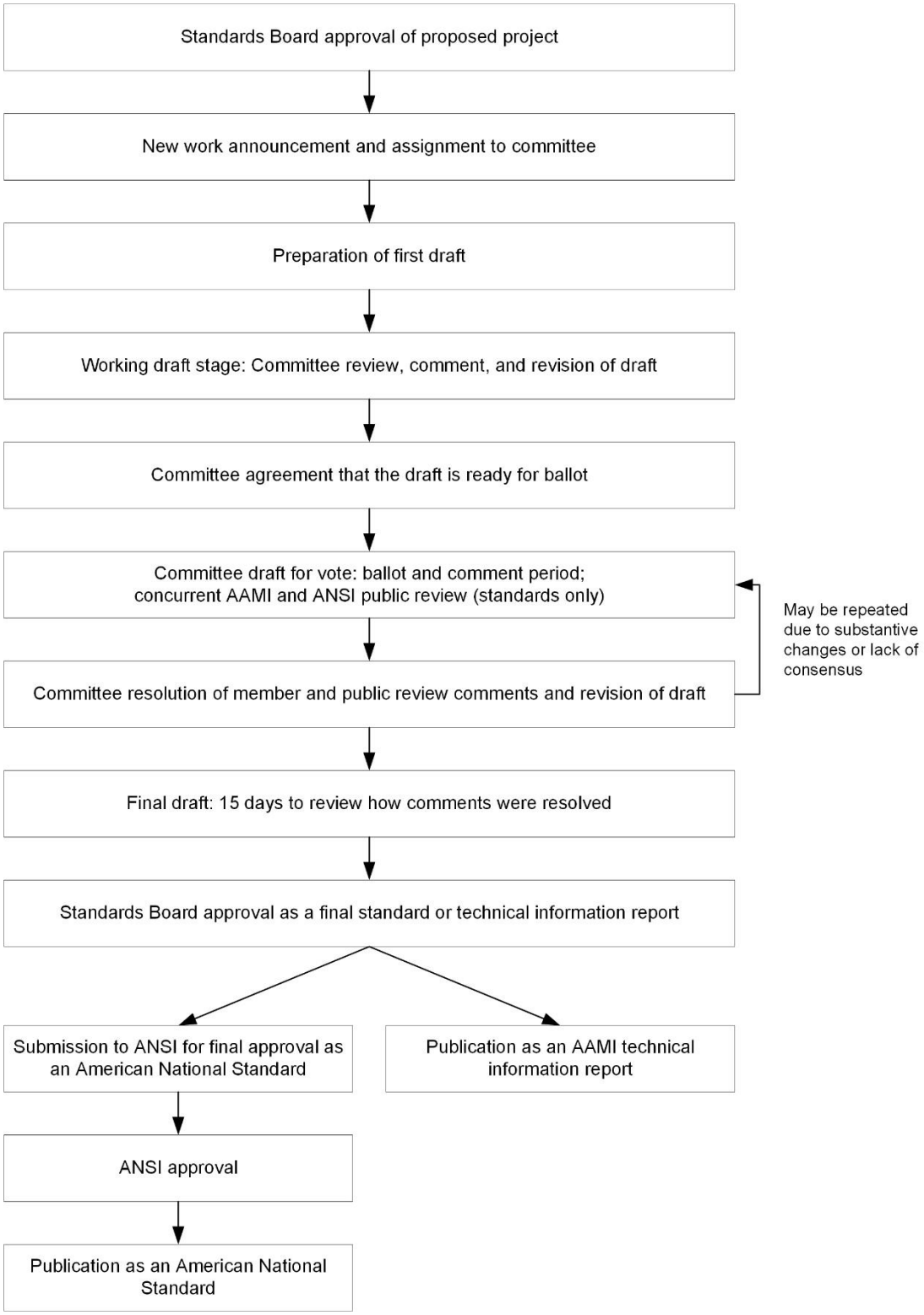

Figure 1 — Steps in the development and approval of an AAMI standard or TIR

Table 1 — AAMI document development stages and typical timeframes

STATUS	ASSOCIATED DOCUMENT		
Document stage	**Name**	**Abbreviation**	**Typical development duration**
Proposal stage	New Work Item Proposal	NWIP	6-12 months
Preparatory stage	Working Draft(s)	WD	12-18 months
Committee stage	Committee Draft(s) for comment	CD	6 months
Committee stage	Committee Draft(s) for Vote and public comment	CDV	6 months
Approval stage	15-day review of Final Draft with committee resolution of comments	FD	6 months
Publication stage	Standard or Technical Information Report	ANSI/AAMI or ANSI/AAMI/ISO (or IEC) Standard or AAMI TIR	Within 6 months of Approval

A.6.2.6 Periodic Review of Published Standards and TIRs

All technical documents are required to be reviewed to ensure that the technical information is still relevant and valid. Standards are reviewed every five year and TIRs are reviewed every three years. See AAMI Standards Program Policies and Procedures Manual for detailed information on this procedure.

B. What is Expected of Committee Members

By assuming an AAMI committee member position, you are obligated to actively participate in the workings of the committee business. The following section outlines what active participation means and what policies committee members are obligated to follow.

B.1 Participate in decision making

All members are expected to actively participate in committee business. Regular attendance at meetings is ideal but is not a requirement. Committee membership does, however, include the responsibility of providing input throughout the standards development process. This is done by attending meetings when possible, commenting on draft documents, voting, meeting deadlines, and staying informed of committee decisions by reviewing meeting reports and other committee documentation.

Members who do not vote on two consecutive ballots may be removed from the committee for non-participation so it is vital to be aware of committee business.

Further guidance on voting and commenting can be found online.

B.2 Adhere to the policies and procedures

There are a number of polices that are in place to protect both AAMI and committee members.

AAMI Standards Program Policies and Procedures: Outlines in detail the operations and structures used by AAMI to develop technical documents in an environment that ensures due process is followed.

Anti-trust policy: AAMI meetings cannot be used, in violation of antitrust laws, to discuss pricing, division or allocation of sales territories/customers, establish blacklists or boycotts of suppliers/purchasers/competitors, coerce members or others to implement particular programs or policies, resolve problems in an arbitrary or unreasonable manner or based solely on the needs of a single party or small group.

Consensus body member code of conduct: The goal is to facilitate AAMI's standards development work and to ensure that the work of the committee is conducted in a respectful and professional manner.

Conflict of interest: Ensures that all members present at meetings fully disclose any potential conflict of interest.

Patent policy: Outlines how patents that are included in technical documents are to be handled.

Guidance on the use of AAMI standards: Copyright policy that states under what circumstances portions of standards can be used freely and when reprint permission is required.

Committee members are expected to comply with all AAMI policies and procedures.

B.3 Inform AAMI of changes in names/addresses/company affiliations

In addition, committee members are responsible for notifying AAMI of changes in address or status. 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. Email standards@aami.org for assistance.

C. Tools and resources

C.1 Committee Central

Committee Central is a web-based platform maintained by AAMI to manage standards projects and facilitate communication among committee members and AAMI staff. All committee documentation and stages are processed through Committee Central. You can locate relevant information regarding the status of documents under development or in publication, membership rosters, member comments on specific documents under development. Online balloting is also conducted through Committee Central.

Access to Committee Central is password protected and accessible only to members of the official roster of the specific committee.

C.2 Useful links

- How to join a Technical Committee
- Full list of technical committees
- List of scheduled meetings
- Password reset / forgot password

C.3 Standards Department Staff list

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C.4 Acronyms

AAMI Association for the Advancement of Medical Instrumentation

ANSI American National Standards Institute (US national standards body member of ISO and IEC, accredits AAMI's standards program)

CD Committee Draft (used in AAMI, ISO, and IEC)

CDV Committee Draft for Vote (used in both AAMI and IEC, equivalent to DIS)

DIS Draft International Standard (used in ISO, equivalent to CDV)

FD Final Draft (used in AAMI)

FDIS Final Draft International Standard (used in ISO and IEC)

IEC International Electrotechnical Commission

ISO International Organization for Standardization

NSB National standards body

NWIP New work item proposal

SDO Standards developing organization

SR Systematic review (used in ISO)

TC Technical committee (used in ISO and IEC)

TR Technical Report (used in ISO and IEC, equivalent to a TIR)

TIR Technical Information Report (used in AAMI)

TS Technical Specification (used in ISO and IEC)

WD Working Draft

WG Working group