

GUIDE FOR **COCHAIRS**

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Association for the Advancement of Medical Instrumentation
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Foreword

Cochairs play a critical role in the development and adoption of AAMI standards. Cochairs are selected from representatives of industry, government, and the user community. In their capacity as cochairs, these healthcare professionals lead a work group of colleagues through the process of drafting, reviewing, editing, and finally publishing what are considered best practices for the industry. As part of their duties, cochairs play an important role in communicating the value and meaning of AAMI standards to stakeholder groups inside and outside of AAMI.

Because cochairs are drawn from various stakeholder groups within the healthcare industry, they understand the needs and the culture of those who will implement the standards. However, cochairs are subject matter experts and not standards development specialists. To draw upon the widest pool of potential leaders, AAMI has an interest in developing and mentoring new cochairs who are inexperienced in leading a standards development process. AAMI staff are professionals in the standards development process and provide direct assistance to cochairs in executing the key responsibilities of the role.

To further the goal of providing guidance to AAMI cochairs, both experienced and inexperienced, AAMI has written a reference guide to help these essential participants in the AAMI process better understand their role and perform their duties.

The concepts incorporated in this guide should not be considered inflexible or static. This guide will be reviewed and updated periodically to reflect best practices in leading standards committees and working groups. It will also draw upon the experience and recommendations of AAMI cochairs.

This guide is intended to provide guidance only for AAMI committee and working group cochairs; it is not applicable to ISO or IEC working group convenors. Suggestions for improving this guide are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road., Suite 300, Arlington, VA 22203 or standards@aami.org.

AAMI Cochairs Guide

1 Scope

This document is intended to provide AAMI cochairs with a guide for managing the various aspects of the cochair position. It includes information on appropriate considerations and methods. It provides a short overview of AAMI as it relates to standards committees and includes information regarding the selection and responsibilities of cochairs, as well as pointers on how to prepare for and run meetings. This guide presumes a level of familiarity with the AAMI standards development process however an overview has been included as Annex A.

The intended readers of this guide are newly designated cochairs of AAMI committees. This guide may also serve as a helpful reference or refresher to current or previous cochairs on current AAMI policy and direction.

NOTE Except where noted, for the purposes of this guide, “committees” refers to both committees and working groups.

2 Fundamental principles of standards development

(taken from the [AAMI Standards Program Policies and Procedures](#))

2.1 Due process

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.

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.

2.3 Openness

Participation shall be open to all persons who are directly and materially affected by the activity in question.

2.4 Lack of dominance / Balance

The standards development process should have a balance of interests and not be dominated by one stakeholder group. Participants from diverse interest categories will be sought with the objective of achieving balance. If a consensus body lacks balance, outreach to achieve balance shall be undertaken.

3 AAMI standards committees

3.1 Overview

Committees are consensus bodies that are formed to develop standards in a particular area and working groups are consensus bodies that are appointed to undertake specialized technical work under the auspices of the main committee. Standing working groups may be established to perform ongoing work in particular technological areas within the general scope of a parent committee. 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.).

Task groups may be appointed to address very specific technical issues, research particular technical questions, or perform the initial organizational or drafting work for new committee projects. Upon completion of their task, these groups are usually disbanded.

Many of the AAMI committees 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 complete list of all AAMI committees [can be found online](#).

3.2 Role of the AAMI Standards Board

The AAMI Standards Board oversees the activities of the standards committees. AAMI Standards Board members serve three-year renewable terms and are appointed by the AAMI Senior Vice President (SVP), Standards Program and Policy. The positions are voluntary.

The following activities are the purview of the Standards Board:

- Approval of new work item proposal for work by a committee.
- Termination of work.
- Final approval of AAMI technical documents.
- Hearing appeals.

In addition to the responsibilities outlined above, the Standards Board also advises the SVP on cochair appointments and reviews progress of committee work.

3.3 AAMI staff

3.3.1 Role

AAMI staff manages the day-to-day aspects of AAMI programs, including (but not limited to):

- advising committees on AAMI policy and procedures,

- scheduling meetings,
- maintaining records,
- preparing committee documentation,
- checking draft documents for possible format and language issues prior to circulation,
- implementing the balloting and public review process,
- 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.

3.3.2 AAMI Connect

AAMI staff is also responsible for disseminating information and communication management through AAMI Connect, an electronic platform maintained by AAMI and restricted to committee members. AAMI Connect is used to manage standards projects and facilitate communication among committee members and AAMI staff. All committee documentation and stages are processed through the AAMI Connect system. The system can help members locate relevant information regarding the status of documents under development or in publication, membership rosters, and member comments on specific documents under development. The system also provides the online balloting capability with reminder notifications. Only AAMI staff can initiate any of the AAMI Connect features for any group.

Cochairs may also supplement such communications via email or telephone regarding meeting places, dates, and times or any other relevant information, including reminders for assigned tasks and deadlines.

3.4 Cochairs

Each AAMI committee has two individuals in leadership positions called cochair, who are relied upon to provide leadership and support to a particular committee. It is a voluntary position with individuals nominated by AAMI staff or other committee members in a call for nominees, reviewed 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/manufacture; 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. Additional information on cochair responsibilities is listed in clause 4.

3.5 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.

3.6 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.

3.7 AAMI policies

There are a number of policies 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 cochairs and members are expected to comply with all AAMI policies and procedures. AAMI also looks to the cochairs to assist and support AAMI staff with the implementation of these policies.

4 Cochair overview

4.1 Selection and qualification

The AAMI committee cochair positions are filled by a wide range of individuals who typically represent one of the five AAMI stakeholder categories listed in 3.5. A cochair possesses in-depth knowledge in the subject area of the specific committee, is recognized as an expert, and has substantial technical, medical, industrial, or other experience in the field. Most cochairs also have several years of experience as active, participating members of AAMI committees prior to obtaining a cochair position and have demonstrated their ability to contribute. New committee members are not normally qualified to serve as cochairs unless they fulfill a specific need, e.g., a clinician for a group working on a document impacting health care delivery organizations.

A cochair must be a good facilitator and leader. Leadership skills are the key attribute of an effective cochair, and experience in managing committee or team activities in hospital policy committees, trade association committees, or technical committees of other standards setting organizations is beneficial.

The cochair's position and skill are crucial to effective and efficient development of an AAMI document. In addition to expertise in the subject area, the cochairs must possess problem solving, and dispute resolution skills; be able to effectively lead a meeting both in person and via teleconference or web; and be respectful and thoughtful of the committee members' opinions, comments, and styles, all while continuing to move through the process of developing a new or revised consensus based document. A cochair will foster collaboration between committee members and be aware of and prevent dominance by one committee member, industry segment, or special interest.

4.2 Termination of cochair appointments

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

4.3 Primary responsibilities

4.3.1 Follow policies

The overarching and primary responsibility of the cochair is, with guidance and assistance from staff, to execute and implement AAMI policies, objectives, and priorities and to follow appropriate procedures (see 3.7 for the policies required).

4.3.2 Conduct committee meetings

Cochairs lead and facilitate all committee meetings, including both face-to-face meetings and any scheduled remote meetings, e.g., teleconferences or web meetings. The cochair, along with AAMI staff, determines the best methods and strategies for completing the committee work. Strong meeting facilitation skills that offer the committee members an opportunity to present and discuss their submitted comments, yet effectively manage the allotted time to complete the work set out in the agenda, are critical aspects to a successful committee meeting.

While cochairs do participate in the development of a document by providing comments, it is important that the all comments be addressed fairly and in an unbiased manner by the committee as a whole. Cochairs may not use their position to influence how their comments are addressed.

4.3.3 Work with AAMI staff

Cochairs are responsible for informing and updating AAMI staff and management on all technical and administrative issues that arise that may be relevant to the committee's work. AAMI staff is also responsible for informing, updating, and advising the cochairs. This can include committee disputes on technical matters that cannot be resolved in the committee meetings or activities, failure of a committee member to contribute to the work project as agreed to, and disruptive or disrespectful committee member behavior to the cochairs or other committee members.

4.3.4 Respond to inquiries

On occasion, AAMI may forward a relevant external inquiry to the cochair for response. Such inquiries typically relate to clarification of a published document developed by the assigned committee or may cover a related issue not addressed in the document. Cochairs are responsible for responding to such inquiries based on their experience with the committee in developing the document and the intent of the committee. However, because AAMI does not develop official interpretations, cochairs must respond as private experts, not as representatives of AAMI or their organization.

Cochairs may periodically be requested by AAMI to represent the committee at other standards related meetings, e.g., ANSI or AAMI policy setting committees, public hearings significant to AAMI membership, or other related functions. Unless delegated authority by the appropriate AAMI staff, committee cochairs do not have the authority to speak officially for AAMI. Any such opportunities should be discussed with AAMI staff first well in advance of said opportunity.

4.3.5 Manage committees and members

Cochairs are responsible for knowing who primary and alternate committee members are for the committees they lead, the stakeholder category of each member, and any affiliation with outside organizations that is of interest or would impact the work of the committee.

If the committee does not have appropriate representation of interested organizations or expertise in the work topic area, the cochair, in collaboration with staff, can do outreach to seek outside groups or individuals to join the committee work activities to improve content input into the work item. Outside experts can participate in the activities of the committee either by joining the committee as a voting member or by using the public review process.

It is also important that cochairs are aware of the work of other active committees and encourage or promote participation and committee membership of individuals who would be helpful to the work of the committee.

A strong cochair is effective at eliciting participation from committee members both through engagement and by seeking specific opinions and comments from all members and managing meetings to ensure consistent and active participation by all members. Cochairs should identify methods that appeal to and motivate their committee members' participation through one-on-one engagement or team building activities appropriate for the specific committee and meeting time availability.

Cochairs also review and provide recommendations on requests for committee members to serve as U.S. experts on related international committees.

4.3.6 Avoid duplication of work/relation/ dependence of documents

It should be recognized that other organizations, such as ASTM or UL, or AAMI committees may have developed similar subject matter documents or standards or may be in the process of developing them. Committee cochairs and members should attempt to keep abreast of such efforts to avoid duplication of effort or conflicting standards. AAMI staff that may be familiar with specific areas under consideration within AAMI or by other entities will assist cochairs in identifying other relevant activities.

4.3.7 Succession planning

A cochair should work with staff to identify and foster the next possible cochair candidate(s) well before the end of the current cochairs term. The process of succession planning should be as integral as the development of documents.

4.3.8 Manage timelines

A cochair should, in cooperation with staff, efficiently manage committee activities to ensure timely completion of technical work and other committee business within defined timelines established by AAMI. Cochair timeline management begins from the approval of a NWIP through the end of the final 15-day review.

4.3.9 Follow the process to avoid appeals

Committee members have the right to appeal a decision(s) made by the committee (e.g., the recommendation for a document to be approved by the Standards Board). The appeal process is an impartial one designed for handling procedural complaints regarding substantive actions or inactions. Complaints can include whether technical comments or issues raised were appropriately addressed and afforded due process. How a cochair conducted the resolution of comments or handled the issue can be a

basis for an appeal. When an appeal is filed, the cochair is relied upon to provide a history of the tasks or actions taken and justification that the process was or was not followed. AAMI policy for filing and addressing grievances is detailed in AAMI Standards Program Policies and Procedures Manual.

4.3.10 Manage scope creep

All documents have a defined scope. With a NWIP, the scope is defined before the drafting of the document is begun. Scope creep is not uncommon, and it is the role of the cochair to effectively manage scope creep to ensure that the issues are fully covered but do not to go beyond the original scope unless it is reasonable and important to the document. Scope creep can also happen during a revision to a document in an attempt to include new information available since publication.

Any change to scope must be discussed and resolved by the committee. It may be appropriate to suggest that the individual who raised the expansion of the scope volunteer to research the issue and bring to the committee relevant information and text for the committee to consider. If the committee ultimately agrees that an expanded scope is required, the AAMI Standards Board must approve it and cochairs should work with AAMI staff to facilitate that.

5 Preparing for a meeting

5.1 Determine the need for a meeting

Committees usually meet when an active document is in process and/or when a new work item is proposed. It is also typical that meetings are held when there are committee member comments that need to be addressed. The cochairs and AAMI staff will discuss and determine the location, logistic requirements, and format of the meeting based on the task to complete and potential member availability.

If there are concurrent meetings taking place, the cochair should take care to determine if their committee members also serve on other committees whose meetings may overlap with one another. The cochairs are encouraged to try to avoid meeting overlap as much as possible.

Task groups may also request a meeting in order to work on a document.

5.2 Develop an agenda

Agendas are developed in collaboration between the cochairs and AAMI staff. The agenda identifies meeting topics, and the content should determine how time should be allocated on the agenda.

Boilerplate agenda items include:

- Header: Name of the committee, date of the meeting and location of the meeting / web meeting information
- Introductions
- Code of conduct, anti-trust, and patent policy review (see 3.7 for the policies)
- Review and approval of the agenda
- Approval of the last meeting report (if applicable)
- ...
- Other business

- Plans for the next meeting
- Adjournment

5.3 Announce meeting and provide supporting documentation

All committee members should be notified of the meeting date, time, and place a minimum of six weeks in advance through the distribution of a draft agenda or email announcement.

If there will be a presentation or a detailed report on an agenda item being discussed, slides or handouts are encouraged. All supporting material for agenda items being discussed should be distributed four to six weeks in advance of the meeting to give attendees time to review the material and arrive prepared for the discussion. Electronic copies of all materials not distributed in advance should be provided to AAMI staff for inclusion with the meeting report.

5.4 Determine roles in advance with staff

It is beneficial to determine in advance who will be projecting the meeting documents during an in-person meeting, who will be the presenter the web portion (if applicable), and who will be taking notes for the meeting report (e.g. the scribe). Customarily, a cochair projects meeting documents (e.g., agenda, draft documents, voting results, comment table) or has the presenter role during a web meeting in order to guide discussions and AAMI staff generate the meeting report. However, these roles may change as needed from meeting to meeting.

If no staff person will be attending the meeting, it is useful to designate a committee member to fill the role of scribe.

6 Essential elements of a meeting

6.1 Introductions

It is customary for the cochair, cochair designee or AAMI staff to open the meeting by first welcoming everybody and announcing his/her name and the name of the committee. If both cochairs are present, they should start the introductions by introducing themselves. Each attendee should be asked to state his/her name and provide a brief background (e.g., institutional affiliation or company representation and area[s] of expertise). Unless attendees are well known to all participants, it is important that the entire group learn about each attendee's area of expertise, which may also include a brief history of their involvement with the current committee or other committees.

Important note: All committee members are required to disclose whether they have an outside liaison with another organization (e.g. the American Dental Association or the American Society of Anesthesiologists). Consultants should also disclose who they are representing: their own consulting company or a company that is paying that is paying them to participate.

New participants should be encouraged to include that information in their introduction. Nonmembers who are present should also introduce themselves.

An attendance sign-in sheet, prepared in advance by AAMI staff, must be circulated, signed by all attendees, and returned to AAMI staff. It is useful for the cochair to remind attendees to keep their affiliations, email, and interest category up-to-date with AAMI.

6.2 Review agenda

The proposed agenda should be the first document to be projected. The cochair running the meeting should review the elements within the agenda and confirm agreement by the attendees of topics to be covered.

If it is determined that the order of the agenda needs to be modified, this fact should be noted and attendees should confirm that the changes are acceptable. If the cochairs have determined in advance that the committee will likely not be able to complete the agenda items within the allotted meeting time, this should be noted to attendees and additional meeting time(s) and location(s) agreed upon in the *Plans for the next meeting* agenda item.

6.3 Policy review

The AAMI Antitrust Statement, Code of Conduct, Patent Policy, and Conflict of Interest policy should be reviewed for committee participants prior to proceeding. Questions or concerns should be directed to AAMI staff.

It should also be stated that no type of recording, audio or video, is permitted at the meeting.

6.4 Facilitate consensus

It is the responsibility of cochair to facilitate committee consensus on documents under development. This is usually done during the resolution of comments submitted on documents. It should be noted that official voting does not take place at meetings but there can be informal polls conducted to assist with the consensus determination.

Consensus is more than a simple majority but does not require (and rarely achieves) unanimity. Consensus requires that all views and objections be considered and responded to, and that a concerted and documented effort be made towards their resolution; consensus does not require that all objections be withdrawn.

7 General meeting information

7.1 Public attendance at meetings

Meetings of AAMI standards committees are open to the public and are not be held in closed session. AAMI committee meetings are listed in the monthly AAMI newsletter, [Standards Monitor Online](#), and posted on the AAMI website. Given the nature of an open meeting, it is typical that nonmembers will be present during a meeting. However, participation at committee meetings should come primarily from official members or alternates to the committee and only AAMI committee members or alternates are permitted to count for the determination of consensus. Also, at the discretion of the cochairs or the staff, it is permissible to limit comments to members and alternates only. Any minutes or other documentation ensuing from such meetings, however, may be made publicly available.

7.2 Sharing AAMI documents

The working documents under development at the committee level are always considered confidential documents and are not to be shared outside of the committee. Exceptions may be made on a case-by-case basis in consultation with AAMI staff. The cochair should clearly communicate and take steps to ensure that committee members understand this AAMI policy. Any breach in the policy that a cochair is aware of should be communicated to AAMI staff and addressed with the individual committee member.

7.3 Conducting meetings

AAMI committee meetings are run loosely based on [Robert's Rules of Order](#) as a guideline, except for official votes. Official votes on documents are conducted electronically via AAMI Connect in order for all members, not just those at the meeting, to have a chance to contribute. Note that cochairs are not eligible to participate in unofficial voting on motions or informal opinion polls taken at a meeting except in the case of a tie.

The cochair should allow for open discussion on a given topic from any attendee wishing to do so. The cochair should be prepared to summarize the major issues before the committee prior to a decision or vote being taken on a topic under consideration. The cochair should be prepared to periodically ask attendees if clarifications are needed, ask for clarifications as needed, and pose appropriate questions so that a reasonable understanding and subsequent consensus may be reached. If there are attendees whose primary language is not English, it is helpful to speak slowly using simple words or phrases to enable effective communication and then to verify that all attendees have sufficiently understood the issue being discussed.

If the meeting has many attendees, it may be necessary for the cochair to ask for a show of hands of members to gauge consensus. Any questions from attendees should be addressed and resolved as best as possible until a consensus is achieved. The cochair should announce the results of the informal opinion poll.

7.4 Action items

It is typical that a number of “homework assignments” may be developed during the course of a meeting, to be completed by a volunteer and due to the cochairs and/or AAMI staff by a certain date. Action items should be called out either in the meeting report or in the comment resolution form. Cochairs and staff should work together to ensure that post-meeting follow up is done.

Committee members who have been assigned to or volunteered for a task but are unable to complete the work by the due date should be handled fairly by the cochair[s] but asked for a firm date when the assignment will be completed. Other strategies and tips to reasonably ensure deliverables are completed on time include the following:

- a) remind committee members of their commitments two weeks before items are due;
- b) make deliverables officially “due” on a Friday, but accept comments until the following Monday morning;
- c) set deadlines for deliverables earlier than necessary, anticipating that some will be late;
- d) other committee members may be offered to partner with another “to help them out” if past experience indicates deliverables may not be forthcoming by the deadline;
- e) specify how past delays have affected the group. In the event a committee member does not complete an assignment in the agreed upon time despite the above strategies being implemented, the work should be assigned to another member.

8 Comment and conflict resolution

8.1 General

This section provides guidance to cochairs regarding potential conflicts that may occur during committee meetings/comment resolution and offers mechanisms for resolving these conflicts. When resolving comments, cochairs should be aware that changes to standards can impact organizations both procedurally and economically, which can lead to conflict within the committee. Understanding the impact on the individual or organization is helpful to determine the most effective method to resolve the conflict.

8.2 Addressing comments

The cochair should describe the approach that will be taken at the beginning of the meeting and seek agreement or discussion on the approach before reviewing and resolving comments.

Consolidated committee comments to a document are typically provided by AAMI staff to the committee and cochair prior to a meeting. It is worthwhile for cochairs to review the comments prior to the meeting and provide proposed responses to the comments for discussion at the next meeting, and/or to suggest to either accept a comment as is or to discuss it further. It is common to propose to accept all truly editorial comments. Proposed responses to the comments can also be provided to the committee in advance of a meeting, if available, by AAMI staff. This approach can assist in efficiently resolving comments in the allotted meeting time. Color-coding or some other system to designate the recommended approach to the comment is helpful and allows the cochair to easily navigate to the items that need specific discussion.

All technical and editorial comments are open for discussion, even those that are recommended for acceptance, in case a committee member wishes to discuss or object to the acceptance of a comment. Alternately, comments can be discussed one at a time without the predesignated recommendation from the cochair on a proposed resolution.

During the committee discussion the commenter or his/her alternate, should provide any additional context that might be helpful as needed. As cochair, it is important to separate personal opinions from those of the rest of the group. It is prudent to encourage discussion of a comment to understand the viewpoints and rationales of the entire committee, as perspectives not previously considered might be aired. The cochair as a facilitator is not allowed to make decisions for the committee based on his/her personal position. The cochair position is considered and carries equal weight with the other committee members' positions.

8.3 Comment responses

Comments should be clearly responded to, keeping in mind that another person may be responsible for incorporating the comments into the draft document. Possible responses are:

- Accepted: the comment is accepted as-is.
- Not accepted: the comment is not accepted, and a technical reason must be included as to why.
- Accepted with modification: the comment is accepted but the wording has been modified by the committee.
- Accepted in principle: the concept of the comment is accepted but with different wording.
- Noted: a comment has been provided that has no bearing on the content of the document.

- Not accepted, no alternative provided: see 8.4 below.
- Comment withdrawn: the comment is withdrawn by the submitter during discussions.

8.4 Incomplete comments

Occasionally, members might submit incomplete comments which are those that do not offer suggestions or alternatives—typically they are along the lines of, “I do not like this clause,” or “I do not like this phrasing.” The committee is under no obligation to consider such comments and they may be rejected without additional consideration. An acceptable response to this type of comment is “Not accepted, no alternative provided”.

8.5 Resolving conflicting comments

There are several techniques that may be used to resolve conflicts. Conflicting comments should be discussed in meetings, allowing all parties a chance to discuss the merits of their comments and other group members a chance to add additional perspectives. It may be useful to go back to a place where the two or more members agree on a topic, then move forward to find exactly where their viewpoints diverge. Often, at the root, the difference is based on personal experience or product knowledge—what one person knows about their product, they may assume is true about other products as well. Once that point of divergence is known and discussed, the resolution to the conflict may become obvious.

Other times, the intention of a clause may not be clearly stated in the wording of the clause, causing a conflict. Often, poor word choice is cause for conflict; discussing the intent of the clause and wordsmithing can resolve some conflicts. What one organization might view as a Best Practice may be difficult for another organization to implement. This type of conflict often can be resolved by moving a clause in the standard to an informative annex. Similarly, a performance clause (e.g., “the device shall operate normally after being dropped from a height of 10 feet”) can be converted to a disclosure clause (e.g., “the operator’s manual shall specify the results of the device being dropped progressively from a height of 6, 8, and 10 feet.”).

8.6 Comments that conflict with other existing standards or regulations

There are many regulations and standards affecting medical devices. Conflicts with other standards are inevitable. In the case of a conflict, there are three options:

- 1) change the proposed document to align with the pre-existing document;
- 2) create a deviation in the document with justification for the deviation; or
- 3) propose a change to the pre-existing document by approaching the governing committee for that document.

8.7 Disruptive behavior

If an attendee or committee member is being disruptive or is felt to be in violation of the Code of Conduct, the cochair and/or AAMI staff has the right to a) warn the person that such behavior is counterproductive to the goals of the committee and, b) if such behavior persists, the offender may be asked to leave the meeting room. Persistently disruptive committee members can be expelled from the committee after consultation and agreement by AAMI staff, in which case AAMI will notify the individual of the expulsion.

8.8 Complaints and grievances regarding committee activities

Complaints and grievances related to committee activities expressed by a committee member should be addressed confidentially and privately either in person or via a teleconference with AAMI staff present. If a potential issue is raised and cannot be resolved within the meeting, it is appropriate to suggest the issue be discussed separately outside of the meeting. Identify the concern and allow the individual to fully express their position, concern, and suggestion on how to resolve the concern. A cochair should ask relevant questions to ensure full understanding. Additional follow-up and discussions with a larger group or the committee may be needed to resolve the complaint.

Complaints about cochairs should be directed to AAMI staff who can help to understand if the complaint is related to a technical issue within the committee, a personal issue with the cochair, or how the cochair handled a specific task or issue.

Annex A: Document development process

NOTE This is a high level overview of information provided in clause 6 of the [Standards Program Policies and Procedures](#).

A.1 Document Development Stages

A.1.1 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.1.2 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 as much information to convey the topic, concept and industry need and should include a rough draft or outline. Committees should discuss the proposal and address any comments or concerns before informing AAMI staff submit the AAMI Standards Board for approval. All proposals for new work must be approved by the AAMI Standards Board before work can proceed.

A.1.3 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 (this could be the cochair) 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 committee then meets (face-to-face or electronically) to discuss the comments and accept or not accept them. Accepted comments are incorporated into the draft document.

A.1.4 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.1.5 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 technical 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 A.1.

A.1.6 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 years and TIRs are reviewed every three years. See [AAMI Standards Program Policies and Procedures Manual](#) for detailed information on this procedure. AAMI Staff will provide guidance and structure for this procedure.

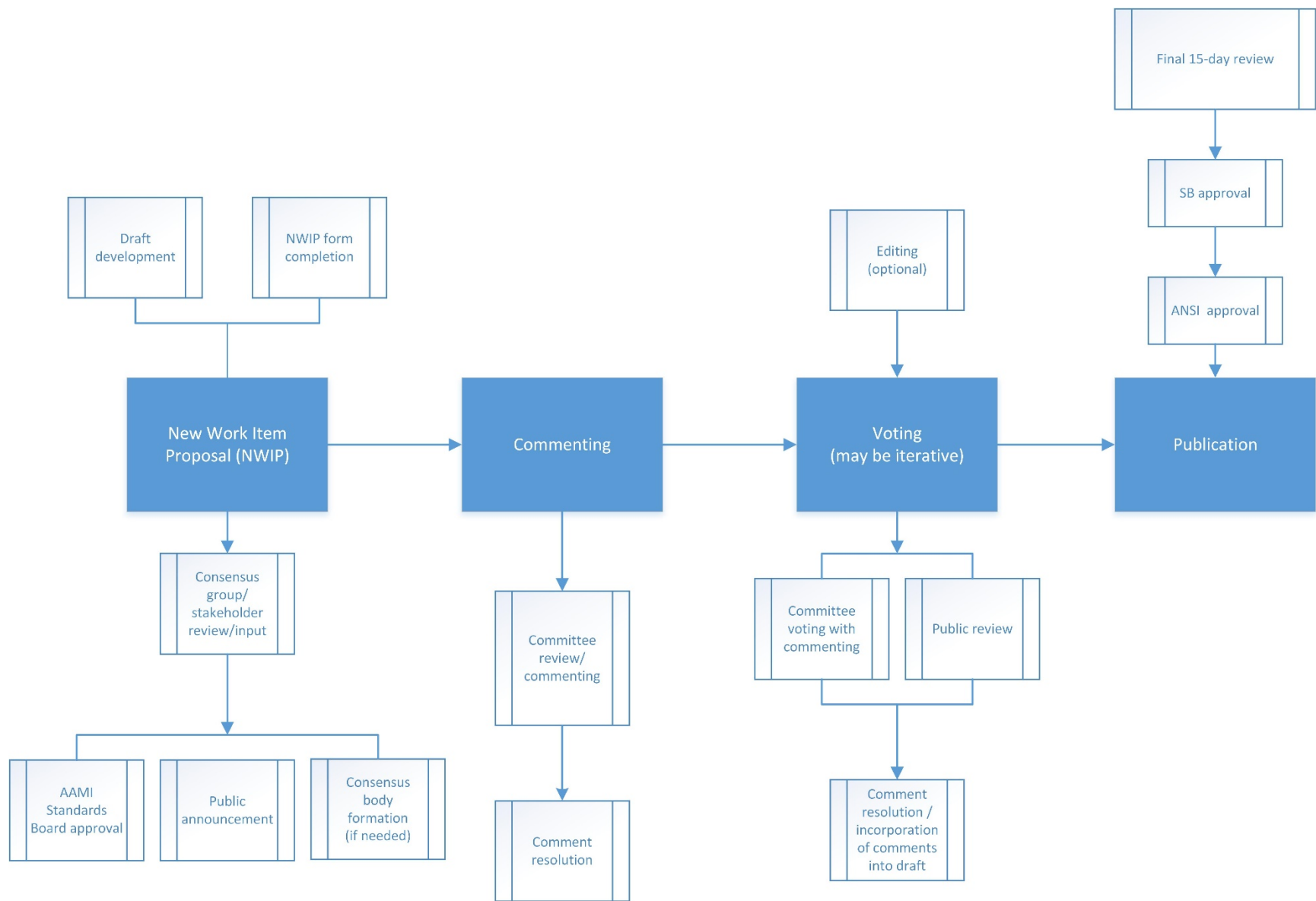


Figure A.1 — Steps in the development and approval of an AAMI standard

Annex B: Additional tools and resources

B.1 AAMI Connect

AAMI Connect 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 AAMI Connect. 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 AAMI Connect.

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

B.2 Useful links

- [How to join a Technical Committee](#)
- [Full list of technical committees](#)
- [List of scheduled meetings](#)
- [Password reset / forgot password](#)
- [AAMI voting and commenting guidance](#)

B.3 Standards Department Staff list

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B.4 Acronym and abbreviation reference

ANSI	American National Standards Institute
ASTM	ASTM International
CD	Committee Draft
CDV	Committee Draft for Vote
DIS	Draft International Standard
FD	Final Draft
FDA	US Food and Drug Administration
FDIS	Final Draft International Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation
ITU	International Telecommunication Union
NP	New Work Item Proposal (ISO, IEC)
NWIP	New Work Item Proposal
PWI	Preliminary Work Item
SDO	Standards Development Organization
TAG	Technical Advisory Group
TIR	Technical Information Report
TR	Technical Report
WD	Working Draft

