

MedBiquitous

MedBiquitous®

Standards Program Operating Procedures

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1.0 General

These procedures meet the requirements for due process and development of consensus for approval of American National Standards (ANS) as given in Clause 1 of the *American National Standards Institute (ANSI) Essential Requirements*.

1.1 Definitions

AAMC	Association of American Medical Colleges, the owner and operator of the MedBiquitous Program
Director	The head of the MedBiquitous Program, an AAMC employee
Program	The MedBiquitous Standards Development Program, a program of the AAMC
Participating Organization	An organization that executes a participation agreement with the MedBiquitous Program to participate in the standards development process of the Program
Participant	An individual or a representative of a Participating Organization that participates in the standards development process on the individual's or organization's behalf, respectively
Steering Committee	A selected group of participants that provides oversight and guidance to the Program
Voting Body	The consensus body of participants that votes on MedBiquitous standards

2.0 Organization of the Standards Development and Consensus Processes

The development of an ANS standard within the MedBiquitous Program takes place largely within the MedBiquitous Steering Committee and the MedBiquitous Voting Body. The Voting Body shall serve as the consensus body. The Voting Body is made up of materially affected parties who have an interest in the standards being developed. Participants in the Voting Body shall consist of interested and qualified individuals who are either representatives of Participating Organizations or individual participants. Public (individual) participation will ensure representation by interested parties who do not have organizational participation in the Program. Participants in the Voting Body will have the ability to comment and approve/disapprove of the standard. The Steering Committee shall have a title, scope, and an interest classification system for Participants. The composition of Participants shall be sufficiently diverse to ensure reasonable balance without dominance by a single interest category, individual, or organization in accordance with Clause 1.2 and 1.3 of the *ANSI Essential Requirements*.

Participating Organizations may appoint representatives to participate in the Working Groups. Working Groups shall perform the technical groundwork necessary to produce a technical standard in the area of its expertise.

3.0 Responsibilities

This section describes the roles and responsibilities of participants in the standards development and approval processes within the MedBiquitous Program. Table 1, which follows, provides an overview of the

actors in the development and approval process for standards intended for review and approval as American National Standards. Figure 1 illustrates how a standards development proposal becomes a standards development project. Figure 2 shows how the Program creates a new standard, ANSI approves it, and the standard is made public. Also included is a description, by role, of standards development responsibilities.

3.1 Steering Committee

The Steering Committee is responsible for evaluating standards proposals submitted to the MedBiquitous Program and selecting the standards projects to be undertaken as ANS Standard Development Projects by the MedBiquitous Program. The Steering Committee is thus charged with implementing the strategic direction given to the Program by the Director by selecting standards projects consistent with those strategic goals. The Steering Committee consists of individuals appointed by the MedBiquitous Director, as well as the MedBiquitous Director. There are no formal prerequisites to serve on the Steering Committee, although an effort will be made by the Director to include individuals who have technical and other expertise relevant to the Steering Committee's decision-making process. The Steering Committee reviews proposals to terminate the activities of a working group or discontinue a standards development project. A two-thirds majority of the Steering Committee is required to approve a Standards Project Proposal, terminate the activities of a working group, or discontinue a standards development project. The Steering Committee determines whether or not to submit a standard for consideration as an ISO or ISO/IEC JTC-1 standard.

The Steering Committee shall make a good faith effort to resolve potential conflicts with existing and candidate American National Standards and to coordinate standardization activities in a manner compliant with section 2.4 of *ANSI Essential Requirements*. If comments are received in response to the project initiation notification, the Steering Committee works with the commenter and other relevant stakeholders to address and resolve any comments or objections in a manner compliant with section 2.5 of *ANSI Essential Requirements*, Notification of standards development and coordination.

3.2 MedBiquitous Director

In the standards development process, the MedBiquitous Director serves as the secretariat, coordinating the efforts of Program Staff, Steering Committee, Technical Advisory Group, Voting Body and Working Groups. In keeping with that responsibility, the Director performs the following tasks:

- a) Serving as an *ex officio* member of the Steering Committee and the Voting Body.
- b) Assigning Standards Project Proposals approved by the Steering Committee to the Technical Advisory Group;
- c) Selecting the appropriate Working Group for each standards development project approved by the Steering Committee.
- d) Appointing a Chairs for the Steering Committee subject to the approval of the Voting Body;
- e) Appointing a Chair and Editor to the Technical Advisory Group;
- f) Appointing a Chair(s) and Editor for each Working Group;
- g) Maintaining a roster of the Voting Body and a list of standards for which it is responsible;
- h) Providing a secretary to perform administrative work, including secretarial services; preparation of meeting notices and the handling of meeting arrangements; preparation and distribution of meeting agendas, minutes, ballots, and draft standards; and maintenance of adequate records;
- i) When applicable, submitting candidate standards approved by the Voting Body, with supporting documentation, for ANSI review and approval as American National Standards;
- j) Publishing approved standards; and
- k) Performing other administrative functions as required by these procedures.

Table 1. Overview of Standards Development and Approval Process

Actor	Responsibilities
Public	<ul style="list-style-type: none"> • Provide comment on standards proposals • Provide comment on standards drafts
ANSI	<ul style="list-style-type: none"> • Publishes standards proposals in <i>Standards Action</i> for public comment • Publishes draft standard in <i>Standards Action</i> for public comment • Accepts or rejects standard as ANS
Voting Body	<ul style="list-style-type: none"> • Approves draft standards by 2/3 majority
Director	<ul style="list-style-type: none"> • Receives and processes requests for new standards, reaffirmation and revision of existing standards • Transmits proposals to ANSI for public comment • Assigns standards development projects to Technical Advisory Group and relevant Working Group • Transmits draft standard to ANSI for public comment • Transmits candidate standard to ANSI for approval • Publishes standard as ANSI/MedBiquitous standard
Steering Committee	<ul style="list-style-type: none"> • Evaluates proposals • Makes decision to accept as a standards project • If public comments are received on standards proposal, works to resolve those comments • Approves draft standard from Working Group • Chair Elect initiates ballot process for Voting Body • If rejected as ANS, determines next steps
Technical Advisory Group	<ul style="list-style-type: none"> • Accepts standards development projects from Director and works with appropriate Working Group to execute development project • Reviews draft standard from Working Group and provides feedback before being sent to Steering Committee • Evaluates official draft standard before it is submitted to the Voting Body for approval
Working Group	<ul style="list-style-type: none"> • Prepares draft standard and presents it to Technical Advisory Group for comment • Resolves any comments from Technical Advisory Group • Resolves any comments from public comment • Resolves any comments from Voting Body

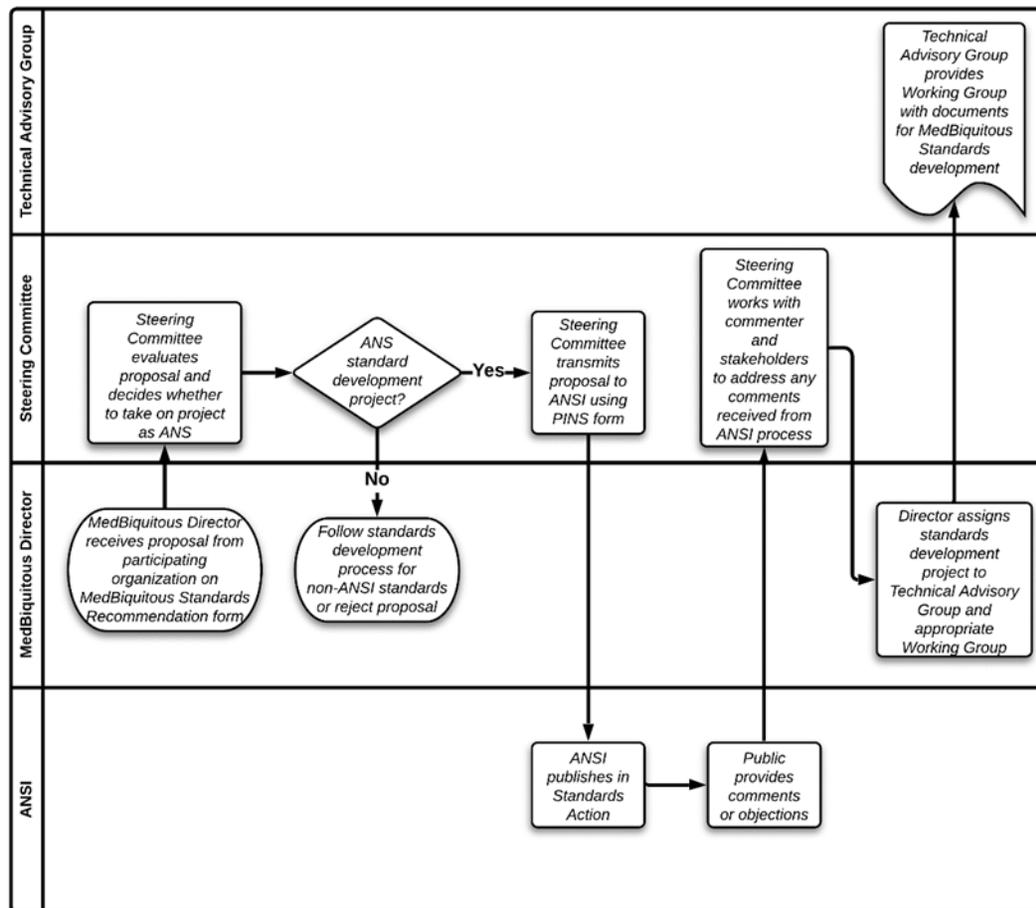


Figure 1. Acceptance of ANS Standards Development Project

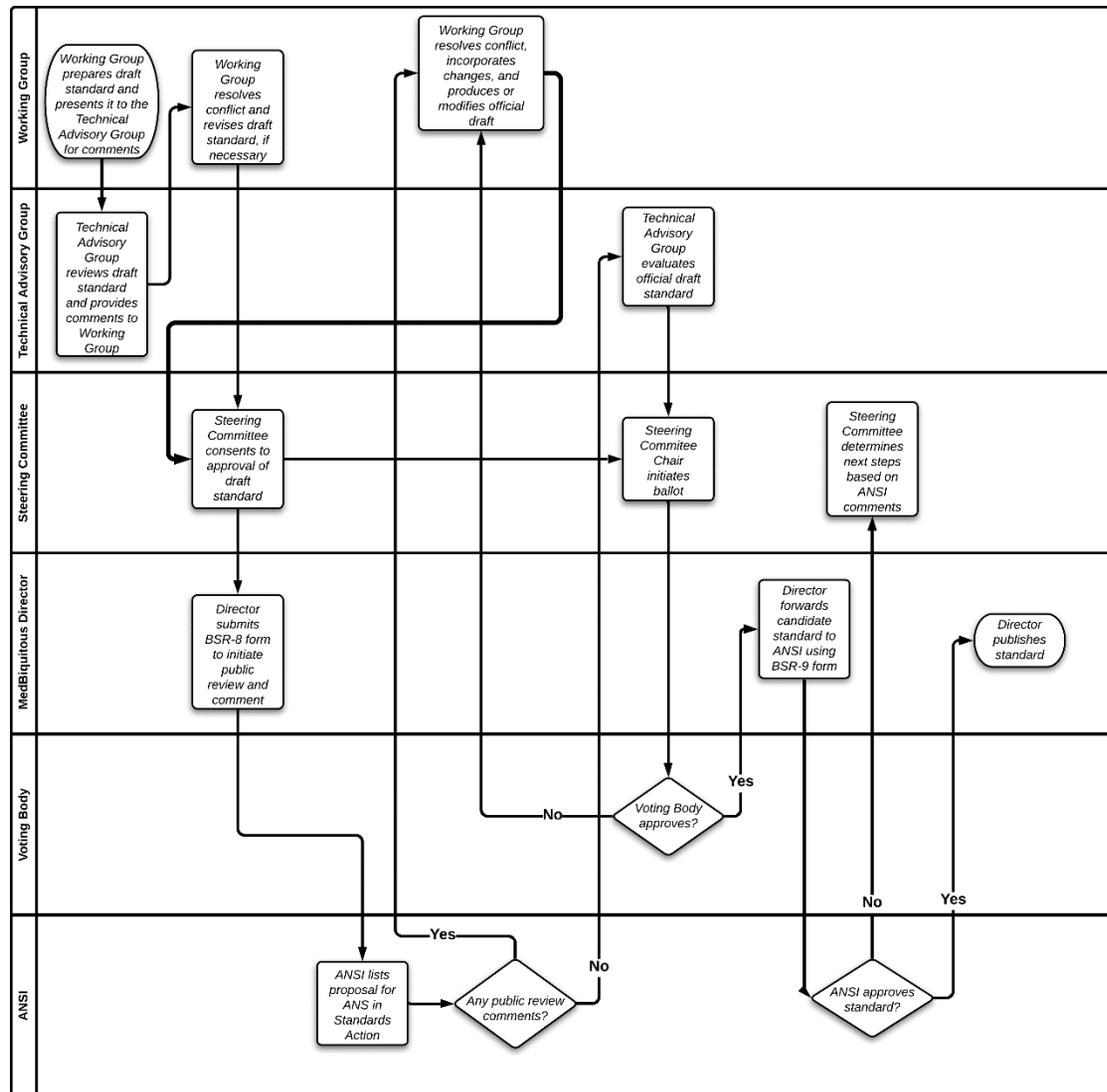


Figure 2. Creation, Approval, and Publishing of an ANS Standard

3.3 Technical Advisory Group

The Director assigns ANSI approved standards proposals to the Technical Advisory Group. The Technical Advisory Group shall guide the standards proposals through the process of creating official ANSI standards.

The Technical Advisory Group shall be responsible for:

- a) Maintaining the standards developed within the Program in accordance with Clause 4.7 of the *ANSI Essential Requirements*;
- b) Adopting policy and procedures for interpretations of the standard(s) developed by the Program; and
- c) Responding to requests for interpretations of the standard(s) developed within the Program.

3.4 MedBiquitous Voting Body

The MedBiquitous Voting Body serves as the consensus body for the MedBiquitous Program. The Voting Body shall be responsible for:

- a) Voting on approval of proposed American National Standards; and
- b) Voting on other matters requiring consensus body action as provided in these procedures.

3.5 Working Groups

The Director appoints the Chair(s) and Editor of each Working Group. Each Working Group consists of Chair(s), one or more MedBiquitous Staff and/or Invited Experts, and Participants. Participating Organizations may appoint representatives to relevant Working Groups. The Working Group provides feedback, evaluation, and when useful or necessary, research throughout the standards development process.

If a Working Group has completed its activities or if it fails to make progress in its activities, the Director, Working Group Chair, or Working Group members may propose to terminate the activities of the working group. The proposal must be presented to the Working Group a minimum of three weeks prior to its consideration by the Steering Committee. The Director, Working Group Chair, or Working Group members may submit comments on the proposal to terminate Working Group activities to the Steering Committee prior to their vote on the matter.

4.0 Appointment of Officers

The Director shall appoint members, Chair(s) and Editor for all MedBiquitous Committees and Advisory Groups. Appointment of the Steering Committee Chairs is subject to review by the Steering Committee and approval by the Voting Body.

5.0 Voting Body Participants

5.1 Composition of the Voting Body

Participation in the MedBiquitous Voting Body shall consist of individuals having a direct and material interest in the activities of the MedBiquitous Program. Each Participating Organization will have the opportunity to select a voting designee and an alternate to serve on the Voting Body. The voting designee shall be the individual to cast a vote for the organization; if the voting designee indicates that the designee is unavailable, the alternate may be the individual to cast the vote for their organization. An organization may change the voting designee or alternate by notifying the Director. Interested parties who are not affiliated with a Participating Organization and who wish to join the Voting Body shall submit an application to the Steering Committee to participate as a public Participant. The Steering Committee shall select Participants based on technical expertise and balance of interests. The selection and addition of Participants, along with their interest category, shall be subject to approval by a majority vote of the Voting Body after the application has been processed by the Steering Committee.

5.2 Application for Participation

A request for participation in the MedBiquitous Voting Body shall be addressed to the MedBiquitous Program and will be referred to the Steering Committee Chair. Applications shall indicate the applicant's direct and material interest in the Program's work, qualifications, and willingness to participate actively. In addition, if the applicant is an organization, company, or government agency, it shall identify a representative (and an alternate, if desired).

In considering applications for participation, the Steering Committee shall consider the:

- a) Need for active participation by each interest;
- b) Need for balance among interest categories as described in section 5.5;
- c) The potential for dominance by any single interest category, organization, or individual;
- d) Extent of interest expressed by the applicant and the applicant's willingness to participate actively; and
- e) Representative identified by the applicant organization, company, or government agency.

An annual fee will be assessed to all Participants (organizational and individual) to defray administrative costs of the Program. An applicant may request for the administrative fee for participating in the Program to be waived if the fee would constitute an undue financial barrier. The Steering Committee shall consider any fee waiver requests. Fee waivers shall be subject to approval by a majority vote of the Voting Body.

5.2.1 Diverse Interests

If distinct divisions of an organization demonstrate independent interests and authority to make independent decisions in the area of the activity of the Voting Body, each is permitted to apply for participation.

5.2.2 Combined Interest

When appropriate, the Steering Committee Chair may recommend that the applicant seek representation through an organization that is already a Participant and represents the same or similar interest.

5.3 Review of Membership

The Director shall review the Voting Body participant list annually with respect to the criteria listed in *Application for Participation*, section 5.2. Participants are expected to fulfill obligations of active participation, including voting and meeting participation. Where a Participant is found in habitual or egregious default of these obligations, the Director shall direct the matter to the Steering Committee for appropriate action, which may include termination of participation.

5.4 Observers and Individual Experts

Individuals and organizations having an interest in the Program's work may apply to be listed as observers. Observers shall be advised of the Program's activities, may attend meetings, and may submit comments for consideration, but shall have no vote.

5.5 Interest Categories

All appropriate interests that are directly and materially affected by the standards activity of the Program shall have the opportunity for fair and equitable participation without dominance by any single interest category, organization, or individual. Each Participant shall propose its own interest category as appropriate and in accordance with the consensus body's established categories. (See clauses 2.1.2.2, and 2.3 of the *ANSI Essential Requirements*).

The Voting Body shall have a balance of interests. For non-safety related items, no single category shall constitute a majority. For safety-related items, no single interest category shall constitute more than one third of the consensus body. Participants from diverse interest categories shall be sought with the objective of achieving balance.

The interest categories appropriate to the development of consensus in any given standards activity is a function of the nature of the standards being developed. In defining the interest categories appropriate to a standards activity, consideration shall be given to at least the following:

- a) Academic society – including, but not limited to, associations that represent and provide services to the constituents of a specific health profession or healthcare specialty.
- b) Training program – including, but not limited to, institutions of higher education.
- c) Regulatory – including, but not limited to, licensing boards, certifying boards, and accrediting bodies.
- d) Government – government agencies at the federal, state/province, or local level.
- e) Technology or content developer – including, but not limited to, software companies, IT service companies, medical education companies, and other developers of content or technologies.
- f) Healthcare company – including, but not limited to, manufacturers of pharmaceutical products or medical devices, manufacturers of other healthcare related products, and companies providing consulting services to those companies.
- g) Healthcare delivery – including, but not limited to, health systems and hospitals.
- h) General Interest – any materially affected interests that do not fall into one of the other categories.

An individual in professional practice or a consultant, retained under continuing agreement with an organization, shall be classified in accordance with the classification of the organization retaining the individual and shall be so identified. There shall be a limit of one voting designee from each entity, company, or organization, except as under 5.2.1, Diverse Interests.

Appropriate, representative user views shall be actively sought and fully considered in standards activities. Whenever possible, users shall be those with the requisite technical knowledge, but other users may also participate. User engagement should come from both individuals and representatives of organized groups.

5.6 Membership Roster

The Director shall maintain a current and accurate Voting Body roster and shall distribute it to Voting Body Participants at least annually, and otherwise on request. The roster shall include the following:

- a) Title of the Voting Body;
- b) Scope of the Voting Body;
- c) Steering Committee members and Chairs;
- d) Participants: name of organization or agency, its representative/voting designee and alternate (as applicable), addresses, and business affiliation; or name, address, and business affiliation of individual participants;
- e) Interest category of each Participant;
- f) Tally of interest categories: total of voting organizations and subtotals for each interest category; and
- g) For each Working Group: title, chair, and names and addresses of all members.

6.0 Approval of Standards

Draft standards and any substantive change in the content of a standard shall be referred to the MedBiquitous Voting Body for approval.

7.0 Meetings

MedBiquitous Voting Body consensus meetings may be called by the Steering Committee, the Director, or by petition of five or more Participants. The purpose of Voting Body meetings is to conduct business, such as making assignments, receiving reports of work, considering draft standards, and considering views and objections from any source. In-person or virtual meeting attendance is not required to vote. If a

member of the Voting Body is unable to attend in real-time, they may vote before or after the meeting, with the vote to be submitted within 7 days. All votes will be conducted by electronic means.

Meetings of Working Groups may be held as decided upon by the members or Chair of the Working Group.

The Voting Body and Working Groups may choose to meet by teleconference or other virtual meeting mechanism.

7.1 Open Meetings

Meetings of the Voting Body shall be open to all Participants and others having a direct and material interest. At least four weeks' notice of regularly scheduled meetings of the Voting Body shall be given by the Director in ANS's *Standards Action*; *MedBiquitous Community Connection Newsletter* or in other media designed to reach directly and materially affected interests; or in all three. The notice shall describe the purpose of the meeting and shall identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to Participants and to others expressing interest.

7.2 Quorum

A simple majority of the Participants of the Voting Body shall constitute a quorum for conducting business at a meeting. If a quorum is not present, actions shall only be taken subject to subsequent confirmation by an equivalent formal recorded vote or vote at a future meeting.

8.0 Voting

8.1 Vote

Ballots cast by the Voting Body, including votes for the approval of a document or portion thereof as a candidate ANS, shall be conducted by electronic means, whether in real-time or asynchronously. Except in regard to votes on participation and officer-related issues, each Participant shall vote one of the following positions:

- a) Affirmative;
- b) Affirmative, with comment;
- c) Negative, with reasons (the reasons for a negative vote shall be given and if possible, should include specific wording or actions that would resolve the objections);
- d) Abstain, with reasons.

For votes on participation and officer-related issues, the yes/no/abstain method of voting shall be followed.

8.1.1 Vote of Alternate

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

8.1.2 Single Vote

Generally, no representative shall have more than one vote. However, if two or more Participating Organizations appoint the same individual to represent each of them, that individual may cast a separate vote for each organization represented. The Participating Organizations shall confirm in writing to the Director that they are aware of and will accept the results. Additionally, representation of more than one organization by the same individual shall require approval by a majority of the Voting Body, excluding the vote of that individual.

8.1.3 Ballot Pool

The ballot pool shall consist of all those Participating Organizations and individual Participants designated as voting members of the Voting Body at the time the balloting process begins. If a Participating Organization wishes to change its representation on the Voting Body due to employee departure or other circumstances that make the primary representative and alternative unavailable for the ballot, the Participating Organization may request a change in representation. Such modifications will be granted at

the Steering Committee Chair Elect's discretion. Participating Organizations joining the Voting Body after the start of the balloting process are not counted in the ballot pool and are not eligible to vote.

8.1.4 Voting Period

The voting period for ballots shall end 30 days from the date of issue or as soon as all ballots are returned, whichever comes first. An extension may be granted at the Steering Committee Chair Elect's option, when warranted.

A follow-up notice requesting immediate return of the ballot shall be sent, as appropriate, to voting designees and alternates whose votes have not been received within ten calendar days before the ballot closes.

8.2 Actions Requiring Approval by a Majority

The following actions require approval by a simple majority of the Voting Body by a formal recorded vote:

- a) Confirmation of Steering Committee Chairs appointed by the Director; and
- b) Addition of new MedBiquitous Participating Organizations and individual Participants.

8.3 Actions Requiring Approval by Two-Thirds of Those Voting

The following actions require a formal recorded vote with approval by at least a majority of the Voting Body and at least two-thirds of those voting, excluding abstentions:

- a) Adoption of Voting Body procedures, interest categories, or revisions thereof;
- b) Approval of a new standard or reaffirmation of an existing one;
- c) Approval of revision or addendum to part or all of a standard;
- d) Approval of a standards interpretation;
- e) Approval for submission to ANSI of change of Voting Body scope; and
- f) Approval of withdrawal of an existing standard.

8.4 Authorization of Formal Recorded Votes

A formal recorded vote shall be authorized by any of the following:

- a) The Steering Committee Chairs;
- b) The Director; or
- c) Petition of five or more Participants of the Voting Body.

8.5 Other Review

At the initiation of a project to develop or revise an American National Standard, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*. Any comments received in response to the PINS announcement shall be addressed in accordance with clause 2.5.1 (and its subsections) of the ANSI Essential Requirements.

Proposals for new candidate American National Standards or reaffirmation, revision, or withdrawal of existing American National Standards shall be transmitted to ANSI for listing in *Standards Action* for comment.

The Director shall determine whether listing of proposed standards actions shall be concurrent with the final Voting Body ballot and whether announcement in other suitable media is appropriate. The Director shall transmit a copy of the proposed new, revised, or reaffirmed standard to the administrator(s) of the appropriate ANSI Technical Advisory Group(s) at the same time.

Views and objections resulting from the above shall be dealt with in accordance with *Disposition of Views and Objections*, Section 8.6. Any substantive change made in the proposed American National Standard shall be listed again in *Standards Action* for public review.

8.6 Disposition of Views and Objections

When the balloting has been closed, the secretary shall forward the ballot tally to the Chair Elect of the Steering Committee; the Chair Elect shall determine whether the expressed views and objections shall be considered by correspondence or at a meeting.

Prompt consideration shall be given to written views and objections, including those commenting on the PINS announcement, public comment listing in *Standards Action*, or votes of the Voting Body. An effort to resolve all expressed objections shall be made, and each objector shall be advised in writing of the disposition of the objection and the reason therefore. In addition, each objector shall be informed in writing of their right to appeal in accordance with the MedBiquitous appeals policy, Section 13.0. Any comments received subsequent to the closing of the public review and comment period shall be considered in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be notified of this consideration in writing.

Substantive changes and unresolved objections along with attempts at resolution shall be reported to the Chair Elect and recirculated in order to afford all members of the Voting Body an opportunity to respond to them or to reaffirm or change their votes within four weeks.

When the above process is completed, any comments received subsequent to the closing of the public review and comment period may be considered in the same manner as a new proposal.

If comments not related to the proposal are submitted with a negative vote, the comments shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be notified of this consideration in writing. Negative votes accompanied by comments not related to the proposal will be counted as negative votes without comments.

8.7 Report of Final Result

The final result of the voting shall be reported, by interest categories, to the MedBiquitous Voting Body.

9.0 Submittal of Standard

If the standard is a candidate American National Standard, upon completion of the procedures for voting, disposition of views and objections, and appeals, the proposed standard shall be submitted to ANSI by the Director.

The information supplied to ANSI by the Director shall include all relevant material required by ANSI as outlined in the *ANSI Essential Requirements*. If the Director does not submit the proposal to ANSI within a reasonable period of time, any member(s) of the Steering Committee or MedBiquitous Program staff may make the submittal.

10.0 Discontinuance of a Standards Project

The MedBiquitous Program may abandon the processing of a proposed new or revised American National Standard or portion thereof. A two-thirds majority of the Steering Committee is required to discontinue a standards project. The Program will notify ANSI immediately of such actions which will be announced in *Standards Action*.

11.0 Termination of MedBiquitous Voting Body

A proposal to terminate the MedBiquitous Voting Body may be made by a directly and materially affected interest. The proposal shall be submitted in writing to the MedBiquitous Director and shall include at least the following:

- a) Reasons why the Voting Body should be terminated;
- b) The name(s) of the organization(s) that will assume responsibility for maintenance of any existing American National Standard(s) that is (are) the responsibility of the MedBiquitous Program.

If it appears, after review and discussion among the proponent of the action, the Director, Steering Committee and relevant AAMC staff, that the desired objectives can best be reached by termination, the proposal and supporting documentation shall be submitted to the committee with a ballot to terminate the committee and transfer responsibility, as appropriate, for the affected standards. The proposal for termination of the MedBiquitous Voting Body shall be announced for comment in *Standards Action*.

12.0 Communications

12.1 Formal Internal Communication

If correspondence between Working Groups involves issues or decisions (i.e., non-routine matters) affecting other Working Groups, copies shall be sent to all affected Working Group chairs, the Director, the Chair of the Technical Advisory Group, and the Chairs of the Steering Committee.

12.2 External Communication

Inquiries relating to the Voting Body should be directed to the Director, and Participants should so inform individuals who raise such questions. All replies to inquiries shall be made through the Director.

12.3 Requests for Interpretation of Standards

Written inquiries requesting interpretation of approved American National Standards shall be responded to by the Steering Committee in accordance with the Standards Interpretation Policy of MedBiquitous, section 18.0. Revisions to the standard resulting from requests for interpretations shall be processed in accordance with the standards development procedures outlined in this document.

13.0 Appeals

Persons who have directly and materially affected interests and who have been or may be adversely affected by a procedural action or inaction of the Voting Body, or the Director shall have the right to appeal.

13.1 Complaint

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

13.2 Response

Within thirty days after receipt of the complaint, the respondent (Steering Committee Chair, Director, or Director's designee) shall respond in writing to the appellant, specifically addressing each allegation of fact in the complaint to the extent of the respondent's knowledge.

13.3 Hearing

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

13.4 Appeals Panel

The appeals panel shall consist of three individuals who have not been directly involved in the matter in dispute, and who will not be materially or directly affected by any decision made or to be made in the dispute. At least two members shall be acceptable to the appellant and at least two shall be acceptable to the respondent. If the parties to the appeal cannot agree on an appeals panel within six weeks, the matter shall be referred to the Steering Committee or its designee, which shall appoint the members of the appeals panel.

13.5 Conduct of the Hearing

The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the consensus body and the Director took all actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may adduce other pertinent arguments, and members of the appeals panel may address questions to individuals. *American Institute of Parliamentarians Standard Code of Parliamentary Procedure* (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

13.6 Decision

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

- a) Finding for the appellant, remanding the action to the Steering Committee or the Director with a specific statement of the issues and facts in regard to which fair and equitable action was not taken;
- b) Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections; and
- c) Finding that new, substantive evidence has been introduced, and remanding the entire action to the consensus body or the Director for appropriate reconsideration.

14.0 Parliamentary Procedures

On questions of parliamentary procedure not covered in these procedures *American Institute of Parliamentarians Standard Code of Parliamentary Procedure* (latest edition) may be used to expedite due process.

15.0 Record Retention Policy

The MedBiquitous Program shall retain records to demonstrate compliance with all aspects of these procedures and *ANSI Essential Requirements*. Such records shall be available for audit as directed by the ANSI Executive Standards Council (ExSC).

Records shall be retained for one complete standards cycle, 5 years, or until the standard is revised.

Records concerning withdrawals of all American National Standards shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule.

16.0 Designation and Publication of Standards

16.1 Standards Designation

Standards receiving final approval by the MedBiquitous Voting Body shall be designated MedBiquitous Specification No. XXX for [title]. If the standard has been submitted for approval as an American National Standard, the final approval ANSI standard shall be designated ANSI/MedBiquitous Specification No. XXX for [title]. On the cover of the standard shall be "An American National Standard."

16.2 Publication

MedBiquitous shall publish all approved standards within 6 months of approval. A notification to interested parties of the availability of the final standard shall be announced in a suitable media, i.e., *MedBiquitous Community Connection Newsletter* or the MedBiquitous website.

17.0 Maintenance of MedBiquitous Standards

All MedBiquitous standards require review four years from the date of approval. Review may occur sooner if deemed necessary by the Steering Committee Chair. The responsible Working Group shall

recommend reaffirmation, revision, or withdrawal of the standard. The action shall be completed by the end of the fifth year from the initial approval.

17.1 Reaffirmation

Standards recommended for reaffirmation shall be without any substantive change to the main text of the standard. Reaffirmations are to be handled in the same manner as new projects and revisions. All non-substantive changes in the main text of the standard shall be explained, or noted, in a foreword. MedBiquitous standards undergoing an update of references necessary to implement the standard shall be processed as a revision unless the updated reference is only a reaffirmation of the referenced standard. Any substantive changes in such references require processing as a revision.

17.2 Criteria for Withdrawal

The Voting Body may decide by vote to withdraw an ANSI /MedBiquitous Standard. Any materially interested party may request that a standard be withdrawn. If the Voting Body does not concur with the proposed withdrawal, the Steering Committee Chair shall inform the proponent and include reasons.

18.0 Standards Interpretation Policy

Requests for interpretation of standards shall be in writing and shall be addressed to the AAMC, 655 K St NW, Suite 100, Washington, DC 20001-2399, ATTN: MedBiquitous Director, or to medbiq@aamc.org.

Requests shall be reviewed by the Technical Advisory Group, which may request input from other MedBiquitous working groups or committees in developing an interpretation. Proposed interpretations must be approved by the Voting Body. If, as a result of this review revisions are made, the revision process will be initiated in accordance with this document.

Under no circumstances is a Steering Committee or Working Group participant authorized to interpret ANSI/MedBiquitous standards. Interpretation includes officially responding on behalf of MedBiquitous as to whether a specific, named data or information standard(s), meets the requirements of an ANSI/MedBiquitous standard or whether procedures and practices not addressed in a MedBiquitous standard are acceptable. Official interpretations of ANSI/MedBiquitous standards shall be made by the MedBiquitous Program or its designee (i.e., appropriate MedBiquitous Committee) in writing to the requestor. Interpretations shall be posted to the MedBiquitous website once issued. No person shall have the authority to issue an interpretation of an ANSI/MedBiquitous standard in the name of the American National Standards Institute or the MedBiquitous Program.

19.0 Metric Policy

In order to maintain consistency between various ANSI/MedBiquitous Specifications, all MedBiquitous Specifications include SI units as defined in NIST Special Publication 811, 2008 Edition, Guide for the Use of the International Systems of Units (SI).

20.0 Patent Policy

(The text for this section was adapted from clause 3.1 of the ANSI Essential Requirements 2020.)

There is no objection in principle to drafting an American National Standard (ANS) or MedBiquitous Standard (MBQ) in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

Participants in the MedBiquitous standards development process are encouraged to bring patents with claims believed to be essential to the attention of the Working Group Chair(s) and the MedBiquitous Director.

If the MedBiquitous Director receives a notice that a proposed, revised or approved ANS or MBQ may require the use of such a patent claim that is not already covered by an existing assurance, the procedures in this clause shall be followed.

20.1 Statement from patent holder

The patent holder, or a party authorized to make assurances on its behalf, shall provide to the MedBiquitous Director, in written form, either:

- a. assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
- b. assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:
 - i. under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
 - ii. without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

Such assurance shall indicate that the patent holder (or third party authorized to make assurances on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest.

The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

20.2 Record of statement

A record of the patent holder's statement shall be retained by MedBiquitous and shall be made publicly available on the MedBiquitous Knowledgebase (<https://groups.medbiq.org>).

20.3 Notice

When the MedBiquitous Director receives from a patent holder the assurance set forth in 20.1.b above, the Director shall include in the standard a note substantially as follows:

NOTE – The user's attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.

By publication of this standard, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. If a patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then details may be obtained from the standards developer.

20.4 Responsibility for identifying patents

Neither MedBiquitous nor ANSI is responsible for identifying patents for which a license may be required by an American National Standard or for conducting inquiries into the legal validity or scope of those patents that are brought to their attention.

21.0 Antitrust Policy

(The text for this section was adapted from clause 3.3 of the ANSI Essential Requirements 2020.)

The MedBiquitous Program and its Participants and Working Group members shall develop American National Standards and MedBiquitous Standards in accordance with applicable antitrust and competition laws, and meetings amongst competitors to develop ANS or MBQ are to be conducted in accordance with these laws.

22.0 International Standards

The Standards Committee should take ISO standards into consideration and should, if appropriate, base their standards on or consider the adoption of an ISO standard as an American National Standard.

23.0 Commercial Terms and Conditions

(The text for this section was adapted from clause 3.3 of the ANSI Essential Requirements 2020.)

Provisions involving business relations between buyer and seller such as guarantees, warranties, and other commercial terms and conditions must not be included in an American National Standard or MedBiquitous Standard. The appearance that a standard endorses any particular products, services, or companies must be avoided. Therefore, it generally is not acceptable to include manufacturer lists, service provider lists, or similar material in the text of a standard or in an annex (or the equivalent). Where a sole source exists for essential equipment, materials, or services necessary to comply with or to determine compliance with the standard, it is permissible to supply the name and address of the source in a footnote or informative annex as long as the words “or the equivalent” are added to the reference. In connection with standards that relate to the determination of whether products or services conform to one or more standards, the process or criteria for determining conformity can be standardized as long as the description of the process or criteria is limited to technical and engineering concerns and does not include what would otherwise be a commercial term.