



# **MedBiquitous Standards Program Operating Procedures**

**12 May 2015**



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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 as given in Clause 1 of the *ANSI Essential Requirements*.

## **2.0 Organization of the Standards Development and Consensus Processes**

The development of an ANS standard within the MedBiquitous Consortium takes place largely within the Standards Committee. The Standards Committee shall serve as the consensus body. The Standards Committee is made up of materially affected parties who have an interest in the standards being developed. The Executive Director will be a member of the Standards Committee. The Executive Director may also appoint appropriate staff members as non-voting observers on the Standards Committee. Members of the Standards Committee shall consist of interested and qualified individuals who are either Consortium members or the public. Public participation will ensure representation by interested parties who do not have Consortium membership. Members of the Standards Committee will have the ability to comment and approve/disapprove of the standard. The Standards Committee shall have a title, scope, and an interest classification system for members. The membership 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*.

Consortium members 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.

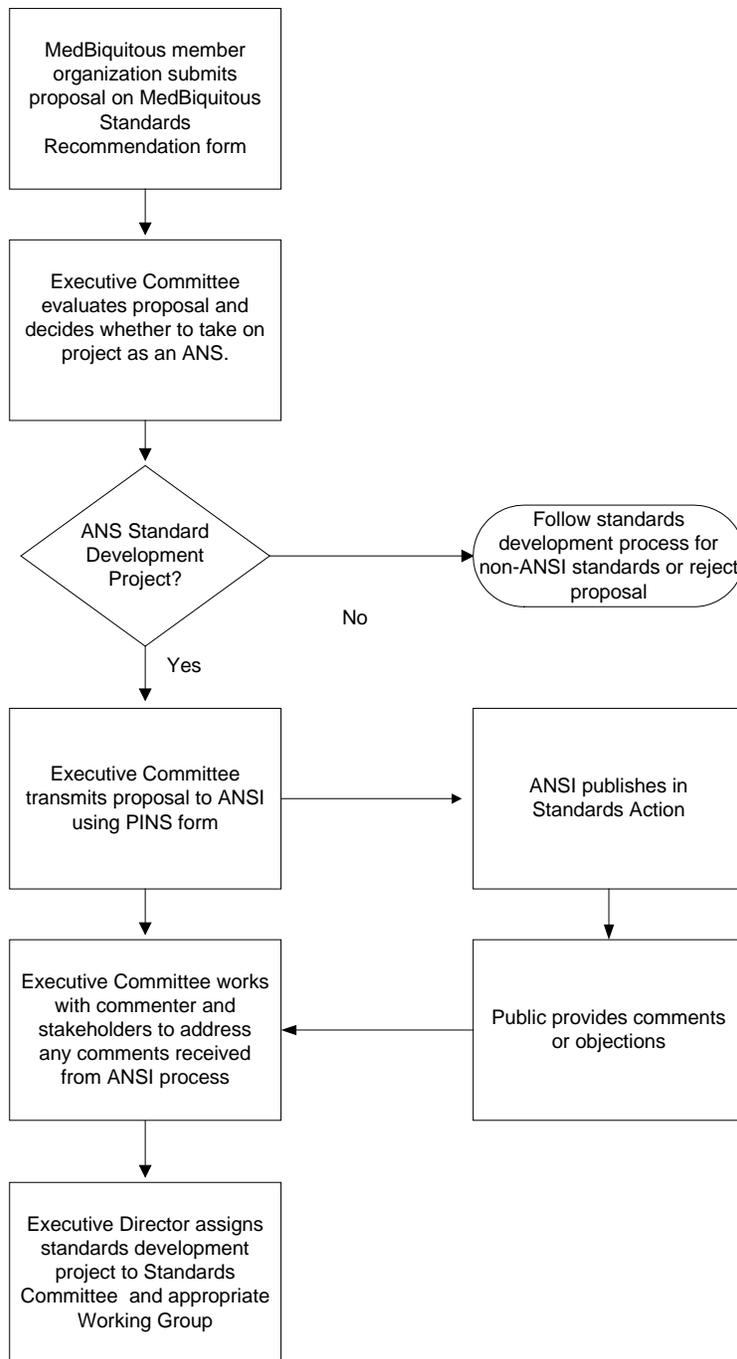
## **3.0 Responsibilities**

This section describes the roles and responsibilities of participants in the standards development and approval processes within the MedBiquitous Consortium. Table 1, which follows, provides an overview of 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 Consortium creates a new standard, ANSI approves it, and the standard is made public. Also included is a description, by role, of standards development responsibilities.

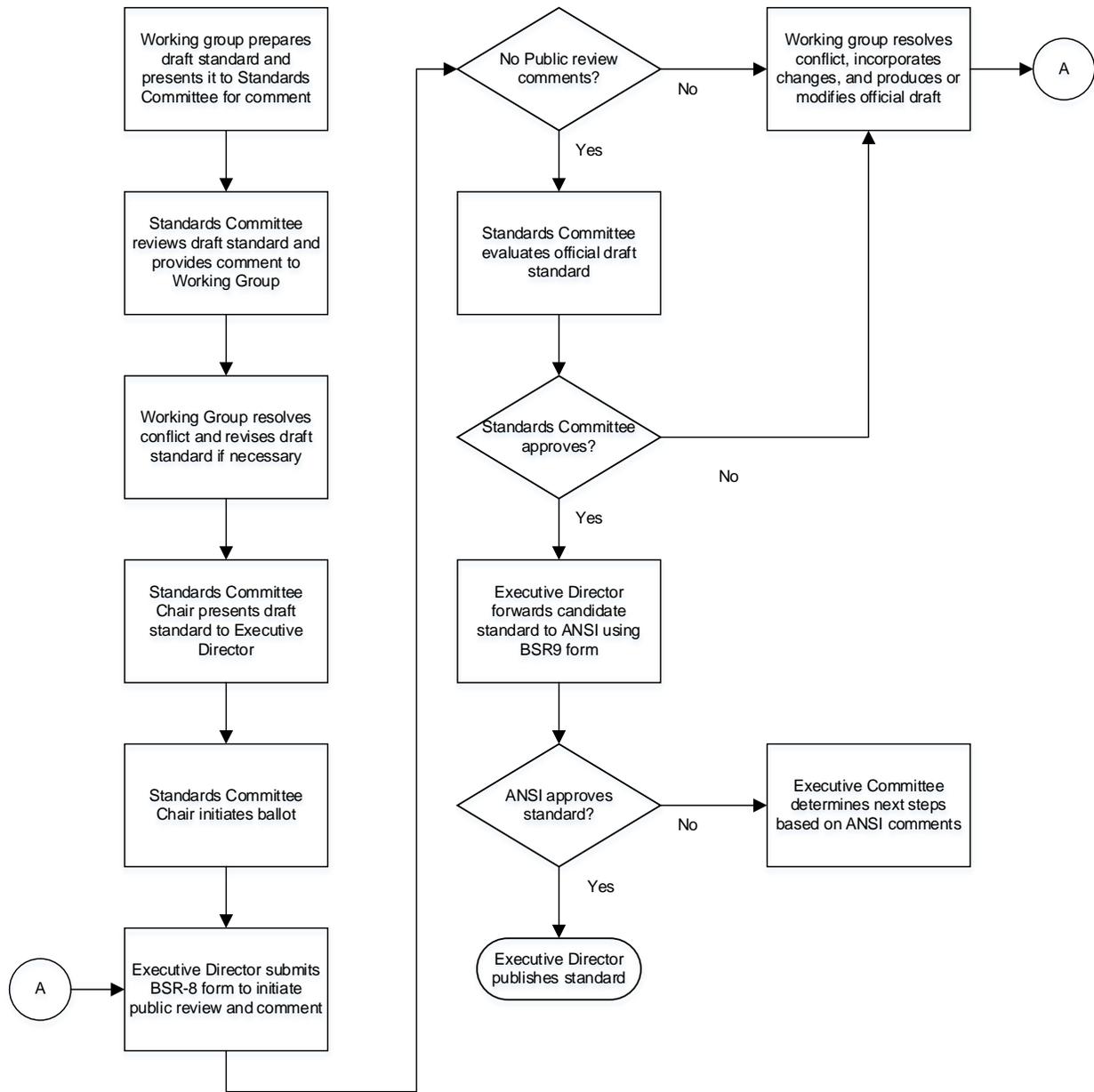
**Table 1. Overview of Standards Development and Approval Process**

<b>Person or Group</b>	<b>Process</b>
Consortium Member	On the MedBiquitous Standards Recommendation form, member submits a proposal for the development of a standard to the Executive Committee.
Executive Committee	Evaluates the proposal and decides to take on the project as an American National Standard. A two-thirds majority of the Executive Committee is required to approve each Standards Project Proposal.  Otherwise, Executive Committee rejects the proposal or takes it on as a non-ANSI standards project. The Executive Committee makes a good faith effort to resolve potential conflicts with existing and candidate American National Standards and to coordinate standardization activities.
Executive Committee	Transmits proposal for new standards to ANSI using the Project Initiation Notification System (PINS) form.
ANSI	Publishes announcement in ANSI's Standards Action.
Public	Provides comments or objections.
Executive 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.
Executive Director	Assigns standards project to Standards Committee and appropriate Working Group based on the area of concern of the proposal.
Working Group	Prepares draft standard.
Working Group	Presents draft standard to Standards Committee and solicits comments.
Standards Committee	Reviews standard and provides comments to Working Group.
Working Group	Resolves any conflict resulting from comments and incorporates changes as appropriate.
Standards Committee Chair	Presents draft standard to Executive Director.
Executive Director	Submits a BSR-8 form to initiate public review and comment.
Standards Committee Chair	Initiates ballot of the draft standard.
Working Group	Addresses comments, recirculates any outstanding

	objections to the Standards Committee.
Standards Committee	Evaluates the draft standard and notifies objectors of disposition of objection and their right of appeal.
Executive Director	Submits a BSR-8 form to initiate public review and comment if substantive changes are made.
Standards Committee	Approves draft standard and promotes to candidate standard.  If the draft standard is not approved, the Working Group resolves issues and incorporates changes until conflict is resolved.  If substantive changes are made, the Executive Director initiates another public review.
Standards Committee Chair	Forwards candidate standard to Executive Director.
Executive Director	Submits candidate standard approved by the Standards Committee, with supporting documentation using BSR-9 form, for ANSI review and approval as American National Standards.
Executive Director	If ANSI approves standard, publishes standard.



**Figure 1. Acceptance of ANS Standards Development Project**



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

### **3.1 Executive Committee**

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

The Executive 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 Executive 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 Executive Director**

In the standards development process, the Executive Director serves as the secretariat, coordinating the efforts of Consortium Staff, Standards Committee, and Working Groups. In keeping with that responsibility, the Executive Director performs the following tasks:

- a) Assigning Standards Project Proposals approved by the Executive Committee to the Standards Committee;
- b) Selecting the appropriate Working Group for each standards development project approved by the Executive Committee.
- c) Appointing a Chair for the Standards Committee subject to the approval of the Standards Committee;
- d) Appointing a Chair for each Working Group;
- e) Maintaining a roster of the Standards Committee and a list of standards for which it is responsible;
- f) 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;
- g) When applicable, submitting candidate standards approved by the Standards Committee, with supporting documentation, for ANSI review and approval as American National Standards;
- h) Publishing approved standards;

- i) Performing other administrative functions as required by these procedures.

### **3.3 Standards Committee**

The Executive Director assigns ANSI approved standards proposals to the Standards Committee. The Standards Committee shall guide the standards proposals through the process of creating official ANSI standards.

The Standards Committee shall be responsible for:

- a) Voting on approval of proposed American National Standards;
- b) Maintaining the standards developed within the Committee in accordance with Clause 4.7 of the *ANSI Essential Requirements* ;
- c) Adopting policy and procedures for interpretations of the standard(s) developed by the Consortium;
- d) Responding to requests for interpretations of the standard(s) developed within this Committee;
- e) Other matters requiring consensus body action as provided in these procedures.

### **3.4 Working Groups**

Consortium members appoint representatives to relevant working groups. The Executive Director appoints the Chair of each Working Group. Each Working Group consists of a Chair, one or more Consortium Staff and/or Invited Experts, and members of the Consortium. 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 Executive 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 Executive Committee. The Executive Director, Working Group Chair, or Working Group members may submit comments on the proposal to terminate Working Group activities to the Executive Committee prior to their vote on the matter.

### **4.0 Appointment of Officers**

The Executive Director shall appoint a Chair for the Standards Committee subject to the approval of the Standards Committee. The Chair will serve a two-year appointment for a maximum of a four-year term.

### **5.0 Membership**

Membership on the Standards Committee shall consist of individuals having a direct and material interest in the activities of the Committee. Each Consortium member organization will have the opportunity to select a voting member and an alternate to serve on the Standards Committee. The voting member shall be the individual to cast a vote for the organization; if the voting member indicates that he or she is unavailable, the alternate may be the individual to cast the vote for his or her organization. An organization may change the voting member or alternate

by notifying the Executive Director. Interested parties who are not members of the Consortium and who wish to join the Standards Committee shall submit an application to that Committee. The Committee shall select members based on technical expertise and balance of interests. The selection and addition of members, along with their interest category, shall be subject to approval by a majority vote of the Standards Committee after the application has been processed.

## **5.1 Application**

A request for membership on the Standards Committee shall be addressed to the MedBiquitous Consortium and will be referred to the Standards Committee Chair. Applications shall indicate the applicant's direct and material interest in the Committee'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 membership, the Standards Committee shall consider the:

- a) Need for active participation by each interest;
- b) Need for balance among interest categories as described in section 5.4;
- 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;
- e) Representative identified by the applicant organization, company, or government agency.

An annual fee will be assessed to all Standards Committee participants to defray administrative costs of the Consortium. An applicant may request for the administrative fee for participating in the Standards Committee to be waived if the fee would constitute an undue financial barrier. The Standards Committee shall consider any fee waiver requests. Fee waivers shall be subject to approval by a majority vote of the Standards Committee.

### **5.1.1 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 Standards Committee, each is permitted to apply for membership.

### **5.1.2 Combined Interest**

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

## **5.2 Review of Membership**

The Executive Director shall review the Standards Committee membership list annually with respect to the criteria listed in *Application*. Members are expected to fulfill obligations of active participation, including voting and meeting participation. Where a member is found in habitual default of these obligations, the Executive Director shall direct the matter to the Standards Committee for appropriate action, which may include termination of membership.

### **5.3 Observers and Individual Experts**

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

### **5.4 Interest Categories**

All appropriate interests that are directly and materially affected by the standards activity of the Standards Committee shall have the opportunity for fair and equitable participation without dominance by any single interest category, organization, or individual. Each member 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 Standards Committee should have a balance of interests. For non-safety related item, no single category shall constitute a majority. For safety-related items, no single interest category shall constitute more than one third of the committee. 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) Professional society – including, but not limited to, associations for individuals of a specific health profession or healthcare specialty.
- b) University – 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 the 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 member from each entity, company, or organization.

Appropriate, representative user views shall be actively sought and fully considered in standards activities. Whenever possible, user participants shall be those with the requisite technical

knowledge, but other users may also participate. User participation should come from both individuals and representatives of organized groups.

## **5.5 Membership Roster**

The Executive Director shall maintain a current and accurate Standards Committee roster and shall distribute it to Consortium members and Standards Committee members at least annually, and otherwise on request. The roster shall include the following:

- a) Title of the Standards Committee;
- b) Scope of the Standards Committee;
- c) Officers: Chair;
- d) Members: name of organization or agency, its representative and alternate (as applicable), addresses, and business affiliation; or name, address, and business affiliation of individual member(s);
- e) Interest category of each member;
- f) Tally of interest categories: total of voting members and subtotals for each interest category;
- 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 entire Standards Committee for approval.

## **7.0 Meetings**

Standards Committee meetings may be held, as decided upon by the Standards Committee, the Chair, the Executive Director, or by petition of five or more members, to conduct business, such as making assignments, receiving reports of work, considering draft standards, and considering views and objections from any source. Votes will not require attendance at an in-person or virtual meeting. Meetings of Working Groups may be held as decided upon by the members or Chair of the Working Group. The Standards Committee and Working Groups may choose to meet by teleconference or other “virtual” meeting mechanism.

### **7.1 Open Meetings**

Meetings of the Standards Committee shall be open to all members and others having a direct and material interest. At least four weeks’ notice of regularly scheduled meetings of the consensus body shall be given by the Executive Director in ANSI’s *Standards Action*; *MedBiquitous 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 members and to others expressing interest.

### **7.2 Quorum**

A majority of the members of the Standards Committee 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**

Votes on approving standards shall be conducted by letter ballot. Except in regard to votes on membership and officer-related issues, each member 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 membership 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 organizations appoint the same individual to represent each of them, that individual may cast a separate vote for each organization represented. The organizations shall confirm in writing to the Executive 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 consensus body, excluding the vote of that individual.

#### **8.1.3 Ballot Pool**

The ballot pool shall consist of all those organizations and individuals designated as voting members of the Standards Committee at the time the balloting process begins. If a voting member wishes to change its representation on the standards committee due to employee departure or other circumstances that make the primary representative and alternative unavailable for the ballot, the voting member may request a change in representation. Such modifications will be granted at the Chair's discretion. Organizations and individuals joining the Standards Committee 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 chair's option, when warranted.

A follow-up notice requesting immediate return of the ballot shall be sent, as appropriate, to members and alternate members 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 majority of the membership of the Standards Committee by a formal recorded vote:

- a) Confirmation of Committee Chair appointed by the Executive Director;
- b) Addition of new Standards Committee members.

## **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 Standards Committee membership and at least two-thirds of those voting, excluding abstentions:

- a) Adoption of Standards Committee 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 Standards Committee scope;
- 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 Chair;
- b) The Executive Director;
- c) Petition of five or more members of the Standards Committee.

## **8.5 Other Review**

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 Executive Director shall determine whether listing of proposed standards actions shall be concurrent with the final Standards Committee ballot and whether announcement in other suitable media is appropriate. The Executive 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*. 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 of the Standards Committee; the chair shall determine whether the expressed views and objections shall be considered by correspondence or at a meeting.

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on either the PINS announcement or public comment listing in *Standards Action*. 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 that an appeals process exists within procedures used by the standards developer. 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 Standards Committee members in order to afford all members 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 Standards Committee.

### **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 Executive Director.

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

### **10.0 Discontinuance of a Standards Project**

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

## **11.0 Termination of Standards Committee**

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

- a) Reasons why the Standards Committee 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 Standards Committee.

If it appears, after review and discussion among the proponent of the action, the Executive Director and the Board of Directors, 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 Standards Committee 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 Executive Director, and the Chair of the Standards Committee.

### **12.2 External Communication**

Inquiries relating to the Standards Committee should be directed to the Executive Director, and members should so inform individuals who raise such questions. All replies to inquiries shall be made through the Executive Director.

### **12.3 Requests for Interpretation of Standards**

Written inquiries requesting interpretation of approved American National Standards shall be responded to by the Standards Committee in accordance with the Standards Interpretation Policy of MedBiquitous. 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 Standards Committee or the Executive Director shall have the right to appeal.

### **13.1 Complaint**

The appellant shall file a written complaint with the Executive 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 (Chair or Executive Director representative) 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 Executive 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 Board of Directors 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 Executive 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. *Sturgis 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 Standards Committee or the Executive 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;
- c) Finding that new, substantive evidence has been introduced, and remanding the entire action to the consensus body or the Executive Director for appropriate reconsideration.

## **14.0 Parliamentary Procedures**

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

## **15.0 Record Retention Policy**

MedBiquitous 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, 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 Standards Committee 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., *The MedBiquitous 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 Standards 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 Standards Committee may decide by vote to withdraw an ANSI /MedBiquitous Standard. Any materially interested party may request that a standard be withdrawn. If the Standards Committee does not concur with the proposed withdrawal, the Standards 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 Executive Director, MedBiquitous Consortium, c/o Johns Hopkins at Mt. Washington, 5801 Smith Ave, Davis 3110C, Baltimore, MD 21209.

Requests shall be reviewed by the Standards Committee, which may request input from other MedBiquitous working groups or committees in developing an interpretation. Proposed interpretations must be approved by the Standards Committee. 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 Committee or Working Group member 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 Consortium 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 Consortium.

## **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, 1995 Edition, Guide for the Use of the International Systems of Units (SI).

## **20.0 Patent Policy**

For any MedBiquitous standards submitted to ANSI for approval as American National Standards, MedBiquitous will comply with the most current version of the ANSI Patent Policy in clause 3.1 of the *ANSI Essential Requirements*.

## **21.0 Antitrust Policy**

For any MedBiquitous standards submitted to ANSI for approval as American National Standards, MedBiquitous will comply with the most current version of the ANSI Antitrust Policy in clause 3.3 of the *ANSI Essential Requirements*.

## **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**

MedBiquitous will comply with the most current version of the ANSI Commercial Terms and Conditions in clause 3.2 of the *ANSI Essential Requirements*.