

**IEEE EMBS P2621.1, P2621.2, and P2621.3
Healthcare Device Security Assurance Working Group
(EMB/Std Com/HDSecWG)**

Policies and Procedures for:

**IEEE EMBS P2621.1, P2621.2, and P2621.3
Healthcare Device Security Assurance Working Group
(EMB/Std Com/HDSecWG)**

Date of Sponsor Approval: August 09, 2019

**IEEE EMBS P2621.1, P2621.2, and P2621.3
Healthcare Device Security Assurance Working Group
(EMB/Std Com/HDSecWG)
Policies and Procedures for Standards Development**

1.0 Introduction

1.0.1 Role of Standards Development and these Procedures

In today's technological environment, standards play a critical role in product development and market competitiveness. In the IEEE, the responsibility for how a standard originates and evolves is managed by a Sponsor. It is essential in the management of a standard's development to avoid any actions by the Sponsor or the participants that result in a violation of procedures. These procedures establish the necessary framework for a sound standardization process.

1.0.2 Modifications to These Procedures

These Policies and Procedures outline the orderly transaction of business by the IEEE EMBS P2621.1, P2621.2, and P2621.3 Healthcare Device Security Assurance Working Group (EMB/Std Com/HDSecWG), hereinafter referred to as "the Working Group".

The Working Group may amend these procedures with the approval of its Sponsor. The Sponsor may modify these procedures. Modification in this context means that material in these procedures may be modified as long as that clause is not indicated as one that cannot be changed. It is strongly recommended that all subjects included in these procedures are addressed by the Working Group or Sponsor. (See also Clause 7.)

In this document, the term "sponsor" means the sole sponsor, or in the case of co-sponsored projects, the primary sponsor.

1.0.3 Hierarchy

Participants engaged in the development of standards shall comply with applicable federal, state, and international laws. In addition, for standards matters, the latest version of several documents takes precedence over these procedures in the following order:

[New York State Not-for-Profit Corporation Law](#)

[IEEE Certificate of Incorporation](#)

[IEEE Constitution](#)

[IEEE Bylaws](#)

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Baseline Policies and Procedures for Standards Development – WGs - Individual
IEEE-SA Standards Board Approved December 2015

IEEE Policies

IEEE Board of Directors Resolutions

IEEE Standards Association (IEEE-SA) Operations Manual

IEEE-SA Board of Governors Resolutions

IEEE-SA Standards Board Bylaws

IEEE-SA Standards Board Operations Manual

IEEE-SA Standards Board Resolutions

Policies and Procedures of *IEEE EMB Standards Committee*

Robert's Rules of Order Newly Revised (RONR) is the recommended guide on questions of parliamentary procedure not addressed in these procedures.

1.0.4 Fundamental Principles of Operation

For the development of standards, openness and due process are mandatory.

Openness means that any person who has, or could be reasonably expected to have, a direct and material interest, and who meets the requirements of these procedures, has a right to participate by:

- a) Attending Working Group meetings (in person or electronically)
- b) Becoming a member of the Working Group
- c) Becoming an officer of the Working Group
- d) Expressing a position and its basis,
- e) Having that position considered, and
- f) Appealing if adversely affected.

IEEE due process requires a consensus of those parties interested in the project. Consensus is defined as at least a majority agreement, but not necessarily unanimity.

Due process is based upon equity and fair play. In addition, due process requires openness and balance (i.e., the standards development process shall strive to have a balance of interests and not to be dominated by any single interest category). However, for the IEEE Standards Sponsor ballot, there shall be a balance of interests without dominance by any single interest category.

1.0.5 Definitions

"Written communication" includes but is not limited to meeting minutes, letter, email, and fax.

2.0 Working Group Responsibilities

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The Working Group shall:

- a) Complete the project from Project Authorization Request (PAR) approval to IEEE-SA Standards Board approval as specified by the PAR, and in compliance with IEEE Standards policies and procedures.
- b) Use the IEEE Standards document template format.
- c) Submit to the Sponsor any documentation required by the Sponsor; e.g., a project schedule or a monthly status report.
- d) Notify the Sponsor of the draft development milestones.
- e) Notify the Sponsor when the draft is ready to begin IEEE Standards Sponsor ballot.

3.0 Officers

There shall be a Chair and a Secretary, and there should be a Vice-Chair. The office of Treasurer is suggested if significant funds are involved in the operation of the Working Group and/or its subgroups or if the group has multiple financial reports to supply to the IEEE-SA. A person may simultaneously hold the positions of Secretary and Treasurer.

The Chair and Secretary (and any person designated to manage the Sponsor ballot) shall each be IEEE members of any grade, or IEEE Society affiliates, and also be members of IEEE-SA.

3.1 Appointment of Officers

The Working Group Chair shall be appointed in accordance with the Sponsor's procedures. After appointment of the Working Group Chair by the entity that established this Working Group, the Working Group Chair shall appoint a Vice-Chair and a Secretary.

The appointment of officers shall be for a term of one year, but an officer may serve until a successor is appointed.

3.2 Temporary Appointments to Vacancies

If an office other than the Chair becomes vacant for any reason (such as resignation, removal, lack of nomination at an election), a temporary appointment shall be made by the Chair for a period of up to 12 months. In the case of Chair, the Sponsor shall make the temporary appointment, with input from the Working Group. An appointment or election for the vacated office shall be made in accordance with the requirements in Clause 3.0 and 3.1 at the earliest practical time.

3.3 Removal of Officers

An officer may be removed by approval of two-thirds of the members of the Working Group, or in accordance with the procedures of the Sponsor. Removal of the Chair requires affirmation by the Sponsor. Grounds for removal shall be included in any motion to remove an officer of the Working Group. The officer suggested for removal shall be given an opportunity to make a rebuttal prior to the vote on the motion for removal.

3.4 Responsibilities of Working Group Officers

When carrying out the duties of an officer described in IEEE's policies and procedures, officers of the Working Group:

- a) shall not act:
 - 1) in bad faith;
 - 2) to the detriment of IEEE-SA;
 - 3) to further the interest of any party outside IEEE over the interest of IEEE; or
 - 4) in a manner that is inconsistent with the purposes or objectives of IEEE; and
- b) shall use best efforts to ensure that participants of the Working Group conduct themselves in accordance with applicable policies and procedures including, but not limited to, the *IEEE-SA Standards Board Bylaws* clause on "Participation in IEEE standards development."

The officers of the Working Group shall manage the day-to-day operations of the Working Group. The officers are responsible for implementing the decisions of the Working Group and managing the activities that result from those decisions.

3.4.1 Chair

The responsibilities of the Chair or his or her designee shall include

- a) Leading the activity according to all of the relevant policies and procedures.
- b) Forming study groups, as necessary.
- c) Being objective.
- d) Entertaining motions, but not making motions.
- e) Not biasing discussions.
- f) Delegating necessary functions.

- g) Ensuring that all parties have the opportunity to express their views.
- h) Setting goals and deadlines and adhering to them.
- i) Being knowledgeable in IEEE standards processes and parliamentary procedures and ensuring that the processes and procedures are followed.
- j) Seeking consensus as a means of resolving issues.
- k) Prioritizing work to best serve the Working Group and its goals.
- l) Complying with the Chair's responsibility with respect to the IEEE-SA Intellectual Property Policies, including but not limited to the IEEE-SA Patent Policy (see "Patents" clause of *IEEE-SA Standards Board Bylaws* and "Call for patents" clause of *IEEE-SA Standards Board Operations Manual*) and Copyright (see "Copyright" clause of *IEEE-SA Standards Board Bylaws* and the *IEEE-SA Standards Board Operations Manual*).
- m) Fulfilling any financial reporting requirements of the IEEE, in the absence of a Treasurer.
- n) Participating as needed in meetings of the Sponsor to represent the Working Group.
- o) Being familiar with training materials available through [IEEE Standards Development Online](#).

3.4.2 Vice-Chair

The responsibilities of the Vice-Chair shall include:

- a) Carrying out the Chair's duties if the Chair is temporarily unable to do so or chooses to recuse himself or herself (i.e., to give a technical opinion) or chooses to delegate specific duties.
- b) Being knowledgeable in IEEE standards processes and parliamentary procedures and assisting the Chair in ensuring that the processes and procedures are followed.
- c) Being familiar with training materials available through [IEEE Standards Development Online](#).

3.4.3 Secretary

The responsibilities of the Secretary include:

- a) Scheduling meetings in coordination with the Chair and distributing meeting notices.
- b) Distributing meeting agenda (as per 6.0). Notification of the potential for action shall be included on any distributed agendas for meetings.

- c) Recording minutes of each meeting according to Clause 6.5 and IEEE guidelines (see <http://standards.ieee.org/develop/policies/stdslaw.pdf>), and publishing them within 60 calendar days of the end of the meeting.
- d) Creating and maintaining the membership roster, referred to in 4.3, and submitting it to the Sponsor (or SCC) Secretary annually.
- e) Being responsible for the management and distribution of Working Group documentation.
- f) Maintaining lists of unresolved issues, action items, and assignments.
- g) Recording attendance of all attendees.
- h) Maintaining a current list of the names of the voting members and distributing it to the members upon request.
- i) Forwarding all changes to the roster of voting members to the Chair.
- j) Being familiar with training materials available through [IEEE Standards Development Online](#).

3.4.4 Treasurer

Not applicable

4.0 Working Group Membership

Persons involved in the standards development process are referred to as participants (see *IEEE-SA Standards Board Bylaws* clause on “Participation in IEEE standards development”).

A member is a participant that has satisfied the requirements for membership, as defined in this clause and its subclauses.

A voting member is a member that has satisfied the requirements for voting membership, as defined in this clause and its subclauses.

All participants who are neither voting members nor non-voting members are classified as non-members.

4.1 Overview

Working Group membership is by individual. Those attending meetings shall pay any required meeting fees if established. Participants seeking Working Group voting membership are responsible for fulfilling the requirements to gain and maintain membership.

4.1.1 Working Group Membership Status

Voting membership shall be granted automatically to those participants attending the first meeting of a newly chartered Working Group upon their request. Thereafter, voting membership shall be granted after the participant attends two consecutive meetings of an existing Working Group, and also requests voting membership status.

Each voting member is expected to attend meetings as required by these procedures. The Secretary records attendance at meetings. A participant shall be considered attending the meeting who attends at least 50% of a meeting's duration. Attendance at a meeting via teleconferencing and/or electronic means, e.g., Internet conferencing, shall count towards the attendance requirements.

Voting member status is maintained through consistent participation at meetings and through Working Group votes. If a Working Group member misses two consecutive meetings, or two consecutive Working Group letter ballots, his or her voting privileges may be revoked. The Chair shall notify, in writing, a voting member who fails to attend two consecutive meetings and who has therefore lost his or her voting privileges.

A person who has lost his or her voting privileges shall have his or her voting privileges reinstated by attendance at two consecutive meetings of the Working Group and upon request for voting member status. All voting privileges and rights shall be restored after attending the second consecutive meeting. If, for reasons of personal hardship, a member cannot attend two consecutive meetings (but that member continues to vote in ballots taken between meetings), the Working Group Chair will be consulted on the status of the member.

4.2 Review of Membership

The Chair shall review the voting membership list annually for the previous year. Voting members are expected to fulfill the obligations of active participation as defined in Clause 4.1.1. When a voting member is found in habitual default of these obligations, the Chair shall consider the matter for appropriate action, which may include termination of membership.

4.3 Working Group Membership Roster

A Working Group roster is a vital aspect of standards development. It serves as a record of voting members and members in the Working Group and is an initial tool if an issue of indemnification arises during the process of standards development.

The Secretary shall make reasonable efforts to maintain a current Working Group roster. The roster shall include at least the following:

- a) Title of the Sponsor and its designation.
- b) Title of the Working Group and its designation.
- c) Officers: Chair, Vice-Chair and Secretary.
- d) Members: for each, include name, email address, affiliation, and status (e.g., voting member, member, etc.).

All Working Group members are required to review their information contained in the roster following each meeting they attend. If a Working Group meets only virtually, it shall determine a schedule to check the accuracy of the roster periodically.

A copy of the Working Group roster shall be supplied to the IEEE-SA at least annually by a Working Group officer or designee. Due to privacy concerns, the roster shall not be distributed, except to the IEEE-SA staff, IEEE-SA Board of Governors and IEEE-SA Standards Board, unless everybody on the roster has submitted their written approval for such distribution.

4.4 Working Group Membership Public List

A Working Group officer or designee shall maintain a current and accurate membership list. The membership list can be posted on the Working Group web site and can be publicly distributed. The membership list shall be limited to the following:

- a) Title of the Working Group and its designation.
- b) Scope of the Working Group.
- c) Officers: Chair, Vice-Chair and Secretary.
- d) Members: for all, name, affiliation.

5.0 Subgroups of the Working Group

The Working Group may, from time to time, form subgroups for the conduct of its business. Voting Membership in the subgroup is granted to any participant of the Working Group. Such formation shall be explicitly noted in the meeting minutes. At the time of formation, the Working Group shall determine the scope and duties delegated to the subgroup, and may decide to allow participation of persons who are not Working Group members and specify the terms and conditions under which they participate in the subgroup. Any changes to its scope and duties will require the approval of the Working Group. Any resolution of a subgroup shall be subject to confirmation by the Working Group.

The Chair of the Working Group shall appoint, and may dismiss, the Chair of the subgroup.

6.0 Meetings

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Working Group meetings may be conducted either exclusively in-person or in-person with one or more participants contributing via electronic means, or exclusively via electronic means. Working Group meetings shall be held, as decided by the Working Group, the Chair, or by petition of 30 % or more of the voting members, to conduct business, such as making assignments, receiving reports of work, progressing draft standards, resolving differences between subgroups, and considering views and objections from any source. A meeting notice shall be distributed to all members at least 30 days in advance of a face-to-face meeting and at least 15 days' notice in advance for an electronic (including teleconference) meeting. A meeting agenda (including participation information) shall be distributed to all members at least 10 days in advance of a face-to-face meeting, and at least 7 days in advance for an electronic meeting. (Meetings of subgroups may be held as decided upon by the members or Chair of the subgroup.) Notification of the potential for action shall be included on any distributed agendas for meetings.

While having a balance of all interested parties is not an official requirement for a Working Group, it is a desirable goal. As such, the officers of the Working Group should consider issues of balance and dominance that may arise and discuss them with the Sponsor.

Participants shall be asked to state their employer and affiliation at each Working Group meeting as required by the *IEEE-SA SA Standards Board Operations Manual* clause on “Disclosure of Affiliation”).

Please note that all IEEE Standards development meetings are open to anyone who has a material interest and wishes to attend. However, some meetings may occur in Executive Session (see Clause 6.3).

6.1 Quorum

A quorum shall be identified and announced before the initiation of Working Group business at a meeting, but if a quorum is not present, actions may be taken subject to confirmation by letter or electronic ballot, as detailed in subclause 7.2 or at the next Working Group meeting. Unless otherwise approved by the Sponsor, a quorum shall be defined as one-half of Working Group voting members.

6.2 Conduct

Meeting attendees and participants in standards activities shall demonstrate respect and courtesy toward each other and shall allow each participant a fair and equal opportunity to contribute to the meeting discussion, in accordance with the [IEEE Code of Ethics](#).

All participants in standards activities shall act in accordance with all IEEE Standards policies and procedures.

6.3 Executive Session

Meetings to discuss personnel or sensitive business matters (e.g., the negotiation of contracts), or for other appropriate non-public matters (e.g., the receipt of legal advice), may be conducted in Executive Session.

The matters discussed in executive session are confidential, and therefore, attendance at the Executive Session shall be limited to those with governance authority, outside advisors (e.g., lawyers or consultants) where necessary to provide professional guidance, and select IEEE-SA staff who may have information or a perspective relevant to the subject matter discussed in Executive Session. An individual may be invited to join for a portion of the discussion and then excused at the appropriate time. In each case, except as authorized by the Working Group, participants in an Executive Session are prohibited from discussing or disclosing any information presented and discussed during such Executive Session to a third party or other person not present during the Executive Session, and shall not continue to discuss such matters after the Executive Session has adjourned.

Executive Sessions should be conducted face-to-face (in person) to provide the greatest assurance that the content of such Executive Sessions will be kept confidential. However, when necessary, Executive Sessions may include participants who participate by teleconference provided such persons agree not to disclose any information so discussed, and agree that they will participate in such conference in a manner that does not result in third parties gaining access to such discussions or information.

6.4 Meeting Fees

The Working Group, or meeting host, may charge a meeting fee to cover services needed for the conduct of the meeting. The fee shall not be used to restrict participation by any interested parties.

6.5 Minutes

The minutes shall concisely record the essential business of the Working Group, including the following items at a minimum:

- a) Name of group
- b) Date and location of meeting
- c) Officer presiding, including the name of the secretary who wrote the minutes
- d) Meeting participants, including affiliation
- e) Call to order, Chair's remarks
- f) Approval of minutes of previous meeting

- g) Approval of agenda
- h) Technical topics
 - 1) Brief summary of discussion and conclusions
 - 2) Motions exactly as they are stated, including the names of mover and seconder and the outcome of each motion
- i) Action items
- j) Items reported out of executive session
- k) Recesses and time of final adjournment
- l) Next meeting--date and location

All submissions, presentations, and reports considered during the meeting by the Committee/WG shall be referenced in the minutes. Urls should be provided where possible.

The following shall not be recorded in minutes:

- Transcriptions of detailed discussions
- Attributions of comments to specific participants

6.6 Suspension of Rules

None of the rules or requirements in these policies and procedures may be suspended.

7.0. Voting

7.1 Approval of an Action

Approval of an action requires approval by a majority (or two-thirds) vote as specified below in 7.1.1 (majority) and 7.1.2 (two-thirds). The “majority, two-thirds vote” is defined as either:

- a) At a meeting (including teleconferences) where quorum has been established, a vote carried by majority (or two-thirds) approval of the votes cast (i.e., Approve or Do Not Approve votes, excluding abstentions) by the voting members in attendance.
- b) By electronic means (including email), a vote carried by majority (or two-thirds) of the votes cast (i.e., Approve or Do Not Approve votes, excluding abstentions), provided a majority of all the voting members of the Working Group responded.

7.1.1 Actions Requiring Approval by a Majority Vote

The following actions require approval by a majority vote:

- a) Formation or modification of a subgroup, including its procedures, scope, and duties
- b) Disbandment of subgroups
- c) Approval of minutes.

7.1.2 Actions Requiring Approval by a Two-thirds Vote

The following actions require approval by a two-thirds vote:

- a) Approval of change of the Working Group scope *
- b) Establishment of fees, if necessary
- c) Approval to move the draft standards to the Sponsor for IEEE Standards Sponsor ballot *

*Item a) is subject to confirmation by the Sponsor. Item c) is subject to confirmation by the Sponsor, unless this authority has been delegated to the Working Group by the Sponsor.

7.2 Voting Between Meetings

At the discretion of the Chair, the Working Group shall be allowed to conduct votes between meetings by the use of a letter or electronic ballot. If such actions are to be taken, they shall follow the rules of IEEE Bylaw I-300.4(4).

8.0 Communications

Formal inquiries relating to the Working Group should be directed to the Chair and recorded by the Secretary. All replies to such inquiries shall be made through the Chair. These communications shall make it clear that they are responses from the Working Group. Communications shall be in compliance with the Sponsor's communication requirements.

9.0 Appeals

Any person dissatisfied with a technical decision shall follow the approved procedures for providing technical input to the Working Group, including but not limited to presenting the concern to the Working Group, and making a technical comment during the applicable comment submission and/or balloting period.

Procedural concerns within the Working Group shall first be presented to the Working Group Chair for resolution. If the procedural concern is not resolved after presentation to the Chair, the concern can be brought to the Sponsor for resolution.