DICOM℠
Digital Imaging and Communications in Medicine

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PROCEDURES

for the

DICOM Standards Committee

1 Scope of the DICOM Standards Committee

Numerous and diverse medical specialties create biomedical images. The DICOM Standards Committee exists to create and maintain international standards for the communication of biomedical, diagnostic and therapeutic information in those medical disciplines that use digital images and associated data.

The goal of the DICOM Standard is to achieve compatibility and improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide.

DICOM is a cooperative standard. Connectivity works because producers cooperate in testing via scheduled public demonstrations, over the Internet, and during private test sessions. Every major diagnostic medical-imaging vendor in the world has incorporated the standard into its product design, and most are actively participating in the enhancement of the standard. Most biomedical professional societies throughout the world support and participate in the enhancement of this standard.

Proposed standards are developed by working groups reporting to the Committee and are approved by the members of the Committee. Standards are published by the secretariat and are international in scope. The Committee is proactive to assure compatibility with related standards developed by other standards-developing and coordinating bodies such as ANSI, CEN, HL7, IEC, ISO and JIRA.

2 Membership

The Committee consists of its members and the secretariat. Membership in the Committee consists of manufacturing companies, service organizations, consulting companies, biomedical professional organizations, trade associations, other standards-developing organizations, academic institutions and government agencies worldwide that have a direct and material interest in the activities of the Committee.

The addition or termination of members shall be subject to approval by vote of the Committee as provided in this section.

2.1 Responsibility of Committee Members

The Committee members are responsible for:

a) Developing proposed standards within the scope of the Committee;

b) Voting to approve proposed standards within its scope;

c) Maintaining the Committee's standard by reaffirming, revising or withdrawing the standard within five years of its approval;

d) Responding to requests for interpretations of the Committee's standard;

e) Adopting Committee policy and procedures and revisions thereof;

f) Considering and acting on proposals for termination of the Committee and

g) Other matters requiring Committee action as provided in these procedures.

2.2 Application

A request for membership shall be addressed to the secretariat and shall indicate the:

a) Applicant's direct and material interest in the Committee's work;

b) Applicant's qualifications and willingness to participate actively;

c) Applicant's agreement to the Committee's Patent Disclosure Policy (Section 9 below)

Interest category of the applicant and

d) Identification of a principal representative (and alternate(s), if desired).

2.2.1 Recommendation

The secretariat shall make a recommendation to the Committee for action on applications for membership it receives. In recommending appropriate action to the Committee, the secretariat shall consider the:

a) Need for active participation by each interest;

b) Potential for dominance by a single interest category;

c) Extent of interest expressed by the applicant and the applicant's willingness to participate actively and

d) The representative identified by the applicant organization, company, or government agency.

The secretariat may consider reasonable limits on Committee size.

2.2.2 Diverse Interests

If distinct divisions of an organization can demonstrate independent interests and authority to make independent decisions in the area of the activity of the Committee, each may apply for membership.

2.2.3 Combined Interest

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

2.2.4 Review of Membership

The secretariat shall review the membership with respect to the criteria of this section. Members are expected to fulfill obligations of active participation and maintaining current payment of dues.

If any member of the Committee is not represented at two consecutive meetings of the Committee, the member will not be counted in the determination of a quorum for the next meeting at which it is not represented. After the second meeting where the member is not represented, the secretariat shall notify the member in writing. The member's representative may vote at the next meeting that he or she does attend.

Members shall be suspended from the Committee if they do not pay their dues within three months of the invoice date. Suspended members have no voting rights in committee meetings or letter ballots. Suspended members will be reinstated if dues are received within six months of the invoice date.

Members shall be terminated from the Committee if they do not pay their dues within six months of the invoice date. Terminated members may be reinstated only by vote of the Committee.

2.2.5 Observers

Individuals and organizations having an interest in the Committee's work may request listing in the Committee's roster as observers (mailers).

Observers shall be advised of the Committee activities, may attend meetings and may submit comments for consideration, but they shall have no vote.

2.2.6 Interest Categories

All appropriate interests that might be directly and materially affected by the standards activity of the Committee shall have the opportunity for fair and equitable participation without dominance by any single interest. Each member shall propose its own interest category as appropriate and in accordance with the Committee's established categories.

Members are classified into the following interest categories: producers, users, and general interest.

The interest categories may be revised by a vote of the Committee upon recommendation of the secretariat. The rationale for the selection of categories shall be included in the Committee ballot.

2.3 Member Affiliation

2.3.1 Producers

Any manufacturing company, service organization or consulting company that wishes to participate in standards development within the scope of the Committee may apply for membership on the Committee.

Each company or service organization elected to membership shall designate one principal voting representative to represent it on the Committee. One or more alternate representatives may also be designated.

Each member company or service organization shall have a single vote in the business of the Committee.

Manufacturing companies, service organizations and consulting companies elected to membership shall be classified as producer members.

2.3.2 Biomedical Professional Organizations

Any biomedical professional organization that wishes to participate in standards development within the scope of the Committee may apply for membership on the Committee.

Each biomedical professional organization elected to membership shall designate one or more voting representatives to represent it on the Committee, providing that representatives from any single organization do not compose more than 20% of the total membership in the Committee.

Each person who represents a biomedical professional organization shall have one vote in the business of the Committee.

Biomedical professional organizations elected to membership shall be classified as user members.

2.3.3 Trade Associations

Any trade association that is not, also, a standards-developing organization and wishes to participate in standards development within the scope of the Committee may apply for membership on the Committee.

Each member association shall designate a principal voting member to represent it on the Committee. One or more alternate representatives may also be designated.

Each member association shall have one vote in the business of the Committee.

Trade associations elected to membership shall be classified as producer members.

2.3.4 Standards-Developing Organizations

Any standards-developing organization that wishes to participate in standards development within the scope of the Committee may apply for membership on the Committee.

Each standards-developing organization elected to membership shall designate one principal voting representative to represent it on the Committee. One or more alternate members may also be designated.

Each standards-developing organization elected to membership on the Committee shall have one vote in the business of the Committee.

Standards-developing organizations elected to membership may be classified either as producers or as general interest members.

2.3.5 Government Agencies

Any government agency that wishes to participate in standards development within the scope of the Committee may apply for membership on the Committee.

Each government agency elected to membership on the Committee shall designate one voting representative to represent it on the Committee. One or more alternate members may also be designated.

Each government agency elected to membership on the Committee shall have one vote in the business of the Committee.

Government agencies elected to membership shall be classified as either users or general interest members.

2.3.6 Academic Institutions

Any academic institution that wishes to participate in standards development within the scope of the Committee may apply for membership on the Committee.

Each academic institution elected to membership on the Committee shall designate one voting representative to represent it on the Committee. One or more alternate members may also be designated.

Each academic institution elected to membership on the Committee shall have one vote in the business of the Committee.

Academic agencies elected to membership shall be classified as either users or general interest members.

2.4 Dues

Dues are determined annually based on an annual budget and operating plan. Dues are collected and administered by the secretariat. Dues are based on the categories of membership.

3 Committee Structure

3.1 Officers

There shall be two co-chairs – one representing a producer and one representing a biomedical professional organization.

Each co-chair shall serve a two-year term and may serve no more than two consecutive terms. The terms of the co-chairs shall expire in alternate years.

At the meeting preceding the meeting before the last Committee meeting each year, the co-chairs shall appoint a three-member nominating subcommittee consisting of at least one representative of a producer , one representative of a biomedical professional organization and one former committee officer (if one is available). The former officer (if one is available) shall chair the nominating subcommittee. Members of the nominating subcommittee shall develop and submit to the secretariat a slate of candidates. The names of the candidates should be submitted to the secretariat no later than 30 days prior to the meeting preceding the last meeting of the year so that their names may be included in the published agenda. Additional nominations may be made from the floor at this meeting.

Prior to the last meeting of the year the secretariat shall conduct a letter ballot. The name of the person elected shall be announced at the last meeting of the year. That person shall assume office immediately following the last meeting of the year.

One co-chair shall be designated as the presiding officer for each portion of Committee meetings.

The Committee has the right to recall a co-chair.

There shall be a secretary who is appointed by the secretariat.

3.2 Executive Committee

The Committee may elect an Executive Committee.

If one is created, the membership shall consist of:

a) The officers of the Committee;

b) The chair of the Base Standard Working Group;

c) The co-chairs of the Strategic Advisory Working Group;

d) The principal individual representing NEMA on the Committee;

e) A minimum of one and a maximum of three members at large (chosen from among the members of the committee) and

f) The two most recent past co-chairs of the Committee (one producer and one user), if they are available to serve and still active in the DICOM Community.

The responsibilities of the Executive Committee are to:

a) Provide advice on, and resolution of, administrative issues as requested by the secretariat;

b) Develop recommendations to the Committee (e.g., agenda for Committee meetings, changes in the Committee procedures and recall of an officer) and

c) Fulfill other responsibilities specifically delegated by the Committee.

4 Subgroups

4.1 Function

The Committee may form subgroups (often called working groups) to expedite the work of the Committee. Their formation (and later disbandment) requires approval by a majority vote of the Committee and appropriate notice to those who have interest in the activities of the Committee.

The scope and duties delegated to the subgroup shall be approved at the time it is formed. Subsequent changes in scope or duties shall also require Committee approval.

All subgroups shall:

a) Be project oriented with clear deliverables or have other, well-defined responsibilities;

b) Have appropriate membership from interest categories represented on the Committee and

c) Have a subgroup secretariat and a secretary (as provided in Section 5.2, below) who will work closely with the Committee's secretariat to assure proper conduct and documentation of subgroup activities.

The charge to the subgroup shall clearly state whether the subgroup is responsible for:

a) The definitive content of one or more proposed standards (or parts of a standard) and for responding to views and objections thereon; or

b) Assisting the Committee in some other way.

Subgroups responsible for the definitive content of a proposed standard shall:

a) Maintain a membership roster in accordance with 5.1(c);

b) Maintain fair and equitable participation in accordance with Section 2.3, except the 20% rule in Section 2.3.2;

c) Conduct open meetings in accordance with Section 6; and

d) Operate in accordance with Section 7 as applied to voting on proposed standards.

The Committee shall annually review the scope, duties and membership of all subgroups.

4.2 Members and Officers of Subgroups

There are two ways that a company, organization or agency may become a member of a subgroup:

a) A member of the Committee may join a subgroup by informing the Committee's secretariat of its desire to participate in the work of the chosen subgroup and designating the name and contact information for its voting representative and, if desired, one or more alternates;

b) The officers of a subgroup may nominate one or more companies, organizations, agencies or individuals for participation on that subgroup. Such a nomination shall be submitted to the Committee and shall include evidence that the proposed member meets the criteria spelled out in Sections 2.2, above. Such nominations shall be accompanied by information regarding the proposed member's voting representative and alternate(s), if any. The Committee shall vote on such nominations and appoint those companies, organizations, agencies or individuals that are approved.

Each subgroup shall elect a chair or co-chairs. Other officers may be elected by the subgroup.

If any member of a subgroup is not represented at two, consecutive, fact-to-face meetings of the subgroup, that member shall be suspended from the subgroup. Suspended members:

a) Will not be counted in determining a quorum for face-to-face meetings and telephone conferences;

b) May vote in telephone conferences, but participation in the conference call will not affect the member's suspension status and

c) Will be reinstated to good standing in the subgroup if they attend one of the next two face-to-face meetings.

If a subgroup member is not represented at four consecutive face-to-face meetings, then, it shall be converted to observer (mailer) status in that subgroup. The company, organization or agency may be reinstated as a member if it is represented at a face-to-face meeting and submits a written request for reinstatement to the subgroup's secretary.

4.3 Observers

Individuals and organizations having an interest in the work of a subgroup may request listing in the subgroup's roster as observers (mailers).

Observers shall be advised of the subgroup's activities, may attend meetings and may submit comments for consideration, but they shall have no vote.

4.4 Base Standard Working Group

The Committee shall form a subgroup with responsibility for assuring technical consistency and maintaining the overall structure of DICOM standards. This subgroup shall be called the Base Standard Working Group.

The responsibilities of this working group are described in Section 8, below.

This working group may also perform other functions, such as the development of proposed standards.

5 Secretariat

5.1 Secretariat of the Committee

The Medical Imaging & Technology Alliance, a Division of the National Electrical Manufacturers Association (NEMA) is secretariat of the Committee.

Meetings of the Committee shall operate under these procedures and the secretariat's appeal procedures. The secretariat shall:

- Organize the committee and subgroups.
- Oversee the Committee’s compliance with these and the secretariat's procedures.

Maintain a current and accurate roster of the Committee and its subgroups; distribute it to the members at least annually and, otherwise, on request. The roster shall include the following:

    - Title of the Committee;
    - Name and address of the secretariat and secretary;
    - Officers;
    - Members -- including the name of the organization, company or agency; its voting representative and alternate(s) with their addresses and other contact information;
    - Classification of each member;
    - Subgroups: title, chair, and names and addresses of all members.
    - Provide a Committee secretary to perform administrative work including:
    - Handling meeting arrangements;
    - Distributing meeting notices, agendas, minutes, ballots and draft standards and
    - Maintaining adequate records;
- Collect Committee dues and provide accounting support;
- Arrange for the publication of Committee standards, revisions, and addenda;
- Maintain a list of ongoing standardization projects and their status and
- Perform other administrative functions as required.

5.2 Secretariat of Subgroups

For the DICOM Standards Committee, Working Group Six (Base Standard) and Working Group Ten (Strategy), the full-time attendance of a member of the secretariat's staff is required at every meeting to provide secretarial services.

For other subgroups, the Committee may designate another organization to perform the duties of the secretariat. Such subgroup secretariats shall be approved by the Committee secretariat. Meetings of all subgroups served by secretariats other than NEMA shall operate under these Committee procedures and the procedures of the subgroup's secretariat. The subgroup secretariat shall:

a) Oversee the subgroup's compliance with these and the subgroup secretariat's procedures;

b) Inform the Committee Secretariat of changes in the subgroup's roster;

c) Maintain a roster of the subgroup;

d) Provide a secretary to perform administrative work including:

- Handling meeting arrangements;
- Distributing meeting notices, agendas, minutes, ballots and draft standards and
- Maintaining adequate records;

e) Forward copies of the meeting minutes to the DICOM secretariat for legal review and for posting to the Committee's web page;

f) Perform other administrative functions as required and

g) Follow the meeting procedures as provided in Section 6.

Additionally, as a means of conserving resources, the Committee secretariat may request a member (which is not a producer) to allow its representative to perform some of the duties of the secretariat for a specific subgroup – e.g., to host a meeting or to prepare minutes of a meeting and, subsequently, assure that they are delivered directly to the secretariat for the working group. That person shall insure that the discussions at the meeting do not violate NEMA's antitrust rules as listed in Section 6.1.

6 Meetings

Committee meetings shall be held to conduct business, such as making assignments, receiving reports of work, considering proposed standards, resolving differences among subgroups, and considering views and objections from any source.

The frequency of Committee meetings shall be determined by the Committee. Additional meetings may be called by an officer, the secretariat, or by petition to the secretariat of five or more members.

Meetings of subgroups may be held as decided upon by the members or the chair of the subgroup.

Meetings of the Committee and subgroups shall be open to all individuals having a direct and material interest.

6.1 Meeting Conduct for Vendor Members

All meetings of the Committee and subgroups shall be conducted under the following procedures and any additional procedures that the secretariat may prescribe to avoid any antitrust problems.

a) No commercial topics shall be acted upon or even considered. To avoid the most sensitive areas, there shall never be a discussion of the following at Committee or subgroup meetings:

   - Current or future prices or components thereof, including discounts, rebates, and credit terms;
   - Price list or procedures for coordinating price changes;
   - Sales or production quotas;
   - Allocation or division of territories of customers among manufacturers, distributors, or retailers;
   - Boycotting any party or denying any party access to markets, products, product inputs, or information;
   - Identified individual company statistics, market shares, inventories or merchandising methods;
   - Commercial practices, warranties, guarantees, or the particular terms and conditions of sales, including credit, shipping and transportation arrangements, or
   - Anything dealing with "arm-twisting," trade abuses, or excluding or controlling competition.

b) Committee and subgroup meetings shall be conducted in such a manner that all members are afforded an adequate opportunity to present their views. All opinions shall be considered before actions are voted upon. The officers shall undertake this responsibility with the assistance of the secretariat's staff.

c) Discussions shall be confined to technical, engineering and safety factors. Commercial considerations (warranties, guarantees, etc.) are not proper factors and shall not be considered. Since the DICOM Standard is voluntary, there must be no agreement to adhere to it or any discussions as to when members will begin to offer products conforming to DICOM.

d) The secretariat shall ensure that minutes of all meetings are clear, complete, and accurate with regard to the actions that were taken and the justification for those actions.

e) There shall be no conversations "off the record" at a Committee or subgroup meetings. If comments are not appropriate for recording, they shall not be brought up at meetings.

f) Committee and subgroup meetings shall be adjourned when all business has been completed. Informal "rump" sessions are not part of Committee or subgroup meetings and should not be held.

6.2 Meeting Conduct for Biomedical Organization Members

The objective of these rules is to create a neutral ground at meetings of the Committee or its subgroups for the biomedical professionals and their influence on producers

a) Members and non-members who attend meetings shall understand that the main goal of the Committee is to develop standards for medical imaging communications and related technologies in the healthcare domain.

b) Potentially contentious issues of professional control over an imaging technique or the resulting images (e.g., who should perform examinations and interpret the resulting images and who should bill for the professional services rendered) are outside the scope of work of the Committee and shall not be topics for discussion at meetings of the Committee or its subgroups.

c) Discussion of professional practice regarding imaging and interpretation shall be permitted provided that they are described in the context of professional practice as conducted in a particular institution. Such discussions shall be permitted for the purposes of generalizing information models, when requested for clarification by manufacturers or other professional societies. They are also justified when Committee or subgroup consensus is that such a discussion is materially important to the task at hand and does not represent a particular professional society's desire to advance its own goals for medical imaging to the detriment of other organizations.

In accordance with item a), a biomedical professional organization or group of such organizations shall not attempt to direct standards development in the DICOM Standards Committee or its subgroups to further their own goals to the disadvantage of other biomedical professional organizations.

These rules are in addition to, not in lieu of, the secretariat's rules for conduct of meetings. These rules shall apply irrespective of the organization serving as secretariat for the meeting.

7 Voting

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 objection); or

d) Abstain.

An alternate's vote is counted only if the principal representative fails to vote. If none of these representatives is able to attend, the organization they represent may designate someone else to cast the vote for the organization. This designation shall be documented by a written proxy from either the member's principal or alternate representative.

7.1 Single Vote

Generally, no representative shall have more than one vote. However, if two or more members 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 secretariat that they are aware of and will accept the results.

7.2 Quorum

A majority of the members of the Committee with voting rights or a majority of members of subgroups with voting rights shall constitute a quorum for conducting business at a meeting. Voting rights are described in Section 2.2.4 and Section 4.2.

If a quorum is not present, actions may be taken subject to confirmation by letter ballot or future approval of the minutes of the meeting.

7.3 Actions Requiring Approval by a Majority

The following actions require approval by a majority of the membership present at a meeting where a quorum is present:

a) Election of officers and at-large members of the Executive Committee;

b) Formation of a subgroup, including its procedures, scope, and duties;

c) Approval of new standardization projects;

d) Appointment of subgroup members who are not members of the Committee;

e) Disbandment of subgroups;

f) Addition of new Committee members and designation of their interest categories;

g) Approval of minutes and

h) Other actions not specifically described in these procedures.

Action on items not published in the meeting agenda, may be postponed until a future meeting at the discretion of the officers and the secretariat.

7.4 Actions Requiring Two Thirds Approval

The following actions require a letter ballot or an equivalent recorded vote:

a) Adoption of Committee procedures, interest categories, or revisions thereof;

b) Approval of new standards or supplements to an existing standard;

c) Approval of, reaffirmation, or withdrawal of an existing standard;

d) Approval of change of Committee scope;

e) Approval of termination of the Committee; and

f) Recall of officers.

Recorded votes on these actions at a Committee meeting require approval by at least a majority of the membership with voting rights and at least two-thirds of those voting affirmative or negative.

These actions shall not be taken at a Committee meeting unless the published agenda for the meeting stated that action was on the agenda and that a vote on the action was expected.

Letter ballots require approval by two-thirds of those voting affirmative or negative and return of more than one-half of the ballots sent to members in good standing relative to letter ballots.

Members are not in good standing relative to letter ballots if they (or their alternate) have not responded to two consecutive letter ballots of the Committee. Members not in good standing will continue to receive and may vote on subsequent letter ballots.

7.5 Letter Ballot Voting

A letter ballot may be authorized by any of the following:

a) A majority vote of those present at a Committee meeting;

b) Either co-chair;

c) The secretariat and

d) A petition by five or more members of the Committee.

Except for approval of standards, the voting period for letter ballots shall end 30 days from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the option of either co-chair, when warranted.

A follow-up letter requesting immediate return of the ballot shall be sent, as appropriate, to members and alternate members whose votes have not been received within ten working days before the ballot closes.

8 Standardization Project Phases

Standardization projects shall be conducted in the following phases.

a) Requirements Definition (optional),

b) Early Draft,

c) Public Comment Draft,

d) Intermediate Draft,

e) Trial-Use Draft (optional),

f) Letter-Ballot Text and

g) Final Text.

All draft standards shall be identified with one of the names in items b) through f) above.

8.1 Requirements Definition (optional)

The proposal to begin this phase should contain:

- A title under which the extension is identified;
- A description of the application and an explanation why this application cannot be handled by the present standard;
- A prediction of the parts of the standard which will be influenced by the proposed extension; and
- An estimate of the required capacity and expertise in the subgroup responsible for the project and other subgroups, such as the Base Standard Working Group.

During this phase, a detailed proposal of the scope of the project, subgroup resources, and timeframe for completion is prepared. This phase should be completed in no more than two meetings of the subgroup.

The Committee may decide that this phase is not required if the project is relatively small. In this case, the Committee may approve starting with the Early Draft phase.

Approval for a project to begin this phase requires a majority vote of the Committee.

8.2 Early Draft

The proposal to begin this phase shall contain either the detailed proposal prepared in the Requirements Definition Phase or a brief proposal as described in Section 8.1.

Approval for a project to begin this phase requires a majority vote of the Committee.

During this phase, the initial drafts of the standard or supplement are prepared.

This phase is completed when the:

- Subgroup prepares a Public Comment Draft of the proposed standard and
- Public Comment Draft is approved by the Base Standards Working Group.

8.3 Public Comment Draft

The time that the document is in the public comment draft is called the Public Comment Period. The Public Comment Period shall be at least 45 days. During this period, the proposed standard is submitted to a group of interested parties outside the Committee and to other interested

subgroups that report to the Committee. The originating subgroup shall make an effort to identify all interested parties worldwide.

8.4 Intermediate Draft

This phase begins following the public comment period.

During this phase the subgroup addresses all comments received and prepares revised drafts of the proposed standard.

The subgroup shall make a recommendation to the Base Standard Working Group regarding whether the proposed standard should go through the Trial-Use Draft Phase or move directly to the Letter-Ballot Phase. The Base Standard Working Group shall make the final decision.

This phase is completed when the:

- Subgroup prepares either a Trial-Use Draft or Letter-Ballot Text and
- Document is approved by the Base Standard Working Group.

8.5 Trial-Use Draft (optional)

This phase begins when the Trial-Use Draft is approved by the Base Standard Working Group.

The purpose of this phase is to provide a stable draft of the proposed standard to encourage prototype implementations. It shall be used when it is believed that implementation experience is needed before the content of the proposed standard can be finalized and submitted for letter ballot.

During this phase, changes to the Trial-Use Draft shall be approved by the Base Standard Working Group and shall only be made following a well-documented change process that is maintained by the Base Standard Working Group.

The following statement, or equivalent, shall be included on the front cover of the draft standard:

> "Publication of this Draft Standard for trial use and comment has been approved by the Base Standard Working Group of the DICOM Standards Committee. Distribution of this draft standard for comment shall not continue beyond ( ) months from the date of publication. It is expected, but not certain, that following this ( ) month period, this draft standard, revised as necessary, will be submitted to the DICOM Standards Committee for approval as an addition to the DICOM Standard. Suggestions for revision should be directed to ...."

This phase is completed when:

- The subgroup determines that sufficient input has been obtained;
- It prepares a Letter-Ballot Draft; and
- The Letter-Ballot Text is approved by the Base Standard Working Group.

8.6 Letter-Ballot Text

Following approval of the Letter-Ballot Text, the secretariat and either co-chair shall authorize a letter ballot of the members of the Committee. This letter ballot shall have a 49-day time limit.

Following the letter ballot, the Base Standard Working Group shall consider all comments from the letter ballot according to the secretariat's procedures. It may prepare a final proposed standard (Final Text) and an explanation of how each comment was resolved. These shall be submitted to the secretariat and officers of the Committee.

Alternatively, the Base Standard Working Group may decide to submit the proposed standard to the subgroup that developed the standard for further action.

8.7 Final Text

If the secretariat and either co-chair determine that all comments received during the letter ballot have been addressed according to these procedures and if there are no technical differences that directly and materially affect the use of the standard between the Letter-Ballot Text and the Final Text, then, the standard is approved.

If the secretariat and either co-chair determine that there are only minor technical differences between the Letter-Ballot Text and the Final Text, the secretariat shall inform all members of the Committee regarding the nature of the changes. Each member shall be given a 30-day opportunity to change its vote. At the conclusion of this period, the secretary shall recount the votes and determine whether, in view of these changes, the standard is approved or rejected.

If the secretariat and either co-chair determine that there are major technical differences between the Letter-Ballot Text and the Final Text, another ballot will be required.

8.8 Excerpts from the Standard

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9. PATENT DISCLOSURE POLICY

9.1 Purpose

Numerous technologies are required for the effective implementation of the DICOM Standard. When it is both possible and practical, such technologies should be available for public use; however, both the DICOM Standards Committee ("the Committee") and its Secretariat, the National Electrical Manufacturers Association, recognize that Members of the Committee (including its subdivisions and working groups) may hold patents or patent applications for technology that, for sound technical reasons, are required to implement the DICOM Standard. The Committee, in connection with its efforts to develop and update the DICOM Standard, would prefer to know, in advance of the development or revision of the DICOM Standard, whether there are claims of a patent or pending patent application, which users seeking to conform to the DICOM Standard would be required to practice, so that informed decisions can be made by the Committee, its subdivisions or working groups about whether to incorporate proprietary technology in the DICOM Standard. On the other hand, the Committee recognizes the difficulty that some Members may have in monitoring and searching patent portfolios in view of an evolving Standard. The Committee also recognizes that the actual participants in the Committee, or its subdivisions and working groups, may not be familiar with the patents and patent applications of their respective employers or affiliated firms. To meet these competing concerns of the Committee, the users of the DICOM Standard, and the holders of patent rights, the Committee adopts the following policy:

9.2 No Duty to Search Patent Portfolio

Committee Members do not have an affirmative duty to search a patent portfolio to determine if they own a patent or patent application whose claims are required to implement the DICOM Standard.

9.3 Duty of Good Faith to Disclose Known Inventions Required to Implement the DICOM Standard

Subject to the above, Members have an affirmative duty to act in good faith toward the Committee and its other Members to bring to the attention of the Committee any patents or patent applications (where disclosure of the latter would not prejudice the intellectual property rights of an applicant), owned by the Member (or an employer, parent company, subsidiary or affiliate of the Member) and known to the Member that practicing one or more claims of a patent or patent application is required to implement any portion of the DICOM Standard or a revision thereof that is proposed for adoption. No Member shall knowingly conceal from the Committee any patents or patent applications owned by it (or any employer, parent company, subsidiary or affiliate of a Member) where practicing the claimed invention(s) is required by a user of the DICOM Standard to conform to the DICOM Standard and any revision thereof that is proposed for adoption.

The Committee further adopts a requirement that each of its Members execute a Declaration in the form set forth below to ensure fair use of the DICOM Standard, which includes a commitment by the Members to make available inventions subject to a patent or patent application that are required to be practiced by a user of the DICOM Standard in order to conform to the DICOM Standard, on terms described in the Declaration, and subject to a condition of reciprocity. As used herein, "reciprocity" means that with respect to other parties that have a patent or patent application required in the use of the DICOM Standard, the Member shall only be required to license to such parties if they are willing to license their patent or patent applications on the terms provided in the Declaration.

9.4 Timing of Disclosure

The Duty of Good Faith includes a requirement that the disclosure to be made by the Member under this Policy shall be made to the Secretariat of the Committee as expeditiously as possible after the Member recognizes the obligation of disclosure. The disclosure shall be made in a manner as prescribed by the Committee, including any documentation required by the Committee.

9.5 Definitions

The term "Member" as used in this Policy refers to any organization that has been elected membership in the DICOM Standards Committee and to any organization or individual that was appointed by the DICOM Standards Committee as a member or participant in one or more of the DICOM Standards Committee's subdivisions and working groups.

DECLARATION

_____ ("Member") agrees that as a condition of its
(Member name)
participation in the DICOM Standards Committee ("the Committee"), its subdivisions and working groups, that it (the Member) will abide by the Duty of Good Faith set forth in the Patent Disclosure Policy of the Committee with respect to patents and patent applications where the claims of any patent or patent application (provided that the intellectual property rights of such application would not be prejudiced by disclosure) are known by the Member to be required to implement any provision of the DICOM Standard or any provision of proposals to extend, expand or modify the Standard, and that it will make disclosure to the Secretariat of the Committee of the patent(s) or patent application(s) (where it is possible to disclose patent applications without prejudicing the intellectual property rights of the applicant) and the provision(s) of the DICOM Standard to which the Member believes that claims of any patent or patent application relate.

The Member further agrees, regardless of whether it has disclosed or knows of claims contained in any patent or patent application owned by the Member (or an employer, parent company, subsidiary or affiliate of the Member) whose use and practice would be required to conform with any part of the DICOM Standard, that, at the discretion of the Member and subject to a requirement of reciprocity as defined in the Patent Disclosure Policy, it will make available on a worldwide and non-discriminatory basis (A) a license without compensation to persons or entities seeking to practice one or more claims of any patent or patent application that are required by a user of the DICOM Standard to conform to the DICOM Standard, OR (B) a license under reasonable and non-discriminatory terms to persons or entities seeking to practice one or more claims of any patent or patent application that are required by a user of the DICOM Standard to conform to the DICOM Standard.

Signed By: _____ _____

Authorized Signature | Title

_____ _____

Print Name | Date

_____

Member Name

10 Communications

Correspondence of Committee and subgroup officers shall employ the Committee's correspondence letterhead or electronic mechanisms.

11.1 Formal Internal Communication

If correspondence between subgroups involves issues or decisions (i.e., non-routine matters) affecting other subgroups, copies shall be sent to all affected subgroup chairs, the secretariat and the Committee officers.

11.2 External Communication

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

12 Appeals

Persons who have directly and materially affected interests and who have been or will be adversely affected by a standard within the Committee's jurisdiction, or by the lack thereof, shall have the right to appeal substantive or procedural actions or inactions of the Committee or the secretariat.

All appeals shall be resolved following the secretariat's procedures.

13 Parliamentary Procedures

On questions of parliamentary procedures not covered in these procedures, *Robert's Rules of Order (*latest edition) may be used to expedite due process.

Yearly Dues Structure for the DICOM Standards Committee

(This section is not part of the procedures. It is provided for reference only.)

Producers

$1,800 for members of one of the sections of MITA, the Medical Imaging & Technology Alliance, a Division of NEMA, COCIR or JIRA.

$8,250 for companies, organizations or agencies that are not members of MITA/NEMACOCIR or JIRA.

Biomedical Professional Organizations

$ 2,500 for each organization. Dues are waived for organizations that provide the secretariat of a subgroup.

Trade Associations

No dues.

Standards-Developing Organizations

No dues.

Government Agencies

No dues.

Observers

No dues.