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Policies and Procedures

for the

DICOM Standard Committee

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1 Scope and Purpose of the DICOM Standard Committee

Numerous and diverse medical specialties create biomedical images. The mission of the DICOM Standard Committee (“DSC”) is to create and maintain an international standard for the communication of biomedical, diagnostic, and therapeutic information in those medical disciplines that use digital images and associated data. That standard for Digital Imaging and Communications in Medicine shall be known as the DICOM Standard (“Standard”).

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

The Standard is cooperatively developed. Its governance has been designed to ensure a balanced representation of stakeholders worldwide who share the vision. 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 Supplements and Change Proposals to the Standard are developed by Working Groups reporting to the DSC and are approved by the Members of the DSC through a process described in Section 8. The Standard is published by the Secretariat and is international in scope. The DSC is proactive to assure compatibility with related standards developed by other standards-developing and coordinating bodies including but not limited to ANSI, CEN, JIC, HL7, IEC, ISO and JISC.

2 Membership

The DSC consists of its Members and the Secretariat. Membership in the DSC consists of manufacturing companies, independent 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 DSC.

The addition or termination of Members shall be subject to approval by vote of the DSC as provided in this Section.

2.1 Responsibility of DSC

Management, authority, and responsibility for the standardization activities of DICOM lie with the DSC. The DSC is responsible for:

- a) Approving and monitoring the development work to add Supplements to the Standard within the scope of the DSC;
- b) Voting on decisions including those described in Section 7;
- c) Approving the creation of, and monitoring the scope and activity of, Working Groups;
- d) Responding to requests for interpretations of the Standard;
- e) Adopting DSC policy and procedures and revisions thereof;
- f) Considering and acting on proposals for termination of the DSC, and
- g) Other matters requiring DSC action as provided in these procedures.

2.2 Membership Application

An application for DSC membership shall be addressed to the Secretariat and shall indicate the applicant's:

- a) direct and material interest in the DSC's work;
- b) qualifications and willingness to participate actively;
- c) acceptance of these procedures;
- d) agreement with the DSC's Patent Disclosure Policy (Section 9 below);
- e) interest category; and
- f) principal representative (and alternate(s), if desired – see Section 7 – Voting).

Upon receipt, the Secretariat shall put on the agenda of the next meeting of the DSC discussion for action on applications for membership it receives. The DSC 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 DSC may consider reasonable limits on DSC size.

2.2.1 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 DSC, each may apply for membership.

2.2.2 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.

2.2.3 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.

2.2.3.1 Suspension

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

2.2.3 Termination

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

2.2.4 Observers

Individuals and organizations having an interest in the DSC's work may request listing in the DSC's roster as observers on the DSC mailing list.

At the discretion of the DSC, observers may be advised of the DSC activities, may attend meetings and may submit comments for consideration, but they shall have no vote.

2.2.5 Interest Categories

All appropriate interests that might be directly and materially affected by the standards activity of the DSC 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 DSC's established categories.

Members are classified into the following Interest Categories: (i) producers, (ii) users, and (iii) general interest.

The Interest Categories may be revised by a vote of the DSC upon recommendation of the Secretariat. The rationale for the selection of categories shall be included in the DSC ballot.

2.3 Member Types

DSC Members commonly belong to one of the following organization types, which in turn typically map to an Interest Category.

2.3.1 Vendor Organizations

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

Each such organization approved for membership shall:

- designate one principal-representative to the DSC. One or more alternate representatives may also be designated.
- be classified as a producer member.

2.3.2 Biomedical Professional Organizations

Any organization of biomedical professionals that wishes to participate in standards development within the scope of the DSC may apply for membership on the DSC. This includes both professional societies, and healthcare provider organizations, such as hospitals or radiology practices.

Each biomedical professional organization approved for membership shall:

- designate one, two, or three voting representatives to the DSC. One or more alternate representatives may also be designated.

2.3.3 Trade Associations

Any trade association representing producers of hardware or software that is not, ~~also,~~ a standards-developing organization and wishes to participate in standards development within the scope of the DSC may apply for membership on the DSC.

Each trade association approved for membership shall:

- designate a principal representative to the DSC. One or more alternate representatives may also be designated.
- be classified as a producer member.

2.3.4 Standards-Developing Organizations

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

Each standards-developing organization approved for membership shall:

- designate one principal representative to the DSC. One or more alternate representative may also be designated.
- be classified as either producer or general interest member.

2.3.5 Government Agencies

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

Each government agency approved for membership shall:

- designate one principal representative to the DSC. One or more alternate representative may also be designated.
- be classified as either user or general interest member.

2.3.6 Academic Institutions

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

Each academic institution approved for membership shall:

- designate one principal representative to the DSC. One or more alternate-representative may also be designated.
- be classified as either user or general interest member.

2.4 Dues

Dues are determined annually by the Secretariat, in consultation with the DSC. Dues shall be based on an annual budget and operating plan. Dues are collected and administered by the Secretariat. At the discretion of the Secretariat, dues may differ based on the Interest Categories of Members.

3 DSC Structure

3.1 Officers

The DSC shall have two co-chairs – one representing a producer member and one representing a user member.

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 third to last DSC meeting each year, the co-chairs shall appoint a three-member nominating subcommittee consisting of at least one producer member, one user member and one former DSC 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 second to 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.

Co-chairs are responsible for scheduling meetings of the DSC and preparing an agenda. One co-chair shall be designated as the presiding officer for each portion of DSC meetings.

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

There shall be a General Secretary who is appointed by the Secretariat; see section 5.1.

3.2 Executive Committee (ExCom)

The DSC shall have an Executive Committee. The co-chairs of the DSC chair the ExCom.

The membership of the Executive Committee shall consist of:

- a) The officers of the DSC;
- b) The chair of the Base Standard Working Group (WG-06);
- c) The co-chairs of the Strategic Advisory Working Group (WG-10);
- d) The principal individual representing the interests of the Secretariat;
- e) A minimum of one and a maximum of three members at large (chosen from among the Members of the DSC) and

- f) The two most recent past co-chairs of the DSC (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) Discuss issues that are urgent and, if necessary, make provisional decisions when a response cannot wait until the next meeting of the DSC;
- b) Provide advice on, and resolution of, administrative issues as requested by the Secretariat;
- c) Develop recommendations and fulfill other responsibilities specifically delegated by the DSC.

The General Secretary shall perform the secretary duties for the Executive Committee.

4 Working Groups

4.1 Function

The DSC may form Working Groups and delegate duties to Working Groups to expedite the work of the DSC. The formation (and later termination) of Working Groups requires approval by a majority vote of the DSC and appropriate notice to those who have interest in the activities of the DSC.

The scope and duties delegated to the Working Group shall be approved at the time it is formed. Subsequent changes in scope or duties shall also require DSC approval. Specific Working Groups with organizational duties are identified at the end of this section.

All Working Groups shall:

- a) Be work-item oriented with clear deliverables or have other, well-defined responsibilities;
- b) Have appropriate membership from interest categories represented on the DSC and
- c) Have a Working Group secretariat and a secretary (as provided in Section 5.2, below) who will work closely with the Secretariat to assure proper conduct and documentation of Working Group activities.

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

- a) The definitive content of one or more Supplements and for responding to views and objections thereon; or
- b) Assisting the DSC in some other way as requested by the DSC.

Working Groups shall:

- a) Maintain a membership roster in accordance with 5.1(c);
- b) Maintain fair and equitable participation in accordance with Section 2.3;
- c) Conduct open meetings in accordance with Section 6; and
- d) Operate in accordance with Section 7 as applied to voting

The DSC shall annually review the scope, duties, and membership of all Working Groups.

A Working Group may occasionally choose to establish temporary subgroups to work on specific topics but such subgroups are not reflected in the governance. The work and meetings of such subgroups are considered to be work and meetings of the parent Working Group. As such subgroups are intentionally temporary; when establishing the subgroup, the Working Group should clearly delimit the scope of their tasks to facilitate their expeditious termination.

4.2 Members and Officers of Working Groups

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

- a) A Member of the DSC may join a Working Group by informing the Secretariat of its desire to participate in the work of the chosen Working Group and designating the name and contact information for its voting representative and, if desired, one or more alternates;
- b) The officers of a Working Group may nominate one or more companies, organizations, agencies or individuals for participation on that Working Group. Such a nomination shall be submitted to the DSC 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 principal representative and alternate(s), if any. The DSC shall vote on such nominations and appoint those companies, organizations, agencies, or individuals that are approved.

4.3 Chairs and Voting Rights

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

If any member of a Working Group is not represented at two, consecutive, face-to-face or teleconference meetings of the Working Group, that member

- a) Will no longer be counted in determining a quorum for face-to-face meetings and telephone conferences;
- b) The member will be reinstated to good standing with voting rights and counting toward quorum in the Working Group at the next face-to-face or teleconference they attend.

4.4 Observers

Individuals and organizations having an interest in the work of a Working Group may request listing in the Working Group's roster as observers.

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

4.5 Base Standard Working Group (WG-06)

The DSC shall have a Working Group with responsibility for assuring technical consistency and maintaining the overall structure of the Standard. This Working Group is called the Base Standard Working Group (designated WG-06).

The responsibilities of WG-06 include:

- a) Providing technical coordination and guidance for all Working Groups;
- b) Reviewing and approving all Supplements for technical consistency, quality and clarity before Public Comment, Letter Ballot, and Final Text release;
- c) Executing the DICOM Maintenance Process (Change Proposals, typically smaller than a Supplement); these Change Proposals are also circulated for ballot.
- d) Developing the content of Supplements assigned to WG-06 (typically when another appropriate WG does not exist);
- e) Coordinating with the Secretariat for the publication of the Standard;
- f) Other tasks relating to management of the technical content of the Standard.

Specific roles of WG-06 in the Work Item Phases are also described in Section 8, below.

4.6 Strategic Advisory Working Group (WG-10)

The DSC shall have a Working Group to provide strategic advice to the DSC. This Working Group shall be called the Strategic Advisory Working Group (designated WG-10).

WG-10 provides the opportunity for a smaller more focused group to identify and frame issues and recommendations in a way that facilitates addressing them effectively in meetings of the DSC, which are larger, less frequent, and have many competing items on the agenda.

The responsibilities of WG-10 include:

- a) Identify high-value objectives (in the form of important threats and opportunities) and evaluate their strategic value and feasibility;
- b) Consider other issues related to the strategic evolution of the Standard;
- c) As appropriate, submit proposals or briefs to the DSC or existing WGs and/or propose new WGs;
- d) Provide liaison to other standards- developing organizations (SDOs).

5 Secretariat

5.1 Secretariat of the DSC

The Medical Imaging & Technology Alliance, (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the designated Secretariat of the DSC.

Meetings of the DSC shall operate under these procedures. The Secretariat shall:

1. Organize the DSC and Working Groups.

2. Make available in-house legal counsel at reasonable times to advise the DSC and the Secretariat on legal issues pertinent to the DSC's conduct or operations, and to review meeting minutes of the DSC and its Working Groups;
3. Oversee the DSC's compliance with these and the Secretariat's procedures.

Maintain and make available a current and accurate roster of the DSC and its Working Groups. Provide a General Secretary to perform administrative work including:

- a. Oversee day-to-day activities of Secretariat staff in execution of meetings and goals;
- b. Coordinate the DSC selection process for new work items within the scope of the Standard, and execution of the development process to achieve them;
- c. In consultation with the DSC, develop and manage annual budgets for Secretariat operations, including financial transactions, membership dues, staff compensation, selecting and evaluating vendors, and relevant logistics;
- d. Support WG-10 (Strategic Advisory), and the ExCom, in vetting and preparing new ideas for review and discussion in the DSC;
- e. Encourage discussion of future opportunities for the Standard to improve patient care and equipment operations;
- f. In coordination with WG-29 (Education, Communication, and Outreach), represent DICOM and its standards vision with target stakeholder audiences through relevant channels including public speaking and media;
- g. Handle meeting arrangements;
- h. Distribute meeting notices, agendas, minutes, ballots and draft standards and
- i. Maintain adequate records;
4. Collect DSC dues and provide accounting support;
5. Arrange for the publication of DSC standards, revisions, and addenda;
6. Own and maintain trademarks and copyright as provided in Section 10;
7. Own and maintain the DSC website (dicomstandard.org);
8. Maintain a list of ongoing DICOM activities and their status and
9. Perform other administrative functions as required.

5.2 Secretariat of Working Groups

For the DSC, WG-06 (Base Standard) and WG-10 (Strategic Advisory), the full-time attendance of a member of the Secretariat's staff is required at every meeting to provide secretarial services.

For other Working Groups, the DSC may designate another organization to perform the duties of the Secretariat. Such Working Group secretariats shall be approved by the Secretariat. Meetings of all Working Groups served by secretariats other than MITA shall operate under these DSC procedures and the procedures of the Working Groups' secretariat. The Working Group secretariat shall:

- a) Oversee the Working Group's compliance with these and the Working Group secretariat's procedures;
- b) Inform the Secretariat of changes in the Working Group's roster;
- c) Maintain a roster of the Working Group;

- d) Provide a secretary to perform administrative work including:
 - Handling meeting arrangements;
 - Preparing and distributing meeting notices, agendas, minutes, ballots and draft standards and
 - Maintaining adequate records;
- e) Forward copies of the meeting minutes to the Secretariat for legal review and for posting to the DSC's web page;
- f) Perform other administrative functions as required and
- g) Follow the meeting procedures as provided in Section 6.

Additionally, for instance as a means of conserving resources, the Secretariat of a Working Group 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 Working Group – e.g., to host a meeting, to ensure discussions at the meeting do not violate antitrust rules (per Section 6.1), or to prepare minutes of a meeting and, subsequently, assure that they are delivered directly to the secretariat for the Working Group.

6 Meetings

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

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

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

Meetings of the DSC and Working Groups shall be open to all individuals having a direct and material interest.

6.1 Member Meeting Conduct

All meetings of the DSC and Working Groups 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 DSC or Working Group 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 or licenses, including credit, shipping, and transportation arrangements, or
 - Anything dealing with "arm-twisting," trade abuses, or excluding or controlling competition.
- b) DSC and Working Group 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 adherence to the 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 the Standard.
- 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 DSC or Working Group meetings. If comments are not appropriate for recording, they shall not be brought up at meetings.
- f) DSC and Working Group meetings shall be adjourned when all business has been completed. Informal "rump" sessions are not part of DSC or Working Group meetings and should not be held.

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 representative of a Member shall take one of the following positions when voting:

- a) Affirmative;
- b) Negative; or
- c) Abstain.

A negative vote shall be accompanied by comments explaining the reasons and if possible specific wording or actions that would resolve the objection. Affirmative or Abstain votes may be accompanied by comments.

The vote of an alternate representative 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 Quorum

A majority of the Members with voting rights shall constitute a quorum for conducting business at a meeting of the DSC, the ExCom, or a Working Group. Note that voting rights in the DSC and Working Groups are independent of each other. Voting rights are described in Section 2.2.4 and Section 4.3.

If a quorum is not present, any action must be deferred to a letter ballot or future meeting.

7.2 Actions Requiring Approval by a Majority

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

For the DSC:

- a) Election of officers;
- b) Election of at-large members of the ExCom;
- c) Formation of a Working Group, including its procedures, scope, and duties;
- d) Approval of new Work Items;
- e) Appointment of Working Group members who are not Members of the DSC;
- f) Termination of Working Groups;
- g) Addition of new DSC Members and designation of their interest categories;
- h) Approval of minutes; and
- i) Other actions not specifically described in these procedures.

For a Working Group:

- a) Election of officers;
- b) Approval of Minutes; and
- c) 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.

7.3 Actions Requiring Two-Thirds Approval

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

- a) Adoption of DSC 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 DSC scope;
- e) Approval of termination of the DSC; and

f) Recall of officers of the DSC or of a Working Group.

Recorded votes on these actions at a DSC 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 DSC 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 their representative or alternate have not responded to two consecutive letter ballots of the DSC. Members not in good standing will continue to receive and may vote on subsequent letter ballots.

7.4 Letter Ballot Voting

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

- a) A majority vote of those present at a DSC meeting;
- b) Either co-chair;
- c) The secretariat and
- d) A petition by five or more Members of the DSC.

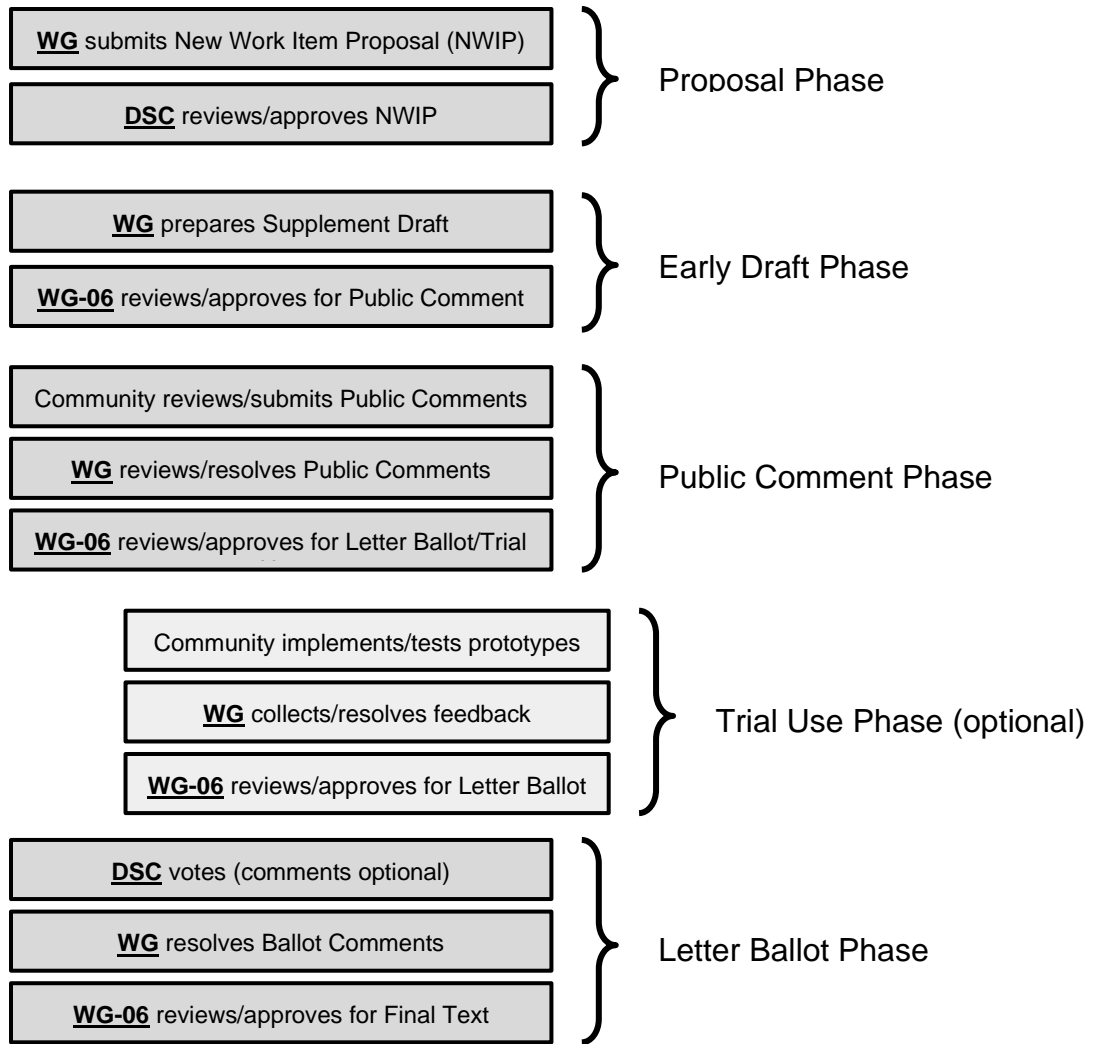
Except for approval of Supplements, voting for letter ballots shall end 30 days from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the option of either co-chair, when warranted.

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

Letter ballots are generally sent electronically.

8 Work Item Phases

DICOM work items shall be conducted in the following phases.



8.1 Proposal

The New Work Item Proposal (NWIP) that is developed in this phase should contain:

- A title under which the work is identified;
- A description of the unmet need or use case and an explanation why this need cannot be handled by the present standard;
- A prediction of the parts of the standard which will be influenced by the proposed work; and
- An estimate of the required resources and workload in the Working Group responsible for the project and WG-06.
- Indications of potential adoption interest amongst both users and producers.

The DSC discusses the content of the NWIP and considerations such as:

- whether the proposal falls within the scope of the Standard;
- whether an alternative standard already exists that would serve the need;

- whether sufficient resources; and special expertise appear to have been marshalled to complete the work;
- whether the proposed solution is technically aligned with the Standard; and
- whether the proposal was triggered by cooperation with another SDO.

Approval of an NWIP requires a majority vote of the DSC.

8.2 Early Draft

During this phase, the initial drafts of the Supplement are prepared by the appropriate WG and reviewed by WG-06.

Time will not be scheduled by WG-06 to review draft documents, unless they are pursuant to an approved NWIP.

This phase is completed when:

- The Working Group prepares a Public Comment Draft of the proposed standard, and
- WG-06 Base Standard approves the Public Comment Draft

8.3 Public Comment

During this phase, the proposed Supplement is submitted to the DICOM Community in the form of the full DSC mailing list and any other identified parties. Identifying and sharing the Supplement with external experts and interested parties outside the DSC is encouraged. The originating Working Group shall try to identify-interested parties worldwide.

The duration of public comment shall be at least 35 days unless a longer duration is specified by WG-06 for the given Supplement.

The Working Group addresses all comments received on the Supplement and prepares revised drafts of the proposed Supplement.

The Working Group shall make a recommendation to WG-06 regarding whether the proposed Supplement should go through the Trial-Use Draft Phase or move directly to the Letter Ballot Phase. WG-06 may require that the Supplement be sent for another public comment cycle in cases where it judges that the resolution of comments resulted in substantial technical changes. WG-06 shall make the final decision.

This phase is completed when the:

- Working Group prepares either a Trial-Use Draft or Letter-Ballot Text of the Supplement, and
- WG-06 approves the Supplement text.

8.5 Trial-Use (optional)

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 WG-06 and shall only be made following the change process that is maintained by WG-06.

The following statement, or equivalent, shall be included on the front cover of the draft Supplement (with the number of months determined by the Working Group and approved by WG-06):

"Publication of this Draft Supplement for trial use and comment has been approved by the Base Standard Working Group (WG-06) of the DICOM Standards Committee. Distribution of this draft Supplement for comment shall not continue beyond (X) months from the date of publication. It is expected, but not certain, that following this (X) 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 dicom@dicom-standard.org.

This phase is completed when:

- Working Group determines that sufficient input has been obtained,
- Working Group prepares Letter Ballot text,
- WG-06 confirms that any open issues have been sufficiently addressed, and
- WG-06 approves the Letter Ballot text.

8.6 Letter Ballot

During this phase, the Secretariat shall send a letter ballot to the Members of the DSC. This letter ballot shall have a 35-day time limit to allow for adequate circulation and consideration in the Member organizations and may be longer at the discretion of WG-06.

Following the letter ballot, the Working Group that developed the Supplement shall record, consider, and document the resolution of all comments from the letter ballot. Particular attention should be given to resolving comments from any negative ballots. The resulting Draft Final Text and comment resolution record shall be submitted to WG-06.

Alternatively, if the submitted comments are purely editorial, the Supplement editor may work directly with WG-06 to prepare the Draft Final Text and resolution record.

WG-06 may require that the Supplement be re-balloted in cases where it judges that the resolution of ballot comments resulted in substantial technical changes. A ballot that did not reach quorum or did not pass shall not proceed without re-balloting.

Once approved by WG-06, the secretariat shall publish the approved Final Text Supplement, at which point it is officially part of the Standard and available for implementation.

Final Text Supplements are rapidly incorporated into the documents that make up the current published Edition of the Standard, and Final Text Supplement documents are not updated by the

DICOM Maintenance Process, so implementers are advised not to refer to or reference the Supplement documents.

This phase is completed when:

- the Working Group prepares Draft Final Text; and
- WG-06 approves the Draft Final Text; and
- the Secretariat publishes the Final Text Supplement.

9 Patent Disclosure Policy

9.1 Purpose

Numerous technologies are required for the effective implementation of the Standard. When it is both possible and practical, such technologies should be available for public use; however, both the Committee and its Secretariat, 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 Standard. The Committee, in connection with its efforts to develop and update the Standard, would prefer to know, in advance of the development or revision of the Standard, whether there are claims of a patent or pending patent application, which users seeking to conform to the 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 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 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 Standard.

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

Subject to the above, Members have an affirmative duty to act in good faith toward the Committee and its other Members to disclose to 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 Standard or a revision thereof that is proposed for adoption. (the Disclosure Statement). 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 of which the Member has knowledge) where practicing the claimed invention(s) is required by a user of the Standard to conform to the 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 in 9.6 below to ensure fair use of the 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 Standard in order to conform to the Standard, on terms described in 9.5 and 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 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 as expeditiously as possible after the Member recognizes the obligation of disclosure. The disclosure shall be made in a manner as prescribed in paragraph 9.5 below, including any documentation required or reasonably requested by the Committee.

9.5 Disclosure Statement

The disclosure required by this Section 9 is a statement:

- (a) identifying the patent registration or application number(s) of the patent(s) or published patent applications that is believed to contain essential patent claim(s);
- (b) identifying the Part and Section of the Standard (published or under development) that would include the use of an essential patent claim; and
- (c) containing an assurance that a license to such essential patent claim(s) will be made available by such party (or any Affiliate as appropriate) to applicants desiring to utilize the license for the purpose of implementing the Standard either:
 - (1) under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
 - (2) without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination, or
 - (3) containing an assurance that the participant or identified party will not enforce any present and/or future essential patent claims against any person or entity making using, selling, offering to sell, importing distributing, or implementing such a compliant implementation; or
 - (4) provided that the written communication is received prior to the Committee’s approval of a new or amended part of a Standard identified pursuant to 9.5(b) above, a statement that the patent holder is unwilling or unable to grant licenses on the terms described above or to agree that it will not enforce its essential patent claims as described above, and
 - (5) at the option of the patent holder, that such license under (c)(1) or (2) or (3) is subject to a condition of reciprocity, where reciprocity means with respect to other parties that have a patent or published patent application containing an essential patent claim under

the Standard, the assurance under (c) is conditioned on their willingness to license their patent(s) containing an essential patent claim on these terms ((c) (1), (2), or (3)). A patent holder who provides an assurance to license without compensation under (c)(2) on a condition of reciprocity or a non-assert assurance under (c)(3), may require a license with compensation on reasonable terms and conditions that are demonstrably free of discrimination if the reciprocating licensee will only license on such terms; and

(d) stating that the assurance contained in the written communication will be brought to the attention of any future assignees or transferees of the essential patent claim, that the assurance will be included in any documents transferring ownership of patents subject to the assurance together with provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest. The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

9.6 Declaration

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, OR (C) a pledge that the member will not enforce the patent against anyone seeking to practice one or more claims of the 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 Trademark and Copyrights

10.1 Ownership

The DSC entrusts the Secretariat with the ownership of all trademarks or copyrights, whether registered or not, relating to all goods or services relating to the Standard, and the Secretariat shall have the right to grant permissions to use any trademark relating to the goods and services or the text of any part of the Standard or other publication of the DSC on such terms and conditions as the Secretariat may approve.

In the event that the DSC decides to designate a different organization as the Secretariat of the DSC, the existing Secretariat shall transfer the ownership of the above trademarks and copyrights to the new Secretariat.

10.2 Copyright

The Secretariat is entrusted with ownership of the copyright in the Standard (regardless of format, whether in print or digital) and other publications of the DSC.

Members as well as others who submit contributions to the DSC, the Secretariat, or any Working Group of the DSC, for inclusion in the Standard or any other publication of the DSC are solely responsible for determining whether disclosure of any contributions that they submit require the prior consent of other parties and, if so, to obtain it.

All contributions from previously published sources under an explicit claim of copyright ownership (e.g., © or “Copyright”) that are not Public Domain shall be accompanied by a Copyright Permission Form that is completed by the copyright owner, or by a person with the authority or right to grant copyright permission. The Copyright Permission Form shall outline the specific material being used and the planned context for its usage in the NEMA Standards Publication.

For any contribution, whatever the source, that has not been previously published under an explicit claim of copyright ownership, and that is not Public Domain:

- a) the Secretariat has the non-exclusive, irrevocable, royalty-free, worldwide rights (i.e., a license) to use the contribution in connection with the development of the Standard or any other publication of the DSC for which the contribution was made.
- b) Upon (i) approval of the standard; or (ii) final release or publication of the Standard, the Secretariat has the right to exploit and grant permission to use the Standard’s content derived from the contribution in any format or media without restriction and without compensation.

Copyright ownership of the original contribution is not transferred or assigned to NEMA.

As used in this paragraph 3.14, “Public Domain” shall mean material that is no longer under copyright protection or did not meet the requirements for copyright protection.

10.3 Excerpts from the Standard

Royalty-free permission is granted to copy, use, and publish excerpts from a DICOM® Standards Publication, including Parts, Supplements, and Change Proposals, (the “excerpt”) for the purpose of incorporating such excerpts in other works, including product manuals, other standards publications, user guidelines, and educational materials on the following conditions:

- 1) It is acknowledged that the source of the excerpt is “DICOM Part(s) _____, © NEMA.”
- 2) It is stated that “The DICOM Standard is under continuous maintenance, and the current official version is available at <http://www.dicomstandard.org>
- 3) The text, artwork, or graphical material from the excerpt may NOT be modified.
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11 Translation and Localization Policy

The DSC desires to have a mutually beneficial, respectful, and collaborative approach to recognition of the Standard in national regulations. To ensure continued global interoperability of diagnostic imaging and therapy equipment, the efficient exchange of healthcare diagnostic information, and to remove barriers to trade, it is critical that there be only one normative global specification of the Standard. The single normative specification is the English language edition produced by the DSC and published by and under the copyright of the Secretariat. Product claims of DICOM conformance shall be to the official English publication of the Standard.

11.1 Translation

Organizations interested in developing and publishing a translation must request prior permission from the DSC. If approved by the DSC, the Secretariat, which holds the Intellectual Property / Copyright on behalf of the DSC, will grant permission. A condition of permission will be inclusion of a Disclaimer, as described in Section 11.3.

Translations shall not include intentional deviations from the meaning of the normative English publication.

11.2 Localization for National or Regional Requirements

DICOM has been designed to address national or regional requirements related to language, local administrative and medical practices.

National or Regional bodies may produce separate specifications that reference the Standard and impose further constraints on the options available in the Standard in order to promote more seamless interoperability in their context such as support for specific character sets as allowed by

the Standard. It is important that these additional constraints not change or deviate from the normative requirements of DICOM. Publishing such national or regional requirements in a separate specification document highlights those requirements and the source authority for implementers, facilitating accurate compliance.

Products may assert conformance to national or regional requirements, profiles, or implementation guides, but such assertions are supplemental to conformance to the underlying Standard.

11.3 Disclaimer Statement

After requesting and receiving permission from the DSC to publish a translation of the Standard (see 11.1), a condition of publication will be that the following text shall be included, in English and in the translated language, on a cover page of each translated document:

DICOM is the worldwide Standard for medical imaging and related information. It is published and copyright by the DICOM Secretariat. The normative DICOM Standard is published in English and is available free on the official website at <http://dicomstandard.org/current>.

This document is a translation prepared under agreement with the DICOM Secretariat, with the intention to help readers understand the DICOM Standard more readily. This translation represents a “best effort”; however, differences in meaning may exist between this translation and the normative DICOM Standard. Further, the DICOM Standard is under continuous maintenance and extension, so readers should expect that there are changes that are not reflected in this translation.

In the event of any difference between this translation and the DICOM Standard published in English by the Secretariat, the English version is normative and takes precedence. Implementations shall claim conformance to the normative DICOM Standard. Users are advised to obtain the most current documents of the DICOM Standard directly from the official website.

12 Communications

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

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 Secretariat and the DSC officers.

12.2 External Communication

Inquiries relating to the DSC 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.

13 Appeals

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

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

14 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.