IMDRF/MC/N2FINAL:2017
(Edition 3)

IMDRF International Medical Device Regulators Forum

Final Document

Title: IMDRF Standards Operating Procedures

Authoring Group: IMDRF Management Committee

Date: 16 March 2017

Kimby Barton, IMDRF Chair

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1.0 Introduction

This document is intended to describe the basic procedures that the International Medical Device Regulators Forum (IMDRF) follows when revising the membership of the Management Committee, establishing Subcommittees or Working Groups, developing IMDRF Documents or managing documents developed under the Global Harmonization Task Force (GHTF).

The Operating Procedures outlined in this document, in conjunction with the *Terms of Reference*, are designed to be flexible so that should the need arise, the IMDRF can respond to challenges with respect to its objectives in a timely manner.

2.0 IMDRF Membership

2.1 Management Committee membership

In considering requests for membership, the Management Committee will consider whether the regulatory authority has:

- a mature or maturing system for medical device regulation,
- a recognized commitment to the objectives of IMDRF,
- a capacity to contribute resources and expertise to the objectives of IMDRF,
- an industry with significant manufacturing activities,
- continued to contribute to scientific or regulatory innovation in the field of medical devices,
- a regional influence, and
- engaged in IMDRF activities and demonstrated its capacity of contribution – through the participation in Public IMDRF meetings, Working Groups as observers, and providing input to document consultations, etc.

New Management Committee members will be accepted with the unanimous agreement of existing Management Committee members.

Applications to become a Management Committee member are to be made in writing to the IMDRF Chair.

2.2 Official Observers

Official Observers from the World Health Organization or other regulatory authorities, not currently on the Management Committee, can be appointed on the basis of perceived contribution or value to IMDRF taking the above factors in 2.1 into consideration. Official Observers must be approved by unanimous consent of the Management Committee. As with full

members, Official Observers may have two consistent representatives per delegation and these representatives need to be fully knowledgeable on IMDRF matters.

Official Observers will be expected to attend all Management Committee meetings which are held face to face or by teleconference or other means. Official observers will be expected to maintain the confidentiality of the "closed" Management Committee meetings per the Terms of Reference document. When a discussion or portion of a Management Committee meeting is designated as "closed" Official Observers may attend. Official Observers do not participate in the decision making process.

2.3 Invited Observers

Invited Observers will be invited by the Chair to "open" portions of face to face Management Committee meetings or a nominated session of a meeting of the Management Committee on the basis of perceived contribution or value to IMDRF, taking the above factors in 2.1 into consideration. Medical device manufacturers are considered to be critical stakeholders to IMDRF. Therefore, the medical device industry will be represented as Invited Observers. The representatives from the medical device industry, by virtue of accepting the IMDRF Invited Observer status on behalf of industry, agree to solicit input for the IMDRF Management Committee upon request and to take IMDRF outputs back to industry organizations or companies for review and comment during consultation stages.

All Invited Observers will be invited on a meeting by meeting basis. When a discussion or portion of a Management Committee meeting is designated as "open" Invited Observers may attend. Invited Observers do not participate in the decision making process.

2.4 Affiliate Organizations

Affiliate Organizations will be appointed by the Management Committee. Affiliate Organizations must have an interest in medical device regulatory activities that are directly related to the common goals of fostering global regulatory convergence, leveraging resources and making available safe and effective medical devices globally.

An Affiliate organization may be invited to attend a Management Committee meeting as an Official Observer or an Invited Observer.

An Affiliate Organization that wishes to become an Official Observer must meet the criteria outlined in the IMDRF Terms of Reference (II. Governance Structure) and must be approved by the unanimous consent of the existing MC.

2.5 Subcommittee membership

IMDRF Subcommittees are groups established by the Management Committee to draft policy documents that are created to address governance, procedural and decision making matters of the IMDRF, or other matters that are not appropriate for a Working Group.

Subcommittee members should be from the Management Committee. In exceptional cases, the Management Committee may invite other participants to contribute to the work of the Subcommittee on a short or long-term basis.

The Chair of a Subcommittee must be a member of the Management Committee.

Calls for representatives to participate in a Subcommittee will be made by the IMDRF Chair. It is not a requirement that all Management Committee jurisdictions be represented on a Subcommittee.

The membership of Subcommittees will be published on the IMDRF website.

2.6 Working Group membership

IMDRF Working Groups are groups that are established by the Management Committee to undertake defined work tasks as identified in the work plan. The Chair of a Working Group should be a member of the Management Committee or a technical expert designated from a Management Committee member. If the Working Group is chaired by a designated technical expert, the Management Committee member from that jurisdiction will be a Rapporteur for the Working Group, and will make the presentations to the Management Committee on behalf of the designated technical expert chair and the Working Group.

When the Management Committee decides to establish a Working Group, it will call for nominations for the role of Working Group Chair. They will also indicate whether the Working Group is to have closed or open membership.

Closed Working Groups are responsible for developing technical documents or undertaking activities that involve the exchange of sensitive or confidential information or involve the specific practices or procedures of the regulatory authorities and will be composed exclusively of representatives from regulatory authority members of the Management Committee or invited experts from other regulatory authorities.

Membership of open Working Groups is to include stakeholders other than regulatory authority members. These stakeholders should be nominated/selected based on their technical capacity or expertise in the specific matter and their ability to actively contribute to the activities of the Working Group. Where appropriate for the nature of the issue, membership may be selected based on geographical or regional considerations.

The Working Group Chair or the Rapporteur is responsible for identifying potential members, extending invitations, considering all nominations received, and proposing a membership list to the Management Committee. Membership of a Working Group is to be determined within four weeks of its creation.

An invitation for Management Committee members to nominate a representative to participate in the Working Group will be issued by the Working Group Chair or the Rapporteur. A decision to participate in a Working Group is discretionary and it is not a requirement (although desirable) that all Management Committee jurisdictions be represented on a Working Group. The proposed membership list will be provided to the Management Committee for consideration and approval.

The membership of Working Groups will be published on the IMDRF website.

3.0 Development of Technical Documents

The rotating IMDRF Secretariat is the contact point during the holding of the rotating Chair. The IMDRF secretariat ensures that the IMDRF Website master maintains the integrity of the information displayed.

The procedures set forth in this section apply to all IMDRF technical documents that are intended to be published on the website as Final Documents.

To assist in effective processing a Document Transmittal Record (Annex A) is to accompany IMDRF documents whenever submitted to the Management Committee for consideration.

3.1 General Principles

Any new work item must have a clearly articulated scope and a timeline for key milestones and delivery.

Working Groups should liaise by e-mail or teleconference as often as required to meet the agreed timelines. Where necessary they may meet in person. It is the responsibility of each Working Group Chair to ensure that work is allocated equitably among group members.

Working Group Chairs must provide a written report to each face-to-face Management Committee meeting on progress against milestones. Written or verbal updates shall be provided for Management Committee teleconferences at the request of the IMDRF Chair or Secretariat.

Where a Working Group is unable to meet the milestones and final delivery timeline, the Management Committee may consider alternatives to completing the work.

3.2 Stage 1 – Assignment of Work Items

3.2.1 New Work Item Proposals and New Work Item Extensions

The Management Committee will consider at each face-to-face meeting the need for new work items to be undertaken. The IMDRF Management Committee may establish a Working Group to undertake the new work item. The IMDRF Management Committee may also direct an existing Working Group to undertake the analysis of a new or related issue through a New Work Item Extension. In each of these cases, the IMDRF Management Committee will be responsible for proposing the rationale for the work assignment.

New Work Item referrals should be drawn up following the format attached in Annex B. The IMDRF Management Committee should, in particular, consider the following issues:

- scope, purpose and rationale including an outline of issues to be addressed and opportunities for regulatory convergence,
- the IMDRF objectives as set out in the *Terms of Reference* document,
- proposed sources of necessary expertise,
- whether an open or closed membership is preferable,
- relevant existing documents at the IMDRF, GHTF and national level, and
- proposed timeframes and milestones.

Upon approval of new work item, a finalized New Work Item proposal will be circulated to Management Committee member if they are revised during the meeting. It is expected that the assigned new work item will be completed by the Working Group within 18 – 24 months of referral. Any departures from the agreed Work Item will require endorsement of the Management Committee.

3.2.2 New Document Request

When a Working Group discovers that it cannot accomplish the tasks within a given New Work Item Proposal or New Work Item Extension as defined by its scope within a single document, the Working Group Chair can request of the Management Committee the approval to split the New Work Item into more than documents. The Working Group Chair will need to provide that

justification and rational as to why the work cannot be completed in one document and must propose a revised timeline for the original document and the additional document(s). This justification and revised timeline should be submitted to the Management Committee for endorsement following the format attached in Annex B.

3.3 Stage 2 – Document Development

Where the Management Committee has asked a Working Group to develop a technical document, the Working Group will undertake the development of a Working Draft consistent with the scope, purpose and rationale of the approved new work proposal.

Once a Working Group has decided that a Working Draft is suitable for circulation, the Chair should invite members to disseminate the Working Draft to relevant experts amongst their country's regulatory authority, affiliate organization, and the stakeholders as appropriate. In the case of Working Groups with closed membership, drafts will only be circulated to regulatory authority members. Any comments at this stage will be coordinated by the country's, affiliate organization or stakeholder representative to the Work Group, as appropriate.

Working Drafts will not be posted on the IMDRF Website and not be publicly available, as they are subject to considerable changes.

Comments should be submitted to the Chair of the Working Group, either directly, or via the country's or stakeholders' representatives to the group.

3.4 Stage 3 – Advancement from Working Draft to Proposed Document

Final Working Drafts should be forwarded, in the prescribed IMDRF format, using the Document Transmittal Record (see Annex A) in electronic format to the IMDRF Chair. The IMDRF Chair will forward a copy of the document, with the Document Transmittal Record, immediately to the IMDRF Management Committee, which will review the document against the following criteria, before proceeding with the advancement process:

- consistency with the project scope, purpose and rationale as originally approved by the Management Committee in the New Work Item Proposal, and
- conformity to IMDRF procedures.

The Management Committee will have four to six weeks from receipt of the document to review the document.

Decisions regarding Working Group requests for advancement of a document to Proposed Document stage shall be authorized by the Management Committee. A document may be referred back to a Working Group where the Management Committee requests further work. Typically the Management Committee would provide direction and not redraft the document.

The Management Committee may also determine that the document should not be advanced further.

The decision of the Management Committee shall be documented in the record of discussion of the Management Committee meeting or teleconference.

3.5 Stage 4 – Consultation on Proposed Documents

Unless the Management Committee determines otherwise, all Proposed Documents will be posted on the IMDRF website by the IMDRF Chair through the Secretariat immediately following the approval as a Proposed Document. Generally, the comment period for Proposed Documents will be no longer than three months, starting from the date the document was posted on the IMDRF website. Working Group Chairs are to nominate the consultation period for approval by the Management Committee. Working Group Chairs should also indicate an appropriate contact person to whom persons accessing the document via the website can address their comments, using the appropriate format. Documents which remain on the website shall be marked with a disclaimer once the comment period has closed. It shall state that the document is under revision.

It is also recommended that each Management Committee jurisdiction establishes a process for soliciting comments from interested persons and organizations within their area and that Working Group members then use this process to solicit comments within their jurisdictions. .

All documents should be available in electronic format.

The Working Group will evaluate the comments submitted and issue a revised document expeditiously, generally within three months from closing the consultation period. The Working Group Chair or the Rapporteur will inform the IMDRF Chair if more time is needed.

3.6 Stage 5 – Advancement from Proposed Document to Final Document

Once consensus is reached within a Working Group that its work on a document is complete, and that all comments have been appropriately resolved, the Working Group Chair or the Rapporteur will present the document proposed as final to the IMDRF Secretariat using the Document

Transmittal Record (Annex A). The following mechanism will then be used to obtain IMDRF endorsement as a Final Document:

The Management Committee will have five weeks to review the document. Any comments from the Management Committee members on a proposed final document should be sent to the Working Group for proposed resolution at a minimum of two weeks prior to the Management Committee meeting.

Decisions regarding Working Group requests for endorsement of a Final Document shall occur by authorization of the Management Committee. A document may be referred back to a Working Group where the Management Committee requests further work.

The Management Committee may also determine that the document should not be advanced further.

Generally to be undertaken at a face-to-face meeting, the decision of the Management Committee shall be documented in the record of discussion of the Management Committee meeting.

Endorsement of the document will be formalized with the signature of the current IMDRF Chair on a standardized cover page (see Annex C), authorizing publication as an IMDRF document. The signature may be given in electronic format.

Signature by the IMDRF Chair signifies acceptance of the Final Document.

3.7 Stage 6 – Publication

Once endorsement of a Final Document is obtained, the IMDRF Chair will make the necessary arrangements to post it in electronic format on the IMDRF website.
In addition, an electronic notification on the availability of the signed-off document on the IMDRF's web site will also be sent by the IMDRF Chair to the Management Committee Members for the purposes of general reference.

3.8 Stage 7 – Implementation

Once endorsement takes place in Stage 6, the Final Document is available for regulatory implementation according to the regulatory process in application in the respective jurisdictions.

4. Development of Information Documents

Information documents can be created to provide clarification, status, and/or needed information about a particular work item or issue where public consultation is not needed. All information documents will be assigned an appropriate identification code, as described below. All information documents must be circulated to the Management Committee for approval prior to any posting on the IMDRF website. The Management Committee will have four to six weeks from receipt of the document to review and clear the document. Any comments or negative opinions should be sent to the Working Group Chair with a copy to the Secretariat within that timeframe for further resolution. If a member does not provide a response in that timeframe, the IMDRF Secretariat will assume it is cleared for posting.

5. Document Status Designation

Documents will bear appropriate identification codes.

The document identification practices described below are intended to apply to all IMDRF outputs created by any person or group involved in IMDRF activities.

5.1 Location of Designation Code

All IMDRF documents are to have their official designation code noted in the upper right hand corner of the cover sheet.

Each document is designated a document number, which remains the same throughout the development of the document. The Secretariat will distribute the document number and maintains a central register of document numbers and titles.

5.2 Working Drafts (WD)

All document identification codes are to include identification of the authoring group, i.e. “MC” for the Management Committee, “SC” for a Subcommittee, or “WG” for a Working Group plus the Working Group identifier, followed by an indication of WD for the document status, followed by an oblique and then the document number (N) and revision number (R). Document numbers will be given according to the following system:

Examples: RPS WG (WD)/N21R5
UDI WG (WD)/N7R3
MC (WD)/N1R2
MDSAP WG (WD)/N2R5

5.3 Proposed Documents

Because documents at the Proposed Document Stage are being disseminated for comment, the document code described above is to be modified with the addition of the letters "PD and version of the document posted" in parentheses (i.e., PD1, PD2), after the authoring group identifier.

Example: MC(PD1)/N1R3
SMDS WG(PD1)/N3R2

5.4 Final Document

Once endorsed by the Management Committee and signed off by the IMDRF Chair, all IMDRF documents are to be designated using the letters "IMDRF", followed by an oblique and the authoring group identifier. This will then be followed by an oblique, the document number (N), the word 'FINAL', a colon and the current calendar year.

Examples: IMDRF/MDSAP WG/N21FINAL:2010 (Edition 1)
IMDRF/RPS WG/N7FINAL:2011 (Edition 1)

For security and to prevent unauthorized alteration, final documents should normally be published in PDF format, unless PDF is not appropriate. Any forms and related documents intended for downloading and use of the public may be posted in another format.

6.0 Revision of IMDRF Documents

Due to the changing regulatory environment in which the IMDRF operates, and the fact that IMDRF documents are in the public domain, all IMDRF documents are to be considered for review on a periodic basis. The revision procedure is to be used when the content of an IMDRF document is no longer up-to-date or valid and needs to be revised or modified. In addition, the revision procedure can be used in cases when there is new information that needs to be incorporated into an existing IMDRF guidance document in order to enhance the document. The formal IMDRF process for the development of Technical Documents outlined in Section 3.0

should be followed for all revision activities in conjunction with the process outlined below. The IMDRF Management Committee will consider at each face-to-face meeting the list of IMDRF documents and whether any reviews are required. Where revision is agreed to be undertaken, the IMDRF Management Committee may refer the revision to either a Subcommittee or a Working Group that is covering a related topic, if possible. If the endorsed revision is not related to any active working group, the IMDRF Management Committee may consider either assigning a Subcommittee, resuming a related Working Group, or establishing a New Work Item following the process outlined in Section 3.0 above.

The contact person for the document indicated on the website should also be re-designated if needed.

Where IMDRF Management Committee members or stakeholders become aware that an IMDRF document requires updating, they should advise the IMDRF Secretariat.

Documents undergoing revision must receive Management Committee endorsement and therefore, proposed changes should be indicated, by highlighting additions and deletions, when they submit a document for re-endorsement using the Document Transmittal Record (Annex A).

When re-published (and therefore re-posted on the IMDRF website), amended documents must be designated as described above but with the inclusion of the text "(Edition X)" (where "X" represents the number of the current revision).

Example: IMDRF/UDI WG/N10FINAL:2000 (Edition 2)
IMDRF/MC/N3FINAL:2000 (Edition 3)

It should be noted that the original year in which the document was originally endorsed will change in the document identification code.

Example: IMDRF/MC/N3FINAL:2000 (Edition 3)
IMDRF/MC/N3FINAL:2001 (Edition 4)

6.1 Maintenance of IMDRF Documents

This procedure applies to IMDRF documents that establish specific terminology and codes unique to IMDRF. These types of documents require periodic review and maintenance of the terminology and codes. Separate procedures may be established by a Working Group to address the review, maintenance, and any changes that might be required for these types of documents.

The maintenance procedure also applies to any IMDRF document that contains out-of-date information. In cases where minor updates are necessary (e.g., out-of-date references, links, etc), the documents may be updated by the IMDRF Secretariat without the establishment of a working group. In cases where an entire document is out of date, the IMDRF Management Committee will review and determine if the document is obsolete. The documents that are being updated or determined to be obsolete must receive Management Committee endorsement prior to publication or removal.
For those minor editorial changes, not involving substantive changes, the updated version will be numbered to indicate the revision, such as "Edition X.X".

Example: IMDRF/MC N3FINAL:2000 (Edition 3) with a minor editorial would become, IMDRF/MC N3FINAL:2000 (Edition 3.1).

7.0 Management and Maintenance of GHTF Documents

Documents created under GHTF will be maintained via a repository on the IMDRF website. GHTF documents will be periodically reviewed to ensure the content remains current. Should IMDRF Management Committee members, Official Observers, or stakeholders become aware that a GHTF document is out of date they are asked to notify the IMDRF Secretariat. The Secretariat will bring this notification to the attention of Management Committee members for their consideration.

During each Management Committee meeting, a standing item will be placed on the agenda for consideration of GHTF documents that may need updating. Each year, it is the responsibility of the Chair of the IMDRF Management Committee to provide a list of GHTF documents that may need to be reviewed/updated based on current work items or feedback received from IMDRF Management Committee members, Official Observers, or stakeholders.
If a working group is tasked with a project that relates to a previously published GHTF guidance document(s), it is the responsibility of the Working Group to review and provide recommendations to the IMDRF Management Committee regarding the potential need for revision of GHTF documents.

The IMDRF website will also have a facility that allows stakeholders to notify the Management Committee of the need to update GHTF documents. GHTF documents that undergo revision will be converted to IMDRF documents and will follow the Revision procedure outlined above

in Section 6.0. The IMDRF document will clearly show what GHTF document it has been derived from.

Example: IMDRF/NCAR WG/N20/R2:2012 (formerly GHTF/SG1/N15/R4:2009).

8.0 Record-Keeping/ Information Archives

The Secretariat will maintain a listed inventory and actual texts of documents and Document Transmittal Records. The inventory will show the stage of development of each document, e.g., WD or PD, along with any relevant notes, e.g., the deadline for comment, etc. The Secretariat will maintain a master list of all IMDRF documents.

The IMDRF Secretariat has custodial responsibility for all hard-copy records passed on from previous and current Chair.

A searchable repository of all IMDRF Final Documents and in-process Proposed Documents will also be maintained on the IMDRF website.

9.0 Translation of IMDRF guidance documents

In general, IMDRF will:

(1) Make available on its website links to external sources of any translated versions of IMDRF documents. Such links will be accompanied by a disclaimer stating that visitors are leaving the IMDRF website and that IMDRF is not responsible for other websites where translated documents may be available or for the quality of those documents.

(2) Where the IMDRF Management Committee is aware of such translated documents, it will encourage the producing party to include a statement, both on the website and in the document itself, to the effect that "This document has been translated from the original IMDRF English version <IMDRF document and revision numbers>, by <Institution or name of translator> on <date>. Where discrepancies exist between this document and the original English IMDRF document they should be resolved in favor of the current original English IMDRF document."

(3) As and when the Management Committee becomes aware of documents translated by other parties, it may invite a Management Committee member, if fluent in the translated document language(s), to review them for accuracy. Significant discrepancies should be brought to the attention of the translating party.

10.0 IMDRF-Related Presentations and Training

It is recognized that persons involved in IMDRF Management Committee, Subcommittee or Working Group work may be called upon to do presentations or provide information on a part or parts of the IMDRF's activities to their peers, trade association groups or regulatory authorities.

In all cases, the member being asked to do the presentation is asked to inform the IMDRF Chair and/or IMDRF Secretariat of the request. In the future, copies of slides used in these presentations may be made available to interested parties via the IMDRF website.

When persons or groups organize a training event and claim to represent IMDRF they shall seek prior consent from the IMDRF Chair.

11.0 IMDRF Logo

The IMDRF has adopted the logo depicted on the front cover of this document. This logo should appear on all formal IMDRF correspondence, reports, and the front cover of all IMDRF documents, and should be displayed within the IMDRF website.
The IMDRF logo is not registered or trademarked in any way so its use by persons outside the IMDRF is not impossible. Knowledge of such activity however, should therefore be reported to the IMDRF Chair.

Annexures

ANNEX A

IMDRF Management Committee Document Transmittal Record	
Date:	
From Subcommittee or WG:	To: IMDRF Management Committee
For consideration at Management Committee meeting on (date):	
Document title:	
Document number and revision:	Date:
Reason: □ Proposed for approval for posting as Proposed Document for public comment (Proposed duration of comment period:) □ Proposed for approval for posting as Final Document □ Recommendations proposed for Management Committee consideration □ Other (explain):	
Approved New Work Item Proposal, New Work Item Extension, or mandate for this document (attach):	
Purpose: □ New document □ Periodic routine revision or update of previously released IMDRF Final Document □ Revision of a GHTF Final Document □ Other (explain):	
Highlight any major revisions (if any) since previous review by Management Committee and generally explain the reason(s):	
Highlight any major points for specific consideration by Management Committee (if any):	

Note any changes required in other IMDRF documents if this document is endorsed (if any):

Remarks:
Management Committee outcome:

ANNEX B

IMDRF International Medical Device Regulators Forum

(Please choose one of the following)
New Work Item Proposal
New Work Item Extension Proposal
New Document Request

For Management Committee consideration

(Please submit to IMDRF secretariat -email address changes with Chairmanship)

Proposed title of the project	
Initiator	
Purpose and Rationale (including a reference to one or more of the goals or objectives of the IMDRF)	Purpose Rationale Alignment with goals/objectives
Scope (including outline of issues to be addressed and opportunities for regulatory convergence)	Issues to be addressed Opportunities for regulatory convergence
General Work Plan and	

Timelines	
Proposed Working Group Chair	
Proposed sources of necessary expertise	
Relevant existing documents at IMDRF or GHTF and national level, as well as in international bodies.	

IMDRF Template: September 2014

ANNEX C

Cover Page for Final IMDRF Documents

IMDRF International Medical Device Regulators Forum

Final Document

Title:

Authoring Group:

Date:

[Signature], IMDRF Chair