IMDRF/MC/N2FINAL:2019 (Edition5)

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: **IMDRF Standard Operating Procedures**

Authoring Group: **IMDRF Management Committee**

Date: **21 March 2019**

Elena M. Astapenko, 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

IMDRF membership criteria, roles, and responsibilities are listed in each of the Sections below and are also outlined in Annex D.

2.1 Management Committee

The Management Committee consists of regulatory authorities and is responsible for the oversight and decision making for all IMDRF activities. Management Committee members are voting members and are expected to attend all IMDRF Management Committee meetings which are held face to face or by teleconference as well as to ensure regular contribution to IMDRF activities and participate in at least 2/3 of the IMDRF Working Groups. Management Committee members have two (2) representatives per delegation and these representatives need to be knowledgeable on IMDRF matters. It is expected that these representatives would consistently attend subsequent IMDRF meetings and that any changes to representatives would require notification to the IMDRF Management Committee chair.

In reviewing application requests for membership, the Management Committee will consider whether the regulatory authority has met each of the following requirements, including having:

- been a regional influence,
- participated in all IMDRF MC meetings (including teleconferences) for the last two (2) consecutive years,
- participated in a majority of Working Groups as an Official Observer for the last wo (2) consecutive years, providing active contribution, and
- been an Official Observer for at least the last two (2) consecutive years prior to the application for membership, and
- sufficient capacity to chair the MC and provide the Secretariat for a year, including hosting two (2) face to face meetings and two (2) scheduled teleconferences.

Having been an Official Observer for the last two (2) consecutive years prior to the application for membership, while being an essential precondition for Management Committee membership, does not give the applicant any automatic presumption of conformity with the other criteria listed above.

Applications to become a Management Committee member are to be made in writing by completing the application form (located on the IMDRF website) and sending it to the IMDRF Chair. All applications must be submitted at least two (2) months before the next management committee meeting for consideration. The application(s) will then be reviewed by the Management Committee at the next Management Committee meeting. The Management Committee will ask the applicant to provide a presentation during that meeting. Any new Management Committee members will be approved with the unanimous agreement of existing Management Committee members.

The membership of the Management Committee will be published on the IMDRF website.

2.2 Official Observers

Official Observers consist of Regulatory Authorities and the World Health Organization (WHO) and participate in the oversight of all IMDRF activities, but do not participate in the decision making process. Official Observers will be expected to attend all Management Committee meetings which are held face to face or by teleconference as well as to participate in IMDRF Working groups. 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. As with full members, Official Observers may have two (2) consistent representatives per delegation and these representatives need to be knowledgeable on IMDRF matters.

In reviewing application requests to become an Official Observer, the Management Committee will consider whether the applicant has met each of the following requirements:

- being a Regulatory Authority,
- operating a mature or maturing system for medical device regulation which should include:
    - established laws and regulations for medical devices building substantially on GHTF and IMDRF foundations and principles,
    - proper competencies for effective implementation and enforcement of the established laws and regulation,

  - a system for conformity assessment of devices building on GHTF and IMDRF guidance documents, and
  - sufficient resources and regulatory expertise to perform its duties.
- contributing to scientific or regulatory innovation in the field of medical devices as demonstrated by development of guidance(s) in emerging technical and regulatory issues,
- having a capacity to contribute resources and expertise to the objectives of IMDRF by participation in public IMDRF meetings for the last two (2) consecutive years, participation in at least two Working Groups the last two (2) consecutive years as observers, and providing input to document consultations, and
- having a recognized commitment to the objectives of IMDRF demonstrated by implementation of IMDRF documents (work items).

Applications to become an Official Observer are to be made in writing by completing the application form (located on the IMDRF website) and sending it to the Management Committee Chair. Applications must be submitted at least two (2) months before the next management committee meeting for consideration. The application(s) will then be reviewed by the Management Committee at the next Management Committee meeting. The Management Committee will ask the applicant to provide a presentation during that meeting. Any new Official Observers must be approved by unanimous consent of the Management Committee.

The list of Official Observers will be published on the IMDRF website.

2.3 Invited Observers

An Invited Observer(s) can be a regulatory authority, global industry association, or stakeholder association. All Invited Observers will be invited by the Management Committee on a meeting by meeting basis. Invited Observers may only attend the "open" portions of face to face Management Committee meetings. Invited Observers do not participate in the decision-making process. Invited Observers may nominate up to two (2) representatives to attend open Management Committee meetings.

Medical device manufacturers are critical stakeholders to IMDRF. Therefore, the medical device industry will be represented as Invited Observers. The representatives from the medical device industry, by accepting the Invited Observer status on behalf of industry, agree to solicit input for the Management Committee upon request and to take IMDRF outputs back to industry organizations or companies for review and comment during consultation stages.

In reviewing requests to become an Invited Observer, the Management Committee Chair will consider whether the applicant has a perceived contribution or value to IMDRF. If the applicant

is a regulatory authority, they should have a mature or maturing system for medical device regulation or long-standing contribution to medical device regulation.

Requests to become an Invited Observer are to be made in writing to the Management Committee Chair. All requests must be submitted at least two (2) months before the next management committee meeting for consideration. The request will then be reviewed and approved/denied by the Management Committee Chair.

2.4 Regional Harmonization Initiatives

Regional Harmonization Initiatives (RHIs) are comprised of legislative or administrative authorities of any jurisdiction with responsibility for the regulation of medical devices. RHIs participate in the "open" sessions of face to face Management Committee meetings or portions of the "closed" sessions of the Management Committee meetings by invitation of the Management Committee Chair. RHIs do not participate in the decision-making process. RHIs may nominate up to two (2) representatives to attend open Management Committee meetings.

In reviewing application requests to participate in IMDRF as an RHI, the Management Committee will consider whether the application has:

- a mandate of regional harmonization amongst its members,
- associations/initiatives comprising medical device regulatory authorities representing the majority of countries in a certain region/area of the world, and
- a demonstrated 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.

Applications to participate in IMDRF as an RHI are to be made in writing by completing the application form (located on the IMDRF website) and sending it to the Management Committee Chair. Applications must be submitted at least two (2) months before the next management committee meeting for consideration and must be submitted by the Chair of the RHI. The application(s) will then be reviewed by the Management Committee at the next Management Committee meeting. Any new RHIs must be approved by unanimous consent of the Management Committee.

The list of RHIs will be published on the IMDRF website.

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.

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, Official Observers, RHIs or invited experts from other regulatory authorities.

Membership of open Working Groups include representatives from the regulatory authority members of the Management Committee, Official Observers, RHIs, stakeholders other than regulatory authority members or invited experts from other regulatory authorities. 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 and Official Observers to nominate a representative to participate in the Working Group will be issued by the Working Group Chair or the Rapporteur. The proposed membership list will be provided to the Management Committee for consideration and approval.

For regulatory authorities or RHIs who are not a part of IMDRF, but are interested in participating in an open working group, they may submit a written request to the Management Committee Chair which includes a justification for their participation. This justification should include a description of the individual's technical capacity or expertise in the specific matter and their ability to actively contribute to the activities of the Working Group. The decision to participate in a Working Group will be made by the Management Committee Chair in consultation with the Working Group Chair and, where necessary, with the Management Committee members.
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

A new work item proposal can be submitted by a Management Committee member or any stakeholder. 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 presentation 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.

A New Work Item Proposal (NWIP) should be submitted in 2 different timeframes depending on the topics.
(1) NWIP for new topics

- The NWIP should be submitted 10 weeks prior to the next Management Committee face-to-face meeting.
- The IMDRF Management Committee will have 4 weeks to review the NWIP and then hold a teleconference to
  - make suggestions to the proposal based on the *Terms of Reference* document and Strategic Plan. If the NWIP is from non-Management Committee stakeholders, the Management Committee will communicate via email after the teleconference.
  - decide whether to ask for advice from outside experts or stakeholders.
  - turn down the NWIP if it's obviously out of the scope of IMDRF.
  - establish a small editors group of interested Management Committee members, if necessary.
- If the NWIP is modified after its first submission, the revised NWIP should be resubmitted 4 weeks prior to the next Management Committee face-to-face meeting.
- If necessary, the IMDRF Management Committee will hold a teleconference to share any remaining concerns on the NWIP 1 week prior to the next Management Committee face-to-face meeting.

(2) NWIP for topics relating to existing Working Groups

- The NWIP should be submitted 4 weeks prior to the next Management Committee face-to-face meeting.
- If necessary, the IMDRF Management Committee will hold a teleconference to share concerns on the NWIP 1 week prior to next Management Committee face-to-face meeting.

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.

After the IMDRF Management Committee approves the NWIP, the launch of new Working Groups should meet the following timelines:

- The call for nominations for the Working Group Chair and members should be done within one week after the Management Committee face-to-face meeting.
- The Working Group Chair should be designated within 2 weeks after the Management Committee face-to-face meeting.
- The Working Group Members should be determined within 4 weeks after the Management

Committee face-to-face meeting.

- Work should commence within 6 weeks of the approval of the NWIP.

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, RHI, 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, RHI 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 as well as the other Management Committee members 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. Updated or revised documents may be approved at a teleconference.

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

ANNEX D

IMDRF Membership Criteria and Roles

	MC Member	Official Observer	Invited Observer	Regional Harmonization Initiatives (RHIs)
Criteria	• Must be a Regulatory Authority • A regional influence • Must have been an Official Observer for at least the last two (2) consecutive years prior to the application for membership • Must have participated in all IMDRF MC meetings (including teleconferences) for the last two (2) consecutive years • Must have participated in a majority of WGs as an Official Observer, providing active contribution for the last two (2) consecutive years. • Must have sufficient capacity to Chair the MC and provide the	• Must be a Regulatory Authority • Regulatory Authority should operate a mature or maturing system for medical device regulation which should include: ○ Established laws and regulations for medical devices building substantially on GHTF and IMDRF foundations and principles ○ Proper competencies for effective implementation and enforcement of the established laws and regulation ○ A system for conformity assessment of devices building on	• Must be a regulatory authority or global industry or stakeholder association • Perceived contribution or value to IMDRF meetings • A regulatory authority should have a mature or maturing system for medical device regulation or long-standing contribution to medical device regulation	• Must be associations/initiatives comprising medical device regulatory authorities representing the majority of countries in a certain region/area of the world • Must have mandate of regional harmonization amongst its members • Must have a demonstrated 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

	Secretariat for a year, including hosting two (2) face to face meetings and two (2) scheduled teleconferences.	GHTF and IMDRF guidance documents ○ Sufficient resources and regulatory expertise to perform its duties • A demonstrated contribution to scientific or regulatory innovation in the field of medical devices as demonstrated by development of guidance(s) in emerging technical and regulatory issues • A demonstrated capacity to contribute resources and expertise to the objectives of IMDRF by participation in public IMDRF meetings for the last two (2) consecutive years, participation in at least two Working Groups the last two (2) consecutive years as observers, and providing input to document consultations. Note: Participation of a regulatory authority as an RHI does not count towards the two (2) consecutive year requirement		medical devices globally

		• A recognized commitment to the objectives of IMDRF demonstrated by implementation of IMDRF documents (work items)		
Roles	• Participates and provides oversight in the decision making process and strategic direction of IMDRF activities • Attends all "open" and "closed" sessions of the MC meetings including MC teleconferences • Ensures regular contribution to IMDRF activities • Participates in 2/3 of IMDRF Working groups • Assumes the chair of the IMDRF Management Committee on a rotating basis	• Does not participate in the decision making process of IMDRF • Attends all "open" and "closed" sessions of the MC meetings • Participates in IMDRF Working Groups	• Does not participate in the decision making process of IMDRF • Only attends "open" MC meetings • Invited on a meeting by meeting basis	• Does not participate in the decision making process of IMDRF • Only attends "open" MC meetings • May attend certain portions of the "closed" sessions of the MC meetings by invitation of the MC chair
Procedure	• Application file (including form) to be submitted to MC	• Application file (including form) for official	• Request to IMDRF chair three months before MC meeting	• Application file (including form) to be submitted to MC

	• Application will be reviewed at the next face to face MC meeting • New MC members will be accepted with the unanimous agreement of existing MC members	observership to be submitted to MC • Application will be reviewed at the next face to face MC meeting • Official observers will be accepted with unanimous agreement of existing MC members	• Decision of chair on the participation in the "open" MC meeting	• RHI will be accepted with unanimous agreement of existing MC members

ANNEX E

IMDRF International Medical Device Regulators Forum

City, Country
March XX-XX, 20XX
Record of Discussions (Draft)

Day X: IMDRF Stakeholder Forum/or Management Committee Meeting
Tuesday XX March 20XX – 9:00am to XX:XXpm Venue: XXXX
Address
Place

AM Session/or PM Session

Session	Lead	Summary of Discussions and Outcomes
1. Welcome		