IMDRF International Medical Device Regulators Forum

Final Document

IMDRF/MC/N2FINAL:2023 (Edition 9)

IMDRF Standard Operating Procedures

AUTHORING GROUP

IMDRF Management Committee

7 February 2023

Preface

Andrzej Rys, IMDRF Chair

Contents

1. Introduction

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to strategically accelerate international medical device regulatory convergence.

This document complements and is intended to be read in conjunction with the IMDRF Terms of Reference. It describes the procedures that the IMDRF follows when revising the membership of the IMDRF Management Committee, Affiliate Members, Official Observers, establishing Subcommittees or Working Groups, developing IMDRF Documents or managing documents previously developed under the Global Harmonization Task Force (GHTF).

The operating procedures outlined in this document, in conjunction with the IMDRF 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. IMDRF Meetings

The IMDRF Management Committee (MC) meets twice a year with Closed Session physical meetings held in March and September. Hybrid meetings (in person and virtual attendance) may be facilitated, should situations arise that prevent IMDRF MC members from attending physically.

The IMDRF MC also holds three successive sessions in March and September each year corresponding with the IMDRF MC Closed Sessions. The IMDRF MC Members are expected to attend physically (face-to-face) the meetings held during the calendar year.

The IMDRF MC meets virtually via web/teleconferences twice a year, in January and June. At the discretion of the Chair, the MC may also meet when required or as a result of extraordinary circumstances.

Information on meetings and how decisions are made by the IMDRF MC are covered in the IMDRF Terms of Reference which can be found here.

3. IMDRF Membership

IMDRF membership criteria, roles, and responsibilities are listed in the Sections below and are also outlined in Annex A. In summary, the IMDRF MC takes part in decision making concerning membership and engagement, sets the direction of IMDRF work, contributes to work outputs and implementation activities.

All IMDRF MC Members, regardless of role, appoint two (2) delegates as part of their representation, unless there are exceptional circumstances in which this is not adequate. For example, regional unions and cooperatives composed of several countries with their own regulatory authority as well as a regional regulatory authority (e.g. the European Union, which appoints four (4) delegates).

3.1. Management Committee

The IMDRF MC consists of regulatory authorities and is responsible for the oversight and decision making for all IMDRF activities. The IMDRF MC Members are voting members and are expected to attend all face-to-face IMDRF MC meetings and teleconferences as well as to ensure regular contribution to IMDRF activities and participate in at least 2/3 of the IMDRF Working Groups. In exceptional circumstances, the IMDRF MC may choose to hold hybrid meetings (in person and virtual attendance) should a situation arise that prevent IMDRF MC Members from attending the face-to-face meetings.

The IMDRF MC Members have two (2) representatives per delegation[1] 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 Chair.

In reviewing application requests for membership, the IMDRF MC 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 two (2) consecutive years, providing active contribution;
- 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 IMDRF 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 MC membership, does not give the applicant any automatic presumption of conformity with the other criteria listed above.

Applications to become a IMDRF MC Member are to be made in writing by completing the application form (located on the IMDRF website) and sending it to the IMDRF Chair and Secretariat. All applications must be submitted at the latest two (2) months before the next MC Closed Session physical meeting for consideration. The application(s) will then be reviewed by the MC at their next physical meeting where the applicant(s) will provide a presentation. Any new MC members will be approved with the unanimous agreement of existing IMDRF MC Members.

The membership of the IMDRF MC will be published on the IMDRF website here.

[1] The European Union appoints four (4) representatives.

3.1.1. Expedited Procedure

In exceptional circumstances, a regulatory authority who is an Official Observer may apply for IMDRF membership under an expedited procedure, to become an IMDRF MC Member. To apply for IMDRF membership, the regulatory authority must:

- demonstrate their regulatory framework includes principles outlined in the IMDRF and GHTF guidance documents;
- be an Official Observer for at least six (6) months and have attended at least one (1) IMDRF MC teleconference and one (1) IMDRF MC face-to-face meeting;
- have previously contributed to IMDRF/GHTF activities including having contributed to a majority of IMDRF Working Groups for more than four (4) years. Note that this contribution could have been on behalf of another jurisdiction or a Regional Harmonization Initiative (RHI);
- have demonstrated that they have sufficient capacity to host IMDRF face-to-face Working Group meetings; and
- have demonstrated that they have sufficient capacity to Chair the IMDRF MC and provide the Secretariat for a year, including hosting two (2) face-to-face meetings and two (2) scheduled teleconferences.

Applications to become a IMDRF MC Member are to be made in writing by completing the application form (located on the IMDRF website) and sending it to the IMDRF Chair and Secretariat. All applications must be submitted at the latest two (2) months before the next MC Closed Session physical meeting for consideration. The application(s) will then be reviewed by the MC at the next physical meeting where the applicant(s) will provide a presentation. Any new MC members will be approved with the unanimous agreement of existing IMDRF MC Members.

3.2. 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 IMDRF MC meetings which are face-to-face, hybrid or by teleconference as well as participating in IMDRF Working Groups. Official Observers will be expected to maintain the confidentiality of the “closed” IMDRF MC meetings per the Terms of Reference document. When a discussion or portion of an IMDRF MC 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 IMDRF MC will consider whether the applicant has met each of the following requirements:

- is 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 MC meetings for the last two (2) consecutive years, participation in at least two Working Groups the last two (2) consecutive years as an Affiliate Member[2] or invited expert, 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 IMDRF Chair and Secretariat. Applications must be submitted at the latest two (2) months before the next MC Closed Session physical meeting for consideration. The application(s) will then be reviewed by the IMDRF MC at the next physical MC meeting where the applicant will provide a presentation . Any new Official Observers must be approved by unanimous consent of the IMDRF MC.

The list of Official Observers are published on the IMDRF website here.

3.3. 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 IMDRF MC on a meeting by meeting basis. Invited Observers may only attend the “open” portions of IMDRF MC meetings. Invited Observers do not participate in the decision-making process. Invited Observers may nominate up to two (2) representatives to attend open IMDRF MC 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 IMDRF MC 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 IMDRF 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 IMDRF Chair and Secretariat. All requests must be submitted at least two (2) months before the next MC physical meeting for consideration. The request will then be reviewed and approved/denied by the IMDRF Chair.

3.4. Affiliate Members

Regulatory Authorities who would like to engage with IMDRF, but do not wish to become or are not Official Observers, may apply to become Affiliate Members. As an Affiliate Member, the regulatory authority will participate in IMDRF by attending “open” meetings and using IMDRF documents in part or in whole as the basis for their own regulatory framework. Affiliate Members may also participate in open Working Groups. Affiliate Members do not participate in the decision-making process of IMDRF. Affiliate Members must be approved by unanimous consent of the IMDRF MC.

As with IMDRF MC Members, Official Observers, and Invited Observers, Affiliate Members may have two (2) consistent representatives per delegation at open meetings and these representatives need to be knowledgeable on IMDRF matters.

Applications to become an Affiliate Member are to be made in writing by completing the application form (located on the IMDRF website) and sending it to the IMDRF Chair and Secretariat. Applications must be submitted at the latest two (2) months before the next IMDRF MC physical meeting for consideration.

[2] Participation of a regulatory authority as an RHI does not count towards the two (2) consecutive year requirement.

In reviewing application requests to become an Affiliate Member, the IMDRF MC will consider whether the applicant has met each of the following requirements:

- being a regulatory authority;
- having a recognized commitment to the objectives of IMDRF demonstrated by implementation of IMDRF documents or a detailed plan for implementation of IMDRF documents as part of their regulatory framework; and
- commit to providing annual updates on the implementation of IMDRF documents at IMDRF MC open meetings.

The IMDRF MC will ask the applicant to provide a presentation at the IMDRF MC physical meeting where the application will be considered. The presentation should provide an overview of the applicant's existing regulatory framework including the extent to which IMDRF documents are currently or are planned to be implemented. In particular, the presentation should outline how the applicant meets the above set requirements.

Affiliate Members will be asked to report on a yearly basis, via presentation at an open meeting, on their progress regarding how they have implemented IMDRF documents or plan to implement IMDRF documents in their regulatory framework.

The list of Affiliate Members will be published on the IMDRF Website.

3.5. 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 IMDRF MC meetings or portions of the "closed" sessions of the IMDRF MC meetings by invitation of the IMDRF Chair. RHIs do not participate in the decision-making process. RHIs may nominate up to two (2) representatives to attend open IMDRF MC meetings.

In reviewing application requests to participate in IMDRF as an RHI, the IMDRF MC 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 IMDRF Chair and Secretariat. Applications must be submitted at the latest two (2) months before the next MC physical meeting for consideration and must be submitted by the Chair of the RHI. The application(s) will then be reviewed by the IMDRF MC at their next physical meeting where te applicant(s) will provide a presentation. Any new RHIs must be approved by unanimous consent of the IMDRF MC.

The RHI will be asked to report on a yearly basis, via presentation at an open meeting, on how they have fostered regulatory convergence, leveraged resources and made available safe and effective medical devices globally.

The list of RHIs is published on the IMDRF Website.

3.6. Subcommittee Membership

IMDRF Subcommittees are groups established by the IMDRF MC 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 IMDRF MC. In exceptional cases, the IMDRF MC 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 IMDRF MC.

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

3.7. Working Group Membership

IMDRF Working Groups are groups that are established by the IMDRF MC to undertake defined work tasks as identified in the work plan. When the IMDRF MC 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.

The IMDRF MC has authority over the scope of work undertaken by the Working Group. The Working Group can not change the scope of work without IMDRF MC approval. If the agreed scope of work requires changes, the Working Group must take their request to the next IMDRF MC for endorsement by the IMDRF MC. The Working Group must take into account IMDRF MC feedback at all times.

The membership of Working Groups is published on the IMDRF website.

3.7.1. 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 IMDRF MC and Official Observers.

Membership of open Working Groups include representatives from the regulatory authority members of the IMDRF MC, Official Observers, Affiliate Members, 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.

3.7.2. Working Group Chair and Rapporteur

The Chair(s) of a Working Group should be a member of the IMDRF MC or a technical expert designated from a IMDRF MC Member. If the Working Group is chaired by a designated technical expert, the designated technical expert shall keep the IMDRF MC Member continuously appraised regarding developments within the Working Group through established regular reporting. The IMDRF MC Member from that jurisdiction will serve as Rapporteur for the Working Group and will make the presentations to the IMDRF MC on behalf of the designated technical expert chair and the Working Group.

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 IMDRF MC.

In the event if a Working Group Chair is unable to continue in the role, he or she shall identify a volunteer among the Working Group Members to be appointed as the Interim Working Group Chair. If a volunteer could not be identified, the Rapporteur or a IMDRF MC Member from the same jurisdiction will be appointed as the Interim Working Group Chair. The Interim Working Group Chair is responsible to call for nominations for the role of a new Chair and to coordinate any outstanding issues within the Working Group. The new candidate will be submitted for approval at the next IMDRF MC teleconference or face-to-face meeting.

In extraordinary circumstances, IMDRF MC may appoint a new Working Group Chair if the current Chair is unable to fulfill their duties or is moving in a direction not endorsed by the IMDRF MC.

3.7.3. Working Group Co-Chair

If not already included as part of the New Work Item Proposal (NWIP), the Working Group Chair or Rapporteur with approval from the IMDRF MC may issue an invitation to Working Group Members requesting nominations for a Working Group Co-Chair at the first Working Group Meeting. The Co-Chair position needs to be agreed by the majority of the IMDRF Working Group. The proposed Co-chair appointment will then be provided at the next IMDRF MC meeting for noting.

3.7.4. Working Group Members

Once the IMDRF MC agrees to establish a new Working Group, IMDRF MC Members and Official Observers will be invited to nominate representatives to participate in the Working Group. The invitation will be issued by the Working Group Chair, Co-Chair or the Rapporteur with the proposed membership taken to the next IMDRF MC for consideration and approval.

When the Working Group is made public on the IMDRF website, Affiliate Members, RHIs or experts from other non-IMDRF regulatory authorities can submit an application form to the IMDRF MC to participate in the Working Group. The application form will include:

- justification for their participation;
- a description of their nominated individual's technical capacity or expertise in the specific matter;
- ability to attend face-to-face meetings and teleconferences for the Working Group; and
- the ability of their nominated individual to actively contribute to the activities of the Working Group.

The decision to include non-IMDRF applicants in a Working Group will be made by the IMDRF MC Members.

3.8. IMDRF Membership Status Change

IMDRF MC Members, Official Observers and Affiliate Members (collectively referred to as "IMDRF Members" hereafter) may have their IMDRF Membership suspended or terminated by the IMDRF MC or individual IMDRF Members may voluntarily withdrawal from the IMDRF at any time.

3.8.1. Membership Status Change via Suspension, Termination, and Withdrawal

Suspension

Suspension is a decision made by the IMDRF MC and must follow the process described below. When IMDRF Membership is suspended, the IMDRF Member is no longer allowed to attend "open" or "closed" meetings, participate in Working Groups, or participate in the decision-making process (where applicable).

All privileges of IMDRF Membership (whether it be IMDRF MC Member, Official Observer, or Affiliate Member) are on hold while IMDRF Membership is suspended.

Suspension of an IMDRF Membership is time limited in order to encourage prompt resolution of the issue(s) resulting in suspension. A Suspension Notice, issued to the IMDRF Member, will include the issues resulting in suspension and the date by which the relevant IMDRF Member may request reinstatement of their IMDRF Membership. This date is typically six months after the issuance of the Suspension Letter but may be a different duration as determined appropriate by the IMDRF MC. The six-month timeline is aligned with the frequency of IMDRF MC face-to-face meetings.

During the period of suspension, it is expected that the relevant IMDRF Member is actively working to address the issues that resulted in the suspension.

All requests to reinstate IMDRF Membership should provide evidence demonstrating that all concerns identified in the Suspension Letter have been addressed. If the relevant IMDRF Member is unable to address all concerns, but has made significant progress, they may request a one-time extension. The one-time extension request should include a detailed plan on how and when the remaining concerns will be addressed.

Suspended IMDRF Members will no longer be listed on the IMDRF website.

Termination

Termination is a decision made by the IMDRF MC to end an IMDRF Membership and must follow the process described below. When IMDRF Membership is terminated, the IMDRF Member is no longer a member of the IMDRF.

Terminated IMDRF Members will no longer be listed on the IMDRF website. A record of the termination will be included in the Outcome Statement published on the IMDRF website.

All former IMDRF Members may reapply to become an IMDRF Member at any time in the future.

Withdrawal

Withdrawal is a voluntary request by the IMDRF Member to no longer be a member of the IMDRF and must follow the process described below. IMDRF Members who voluntary withdrawal will no longer be listed on the IMDRF website.

All former IMDRF Members may reapply to become an IMDRF Member at any time in the future. The "News and Events" section of the IMDRF website will be updated to indicate that the IMDRF Member voluntarily withdrew their membership as of the applicable date.

3.8.2. Considerations for Suspension, Termination, and Withdrawal of IMDRF Membership

Suspension

IMDRF Membership suspension may be appropriate if the IMDRF Member is unable to meet its roles and responsibilities outlined in Section 3.1 to 3.5 of this document. Suspension may also be appropriate if an IMDRF Member, through their behaviour, seriously impairs the proper functioning or reputation of the IMDRF.

Note that an IMDRF Member may not voluntarily request suspension.

Termination

IMDRF Membership termination may be appropriate if an IMDRF Member is unable to adequately address the issues identified in a Suspension Notice. In circumstances where it is brought to the IMDRF MC's attention that behaviour of an IMDRF Member egregiously is unable to meet its role and responsibilities or if the IMDRF Member's actions extremely and critically impairs the proper functioning or reputation of the IMDRF, IMDRF Membership may be terminated prior to suspension (refer to Extraordinary Circumstances below).

Withdrawal

An IMDRF Member may volutnarily request to withdraw their membership at any time and for any reason.

3.8.3. Process for Suspension, Termination, and Withdrawal

Suspension

- **Identification of Concerns**
  - ***Letter of Concern***

Any IMDRF MC Member may bring forward a written request with evidence and a draft letter for the IMDRF MC to consider the suspension or termination of an IMDRF Member.

The IMDRF MC discuss its content and votes to determine how to proceed:

- draft and send a Letter of Concern advising the IMDRF Member that their membership may be suspended; and
- if the majority (75%) is not reached then the letter is not sent.

Voting may occur out of session and, at the discretion of the IMDRF Chair, may be conducted over email. If the IMDRF Member being considered for suspension is a member of the IMDRF MC, that IMDRF Member does **not** participate in any voting related to their membership status. A majority vote (75%) is required for the IMDRF MC to issue the Letter of Concern.

- **Issuing a Letter of Concern**

  If the IMDRF MC votes to send a letter of concern to the relevant IMDRF Member, the IMDRF Chair, on behalf of the IMDRF MC, issues the letter to the appropriate IMDRF contacts. The IMDRF Chair ensures that the language included in the letter is reflective of the IMDRF MC's concerns and it includes a response timeline for the IMDRF Member.

- **Responding to a Letter of Concern**

  The relevant IMDRF Member may respond within three weeks to the IMDRF MC with evidence to address the concerns outlined in the letter. This response may be made in person or via teleconference at an IMDRF MC Closed Session or via written correspondence to the IMDRF MC.

- **Voting on Suspension**

  After the relevant IMDRF Member has responded to the letter or three weeks have passed without response, the IMDRF MC votes on whether to suspend the IMDRF Member's membership. In extraordinary circumstances, voting may occur out of session in a virtual or in-person meeting, or at the discretion of the IMDRF Chair, may be completed over email. If the IMDRF Member being considered for suspension is a member of the IMDRF MC, that IMDRF Member does **not** participate in any voting related to their membership status.

  The decision to suspend an IMDRF Membership will be decided by a three quarters (75%) majority of all other IMDRF MC Members.

- **After the Vote**

  After a decision is made, the IMDRF Chair notifies the relevant IMDRF Member.

  If the IMDRF MC voted to suspend IMDRF Membership, the IMDRF Chair sends an official Suspension Notice to the relevant IMDRF Member, with an effect date being the date of the Notice. The Suspension Notice lists the specific concerns that resulted in the suspension and provides a date (e.g., six months from the issuance of the Suspension Notice) by which a response may be provided by the suspended IMDRF Member before their membership is terminated. The IMDRF Chair requests that the IMDRF website be updated to remove the suspended IMDRF Member.

- **Responding to Suspension Notice**

  A response from the suspended IMDRF Member must be provided within a prespecified period of time (e.g., six months) to the IMDRF MC. This response should include evidence demonstrating that the concerns outlined in the Suspension Notice have been recitified. This response may be made in person or via teleconference at an IMDRF MC Closed Session or via written correspondence to the IMDRF MC.

In extraordinary circumstances, a suspended IMDRF Member may request a single extension if necessary to fully address all of the issues that resulted in suspension. A request for extension needs to include a detailed plan and timeline of activities the IMDRF Member proposes to take in order to recitfy all remaining isues. This request may be made in person or via teleconference at an IMDRF MC Closed Session or via written correspondence to the IMDRF MC.

- **Voting on an Extension to the Suspension**

  After the relevant IMDRF Member has responded to the Suspension Notice (either by providing evidence to demonstrate all issues have been resolved or by requesting an extension) or the timeframe specified on the Suspension Notice (e.g., six months) has passed without response, the IMDRF MC will vote on whether to extend the suspension of IMDRF Membership.

  An extension to the suspension may only be granted once and is intended for circumstances in which a suspended IMDRF Member has made significant, but incomplete progress towards addressing the issues identified in Suspension Notice. As with the initial suspension, an extension is for a limited period of time.

  Voting on whether to extend the suspension may, in extraordinary circumstances, occur out of session in a virtual or in-person meeting, or at the discretion of the IMDRF Chair, may be completed over email. If the IMDRF Member being considered for extension of IMDRF Membership is a member of the IMDRF MC, that IMDRF Member does **not** participate in any voting related to their membership status.

  The decision to extend the suspension of an IMDRF Membership will be decided by a three quarters (75%) majority of IMDRF MC Members. If three quarters (75%) majority is not reached for extension of suspension (including if an extension has been granted previously), the IMDRF MC will vote on terminating the Membership.

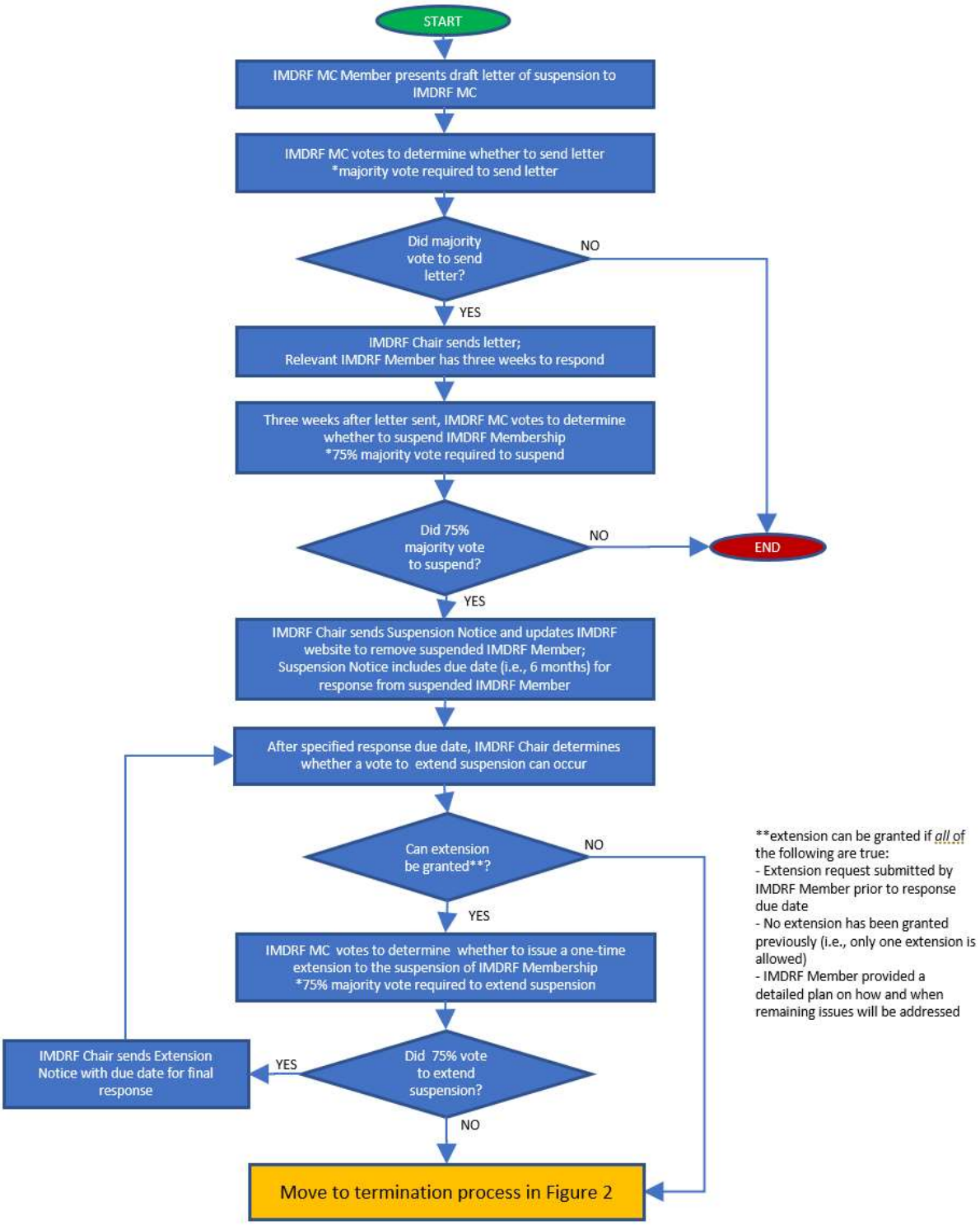

Figure 1 Process Flow for Suspension of IMDRF Membership.

Termination

- **Identification of Concerns**
  - **Letter of Concern**
    - ***Voting to Send Letter of Concern***

      Any IMDRF MC Member may bring forward a request for the IMDRF MC to consider termination of an IMDRF Member. The request should include a draft letter stating why the IMDRF Member should be terminated and should be made available to the relevant IMDRF Member by the IMDRF MC. The letter should outline the specific concerns that may result in termination.

      The IMDRF MC then discusses and votes on whether to send the letter. In extraordinary circumstances, voting may occur out of session and, at the discretion of the IMDRF Chair, may be conducted over email. If the IMDRF Member being considered for termination is a member of the IMDRF MC, that IMDRF Member does **not** participate in any voting related to their membership status. A majority vote (75%) is needed for the IMDRF MC to send a letter.

    - ***Sending a Letter of Concern***

      If the IMDRF MC votes to send a letter of concern to the relevant IMDRF Member, the IMDRF Chair, on behalf of the IMDRF MC, sends the letter to the appropriate IMDRF contacts. The IMDRF Chair ensures that the language included in the letter is reflective of the IMDRF MC's concerns and it includes a response timeline for the IMDRF Member.

    - ***Responding to a Letter***

      The relevant IMDRF Member may respond within three weeks to the IMDRF MC with evidence to address the concerns outlined in the letter. This response may be made in person or via teleconference at an IMDRF MC Closed Session or via written correspondence to the IMDRF MC.

- **Voting on Termination**

  After the relevant IMDRF Member has responded to the letter or three weeks have passed without response, the IMDRF MC votes on whether to terminate the IMDRF Member's membership. In extraordinary circumstances, voting may occur out of session in a virtual or in-person meeting, or at the discretion of the IMDRF Chair, may be completed over email. If the IMDRF Member being considered for termination is a member of the IMDRF MC, that IMDRF Member does **not** participate in any voting related to their membership status. The decision to terminate an IMDRF Membership will be decided by a three quarters (75%) majority of IMDRF MC members.

- **Extraordinary Circumstances**

  In circumstances where it is brought to the IMDRF MC's attention that behaviour of an IMDRF Member egregiously is unable to meet its role and responsibilities or if the IMDRF Member's actions extremely and critically impairs the proper functioning or reputation of the IMDRF, IMDRF Membership may be terminated prior to suspension.

  The IMDRF MC may consider the suspension or termination of an IMDRF Member, in extraordinary circumstances, without a letter of concern being brought forward to the IMDRF MC for consideration. The need to proceed directly to termination without first suspending an IMDRF Member is informed by the severity of the issues identified.

  The suspension or termination of an IMDRF Member may be raised by the IMDRF Chair, or an IMDRF MC Member, and added to a Closed Session agenda for discussion. The matter would be discussed, including why the IMDRF Member should be suspended or terminated, prior to voting on whether to send a letter of suspension or termination. The process for voting and sending a suspension or termination letter would be followed as outlined in the above paragraphs.

- **After the Vote**

  After a decision is made, the IMDRF Chair notifies the relevant IMDRF Member of the decision.

  If the IMDRF MC voted to terminate IMDRF Membership, the IMDRF Chair sends a Termination Notice to the relevant IMDRF Member, with an effect date being the date of the Notice. The Termination Notice lists the specific concerns that resulted in the termination and reminds the recipient that they may reapply for IMDRF Membership at any time in the future. The IMDRF Chair requests that the IMDRF website be updated to remove the terminated IMDRF Member.

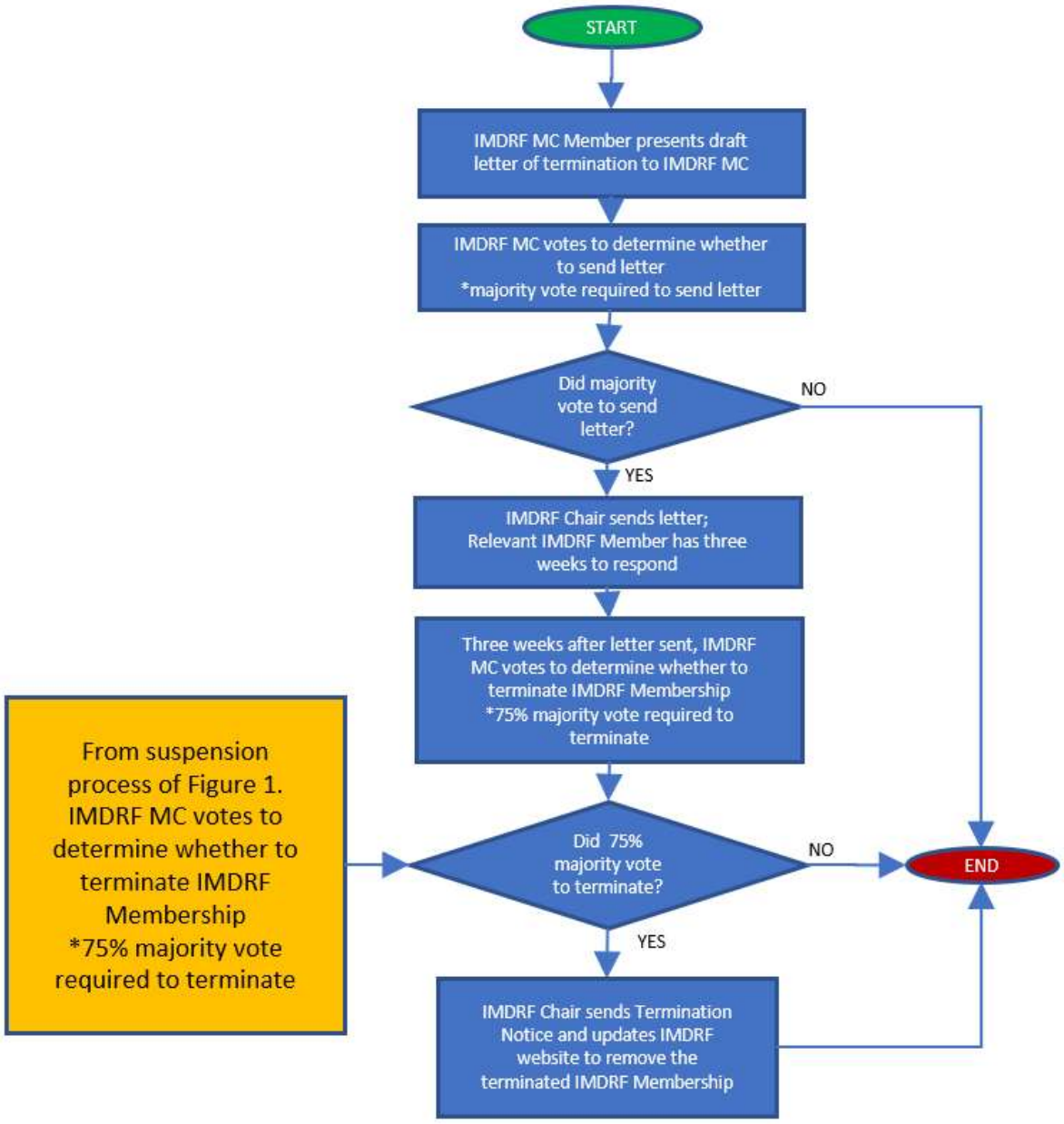

Figure 2 Process Flow for Termination of IMDRF Membership.

Withdrawal

- ### Voluntary Request

  Any IMDRF Member may request to withdraw their membership at any time by written notification to the IMDRF Chair. The IMDRF Chair will notify the IMDRF MC of the voluntary request for withdrawal. No vote or review by the IMDRF MC is needed given that the request is voluntary.

- ### Communication of Withdrawal

  A communication statement will be placed on the “News and Events” section of the IMDRF website stating that the IMDRF Member has voluntarily withdrawn their IMDRF Membership and is, therefore, no longer a member of the IMDRF. As with any termination of IMDRF Membership, the former IMDRF Member will no longer be listed as an IMDRF Member on the IMDRF website, and they may reapply at any time in the future for IMDRF Membership.

Figure 3 Process Flow for Withdrawal of IMDRF Membership.

4. Development of Technical Documents

The rotating IMDRF Secretariat is the contact point during the holding of the rotating IMDRF 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.

4.1. General Principles

A new work item proposal can be submitted by a IMDRF MC 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 and/or meet as often as required to meet the agreed timelines. It is the responsibility of each Working Group Chair to ensure that work is allocated equitably among group members.

Working Group Chairs or their Rapporteur must provide a presentation to IMDRF MC meeting on progress against milestones. Should a Working Group require more time to complete the work at any stage of document development, the Working Group Chair shall keep the IMDRF MC informed. Written or verbal updates shall be provided for IMDRF MC at the request of the IMDRF Chair or IMDRF Secretariat.

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

4.2. Stage 1 – Assignment of Work Items

4.2.1. New Work Item Proposals (NWIP) and New Work Item Extensions (NWIE)

The IMDRF MC will consider at each meeting the need for new work items to be undertaken. The IMDRF MC may establish a Working Group to undertake the new work item. The IMDRF MC 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 MC will be responsible for proposing the rationale for the work assignment.

All New Work Item referrals should be drawn up following the format attached in Annex B.

The IMDRF MC 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.

There are two categories of New Work Item.

(1) NWIP for new topics, where a new Working Group could be established to undertake the new work item; and
(2) NWIE for topics relating to existing Working Groups,

Upon approval of a new work item, a finalized version of the New Work Item referral will be circulated to IMDRF MC Members 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 changes to the agreed work item will require endorsement of the IMDRF MC.

4.2.2. New Document Request

When a Working Group discovers that it cannot accomplish the tasks within a given NWIP or NWIE as defined by its scope within a single document, the Working Group Chair can request if the IMDRF MC would approve splitting the New Work Item into more than one document. The Working Group Chair will need to provide justification and rationale as to why the work cannot be completed in one (1) 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 IMDRF MC for endorsement following the format attached in Annex B.

4.3. Stage 2 – Document Development

Where the IMDRF MC 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.

The Working Group Chair is responsible for ensuring that terms and definitions used in their documents are consistent with previously established IMDRF and GHTF definitions. These definitions should be referenced using the original source IMDRF or GHTF document.

Once a Working Group has decided that a Working Draft is suitable for circulation, the Working Group 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 Working Group Chair, either directly, or via the country's or stakeholders' representatives to the group.

4.4. 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. Working Group Chairs are to nominate the consultation period for approval by the IMDRF MC. Generally, the comment period for Proposed Documents will be no longer than three (3) months, starting from the date the document is posted on the IMDRF website. Under Part II of the Transmittal Record, Working Group Chairs should also indicate an appropriate contact person to contact, for when persons accessing the document via the website can address their comments, using the appropriate format under Annex G.

The IMDRF Chair will forward a copy of the document, with the Document Transmittal Record upon receipt to the IMDRF MC, 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 NWIP or NWIE; and
- conformity to IMDRF procedures.

Decisions regarding Working Group requests for advancement of a document to Proposed Document stage shall be authorized by the IMDRF MC. A document may be referred back to a Working Group where the IMDRF MC requests further work. Typically, the IMDRF MC would provide direction and not re-draft the document.

The IMDRF MC may also determine that the document should not be advanced further.

The decision of the IMDRF MC, including document change requests, should be documented in the record of discussion of the IMDRF MC meeting or teleconference.

4.5. Stage 4 – Consultation on Proposed Documents

Unless the IMDRF MC determines otherwise, all Proposed Documents will be posted on the IMDRF website by the IMDRF Webmaster through the IMDRF Secretariat immediately following approval by the IMDRF Chair as a Proposed Document. Documents, which remain on the website, will be marked with a disclaimer once the comment period has closed. It should state that the document is under revision.

It is also recommended that each IMDRF MC 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 merge/facilitate responses/comments within their jurisdictions.

All documents should be available in electronic format.

4.6. Stage 5 – Advancement from Proposed 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). Under Part III of the Transmittal Record, the Working Group Chair must provide the Secretariat with clarification on where to upload the document on the IMDRF website and must confirm in the notification what document (both GHTF and/or previous versions of the IMDRF document) are outdated and can be archived.

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

Note: The IMDRF MC 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 IMDRF MC shall be documented in the record of discussion of the IMDRF MC 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.

4.7. Stage 6 – Publication

Once endorsement of a Final Document is obtained from the IMDRF MC, the Working Group Chair provides the IMDRF Secretariat with the clean, final version of the document with the appropriate designation codes provided by the IMDRF Secretariat (Section 5.0).

Once the final document has been received by the IMDRF Secretariat, the IMDRF Secretariat must check that the document contains the appropriate document designation before forwarding to the IMDRF Chair for signature. The signed scanned copy (PDF) and its corresponding Word version, or other related documents, must be then sent to the IMDRF Webmaster for publication (see Section 6.2).

The IMDRF Webmaster is responsible for publication of the correct information after receiving it from the IMDRF Secretariat. The IMDRF Webmaster will not place the document/s on the IMDRF Website if there are any discrepancies between the word and PDF version provided, and an email will be sent to the IMDRF Secretariat to provide the correct documents.

Once publication has occurred, the IMDRF Webmaster will notify the IMDRF Secretariat, who will then notify the relevant Working Group/s that the information has been published.

The IMDRF Chair may also notify the IMDRF MC Members, if they believe the document should be disseminated further.

4.8. Stage 7 – Implementation

Once endorsement takes place in Stage 6, the Final Document is available for implementation in the respective jurisdictions.

There are 4 (four) criteria for implementation to follow by each jurisdiction:

Fully implemented: All relevant elements, concepts and principles of the IMDRF document are followed.

Partly implemented: The IMDRF document has been implemented in a modified way that a) incorporates additional requirements beyond those defined in the IMDRF document, or b) does not include all relevant elements, concepts and principles of the IMDRF document, or c) requires application of the document for a smaller range of products than outlined in the IMDRF document.

Not applicable: The implementation of a specific IMDRF document is not applicable in a country/region.

Not implemented: The process for the implementation of the IMDRF document has not yet started or is not completed.

The form of Implementation table is presented in Annex F.

5. 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 IMDRF MC for approval prior to any posting on the IMDRF website.

The IMDRF MC will have six (6) 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 IMDRF 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.

6. 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.

6.1. 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 IMDRF Secretariat will distribute the document number and maintains a central register of document numbers and titles.

6.2. 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

6.3. Proposed Documents (PD)

Documents at the Proposed Document Stage are being disseminated for comment. The document code described above (Section 5.2) 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

6.4. Final Document

Once endorsed by the IMDRF MC 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.

7. Review and Revision of IMDRF Documents

All IMDRF documents are to be considered for review on a periodic basis, typically three (3) years after publication. The revision procedure is to be used when the content of an IMDRF document 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 IMDRF Secretariat is responsible for maintaining a table with information that includes all current IMDRF documents and their publication date. On an annual basis, during the January IMDRF MC teleconference, the IMDRF Secretariat will identify the documents requiring review and include this on the meeting Agenda for discussion with the IMDRF MC.

The formal IMDRF process for the development of Technical Documents (Section 3.0) should be followed for all revision activities in conjunction with the process outlined below.

Where revision is agreed to be undertaken, the IMDRF MC 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 MC 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.

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

Where IMDRF MC Members or stakeholders become aware that an IMDRF document requires updating, they should advise the IMDRF Secretariat.

Documents undergoing revision must receive IMDRF MC 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)

7.1. 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 MC will review and determine if the document is obsolete. The documents that are being updated or determined to be obsolete must receive IMDRF MC 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).

8. 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 MC Members, Official Observers, Affiliate Members or stakeholders become aware that a GHTF document is out of date, they are asked to notify the IMDRF Secretariat. The IMDRF Secretariat will bring this notification to the attention of IMDRF MC Members for their consideration.

During each IMDRF MC 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 IMDRF Chair to provide a list of GHTF documents that may need to be reviewed/updated based on current work items or feedback received from IMDRF MC Members, Official Observers, Affiliate Members 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 MC regarding the potential need for revision of GHTF documents.

The IMDRF website has a facility that allows stakeholders to notify the IMDRF MC of the need to update GHTF documents. GHTF documents that undergo revision will be converted to IMDRF documents and will follow the Revision procedure (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).

After new IMDRF documents are endorsed by the IMDRF MC, any GHTF or IMDRF documents which are superseded by these new IMDRF documents are to be moved to the GHTF or IMDRF archive on the IMDRF website. The IMDRF Secretariat is responsible for notifying the IMDRF Webmaster which documents are to be archived.

9. 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 MC 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 IMDRF MC becomes aware of documents translated by other parties, it may invite an IMDRF MC 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. IMDRF-Related Presentations and Training

It is recognized that persons involved in IMDRF MC, 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. 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. If the IMDRF adopts a new logo, previously developed GHTF and IMDRF documents do not need to indicate the new logo on the front cover. The new logo only appears on the newly developed documents since then.

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.

12. Annex A - IMDRF Membership Criteria and Roles

	MC Member	Official Observer	Invited Observer	Affiliate Member	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 Secretariat for a year, including hosting two (2) face-to-face meetings and two (2) scheduled teleconferences. • In exceptional circumstances, a regulatory authority who is an Official Observer may apply for the membership under the expedited procedure to become an IMDRF Management Committee Member.	• 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 GHTF and IMDRF guidance documents – Sufficient resources and regulatory expertise to perform its duties	• 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 a regulatory authority • Recognized commitment to the objectives of IMDRF demonstrated by implementation or a plan for implementation of IMDRF documents • Commitment to provide annual updates on the implementation of IMDRF documents at Management Committee meetings	• 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 medical devices globally

	MC Member	Official Observer	Invited Observer	Affiliate Member	Regional Harmonization Initiatives (RHIs)
Criteria (Continued)	• To apply for the membership, the regulatory authority must: – demonstrate their regulatory framework includes principles outlined in the IMDRF and GHTF guidance documents; – be an Official Observer for at least six (6) months and have attended at least one (1) IMDRF Management Committee teleconference and one (1) IMDRF Management Committee meeting; – have previously contributed to IMDRF/GHTF activities including having contributed to a majority of Working Groups for more than four (4) years. Note that this contribution could have been on behalf of another jurisdiction or a Regional Harmonization Initiative (RHI); – have demonstrated that they have the ability to host IMDRF face-to-face Working Group meetings; and – have demonstrated that they have 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	• 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 an Affiliate Member or invited expert 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 • A recognized commitment to the objectives of IMDRF demonstrated by implementation of IMDRF documents (work items)		•	•

	MC Member	Official Observer	Invited Observer	Affiliate Member	Regional Harmonization Initiatives (RHIs)
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" IMDRF MC meetings • Invited on a meeting-by-meeting basis	• Does not participate in the decision-making process of IMDRF • Only attends "open" IMDRF MC meetings • May participate in open Working Groups • Provides annual update on implementation status of IMDRF documents	• 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 will be reviewed at the following MC meeting • New MC members will be accepted with the unanimous agreement of existing MC members	• Application file (including form) for official observer ship to be submitted to MC • Application will be reviewed at the following MC meeting • Official observers will be accepted with unanimous agreement of existing MC members	• Request to IMDRF chair three months before MC meeting • Decision of chair on the participation in the "open" MC meeting	• Application file (including form) for affiliate membership to be submitted to MC • Application will be reviewed at the following MC meeting • Affiliate members will be accepted with unanimous agreement of existing MC members	• Application file (including form) to be submitted to MC • RHI will be accepted with unanimous agreement of existing MC members

Please visit our website for more details.

www.imdrf.org