



IMDRF International Medical Device
Regulators Forum

Final Document

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IMDRF Standards Liaison Program Framework

AUTHORING GROUP

Standards Working Group

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Preface

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1. Introduction

The use of consensus standards is integral to the design, development and review of medical devices and can contribute to a harmonized approach to ensuring their safety and performance. The International Medical Device Regulators Forum (IMDRF) believes that the incorporation of regulators' perspectives and input into standards development can enhance standards' usefulness in device evaluation, performance and overall quality. After a survey of IMDRF members found wide variability in how standards are used by Regulatory Authorities (RAs), IMDRF convened a Working Group to drive the improvement of international consensus standards for regulatory use. One outcome of this initiative was that IMDRF received Category A liaison status from two important standards development organization (SDO) Technical Committees (TCs): ISO TC210 [Quality management and corresponding general aspects for medical devices] and IEC TC62 [Electrical equipment in medical practice].

IMDRF members recognize the important role standards play in global harmonization of device review policies and practices. A reliance upon quality consensus standards will facilitate a practicable application of IMDRF's [Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices](#), a measurable enhancement to conformity assessment practices. In 2018, IMDRF published a document entitled [Optimizing Standards for Regulatory Use](#) which serves as a resource identifying areas for improvement in the standards development process and best practices for more effective RA participation in standards development.

The most consequential way to ensure that standards are fit for regulatory purpose is for regulators to help write them. Doing so in coordination with other regulatory authorities further maximizes their potential. IMDRF's contributions to consensus standards development, utilizing existing SDO tools and resources, will enable IMDRF to enhance standards and improve RAs' confidence in their use.

Liaison relationships provide a valuable opportunity for IMDRF members to make standards engagement more efficient and effective, while advancing the development of standards that are 'regulatory-ready.' In order to fulfill its obligations as liaison, IMDRF members have established the IMDRF Standards Liaison Program. The program offers a powerful means to ensure regulatory input into standards development.

IMDRF's liaison role with SDOs will provide significant benefits to RAs as well as other stakeholders engaged in standards and conformity assessment activities. The Standards Liaison Program offers the opportunity for IMDRF to present the harmonized and representative voice of member jurisdictions, to improve standards development on a broad scale, and to influence the content of specific standards in an effective and resource-efficient way. Ultimately, liaison engagement will enhance IMDRF's stature as a global regulatory organization and drive measurable progress toward its goal of global harmonization.

The purpose of this document is to provide a framework for IMDRF's participation as liaison to SDOs and outline the responsibilities and operating policies needed to establish and maintain the roles associated with assigned liaison relationships. The proposed structure of the Program is simple: the IMDRF Management Committee (MC) retains authority and provides strategic direction. MC members appoint a Liaison Officer (LO) to serve as an intermediary, facilitating communications between the MC and the TCs. The LO may also be an MC member. The LO identifies standards and matters of interest to IMDRF, helps develop consensus among its members when needed, and conveys regulators' priorities and positions to the TCs.

2. Scope

This document describes the internal IMDRF framework to establish and maintain the responsibilities associated with its liaison relationships within ISO and IEC Technical Committees.

Liaison status entails opportunities and expectations for communication, policy inputs, consensus standards development activities, and RAs' contributions to support the development of standards optimized for regulatory use. The document also provides the framework necessary to ensure effective participation within SDO Technical Committees.

3. References and Key Resources

- IMDRF/GRRP WG/N47 FINAL: 2018 [*Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*](#)
- IMDRF/Standards WG/N51 FINAL: 2018 [*Optimizing Standards for Regulatory Use*](#)
- International Electrotechnical Commission (IEC) [Web site](#)
- International Organization for Standardization (ISO) [Web site](#)
- [*IEC About TC/SC liaisons*](#)
- [*IEC Code of Conduct*](#)
- [*ISO Code of Conduct*](#)
- [*ISO/IEC – Directives and Policies*](#)
- [*IEC Reference Material*](#)
- [*Guidance for ISO Liaison Organizations*](#)
- [*ISO/IEC Guide 59, Code of good practice for standardization 1994*](#)
- [*ISO Training Videos*](#)
- [*ISO Liaison Report Model*](#)

4. Liaison Program Framework

4.1 Principles

- (A) The framework will be as simple as possible, reflecting ‘must-haves’ versus ‘nice-to-haves.’
- (B) The Liaison Program will prove itself and its effectiveness incrementally before adding responsibilities (e.g., new TCs).
- (C) Liaison status with TCs will only be considered if their efforts align with IMDRF members’ interests. Future proposed liaison relationships must demonstrate how both IMDRF and the relevant committee will benefit from the liaison relationship.
- (D) The program will align closely with ISO/IEC and/or other relevant SDO expectations for liaison behavior and contributions.
- (E) Open communication is its cornerstone.
- (F) The program will rely whenever possible upon existing/interested member resources already engaged with standardization work.
- (G) Consensus, not unanimity, will provide the basis for decision making.
- (H) The Liaison Program will focus on IMDRF priorities taking place within liaised committees’ work and on those standards development activities of highest importance to IMDRF.
- (I) The Liaison Program will help ensure that standards produced by liaison SDO TCs are suitable for regulatory purposes by encouraging the TCs to follow the recommendations in the IMDRF guidance *Optimizing Standards for Regulatory Use*.

4.2 Objectives

- (J) Help educate TC/RA members on the development and use of standards for regulatory purposes.
- (K) Speak with a common voice to support IMDRF priorities using the principles outlined in its *Optimizing Standards for Regulatory Use guidance and Essential Principles of Safety and Performance of Medical Devices and IVDs*.
- (L) Enhance RAs’ confidence in standards and standards development while minimizing the need for additional resources.
- (M) Represent IMDRF effectively in liaised committees.
- (N) Facilitate communications between the IMDRF MC and SDOs.
- (O) Foster and convey consensus among IMDRF members to establish positions of regulatory importance to share with SDOs.
- (P) Report to IMDRF on the effectiveness of IMDRF documents in standards development, where appropriate.

4.3 Framework

The Liaison Program will be organized simply and will require few, if any, additional resources from IMDRF members. It is not the intent of this program to manage positions on every standard within each liaised committee. Rather, the MC and LO will identify those standards and/or areas of standards development that have high impact and would benefit from IMDRF’s input.

The IMDRF MC will retain authority over the program. The MC should assign an individual to serve as the LO for issues related to the Liaison Program; e.g., when IMDRF has identified a standards-related concern, has been approached for input, or when the establishment of positions requires obtaining consensus from RA members. The LO will attend relevant standards meetings and communicate with the MC members to gain input and develop consensus on topics of interest to IMDRF.

5. Roles and Responsibilities

5.1 Liaison Officer (LO)

Responsibilities and Qualifications

When an official liaison agreement is established, the LO will represent IMDRF to the TC and is responsible for identifying issues of common concern to IMDRF regulators, building consensus and reporting to the SDO Committees. The LO will be an employee of an IMDRF member RA and should have experience in standards activities and working knowledge of regulatory science.

Specifically, the LO will:

1. Abide by IMDRF and SDO expectations
2. Serve as lead contact to the TC representing the IMDRF position
3. Monitor the liaised TC activities to identify issues of importance and opportunity to medical device regulators
4. Evaluate, with input from the MC members whether engagement in a particular TC/SC activity is warranted
5. Collaborate with the MC members to develop consensus and advance IMDRF positions on projects deemed appropriate for IMDRF's participation.
 - a. The LO will assess New Work Item Proposals, draft standards and other TC priorities of regulatory importance to IMDRF.
 - b. When IMDRF input is solicited by a committee or action is desired by IMDRF, the LO will work to develop a consensus position among existing RAs.
 - c. A simple majority of MC positions submitted to the LO is needed to put forward an IMDRF position.
 - d. The LO will draft and communicate IMDRF conclusions and comments, including liaison plenary reports, to the TCs.
 - e. The LO may present updates on IMDRF activities to the TCs when the updates have been publicly disclosed or the IMDRF MC has approved the LO to disclose the updates to the SDOs.

Note: In accordance with the ISO/IEC Directives Part 1, IMDRF as a liaison organization does not submit a vote, but is able to provide substantive General, Technical, and/or Editorial comments to draft standards and other consensus documents. Comments submitted by IMDRF may not be used to submit positions of a single or minority number of IMDRF jurisdictions.

6. Meeting participation: the LO may represent IMDRF and its positions in relevant meetings either in person, by teleconference or in writing via liaison reports, including during plenaries.
7. The LO will provide the MC with a brief report¹ on relevant standards activity of importance to the IMDRF after a main committee/subcommittee meeting (e.g., plenary meetings) to keep the IMDRF informed of activities.

Conduct

The LO agrees to comply with all IMDRF norms and expectations. They will also adhere to principles of proper conduct, including:

- (A) Ethics: LOs will be familiar with the relevant Code of Conduct and Code of Ethics from each liaised SDO.
- (B) Conflicts of interest: it is recognized that LOs, as RA employees, may face occasions in which their RA will hold a different position than IMDRF. When acting on behalf of IMDRF, LOs will clearly articulate that role in all actions and communications.
- (C) Impartiality: in all IMDRF-related activities, LOs will exhibit impartiality toward all members.
- (D) Confidentiality: Though it is not expected that LOs will receive or access confidential information, they will take due care that anything that may be reasonably considered private/not publicly available will be held in confidence.

5.2 IMDRF Management Committee (MC)

The IMDRF MC maintains final authority over the Liaison Program and will provide strategic guidance on IMDRF's priorities with SDOs through the LO. The IMDRF MC will include a standing agenda item during each IMDRF face to face meeting and teleconference to cover standards LO activities such as:

- Reviewing and determining appropriateness of requests for liaison relationships with SDOs/TCs.
- Facilitating and determining LO participation in SDO meetings.
- Assigning a suitable expert as a LO.
- Reviewing LO reports and discussing any necessary actions.
- Supporting the LO in the development of consensus positions.
- Providing feedback on LO's reports and activities.

¹ See Appendix A for IMDRF Report Template

Appendix A

IMDRF Liaison Officer Meeting Report

Please submit this completed report within one month of the international standards meeting to the IMDRF Chair/Secretariat listed @ www.IMDRF.org/contact.asp

Liaison reports can be used for a variety of purposes. For example:

- To report results of a TC meeting to the IMDRF Management Committee
- To publicize the work of the TC to IMDRF via email or other media
- To support current IMDRF objectives related to optimizing standards for regulatory use by suggesting topics for possible development for featured articles, new standards development and/or related material such as educational workshops, etc.
- To address specific challenges and concerns that the IMDRF may bring to the attention of related TC leadership
 - Convey updates from liaised TCs

PLEASE REMEMBER: The liaison report should only be submitted to the IMDRF Chair/Secretariat and members of the IMDRF and may not be shared outside IMDRF. Consider using a more limited and secure means of correspondence to convey sensitive issues that require confidentiality.

Meeting Details	Remarks
IMDRF LO Name	
Email	
Date	
Technical Committee	
Meeting Date/s	
Meeting Location/s	
Meeting Summary	<i>Please provide a summary of the key items/working groups covered during the meeting (e.g., provide an agenda of the meeting, highlight key issues, etc.).</i>
Meeting Attendance	<ul style="list-style-type: none"> - <i>Please indicate or attach, if available, both the number of delegates and the countries represented at the meeting:</i> - <i>Please indicate the Regulatory Authorities that participated in the technical committee meetings and/or its working group meetings:</i>

Please comment on significant or unusual attendance matters (e.g., new member bodies, regular members not in attendance, new Chairman or Secretariat, non-accredited attendees, etc.).

Meeting Observations Remarks

Overall, how well did the IMDRF meet its objectives on policy/technical matters?

*Very Successful – IMDRF positions were accepted; or
Successful -- Compromises were reached which are acceptable to IMDRF; or
Not Successful -- IMDRF positions were not accepted.*

Comments

Any issues of significance which might have an impact upon IMDRF or other Regulatory Agencies or Regional Harmonization Initiatives?

Comments

Were there any New Work Items, working/advisory groups, or new liaisons proposed or approved?

Yes (please specify) or No

Comments

Are work items in the TC or SC being affected by related work in regional standards bodies (e.g., CEN, CENELEC, ETSI, PASC, NAFTA, COPANT, etc.)?

Yes (please explain) or No or No related regional activity

Comments

Were any issues raised which may relate to or impact existing IMDRF documents or specific member regulatory requirements?

Yes (please specify) or No

Comments

Please identify any IMMEDIATE IMDRF actions which will be required as a result of this international meeting.

Comments

Other comments

Comments

Appendix *Append any relevant reports from the TC meeting.*



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Please visit our website for more information.

www.imdrf.org

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