

IMDRF Standards Liaison Program

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IMDRF's Goals for Standards

- Enhance the regulatory usefulness of standards
- Drive their use to harmonize regulatory approaches

Optimizing Standards for Regulatory Use **(2018 Guidance)**

Key Recommendations

- Standards must be improved for regulatory use
- IMDRF members should participate – as early as possible – in standards development

Benefits of Category A Liaisonship

- Opportunity for IMDRF to present the harmonized and representative voice of member jurisdictions, to improve standards development on a broad scale
- Influence the content of specific standards in an effective and resource-efficient way
- Enhance IMDRF's stature as a global regulatory organization
- Drive measurable progress toward its goal of global harmonization

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

Final Document

IMDRF/Standards WG/N72

IMDRF Standards Liaison Program Framework

AUTHORING GROUP

Standards Working Group

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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

Liaison Program Documents

Responsibilities: Liaison Officer

- Identifies standards and matters of interest to IMDRF
- Helps develop consensus among its members when needed
- Conveys regulators' priorities and positions to the Technical Committees

Actions: Liaison Officer

- Serve as lead IMDRF contact to the Technical Committees
- Monitor the liaised Technical Committee activities
- Evaluate whether engagement in a particular standards activity is warranted
- Collaborate with the Management Committee members to develop consensus and advance IMDRF positions
- Represent IMDRF and its positions in relevant meetings
- Provide the Management Committee with a brief report on standards activity after a Technical Committee event (e.g., plenary meetings)

Responsibilities: Management Committee

- Strategic direction and general authority over the Program
- Appoint Liaison Officer(s)
- Communicate with Liaison Officer and each other

Upcoming Liaison Events

- IEC General Assembly Regulators Forum
 - 30 October 2022, 1-5 pm (San Francisco, CA)
 - All regulators and other stakeholders encouraged to participate
 - Topic: how to incorporate conformity assessment into standards and improve them for regulatory use
- IEC TC62 and sub-committees (during General Assembly)
- ISO TC210, week of 12 December 2022 (Arlington, VA)

Standards Working Group Recommendations to IMDRF Members

- Participate (or delegate participation) in National Bodies
- Serve on national delegation to IEC and ISO Technical Committees
- Contribute to and support IMDRF's positions and recommendations within liaised Technical Committees
- Drive regulatory convergence: *put standards to work on behalf of harmonization*

“The most consequential way to ensure that standards are fit for regulatory purpose is for regulators to help write them.” – Optimizing Standards guidance

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