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
IMDRF Standards Liaison Program Framework

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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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