How IEC can contribute to IMDRF to support regulatory convergence

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IMDRF vision = IEC vision

Bring affordable and safe medical treatments to all patients who need them:

• Establish mechanism to recognize International Standards + method of demonstrating conformity

• Accelerate regulatory harmonization and convergence
IEC: a key harmonization tool

International Standards

Conformity Assessment Systems
Input from many stakeholders

86 National Committees

Consensus: main principle

State of the art: top experts

Fairness: public and private sector involvement

Verification: IECCEE is a unique approach

Efficiency: applicable worldwide
Using IEC & ISO work

- Advantages
- Methods
- Considerations
- Access
- Case studies
Particular attention should be given to regulators and policy makers.
The partnership

Memorandum of Understanding

<table>
<thead>
<tr>
<th>IMDRF</th>
<th>List of TC/SCs Liaisons</th>
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| Total A Liaisons | 5 | Total | 5 |

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<tr>
<th>Liaisons with IEC TC/SCs</th>
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<tbody>
<tr>
<td><strong>Committee</strong></td>
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<tr>
<td>Liaison A</td>
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<td>TC 62</td>
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<td>SC 62D</td>
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How to have influence

• Individually:
  – NC mirror committee
  – Public commenting

• As IMDRF
  – Attend TC/SC meetings
  – Comment on working documents
  – Send experts to WGs
Liaison benefits

- Collaboration Platform: access documents, commenting
- Meetings
- Nominate experts
- New work item proposals
Upcoming meetings

• IEC 60601 series future architecture: AhG meeting, 7-9 May, Germany
• TC 62 plenary meeting, 20-25 October, China
How IEC can help

• Webinar series on IEC
• IMDRF - IEC event
• Connect IMDRF member to NC training