



How IEC can contribute to IMDRF to support regulatory convergence

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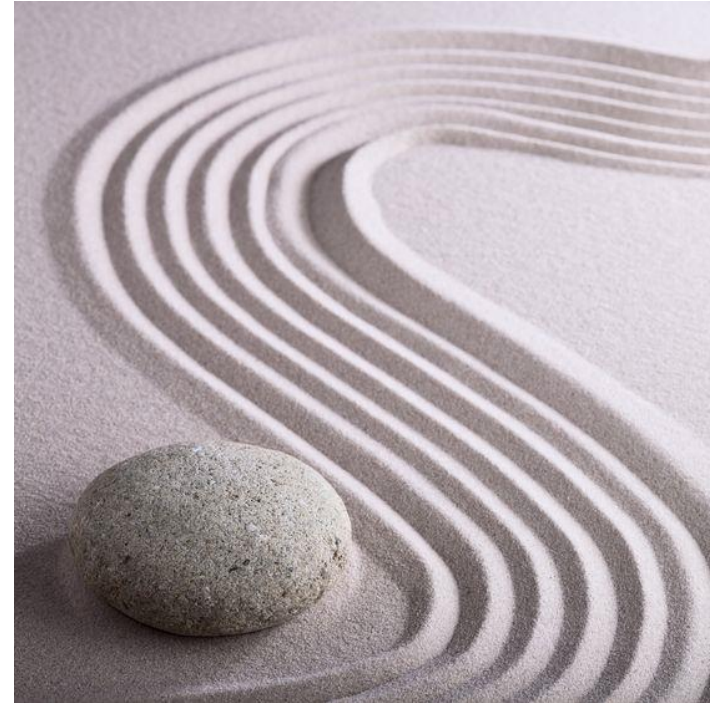
IMDRF-DITTA
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Moscow



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: IECEE is a unique approach

Efficiency: applicable worldwide



Using IEC & ISO work



- Advantages
- Methods
- Considerations
- Access
- Case studies



International Electrotechnical Commission
Commission Electrotechnique Internationale
Международная Электротехническая Комиссия

“Particular attention should be given to regulators and policy makers”

IEC Masterplan



Vision

—

IEC everywhere for a safer, more efficient world.

Mission

—

Our mission is to achieve worldwide use of IEC International Standards and Conformity Assessment Services that ensure the safety, efficiency, reliability and interoperability of electrical, electronic and information technologies, to enhance international trade, facilitate broad electricity access and enable a more sustainable world.

Values

—

- **Trustworthy:** collaboration of the world's top experts through consistent and well established processes and procedures
- **Inclusive:** broad participation of all public and private sector stakeholders from developed and developing countries working together as volunteers under a one country, one vote principle
- **Independent:** not-for-profit and neutral, working through consensus



A global network of some 170 countries that covers 99% of world population and electricity generation



The partnership



IMDRF International Medical
Device Regulators Forum

Memorandum of Understanding

IMDRF List of TC/SCs Liaisons

Total A Liaisons 5 Total 5

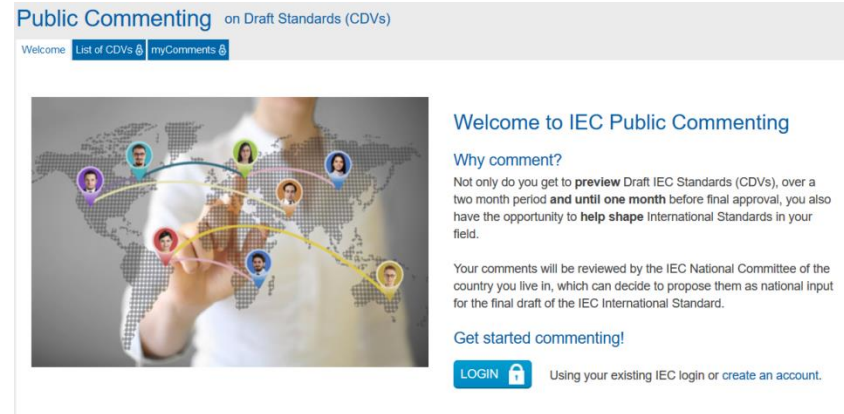
Liaisons with IEC TC/SCs



Committee	Description
Liaison A	
TC 62	Electrical equipment in medical practice
SC 62A	Common aspects of electrical equipment used in medical practice
SC 62B	Diagnostic imaging equipment
SC 62C	Equipment for radiotherapy, nuclear medicine and radiation dosimetry
SC 62D	Electromedical equipment

How to have influence

- **Individually:**
 - NC mirror committee
 - Public commenting
- **As IMDRF**
 - Attend TC/SC meetings
 - Comment on working documents
 - Send experts to WGs



Public Commenting on Draft Standards (CDVs)

Welcome [List of CDVs](#) [myComments](#)


Welcome to IEC Public Commenting

Why comment?

Not only do you get to **preview** Draft IEC Standards (CDVs), over a two month period **and until one month** before final approval, you also have the opportunity to **help shape** International Standards in your field.

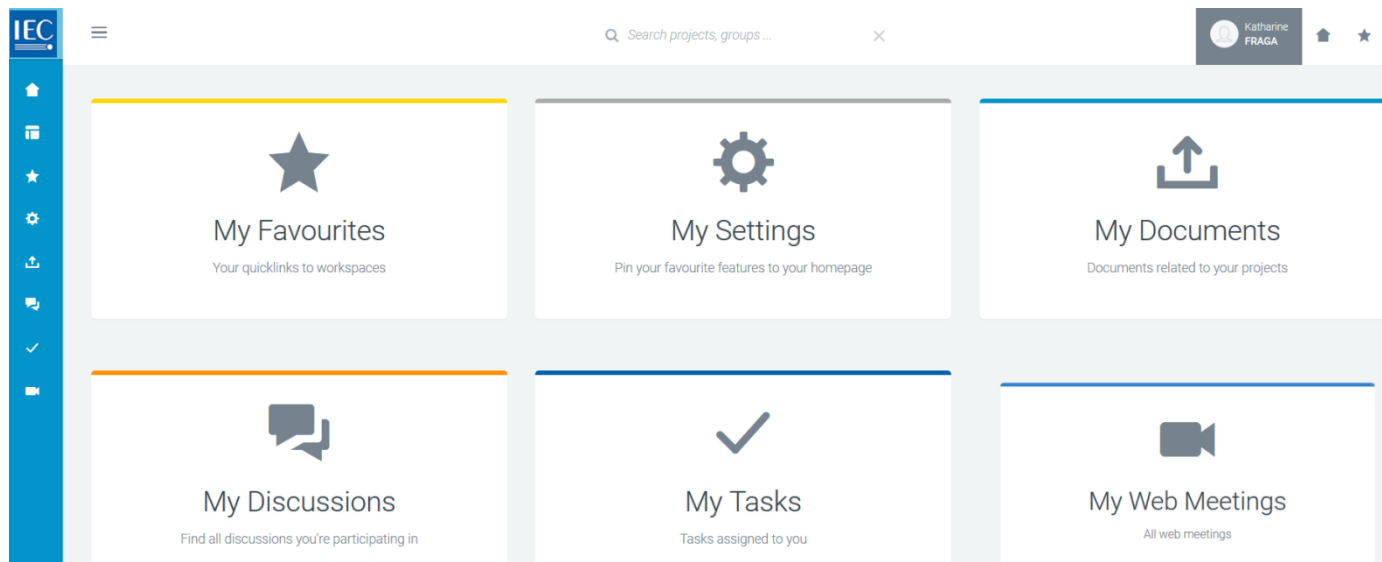
Your comments will be reviewed by the IEC National Committee of the country you live in, which can decide to propose them as national input for the final draft of the IEC International Standard.

Get started commenting!

[LOGIN](#)  Using your existing IEC login or create an account.

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

TC 62 Electrical equipment in medical practice

Scope Structure Projects / Publications Documents Votes **Meetings** Collaboration Platform

Log out


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TC 62 Scope

To prepare international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment. NOTE : This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).



Further information

Secretariat	Germany
Strategic Business Plan	
Contact	TC 62 Officers

How IEC can help

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



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