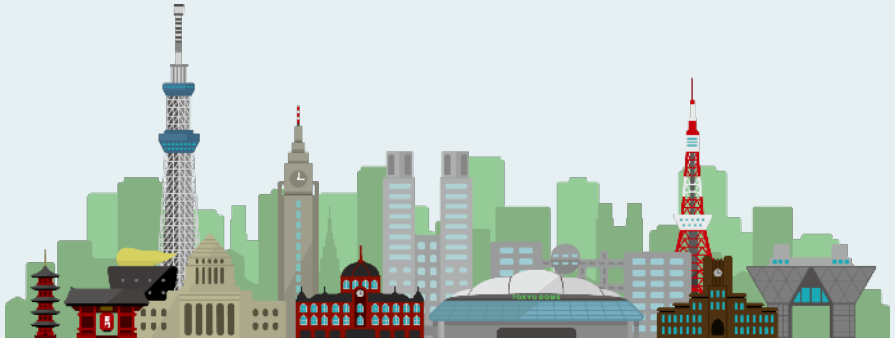
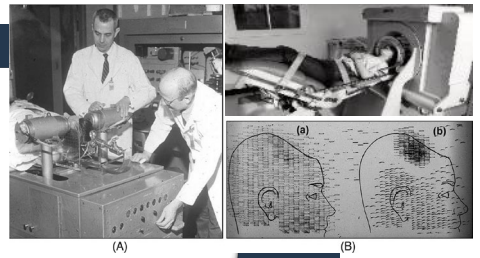
IMDRF International Medical Device Regulators Forum



How IMDRF influences the international standardisation work

as example IEC TC62

IEC TC 62 Medical equipment, software, and systems (est. 1967)

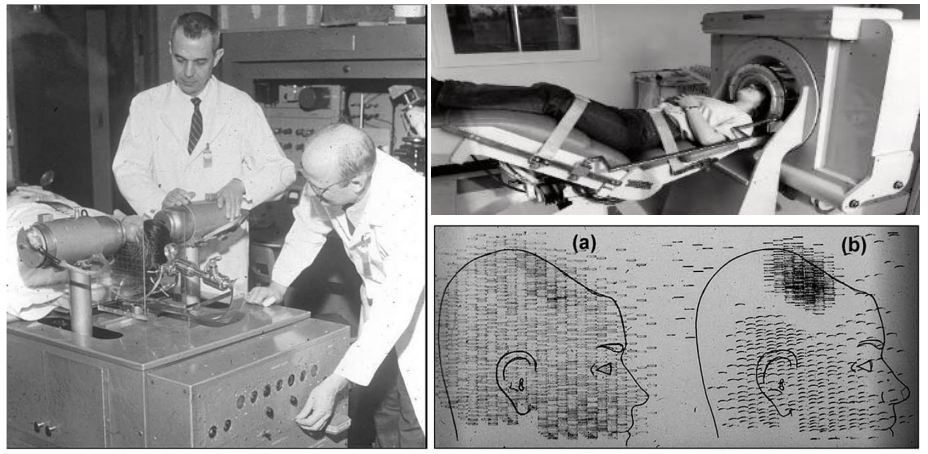


IEC TC 62 — Medical equipment, software, and systems

SC 62A	SC 62B	SC 62C	SC 62D	AGs	project groups
Common aspects of medical equipment, software, and systems	Medical imaging equipment, software, and systems	Equipment for radiotherapy, nuclear medicine and radiation dosimetry	Particular medical equipment, software, and systems	SNAIG, JAG5,...	i.e. AI, computational modeling

> 80 groups / > 70 projects / > 1800 experts / > 300 publications

IEC TC62 has been developing for six decades



(A) (B)

executable standards, which also

serve as the basis for **test** report templates (TRF)

be coordinated between **all interest groups** that participate and to a large extent

"**recognized**" and harmonized by the **regulatory authorities** in order to facilitate the process of

placing **safe, state-of-the-art** medical devices on the market

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IMDRF* documents acted as compass in the maze of regulatory requirements

- IMDRF brings together around a third of the existing regulatory authorities for medical device
- Many more consider its documents (e.g., via GHWP)
- This reduces the variability for writers of international standards

*before GHTF

Example: AI standards for medical devices – rules for standards in essential principles

Standards suitable to address the essential principles should be based on:

a) a close relationship of the scope of the standard to one or more of the essential principles,

b) the clarity, effectiveness, and completeness of the technical requirements contained in the standard as it relates to a specific essential principle,

This is base for recognition / harmonization of standards. If the agency for new regulatory rules is not the medical device authority, like AI, standards are a mean to close the gap

c) …

d) the definition of clear acceptance criterion for determining that each technical requirement is met.

…what means “clear” in probabilistic behaviour? All AI is subjected to clinical investigations? Standards can provide here clarification.

Example: Artificial Intelligence – general product requirements

- AI related risk management: *5.1.2 already defines the need for a risk management to ensure ongoing quality, safety and performance –*
- AI concept of robustness: *5.1.6 The characteristics and performance of a medical device and IVD medical device should not be adversely affected... when the medical device and IVD medical device is subjected to the stresses …*

Medical device standard requirements are already sufficient. They only need to include new guidance how to fulfill the principles in case of AI, which might be under another regulatory agency

BUT the documents can also have unintended interactions – e.g. clinical association

Guidelines for software evaluation require a “valid clinical association” (~scientific validity)

Medical science is also biased, e.g., with fewer studies on women and residents of low-income countries.

An AI-enabled medical device runs the risk of adopting the bias of medical science if it follows the guidelines for software clinical evaluation as part of the approval process.

Standards shall strike a balance to show how the core of the principle can be upheld and how products can be brought to market for underserved patient populations.

Conclusion

The IMDRF documents are the backbone of any medical device standard.

They are still high-level and challenging enough to task standards developers with specifying details and clarifying how to overcome complicated real-world implications.

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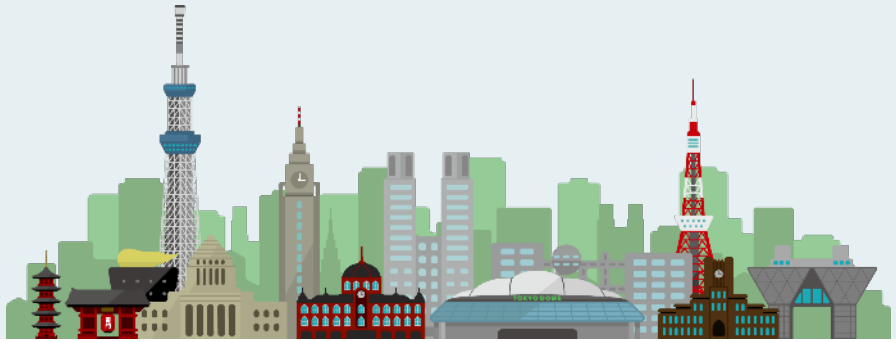

Feel free to make the life of standard writers easier

Thank you for your work up to now