



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

THE FUTURE OF THE IEC 60601 SERIES

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SWG Member; Vice-Chair DITTA Standardization WG





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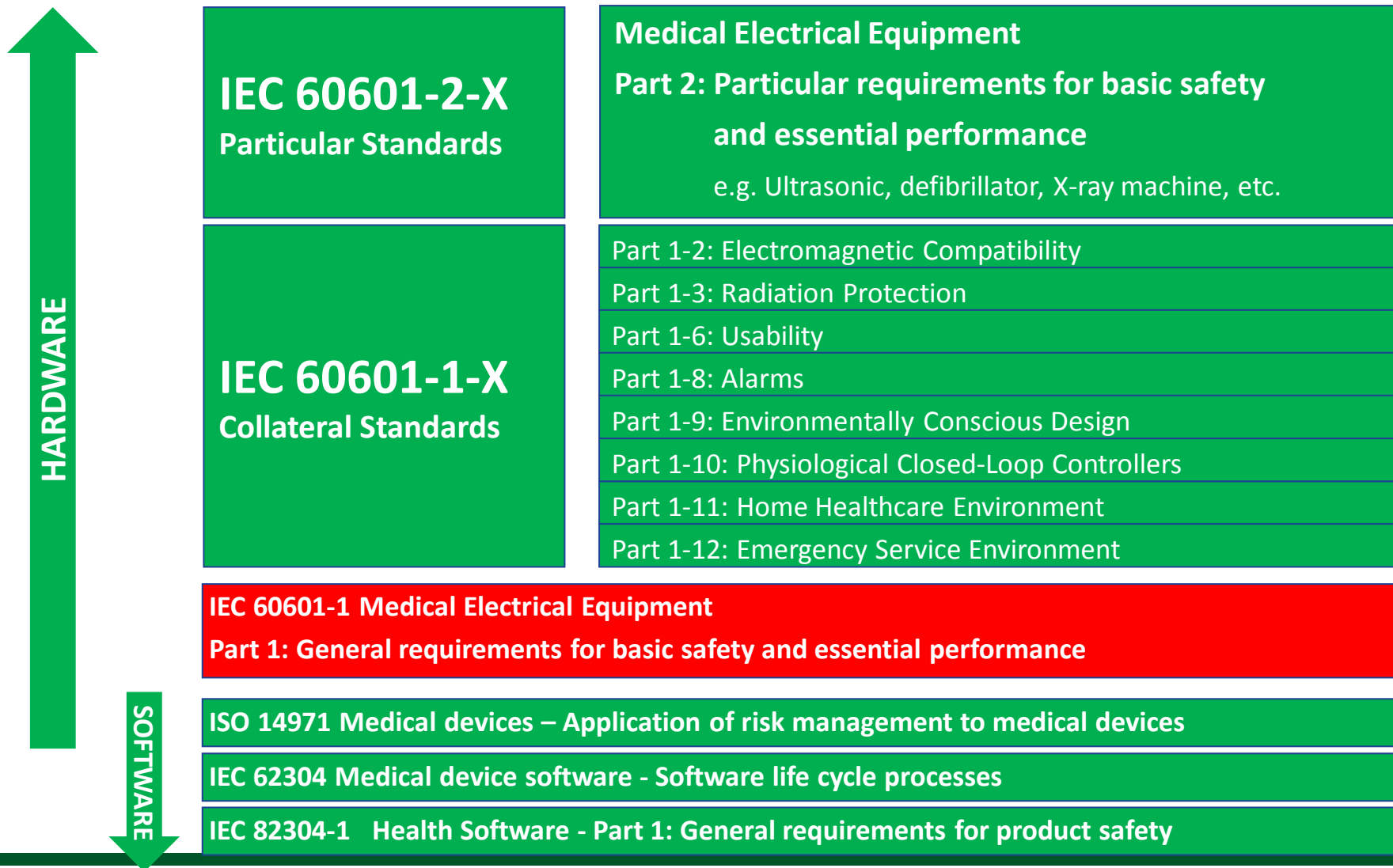
PRESENTATION OUTLINE

- 1. Overview IEC TC 62 Safety Standards, Structure and Leadership**
- 2. IEC TC 62 Value Proposition**
- 3. Amendment 2 to Third Edition of IEC 60601-1**
- 4. Edition 4 of IEC 60601-1 AND related updates**
- 5. Take Aways**



IEC TC 62 SAFETY STANDARDS

IEC 60601 SERIES & OTHERS





IEC TC 62 STRUCTURE AND LEADERSHIP

TC 62 Electrical equipment in medical practice

Chair Michael Appel, US

Sec DE Norbert Bischof

Asst Sec Ms Annette Hagen

3 Advisory and Ad-hoc Groups

SC 62A Common aspects of electrical equipment used in medical practice

Chair Richard Scott, UK

Sec US, Ms Hae Choe

Vice Chair Brodie Pedersen, US

Asst Sec Charles Sidebottom

25 Working Groups and Maintenance Teams

SC 62B Diagnostic imaging equipment

Chair Yan Kang, CN

Sec DE Norbert Bischof

Asst Sec Ms Annette Hagen

17 Working Groups and Maintenance Teams

SC 62C Radiotherapy, nuclear medicine and radiation dosimetry

Chair Alan Cohen, US

Sec DE Norbert Bischof

Asst Sec Ms Annette Hagen

4 Working Groups and Maintenance Teams

SC 62D Electromedical equipment

Chair Klaus Neuder, DE

Sec US Ms Hae Choe

Vice Chair Jeffrey Eggleston, US

32 Working Groups and Maintenance Teams



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IEC TC 62 VALUE PROPOSITION

For Industry:

Comply with one set of safety standards to serve the world markets for medical devices.

For Regulators:

Make use of state-of-art requirements while saving resources when writing rules for medical devices.

For Equipment User Organizations:

Buy the best and most cost efficient medical devices from the world market.





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AMENDMENT 2 TO THIRD EDITION OF IEC 60601-1

- Shortlist of ~160 modifications for the General and the Collateral Standards.
- Goal of Edition 3.2 → Address safety gaps, known problems for regulatory bodies, inconsistencies, technical errors and update of key standard references.
- No modification of the structure of existing General and Collateral Standards.
- As far as possible no changes creating a need to revise Particular Standards.

Timeline

Part 1 of the IEC 60601 series:

IEC 60601-1 and IEC 60601-1-X

CDVs expected

Mid 2019

Publication forecast

2020

Part 2 of the IEC 60601 series (*no technical changes expected*):

IEC 60601-2-XX (~70 publications)

First Publications

2021





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EDITION 4 OF IEC 60601-1 AND RELATED UPDATES

- First published in 1977, growing need to increase usability and future maintenance.
- New edition (26 sub goals identified) will focus on structure, maintainability, risk management, separation of process and product requirements, relationship to the Essential Principles of the IMDRF (coverage), etc.
- Architecture Team of TC 62 preparing a Technical Report as basis for revision (see 62/328/DC, open for comments until 2019-04-12).
- Publication of new General Standard not expected before 2024.
- Next Architecture Team meeting with Representatives from National Committees and Liaisons, May 7 to 9, in Luebeck, Germany.





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TAKE AWAYS

- Compliance with IEC 60601 series has become an important part for the commercialization of safe medical electrical equipment around the world.
- Value of IEC 60601 series for basic safety and essential performance evident for all stakeholders.
- Release of Edition 3.2 addressing safety gaps while assuring necessary stability.
- Contribution to Edition 4 from all stakeholders desirable.





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