THE FUTURE OF THE
IEC 60601 SERIES

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SWG Member; Vice-Chair DITTA Standardization WG
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 60601-1-X Collateral Standards

IEC 60601-2-X Particular Standards

Medical Electrical Equipment
Part 2: Particular requirements for basic safety and essential performance
e.g. Ultrasonic, defibrillator, X-ray machine, etc.

- Part 1-2: Electromagnetic Compatibility
- Part 1-3: Radiation Protection
- Part 1-6: Usability
- Part 1-8: Alarms
- Part 1-9: Environmentally Conscious Design
- Part 1-10: Physiological Closed-Loop Controllers
- Part 1-11: Home Healthcare Environment
- Part 1-12: Emergency Service Environment

IEC 60601-1 Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

ISO 14971 Medical devices – Application of risk management to medical devices

IEC 62304 Medical device software - Software life cycle processes

IEC 82304-1 Health Software - Part 1: General requirements for product safety
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

SC 62A Common aspects of electrical equipment used in medical practice
Chair Richard Scott, UK
Vice Chair Brodie Pedersen, US
Sec US, Ms Hae Choe Asst Sec Charles Sidebottom

SC 62B Diagnostic imaging equipment
Chair Yan Kang, CN
Sec DE Norbert Bischof Asst Sec Ms Annette Hagen

SC 62C Radiotherapy, nuclear medicine and radiation dosimetry
Chair Alan Cohen, US
Sec DE Norbert Bischof Asst Sec Ms Annette Hagen

SC 62D Electromedical equipment
Chair Klaus Neuder, DE
Vice Chair Jeffrey Eggleston, US
Sec US Ms Hae Choe
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.
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
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.
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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