Fourth edition of IEC 60601-1

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IEC 60601-1 Series 4th Edition

Objectives:

- Review the goals for the fourth Edition
- Overview the Design specification contents
- General development schedule for publication

IEC 60601-1

Goals for the fourth Edition

The goals are presented in the previously published Architecture specification

Architecture spec web link (free download from IEC)

Architecture Goals for the fourth Edition

- Incorporation of the collaterals
- Updating the Structure (new clause numbers)
- Include broad use environments outside the hospital. EMS, Home, transportation, assisted living.
- Scope: Children/Animals
- Cover: parts, pieces and systems

- Consolidation of terminology: IEV Part 880.
- Reconcile requirements to a single statement
- Reduce references, focus type testing and fewer process requirements
- Compliant with ISO/IEC Directives Part 2
- Utilize ISO/IEC Online Standard Development OSD

- **Implementation**

Overview the Design specification

The design Specification lays out the content and structure for the new edition

https://assets.iec.ch/public/sc62a/IEC_60601-1_Ed._4.0_Design_Specification_2023-11-03.pdf?2024021546

Design Specification: Outline for the fourth edition of IEC 60601-1

Purpose: guidance and Mapping

Clustering of requirements

Deleted Requirements, not included

Title, Scope

Terminology

Principles for Drafting

Process Standard implementation

Work Break out

4th Ed. Outline

Traceability of Architecture requirements

Purpose: guidance and Mapping

Guidance

- The Design Spec is provided as directions for the working groups.
- It is provided to capture how the architecture spec is implemented

Mapping

- Section 13 provides a map of the current edition, collaterals and ‘horizontal’ particulars to the proposed 4th Ed.

Clustering of Requirements

- WG 37 - General requirements
- WG 38 - Physical environment hazards
- WG 39 - User interface related hazards (including all labelling and information to be provided)
- WG 40 - Materials hazards
- WG 41 - *PEMS* (e.g., SaMD (Software as a medical device), SiMD (Software in a medical device), firmware, software, apps, OS, drivers) related hazards
- WG 42 - Electrical hazards
- WG 43 - Mechanical hazards
- WG 44 - Thermal and fire hazards
- WG 45 - Optical radiation (visible, UV and IR) hazards
- WG 46 - Ionizing radiation hazards
- WG 47 - Electromagnetic exposure (not optical or ionizing but including SAR) hazards
- WG 48 - Electromagnetic disturbances (including coexistence) hazards

Deleted Requirements, not included

- Specific single fault cross-references
- Specific mechanical hazard cross-reference to a clause
- Cathode-ray tubes (IEC 60601-1, 9.5.2) because this technology is no longer used
- Flammable anesthetics (IEC 60601-1, 11.4, Annex G) because 11.4 is only a reference to Annex G and such gases are no longer in use.

Not included: Circular economy elements

- IEC 60601-1-9
- Energy Efficiency

IEC 60601-1 4th Edition

- Title
- Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

Scope

This document applies to *medical electrical equipment* and *medical electrical systems*, hereafter referred to as *MEE* and *MES.*

This document specifies the general requirements for the *basic safety* and *essential performance* of *MEE* and *MES,* intended for use by the specific *users* and in the specific environments of use as specified in the *instructions for use*.

This document applies to software integrated into an *MEE* (SiMD). This document applies to software as a m*edical device* (SaMD) in an *MES* when the SaMD contributes to *basic safety* or *essential performance*.

This document can be applied to subassemblies of *MEE* or *MES*.

EXAMPLE Power supply unit or x-ray tube assembly.

Hazards related to the intended physiological effect of *MEE* or *MES* are not covered by the specific requirements of this document except in xxx (formerly 7.2.13) and xxx (formerly 8.4.1).

NOTE 1 See also xxx (formerly 4.2).

The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of *MEE*, which is covered by the IEC 61010 series;

– implantable parts of active implantable medical devices covered by the ISO 14708 series; or

– medical gas pipeline systems covered by ISO 7396-1.

NOTE 2 ISO 7396-1 applies the requirements of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

Electropedia: The World's

Online Electrotechnical

Vocabulary

Terminology IEV Part 880

- IEC TC62 WG4 Terminology includes 880, and 881(radiology)
- This project team is defining the terms of the TC.
- Inclusive of all terms used in IEC 60601-1
- The current collaterals including IEC 60601-1-2 EMC
- Horizontal type language from particular standards
- Many medical sector terms, for example ISO 13485, ISO 14971 etc.

- IEC 60050-880 terms are included for reference in the OSD draft document.
  - The definitions are not yet included until they are complete.

Principles for Drafting

- Incorporation of the collaterals
- Updating the Structure (new clause structure)
- Include broad use environments outside the Hospital. Emergency Medical Service, Home Healthcare
- Expand Patient Scope: goal to include all ages, all sizes, humans and animals
- Consolidation of terminology: Cover expand parts and pieces and systems
- Reconcile requirements to a single statement
- Reduce cross-references,
- Focus on type testing
- Fewer process requirements (RMF, Usability, Software)
- Use of the Online Standards Development (OSD) tool to write a database standard

Process Standard implementation

- References to the outputs of processes (e.g., usability engineering, software development, risk management) in conformance statements should be minimized

- Conformance statement for each process document shall be clear and specific

- Example of IEC 60601-1-6 Usability is provided in section 11 adopted from the IECEE TRF

Outline

- Content and specific requirements are grouped into general requirements and clusters according to kind or source of harm/hazardous situation.
- Each cluster is intended to be managed by one Working Group who will implement the structure of clauses/ subclauses within the rules of the Directives Part 2.
- ISO style guide
- SC62A 4th edition style guide (Living document)
- The outline of requirements provides a map of current requirements to the new edition WG.
- Additional new requirements are also mapped.

Work Break out

- Work Groups will prepare the text for the assignments according to Tables 1-13 in Section 13.
  - Organize the requirements into logical order for the clauses within the directive part 2 rules
  - Work will be published in the online standard Development tools
  - Prepare the text of the revised document:
    - Rewrite current requirements into single statements
    - Prepare new requirements to address new hazards (Design Spec)
    - Review the long list for unaddressed issues
    - Repair the new text to address the issues
    - Issue fragment CD
    - Comment resolution
- Once fragments are clean, merge to the main document
- Issue CD of the merged standard fragments
- Issue CDV
- Issue FDIS

WG 47 - Electromagnetic exposure hazards (not optical or ionizing but including SAR)

Electromagnetic exposure hazards

MEE/MES unintentional emissions (include patient/operator radiation safety, e.g., electric blankets, e.g., SARs)	Parts of 10 (10.3) New, IEEE C95.1, IEC 62209, IEC 62311
• functional connection intentional radiation (include human radiation safety, SAR, include DC magnetic fields)	New, IEEE C95.1, IEC 62209, IEC 62311

WG meeting this week, Mostly new content draft coming soon

- Microwave radiation,
- Human Exposure to Radio Frequency Electromagnetic Fields
- RF and magnetic fields, limitations not to infringe upon specific policies of authorities having jurisdiction.

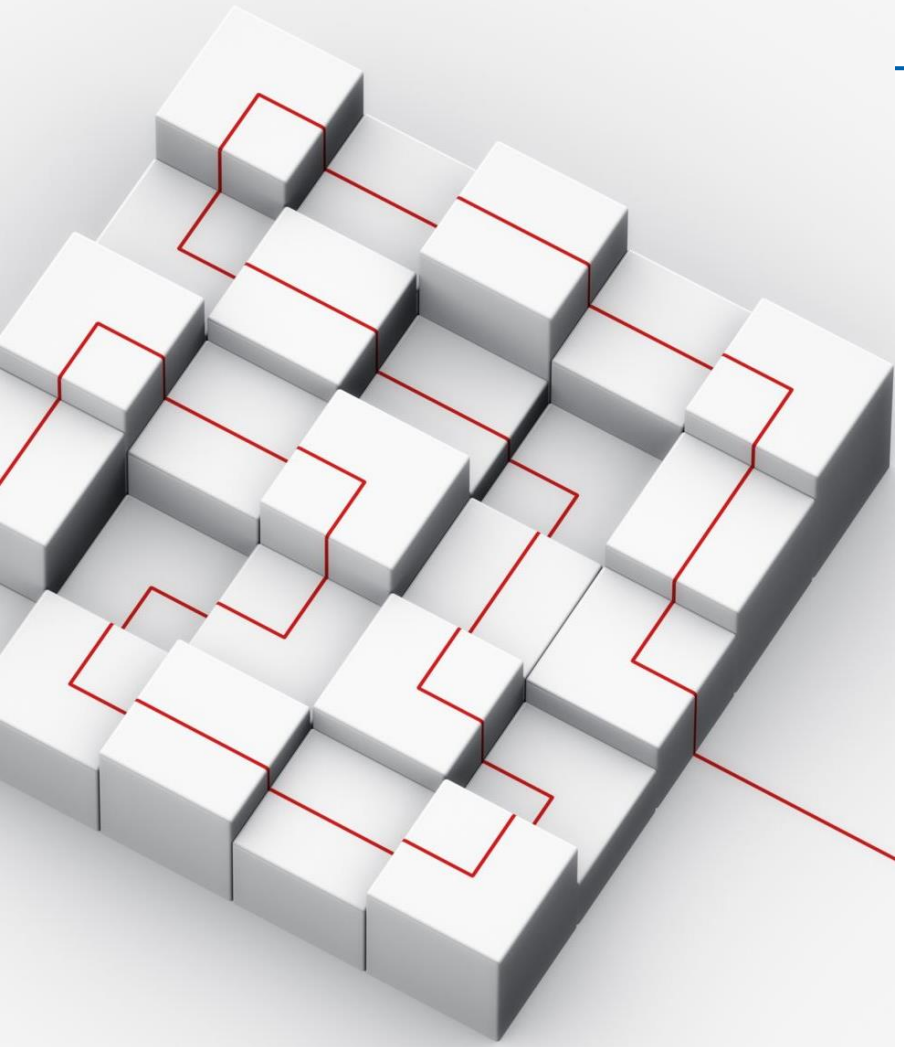
WG 48 - Electromagnetic disturbances (including wireless coexistence) hazards

Electromagnetic disturbances hazards

Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)
General requirements	[60601-1-2 4.2, 4.3, 6, 9]
Emissions	6, 7, 9, 17, [60601-1-2 Clause 7], [60601-1-11 Clause 12], [60601-1-12 Clause 11], [80601-2-49 202.7]
• **wireless coexistence**	IEEE/ANSI C63.27, AAMI TIR69
Immunity (include DC magnetic fields)	6, 8, 9, 17, [60601-1-2 8], [80601-2-49 202.8], new

WG 48 meeting this week

- The project will follow the traditional IEC 61000-4-x basic test methods, ESD, Rad cond. Immunity and emissions, EFT, Surge, power freq. Mag, VD Interruptions, proximity Mag fields.
- Emissions, for conducted and Radiated as well as Flicker and Harmonics.
- Wireless coexistence for intentional radiators.
- The collateral environments for Home Healthcare and EMS are included in the base standard.
- Disturbance from HF surgical equipment is new.



Traceability of Architecture requirements

Section 10.2 outlines goals from the architecture specification with more detailed instruction.

These are traced in Annex A for completeness as any good design file should.

The trace table identifies who is responsible for each architecture task.

AG 50 the editing team is responsible for implementing the architecture in the most complete fashion.

AG50 made up of the WG convenors/secretaries is the editorial team of the 4th Ed.

Secretaries must be confirmed by their National Committee

General development schedule

Committee Draft	CDV Fragments	CDV2 Merged	FDIS	DOP
• Published • 3/27/2025 • Internal Goal 11/2024 CD1 3/2025 CD2	• Published 05/06/2026 • Internal Goal 11/2025 CDV1 05/06/2026 CDV2	• Published 06/06/2027 • Internal Goal 06/06/2027 CDV1 06/07/2028 CDV2	• Published 01/04/2029	• Published 04/06/2029

Fourth Edition

The project officially began in March 2024.

First meeting was at AAMI April 29 – May 3

You must be a registered expert to attend any meeting.

Regular monthly online meetings will follow for WG members

Next face to face in Oct. 2024 at BSI London UK prior to the IEC General meeting

First fragment CDs goal in 2024.

Thank you

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