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

1. About this Design Specification

This Design Specification is developed to provide guidance and mapping for drafting the 4th edition of IEC 60601-1.

This Design Specification supplements t*he Architectural Specification for Safety Standards of Medical Electrical Equipment, Medical Electrical Systems, and Software used in Healthcare* (62/348/Q) that was drafted by the representatives of IEC TC 62 and its subcommittees and finalized in 2020. It outlines the concepts and goals for the IEC 60601 series of standards. This includes the IEC 80601 and ISO 80601 series of standards.

Once the Architectural Specification was finalized and approved by the National Committees of IEC/TC 62 and subcommittees, IEC/SC 62A was tasked with developing this Design Specification. The aim of this Design Specification is to provide clear, concise basis for developing the next edition of IEC 60601-1. It is intended to provide information to develop a user-friendly, distinct and easily readable edition of IEC 60601-1.

The new structure of the requirements is mirrored by a new structure of the Working Groups, each working on a separate cluster. A table is provided which maps the clauses of Ed.3.2 and other documents into each cluster. The numbering (A … L) of the clusters does not reflect the final numbering of the Clauses of Ed.4.

This document provides the philosophy, principles in drafting the fourth edition as well as how the proposed grouping of the work will be performed.

The Design Specification and the 4th edition are intended to support the UN sustainable Development Goal 3: Good health and well-being—ensure healthy lives and promote well-being for all.

2. Clustering of requirements

The IEC 60601 series contains requirements for medical electrical equipment, medical electrical systems and its software. Those requirements can apply to all equipment/systems (as in the general standard), to specific groups of equipment or to specific properties/aspects of equipment (as in the collateral standards and in some particular standards that address general issues (i.e., 60601-2-22, 80601-2-49, 60601-2-57, 60601-2-75).

It is the intention of the 4th edition to include the requirements of the general standard and collateral standards (as well as some “general” particular standards) into one document. To better manage the number of requirements in the development phase of the standard, corresponding requirements are grouped into clusters. All technical requirements related to specific hazards (e.g., electrical, mechanical, electromagnetic, radiation) are grouped into separate clusters.

The clusters are indicated with capital letters (A, B, C, …) to distinguish them from clauses. It is the intention that each cluster be managed by one Working Group (WG). The responsible WG can decide on grouping the requirements into one clause or into more clauses where necessary or appropriate.

To be consistent with Directives part 2, defined terms are denoted in italics.

3. Proposed title of the 4th edition:

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

4. The first three clauses are determined per ISO/IEC Directives, Part 2 (and will be handled by the editing team):

1. Scope
2. Normative references
3. Terms and definitions

5. Clusters of requirements

The content and specific requirements are grouped into general requirements and a set of clusters according to kind or source of harm/hazardous situation: [62/348/Q-Goal 3]

A. General requirements
B. Physical environment hazards
C. User interface related hazards (including all labelling and information to be provided)
D. Materials hazards
E. *PEMS* (e.g., SaMD (Software as a medical device), SiMD (Software in a medical device), firmware, software, apps, OS, drivers) related hazards
F. Electrical hazards
G. Mechanical hazards
H. Thermal and fire hazards
I. Optical radiation (visible, UV and IR) hazards
J. Ionizing radiation hazards
K. Electromagnetic exposure (not optical or ionizing but including SAR) hazards
L. Electromagnetic disturbances (including coexistence) hazards

A separate cluster for medical electrical systems is not included in this list, because system aspects are covered in the hazard-specific clusters. Where applicable, the system-specific requirements need to be indicated clearly in those clusters.

A separate cluster for 'Hazardous situations and fault conditions for ME Equipment', former Clause 13, is not included because hazardous situations and single fault conditions are distributed into the hazard-specific clusters.

6. The following topics are deleted.

- Specific single-fault conditions (IEC 60601-1, 13.2.2-5, 13.2.11-12) because these subclauses are only references to other subclauses.
- Specific mechanical hazards (IEC 60601-1, 16.7) because it is only a reference to Clause 9.
- Cathode-ray tubes (IEC 60601-1, 9.5.2) because this technology is no longer used.
- Flammable anaesthetics (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. Hospitals are no longer designed to be able to safely use these gases.

7. The following topics were considered but are not to be included in the 4th edition.

Following topics have been moved to the scope of IEC/SC 62A/WG 20 and IEC/TC 62 – ISO/TC 210/JAG 5 to be considered in a separate standard in the future.

- Content of IEC 60601-1-9
- Energy efficiency, (IEC guide 118, 119; annex C 118 overview).

8. Proposed scope for the 4th edition:

8.1 Scope [62/348/Q-Goal 5]

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 me*dical 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.

9. Terminology and definitions

Currently, IEC TC62/WG 4 62/WG4 is still working on these definitions so they are subject to change.

Definitions in this document are only informative for better understanding of this document; definitions will be specified in IEC 60050-880.

Once they are published in IEC 60050-880, they will be used in IEC 60601-1 Ed.4.

9.1 medical electrical equipment
MEE
ME equipment

electrical *medical device* (IEV 880-09-23) having an *applied part* (IEV 880-09-07) or transferring energy or substances to or from the *patient* (IEV 880-14-16) or detecting such energy or substance transfer to or from the *patient* and which is provided with not more than one connection to a particular *mains* (IEV 880-06-10)

Note 1 to entry: The *MEE* also includes those *accessories* and *detachable* parts as defined by the *manufacturer* that are necessary to enable the *normal use* of the *MEE*.

Note 2 to entry: An electrical *medical device* having more than one connection to a particular *mains* is considered *MES*.

Note 3 to entry: Not all electrical equipment used in medical practice falls within this definition (e.g., in vitro diagnostic equipment for the laboratory).

Note 4 to entry: The definition of *medical device* is broader than that of *MEE*.

Note 5 to entry: The transfer or detecting of energy includes optical radiation and imaging (e.g., infrared, x-ray and ultrasound imaging).

[SOURCE: IEC 60601-1:2005, 3.63, modified — added "*MEE*" as a term, "electrical equipment" with "electrical *medical device*" and "supply mains" with "*mains*", added "or substances", deleted item b) and notes 3 to 5, and added note 2.]

9.2 essential performance

performance of a clinical or diagnostic function, other than that related to *basic safety* (IEV 880-18-02), where loss or degradation beyond the limits specified by the *manufacturer* (IEV 880-14-14) results in an unacceptable *risk* (IEV 880-18-14)

Note 1 to entry: *Essential performance* is most easily understood by considering whether loss of the function or degradation of the performance would result in an unacceptable *risk*.

Note 2 to entry: Clinical and diagnostic functions include therapeutic, *patient* monitoring and in vitro diagnostic functions.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.27, modified — added "or diagnostic" and note 2 and replaced "its absence or degradation" with "loss of the function or degradation of the performance" in note 1.]

9.3 medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (IEV 880-14-14) to be used, alone or in combination, for *patients* (IEV 880-14-16), for one or more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
— investigation, replacement, modification, or support of the anatomy or of a physiological process,
— supporting or sustaining life,
— control of conception,
— *disinfection* (IEV 880-04-02) of *medical devices* (IEV 880-09-23),
— providing information by means of in vitro examination of specimens derived from the *patient*,

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the *patient*, but which can be assisted in its intended function by such means

Note 1 to entry: *Products* which can be considered to be *medical devices* in some jurisdictions but not in others include:
— *disinfection* substances,
— aids for persons with disabilities,
— devices incorporating animal or human tissues,
— devices for in-vitro fertilization or assisted reproductive technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7, modified — replaced “and/or” with “or” and “human being” and “human body” with “*patient*”.]

9.4 medical electrical system
MES
ME system

combination, as specified by its *manufacturer* (IEV 880-14-14), of items of equipment or software, at least one of which is *MEE* (IEV 880-09-25) interconnected by *functional connection* (IEV 880-05-03)

Note 1 to entry: The *manufacturer* of an *MES* can also be an *IT integrator*, *implementer, distributor* or a *healthcare delivery organization*.

Note 2 to entry: When *SaMD* contributes to *basic safety* or *essential performance* of an *MEE*, then the *SaMD* shall be considered an element of a *MES*.

Note 3 to entry: Elements of an *MES* can be in different locations.

[SOURCE: IEC 60601-1:2005, 3.64, modified — added “MES” as a term, added “software” and notes 2 to 3 and replaced “to be inter-connected by functional connection or by use of a multiple socket-outlet” with “interconnected by *functional connection*” and note 1.]

9.5 functional connection

connection by electrical, mechanical, wireless or other means, including those intended to transfer signals, data, power or substances

Note 1 to entry: A connection to the *fixed mains socket outlet*, whether single or multiple, is not considered to result in a *functional connection*.

Note 2 to entry: *Permanently installed* equipment is not considered to have a *functional connection* to *mains*.

Note 3 to entry: A *patient connection* is not considered a *functional connection*.

Note 4 to entry: Power can be electrical, gas, mechanical, etc.

[SOURCE: IEC 60601-1:2005, 3.33, modified — replaced “, electrical or otherwise” with “by electrical, mechanical, wireless or otherwise” and replaced note 1 with notes 1 to 4.]

9.6 patient
subject of care

living being (person or animal) receiving healthcare services

Note 1 to entry: Healthcare services include diagnostic, therapeutic, monitoring, surgical or dental *procedures* and can be delivered in the *home healthcare environment*, *professional healthcare environment* and *emergency medical services environment*.

Note 2 to entry: A *patient* can be a *user*.

Note 3 to entry: *Safety* limit values can be different for different *patients*, especially for non-human *patients*.

[SOURCE: IEC 60601-1:2005, 3.76, modified — replaced “undergoing a medical, surgical or dental procedure” with “receiving healthcare services” and "operator" with "*user*" and added notes 1 and 3.]

9.7 applied part

part of *MEE* (IEV 880-09-25) that in *normal use* (IEV 880-21-07) necessarily comes into physical contact with the *patient* (IEV 880-14-16) for an *MEE* to perform its function

[SOURCE: IEC 60601-1:2005, 3.8, modified — deleted "or an *MES*" and notes.]

9.8 user

DEPRECATED: operator

person interacting with (i.e., operating or handling) the *medical device* (IEV 880-09-23), *accessory* (IEV 880-09-04) and associated items

Note 1 to entry: There can be more than one *user* of a *medical device*.

Note 2 to entry: Common *users* include, among others, *healthcare professional* providers, *patients*, *lay* persons, *processors*, *maintenance* and *service personnel*.

[SOURCE: IEC 62366-1:2015, 3.24, modified — added ", *accessory* and associated items" and "*lay* persons", replaced "cleaners" with "*processors*".]

10. Principles for drafting the fourth edition

10.1 General

The clusters are indicated with capital letters (A, B, C, …) to distinguish them from clauses. Each cluster is intended to be managed by one Working Group (WG). The responsible WG decides on grouping the requirements into the clausal structure (e.g., into one Clause or into multiple Clauses where necessary or appropriate). This means that the current structure of IEC/SC 62A will be disrupted and will be restructured. When work on the 4th edition is approved, the working groups and maintenance teams under SC 62A related to the 3rd edition will be dissolved and new working group structure will be put in place for the 4th edition. There will be call for nominations for the new working groups, with possible call for new leaders, before the work on 4th edition begins.

Additionally, IEC/SC 62A will utilize an editing team to ensure consistency of content and writing style authored by the different WGs as well as making the document consistent with the current ISO/IEC Directives, Part 2.

Also, to assist in developing the 4th edition, there will be two phases of training provided. First set will be for the groups drafting the texts for IEC 60601-1. Second set will be for those who will need to reference IEC 60601-1 in their publication, most notably the writers of part 2 standards and other documents in the IEC 60601 series.

A mapping between the relevant goals of the Architecture Document 62/348/Q and how each goal will be implemented for the 4th edition project is detailed in Annex A.

10.2 Goals from the Architecture Document, 62/348/Q.

The Architecture Specification contains very broad and comprehensive descriptions of architectural goals to be considered when writing Ed. 4. The authors of Ed. 4 are expected to consider the description of the architectural goals in the Architecture Specification for additional guidance.

a) Regarding normative references, the following text will be added to the general Clause (WG A): [62/348/Q-Goal 3]

Where this document specifies a specific edition of a normatively referenced document, the *manufacturer* may substitute a more current version provided the *manufacturer* can demonstrate that the *residual risk* that results from the substitution remains acceptable and is comparable to the *residual risk* that results from applying the normatively referenced document.

b) Terminology shall be consistent and shall utilize the terminology of IEC 60050-880, *International Electrotechnical Vocabulary (IEV) - Part 880: Electrical equipment, electrical systems and software used in healthcare*, where appropriate. [62/348/Q-Goal 3]

c) Each Clause shall cover the needed requirements for *MEE*, *MES* and, as appropriate, should cover the needed requirements for subassemblies or components. [62/348/Q-Goal 5]

d) Requirements shall clearly indicate whether they are applicable to *MEE*, *MES*, subassemblies or components, as appropriate. [62/348/Q-Goals 5.5.3 and 5.5.6]

e) Each Clause shall consider whether requirements need to vary based on e.g., intended *use environment*, intended *patient* or intended *user*. [62/348/Q-Goal 5]

f) Each requirement shall be reconciled into a single statement (i.e., each requirement is distinct and has a unique identifier). [62/348/Q-Goal 2]

g) Each requirement should include rationale for the safety goal in the rationale annex. [62/348/Q-Goal 1],

h) Each requirement should include the correlation with IMDRF N47 and N52 in an Annex. [62/348/Q-Goal 6]

i) Each requirement will be reviewed to ensure that it still reflects the generally acknowledged state of the art. [62/348/Q-Goal 1]

j) Each requirement will be reviewed to ensure that the acceptance criteria are verifiable (quantitative where possible). [62/348/Q-Goal 4]

k) Test methods should be described in sufficient detail, or referenced to an existing accepted standard, to ensure that the test can be successfully reproducibly conducted and have consistent results. [IMDRF N51]

l) Cross references within the document shall be avoided where practicable and, if necessary, be as short as possible. [62/348/Q-Goal 3]

m) Normative reference to external standards should be as precise as practicable to avoid referencing more of a standard than is necessary. Such references should be as specific as practicable. [62/348/Q-Goals 3 and 4]

n) Small parts of external standards should be copied into the document (if possible verbatim) to avoid the normative reference (e.g., a single requirement from an external standard). In such a case, a note or the rationale should indicate the source of the requirement. [62/348/Q-Goal 3]

o) Informative references should be limited to notes or the rationale. [62/348/Q-Goal 3]

p) References to the outputs of processes (e.g., usability engineering, software development, risk management) in conformance statements should be minimized, where practicable. However, the conformance statement for each process document shall be clear and specific. [62/348/Q-Goal 4]

EXAMPLE Following a mechanical stress test:

1. Confirm that *basic safety* and *essential performance* are maintained.

2. Confirm that the *enclosure* integrity is maintained and access to live parts is prevented.

11. Process standard implementation example

The following is an example of how to call out a process standard with the related conformity statement. As this is an example for usability to demonstrate the intended approach, it is not final text for insertion into the 4th edition. The conformity check was adapted from the IECEE TRF for 60601-1-6.

A *usability engineering process* complying with IEC 62366-1:2015+A1:2020 shall be performed except for:

a) the planning for and execution of production and *post-production* monitoring in the context of applying the *usability engineering process* within the framework of ISO 14971, and

b) the maintenance of the *usability engineering process*.

Check conformity by *inspection* of the *usability engineering file:*

1. to confirm that the *manufacturer* has:
   a. established a *usability engineering process*,
   b. established acceptance criteria for use-related *residual risk*, and
   c. demonstrated that the acceptance criteria for use-related *residual risk* is acceptable;
2. to confirm that:
   a. the interactions with the *medical device* according to the *accompanying document* have been addressed in the *usability engineering process,*
   b. *Information for safety* and *training* (if appropriate) used as a *risk control* measure has been evaluated according to the *usability engineering process*, and
   c. the results of the *usability engineering process* are recorded in the *usability engineering file;*
3. to confirm that the *usability engineering file* contains a *use specification* addressing:
   a. intended medical indication,
   b. intended *patient* population,
   c. intended part of the body or type of tissue applied to or interacted with,
   d. intended *user profile,*
   e. intended *use environment*, and
   f. operating principle;
4. to confirm that the *manufacturer* has identified:
   a. *user interface* characteristics that could be related to *safety and potential use errors*, and
   b. known or foreseeable *hazards* and *hazardous situations* which could affect *patients*, *users* or others, related to the use of the *MEE*;
5. to confirm that the:
   a. *risk analysis* includes a description of all the reasonably foreseeable *hazard-related use scenarios* associated with the identified *hazard* and *hazardous situations*,
   b. description of each identified *hazard-related use scenario* includes all *tasks* and their sequences, and
   c. *severity* of the possible resulting associated *harm* was determined;
6. to confirm that the *manufacturer* has selected the *hazard-related use scenarios* to be included in a *summative evaluation* by selecting:
   a. all *hazard-related use scenarios*,
   b. a subset of the *hazard-related use scenarios* based on the *severity* of the potential *harm* that could be caused by *use error*, or

   c. a subset of the *hazard-related use scenarios* based on the *severity* of the potential *harm* and based on other circumstances specific to the *MEE* and the *manufacturer*;
7. to confirm that the *manufacturer* has established and maintained:
   a. a *user interface specification* which includes whether *accompanying documentation* is required and whether training is required, and
   b. a *user interface evaluation* plan for the *user interface*;
8. If training on the *medical device* is required for the safe use by the intended *user*, to confirm that the *manufacturer* has designed and implemented a training capability for the *expected service life* of the *medical device* by doing at least one of the following:
   a. provided the materials necessary for training, and
   b. ensured the materials necessary for training are available,
   c. make the training available, or
   d. make training available to the *responsible organization* that enables it to train its *users;*
9. to confirm that the *manufacturer* has performed a *summative evaluation* of each selected *hazard-related use scenario;*
10. to confirm that all *use errors* and use difficulties that occurred are to be identified;
   a. Identify if new use errors, hazards, hazardous situations or hazard-related use scenarios occurred.
11. to confirm whether further improvement of the *user interface* design as it relates to *safety* is necessary and practicable:
   a. if not, confirm that the *manufacturer* has documented why improvement is not necessary or not practicable,
   b. if not, confirm that the data from the *usability engineering process* needed to determine the *residual risk* related to use is documented, and
   c. confirm that the *residual risk* has been evaluated according to ISO 14971:2019, 7.3 (see IEC 62366-1:2015 + A1:2020, Figure A.5); and
12. if *user interface of unknown provenance* (*UOUP*) is present, confirm that it was evaluated to Annex C.

Add to Cluster C, for the IFU:

   a. The *instructions for use* shall contain a summary of the *use specification* as specified in IEC 62366-1:2015 + A1:2020, 5.1;
   b. The same information is also included in the *technical description*, if this is provided as a separate document from *instructions for use.*

12. Dividing the work

Each WG has an area of responsibility and will be assigned the relevant items from the "Long List". The "Long List" is a database of known issues in the 3rd edition of 60601 (series). The issues will be distributed to the relevant WG.

Where an entry indicates new, the existing 3rd edition does not address the issue and the WG will need to identify or develop appropriate requirements. When a question mark is indicated in the “3rd edition or other standard’s clauses/subclauses (specified numbering)” column, it represents work that the cluster will need to do determine the specifics to be incorporated.

There are classifications in Cluster A that will be used to determine which subclauses of the standard are applicable to a given product and which test levels are applicable.

The following working groups need to be formed:

A. General requirements: general issues with respect to underlying concepts (e.g., basic safety/essential performance, single fault safety, type testing), correlation with processes relevant for the IEC 60601-1 defined by other process standards (e.g., risk management).
B. Physical environment hazards: safety issues due to specific environmental conditions, including power supply.
C. User interface (means by which user and medical device interact) aspects (including all labelling and information to be provided) hazards: safety issues related to user interfaces including marking, indications, accompanying information, alarm systems and usability.
D. Materials hazards: safety issues related to interferences of materials of MEE/MES with users, patients, used substances, including cleaning, disinfection, sterilization.
E. *PEMS* related hazards (e.g., Software as a medical device, Software in a medical device, firmware, software, apps, operating system, drivers): safety issues related to software driven functionality.
F. Electrical hazards: safety issues related to electricity.
G. Mechanical hazards: safety issues related to mechanics, including acoustic and pneumatic energy and vibration energy.
H. Thermal and fire hazards: safety issues related to thermal effects caused by MEE/MES and to fire in MEE or MES.
I. Optical radiation (visible, UV and IR) hazards: safety issues related to (visible radiation, UV and or IR).
J. Ionizing radiation hazards: safety issues related to ionizing radiation.
K. Electromagnetic exposure (not optical or ionizing but including SAR) hazards: safety issues related to radiation not (not optical or ionizing radiation hazards but including SAR).
L. Electromagnetic disturbances (including wireless coexistence) hazards: safety issues related to electromagnetic emissions or electromagnetic immunity, (including wireless coexistence).

13. Proposed groupings for the IEC 60601 4th Edition development [62/348/Q-Goal 3]

Table 1 — First 3 Clauses required by the Directives

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**editing team**		Scope	1 (required by Directives)	1
2.	**editing team**		Normative references	2 (required by Directives)	2
3.	**editing team**		Terminology and definitions	3 (required by Directives)	3

Table 2 — General requirements

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**A**	General requirements	• applicability of standard	1.1+1.2; (60601-1-2: 1.1+1.2); (60601-1-3: 1.1+1.2); (60601-1-6: 1.1+1.2); (60601-1-8: 1.1+1.2); (60601-1.10: 1.1+1.2); (60601-1-11: 1.1+1.2); (60601-1-12: 1.1+1.2)	1
2.	**A**	General requirements	General philosophy	4.1, 16.1; Selective from 60513	
3.	**A**	General requirements	• how to deal with multiple applicable particular standards	[80601-2-49 201.4.5]	
4.	**A**	General requirements	Application of risk management	4.2, (4.6, 5.9.1)	
5.	**A**	General requirements	• intended use/use specification	[in IFU, 20417 6.6.2 a) 4)], [60601-1-2 5.2.1.1 a)]	
6.	**A**	General requirements	• alarm system	[60601-1-8 Clause 4]	
7.	**A**	General requirements	• alternative risk controls	4.5, include newer standard version text	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
8.	**A**	General requirements	Single fault safety concept		
9.	**A**	General requirements	• basic safety and essential performance	4.7, (5.1 paragraph 3), 13.1.1, [13.2.1 first paragraph] expand discussion of BS vs EP and how to confirm; Selective from 60513 New SFC (including any single failures) for basic safety and need for safe fall back	
10.	**A**	General requirements	• identification of essential performance (and means to confirm)	4.3, [60601-1-2 5.2.1.1 b)]	
11.	**A**	General requirements	• includes verification of essential performance in single fault condition	IEC 60601-1:2005/AMD1:2012 /ISH1:2021	
12.	**A**	General requirements	• specific hazardous situations	13.1	
13.	**A**	General requirements	• specific single fault conditions	13.2	
14.	**A**	General requirements	• use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	4.9, +new [new—how to prove it is such a component IEC 62308 & 61709]. Is it a critical component?	
15.	**A**	General requirements	Expected service life and shelf life	4.4, 15.3.7, [60601-1-11 7.4.8], [new—how to evaluate expected lifetime]	
16.	**A**	General requirements	• disclose and what to do at the end of expected service life or if maintenance and repair not performed (properly)	new	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
17.	**A**	General requirements	• maintenance and repair	new; 62353, 62354, [new disclose effect of not doing maintenance and repair] Parts of 7.9.3 identify critical components and how to verify or validate a replacement component how to verify BS and EP following maintenance and repair	
18.	**A**	General requirements	• reliability	new	
19.	**A**	General requirements	General requirements for testing	5.1, 5.2, 5.4, 5.6, [80601-2-49 201.5.4], [60601-1-2 4.3.1, 4.3.2]	
20.	**A**	General requirements	• create test plan, include sequence of testing	5.8, New [See 60601-1-2,6.2], Annex B	
21.	**A**	General requirements	• 60601 testing procedure	5.8, 62354	
22.	**A**	General requirements	• production tests	New, 62354, Annex K	
23.	**A**	General requirements	• accelerated life evaluation	new	
24.	**A**	General requirements	Accuracy aspects requiring validation (testing in subjects or testing in lab) i.e. essential performance		
25.	**A**	General requirements	• Validation (of EP)	new [60601-1-10 8.2.5]	
26.	**A**	General requirements	• accuracy of controls and measurements	12.1, [60601-1-11 Clause 9]	
27.	**A**	General requirements	• using non-human subjects	new	
28.	**A**	General requirements	Classification	6	
29.	**A**	General requirements	• clinical environment (home, ambulance, OR, ICU, special, critical care, intermediate care, basic care, etc.)	new	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
30.	**A**	General requirements	• continuous/non-continuous [continuous should be default]	6.6, 7.2.11, part continuous and part non-continuous. Review 2nd edition	
31.	**A**	General requirements	• type of mobility (mobile, fixed, etc.)	new	
32.	**A**	General requirements	• type of applied part, class I & II, internally powered, IPxx, single use/multiple use, O2, mode of operation	5.9.1, 6.3, 6.4, 6.5, 6.6, (6.1, 6.2, 8.3), 7.2.5, 7.2.6, 7.2.10, 7.2.11, [60601-1-11 Clause 6], [60601-1-12 Clause 5], [20417]	
33.	**A**	General requirements	• type (size, etc.) of patient	new	
34.	**A**	General requirements	• type/use of gas input	7.2.18 new	
35.	**A**	General requirements	• type/use of liquid input	new	
36.	**A**	General requirements	• multiple applied parts	[80601-2-49 201.6.2, 201.8.3]	
37.	**A**	General requirements	• size/mass of equipment	7.2.21	
38.	**A**	General requirements	• degree of autonomy present	new	
39.	**A**	General requirements	○ PCLC	New [60601-1-10]	
40.	**A**	General requirements	○ AI/ML	new	
41.	**A**	General requirements	○ robotics	New [60601-4-1]	
42.	**A**	General requirements	• pieces of equipment (subassemblies and accessories)	new	
43.	**A**	General requirements	• components ○ differentiate detachable part vs accessory (? Delete 7.2.2 and 7.2.4 and use 20417, 6.1)	4.8	
44.	**A**	General requirements	• functional connections (e.g., systems, sip/sop, wireless, network. other connections)	new	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #

45.	**A**	General requirements	• distributed essential performance present?
			  ○ distributed UI present?
			  ○ distributed alarm system present?
			  ○ distributed control present?
				new	

46.	**A**	General requirements	• determining accessible parts	5.9.2, [8.4.2 part], 13.2.1 (parts), 16.4 (determining), [60601-1-11 Clause 5]	

Table 3 — Physical environment hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**B**	Physical environment		5.3	
2.	**B**	Physical environment	Environmental requirements (operating, transport in use/ transport & storage between uses; transport & storage prior to first use; temperature, humidity & pressure range, shock & free fall/ vibration/robustness/strength, physical security) EMC classification	New, [60601-1-11 4.2.2, 4.2.3], [60601-1-12 4.2] 7.2.17, 13.2.8 (parts), [15.3 except 15.3.7], 15.4.7.1, [shock and vibration missing], packaging tests missing, [60601-1-11 Clause 10.1], [60601-1-12 Clause 10.1] IEV part 880 and 60601-1-2	
3.	**B**	Physical environment	• earthquake (fixed or stationary MEE)	New – {OSHPD (HCAI), or Japan certificate} IEC 60721-2-6	
4.	**B**	Physical environment	• corrosion (by ambient, due to electrochemical action between dissimilar metals, by patient)	New, 62368-1, Annex N & Annex Y.3	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
5.	**B**	Physical environment	• power supply input	4.10, 5.5, 7.2.5; 7.2.6; 7.2.7; 7.2.8; 8.2; 16.3, [60601-1-11 4.1], [60601-1-12 4.1], [new — emergency backed up power vs. non backed up]	
6.	**B**	Physical environment	• batteries	7.3.3; 15.4.3 (need extension, include battery management, and charging and discharging); [60601-1-11: 7.4.2; 8.5]; [60601-1-12: 6.3.2; 8.3]	
7.	**B**	Physical environment	• ingress particulates and water (IPNN)	6.3, (60601-1-11 7.2 except safety sign), (60601-1-12 6.2 except safety sign), 7.2.9, [11.6.1, 11.6.2, 11.6.3, 11.6.5], 15.4.7.3, [60601-1-11 7.2, 8.3], [60601-1-12 6.2, 8.1], [80601-2-49 201.11.6.5] Review reference to 60529 and add appropriate acceptance criteria	
8.	**B**	Physical environment	• oxygen rich environment	6.5, 11.2.2	
9.	**B**	Physical environment	• US deviation for x-ray • MRI • OR • shielded • Other?	NFPA 70 Call out ASTM test methods with limits; See IEC 62570	

Table 4 — User interface aspects

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**C**	User interface aspects	Information provided by the manufacturer	7, 16.2, 16.3 (overvoltage category), [60601-1-6 Clause 5], [60601-1-11 7.1, 7.3.1], [60601-1-12 6.1, 7.3.1], [60601-1-3 5.2]	
2.	**C**	User interface aspects	• elements to be established (classifications)	[20417 5]	
3.	**C**	User interface aspects	• label	[20417 6.1]	
4.	**C**	User interface aspects	• marking	[20417 6.1.1], [80601-2-49 201.7.2.101], 7.2.8.2, 7.2.13, 7.2.20, [60601-1-3 5.1], [60601-1-2 5.1], 62570	
5.	**C**	User interface aspects	• legibility of marking	7.1.2, [20417 6.3], 60601-1-11, 60601-1-12, 6.1 ISO/TR 22411	
6.	**C**	User interface aspects	• legibility of marking/display including with PPE	new	
7.	**C**	User interface aspects	• durability of marking	7.1.3, [20417 6.4]	
8.	**C**	User interface aspects	• packaging	[20417 6.5]	
9.	**C**	User interface aspects	• IFU	[20417 6.6.2, 6.6.3], [60601-1-6, 5], [60601-1-8 5.2.1], [60601-1-11 7.3.2, 7.4.1, 7.4.2, 7.4.3, 7.4.4, 7.4.5, 7.4.6], [60601-1-12 6.3.2, 6.3.3, 6.3.4, 6.3.5], [80601-2-49 201.7.9.2.9.101], [60601-1-3 5.2.4], [60601-1-2, 5.2.1.1 c) to f), 5.2.1.2], 7.9.2	
10.	**C**	User interface aspects	• technical description	[20417 6.6.4], [60601-1-8 5.2.2], [60601-1-11 7.5.1], [60601-1-12 6.4], [60601-1-2 5.2.2], 7.9.3	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
11.	**C**	User interface aspects	• e-documentation	[20417 6.6.5]	
12.	**C**	User interface aspects	• site planning safety information (power, cooling, ventilation, shielding, installation)	[60601-2-33,201.7.101]	
13.	**C**	User interface aspects	Covered by 20417, marking, packaging, IFU, technical description	7.2.2, 7.2.3, 7.2.4, 7.2.17, 7.5, 7.6, (7.9.1 mostly), (7.9.2.1 except classifications), (7.9.2.2 except EMC & MSO), (7.9.2.5 except applied part & SIP/SOP), 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.12, 7.9.2.13, 7.9.2.14, 7.9.2.15 (+consumables in use, biohazard), 7.9.2.16, 7.9.2.17, 7.9.2.18, 7.9.2.19, (some of 7.9.3.1), 14.13 [60601-1-11 7.3.1, 7.4.9], [60601-1-12 6.3.1]	
14.	**C**	User interface aspects	Other information	7 (some parts)	
15.	**C**	User interface aspects	• accessory compatibility	New, see ventilators 201.102.1 & 2	
16.	**C**	User interface aspects	Displays (graphical user interface), controls and indicators	12.4.2, 12.4.3, 12.4.4, 15.1, 15.4.4, 15.4.5, 15.4.6, [60601-1-11 10.2], [80601-2-49 201.15], new (voice, gesture, feedback, etc.]	
17.	**C**	User interface aspects	• distributed user interface	New, include nurse call	
18.	**C**	User interface aspects	• autonomy (including AI)	new	
19.	**C**	User interface aspects	Touch sensitivity including with PPE	New, ISO 9241-910	
20.	**C**	User interface aspects	Indication of state of internal electrical power source	[60601-1-11 8.5.1], [60601-1-12 8.3 part]	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
21.	**C**	User interface aspects (includes construction)	Alarm systems (me equipment and me systems)	12.3, [60601-1-8 clause 6 & annex G], [60601-1-11 7.4.10], [60601-1-11 Clause 13], [80601-2-49 208.6], include nurse call	
22.	**C**	User interface aspects	Primary operating functions	[62366-1, 5.2], [80601-2-49 206], [60601-1-3 6.2.1]	
23.	**C**	User interface aspects	Indicator lights	[7.8.1 & 60601-1-8 5.1], 7.8.2?	
24.	**C**	User interface aspects	Usability	12.2, 12.4.1, [60601-1-6 clause 4], (60601-1-11 7.1), [60601-1-12 Clause 9]	
25.	**C**	User interface aspects	• installation	7.9.2.6, 7.9.3, +new (proper)	
26.	**C**	User interface aspects	• serviceability, maintenance and repair	[15.2 for the expected service life]; [7.3 safety of service personnel], 5.1 test after repair (62353, 62354),	
27.	**C**	User interface aspects	• use error	(15.4.1 & 16.9.1), 15.4.2.2, 15.4.7.2, [60601-1-3 6.4]	
28.	**C**	User interface aspects	• Protection from interruption of power source (are they NC or SFC?)	11.8, 16.8, [60601-1-11 8.4], [60601-1-12 8.2, 8.3 part], [80601-2-49 201.11.8]	
29.	**C**	User interface aspects	• protection from hazardous output	12.4	
30.	**C**	User interface aspects	• Require usability evaluation of information for safety	62366-1, 4.1.3	

Table 5 — Materials hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**D**	Materials		new	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
2.	**D**	Materials	• biocompatibility	11.7, 10993 series, 18562 series	
3.	**D**	Materials	• cleaning and disinfection; cleaning and sterilization (biological hazards)	6.4, 11.6.6, 11.6.7, [60601-1-11 7.4.7, 7.5.2, 8.1, 8.2], 17664 series	
4.	**D**	Materials	• compatibility with substances	11.6.8	
5.	**D**	Materials	• hazardous substances (chemical hazards)	new	
6.	**D**	Materials	• surface coatings	8.6.5, 8.9.1.16, [62368-1 5.6.2, Annex N]	
7.	**D**	Materials	• enclosures, outdoor exposure	UL 50E, CSA 94-2, 60721-4-x	
8.	**D**	Materials	Adhesive • applied part (too sticky) • hold for expected service life	new	

Table 6 — PEMS related hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**E**	PEMS	PEMS	[14 except 14.13], annex H	
2.	**E**	PEMS	• data exchange	new	
3.	**E**	PEMS	• ADT (admit, discharge, transfer)	new	
4.	**E**	PEMS	Security (physical and cyber)	New, 60601-4-5, 81001-5-1	
5.	**E**	PEMS	• SBoM (software bill of materials)	new	
6.	**E**	PEMS	• Cybersecurity patches	new	
7.	**E**	PEMS	Big data	new	
8.	**E**	PEMS	Clinical Decision Support	new	
9.	**E**	PEMS	AI/ML in use with MEE	new	
10.	**E**	PEMS	Degree of autonomy (including situational awareness)	new	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
11.	**E**	PEMS	Distributed essential performance including cloud computing	new	
12.	**E**	PEMS	Remote control	new	
13.	**E**	PEMS	• locus of control	new	
14.	**E**	PEMS	Safety of Physiologic Closed Loop Controllers	60601-1-10 except 8.2.5	
15.	**E**	PEMS	Impact on basic safety	New (need to expand SFC)	

Table 7 — Electrical hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**F**	Electrical	Electrical safety	4.11, 5.7, 7.2.7 (should be with 4.11), 7.2.12, 7.2.14, 7.2.19, 7.4 – 7.4.2, 7.7	
2.	**F**	Electrical	General	(8)	
3.	**F**	Electrical	• SFC	8.1, 8.9.2 a), 13.1.3, 13.2.9, 13.2.10, 15.5.2	
4.	**F**	Electrical	• power sources	8.2	
5.	**F**	Electrical	• classifications	8.3, [8.9.1.7, 8.9.1.8, 8.9.1.9]	
6.	**F**	Electrical	• limitation of voltage, current or energy	8.4 [only part of 8.4.2], 16.4 (limitation) IEC 61201	
7.	**F**	Electrical	• separation of parts (fix defib test)	8.5, 16.5, [60601-1-11 8.5.3], [80601-2-49 201.7.9.2.2, 201.8.5.2.3, 201.8.5.5.1]	
8.	**F**	Electrical	• earthing, functional earthing and potential equalization	8.6 except 8.6.5, 16.9.2.2	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
9.	**F**	Electrical	• leakage currents and patient auxiliary currents	8.7, 16.6 IEC 60479-1 & -2 3-phase (60990)	
10.	**F**	Electrical	• Insulation	[8.8 +13.2.1 2nd paragraph + Annex L], 60664	
11.	**F**	Electrical	• creepage distances and air clearances	[8.9 except 8.9.1.7], [8.9.1.8 + annex M], [60601-1-12 Clause 7], 60664	
12.	**F**	Electrical	Construction	7.2.8.1, 8.10, [8.10.5 acceptance criteria for mechanical stress and expected service life use], 8.11, 15.4.1 a), 15.4.8, 15.5.3, 16.9.2.1, 16.9.2.3	
13.	**F**	Electrical	production line test for bonding, leakage current and dielectric or insulation resistance	New, 62354, Annex K (non-destructive testing)	

Table 8 — Mechanical hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**G**	Mechanical	Mechanical safety (review applicability to ME systems)		
2.	**G**	Mechanical	• moving parts	9.2	
3.	**G**	Mechanical	• surfaces, corners and edges	9.3, need test protocol (UL1439)	
4.	**G**	Mechanical	• Instability	9.4	
5.	**G**	Mechanical	• handling	9.4.4	
6.	**G**	Mechanical	• expelled parts	9.5, except 9.5.2	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
7.	**G**	Mechanical	• acoustic energy/vibration	9.6, 12.4.6, [80601-2-70 201.9.6.2.1.101], [80601-2-12 201.9.6.2.1.101]	
8.	**G**	Mechanical	• pressure vessels and pieces	9.7	
9.	**G**	Mechanical	• support systems	9.8, [60601-1-12 10.2]	
10.	**G**	Mechanical	• suspension/lifting systems	9.8, [60601-1-12 10.2]+machinery directive	
11.	**G**	Mechanical	Strangulation or asphyxiation or choking	[60601-1-11 7.4.1, 8.5.2, Clauses 9 and 11], [60601-2-52 figures AA.11 to AA.17]	

Table 9 — Thermal and fire hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**H**	Thermal, fire	Thermal safety • contact duration • SFC vs NC limits • Patient vs user • Patient (internal vs skin) • Ambient temp greater than limit	7.2.15, 13.2.8, 13.2.9, 13.2.10, 13.2.13, 15.5.1 80601-2-74 enthalpy (moist air)	
2.	**H**	Thermal, fire	Construction	11.3, 15.4.2.1, review 62368-1 New: Polymer aging for enclosures (temperature, UV) Fix wiring call out	
3.	**H**	Thermal, fire	• excessive temperatures (high and low)	11.1, 13.1.2, 13.2.7, Table 26, consider adding thermal imaging for testing	
4.	**H**	Thermal, fire	• fluid Egress protection	13.2.6, [15.4.9 why only oil?]	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
5.	**H**	Thermal, fire	Fire protection	7.3.8, 11.2, 11.5	

Table 10 — Optical radiation hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**I**	Optical radiation (IEV 731-01-03)	1 nm-1 mm wavelength	10.4, 10.5, 10.6, 10.7	
2.	**I**	Optical radiation	• Class 3B and 4 Lasers	60601-2-22	
3.	**I**	Optical radiation	• non-laser sources of 200 nm to 3,000 nm for non-visual photobiological effects	12.4.5.4, 62471; 60601-2-57 Need inexpensive way to exempt indicator lights	
4.	**I**	Optical radiation	• therapy and diagnosis equipment	12.4.5.4, 62471; 60601-2-75	

Table 11 — Ionizing radiation hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**J**	Ionizing Radiation (IEV 881-02-05)	Include X-ray, gamma and particle radiation	7.9.2.17, 10.2, 12.4.5	
2.	**J**	Ionizing Radiation	• radiation quality	[60601-1-3 7 except 7.2 which is moved to particulars]	
3.	**J**	Ionizing Radiation	• MEE/MES unintentional (include patient/operator radiation safety)	10.1.1, Parts of 10	
4.	**J**	Ionizing Radiation	• PPE for patient and user	new	

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
5.	**J**	Ionizing Radiation	• MEE/MES intentional (include patient radiation safety)	10.1.2, 12.4.5, Parts of 10 (10.2), [60601-1-3 Clause 4, (Clause 6 except 6.2.1, 6.2.2, 6.4, 6.5 & 6.7 that will go to the relevant particulars)];	

Table 12 —Electromagnetic exposure hazards

#	WG	WG Title	Areas of responsibility	3rd edition or other standard's clauses/subclauses (specified numbering)	New Clause #
1.	**K**	EM Radiation (Not Optical or Ionizing)	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	
2.	**K**	EM Radiation (Not Optical or Ionizing)	• functional connection intentional radiation (include human radiation safety, SAR, include DC magnetic fields)	New, IEEE C95.1, IEC 62209, IEC 62311	

Table 13 —Electromagnetic disturbances hazards

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

Annex A
Mapping of the goals of the Architecture Document to the implementation plan for the 4th edition

No.	Goal No.	Goal in 62/348/Q	Implementation in 60601-1 Ed. 4 project
1	1	Sharpen the focus on basic safety and essential performance	Cluster A and WG training
2	1.1	Clarify the basic safety and essential performance concept (specifications for design & type testing for a "product standard", Basic safety & Essential Performance in NC and SFC, not safety related aspects outside of the scope)	Cluster A and Handbook for WG convenors covering these aspects
3	1.2	Streamline the approach for safe use of new technologies (for non-patient related safety use of external IEC/ISO standards / collaboration with other TCs, for patient safety input from clinicians/manufacturers, process elements to be kept outside added to existing process standards)	Handbook for WG convenors covering these aspects “New” text needed in multiple clusters
4	1.3	Include protection goals (rationale) for each of the safety requirements (goals for each subclause at the beginning of the subclause entry in the informative annex with rationales where necessary for compliance criteria and selected test methods)	Protection goals and where appropriate rationales why the normative requirements support that goals shall be written in Annex A for at least each "first-level" sub-clause (i.e., subclause x.y) in the beginning of the text (see examples in 5.1.3.4 of 62/348/Q for an appropriate level of detail). The 62A review team that assists the consistent implementation of architecture and design spec will review this aspect before each document stage and can propose solutions to the corresponding WG, if necessary.
5	1.4	Include, where appropriate, explanatory rationale for test methods and the selected pass/fail criteria (especially where test methods / conditions or the pass/fail criteria do not obviously mirror the correlating technical requirements, to be included in the annexes)	
6	1.5	Justify changes, to make it clear, if they are improvements, safety gap closures or for other important reasons (e.g., changing technology) (project start: document with justification including information about gaps to be filled and new safety aspects and added value aspects for user groups and list of recommended changes for legacy devices; publication of the standard: publicly visible justification in IEC marketing information or in the standard foreword listing filled gaps, new safety aspects, added value for user groups and recommendations for legacy devices)	

No.	Goal No.	Goal in 62/348/Q	Implementation in 60601-1 Ed. 4 project
7	1.6	Improve the correlation between the IEC 60601 series, applicable ISO/IEC guides and process documents, including risk management, usability evaluations and software lifecycle process (base standard on ISO/IEC Guide 63, clarify normative references to process standards as specified in 5.1.6.2 of 62/348/Q for the scope section of IEC 60601-1)	
8	1.7	Establish a policy for using post-production information to review the standards (convenors / project leaders shall evaluate post-production information available e.g., on regulatory authority websites or specified in ISO/IEC Guide 63 and IEC Guide 104)	
9	1.8	Include where appropriate information to be communicated to support safe interoperability (in IEC 60601-1 inclusion of general safety requirements related to interoperability of MEE that are intended to support interoperability, inclusion of correlated IT security safety aspects, decision if to be included into the PEMS clause or a new clause)	
10	2	Reconcile requirements to a single statement	WG training
11	2.1	Understand the user need (each requirement to be placed into a uniquely identified paragraph)	
12	2.2	Utilize standardized file format (XML and other publication formats to support preparing standards with uniquely identified requirements)	
13	3	Simplify the structure of the IEC 60601 series	Cluster organization, integration of the collaterals
14	3.1	Integrate the collateral standards (integrate existing ones except for IEC 60601-1-9, retain collateral concept for urgently needed new safety aspects until next revision of the general standard but not reference the general standard or modify a requirement or test of the general standard)	
15	3.2	Rationalize the organization of the documents in the IEC 60601 series (retain basic clause / subclause structure where possible, establish rules for clause numbers of particular standards in IEC 60601-1, add general clauses behind clause 3 followed by technical clauses related to safety aspects, include all requirements related to a safety aspect ina single major clause, clause numbering in particular standards starting with 101, add reference no. for the revision like Ed. 4.0)	

No.	Goal No.	Goal in 62/348/Q	Implementation in 60601-1 Ed. 4 project
16	3.3	Reduce cross-referencing within parts of the IEC 60601 series (especially no cross-reference to an identifiable requirement or test method if it includes further cross references or includes more than a single testable requirement)	
17	3.4	Reduce referencing between parts of the IEC 60601 series (avoid references between the standards of the IEC 60601 series except of references from particulars to the general standard, no cross-references between particular standards if the referenced text includes further cross references or includes more than a single testable requirement)	
18	3.5	Streamline the use of terminology in the IEC 60601 series (establish a firm policy for creating/using defined terms in the 60601 series, include in 60601-1 only generally applicable terms, use them in particulars - if needed only with an additional adjective, no modification of those terms in collaterals which may be created in future)	
19	3.6	Reduce normative references to external standards (enhance usefulness by reduction of normative references without leaving gaps, replace them with precise informative references to exemplary external standards where possible as shown in 5.3.6.2.2 & 5.3.6.2.3 of 62/348/Q, integrate small sections - of max. one subclause - or description of tools into the standard with informative reference to the source, use normative references only for introduction of type testable requirements or specific test methods)	
20	3.7	Clarify the IEC/TC 62 policy for the use of dated and undated references (all normative references dated, amendments only if they modify the affected contents, state in each document that subsequent revisions of dated references standards can be accepted provided it is demonstrated that the affected hazard/ hazardous situation is also resolved adequately in the subsequent revision, acceptance of dated or undated informative references)	
21	4	Increase separation of type testing and process requirements	See example process standard reference

No.	Goal No.	Goal in 62/348/Q	Implementation in 60601-1 Ed. 4 project
22	4.1	Reduce process requirements in the IEC 60601 series to the extent feasible (collect process requirements in corresponding process standards and reduce them in type test standards)	
23	4.2	Clarify the application of ISO 14971 (risk management) in the IEC 60601 series (except of 4.3-4.9 in Ed. 3.2 of 60601-1, review all instructions using risk management process to see if replaceable with type tests, review type test requirements if they reflect an acceptable level of residual risk and are unambiguous with limits for measurable values or detailed description of required observable product behaviour), use of risk assessment output - outside of 4.3-4.9 - only when specific acceptance criteria cannot (yet) be identified, use of "maintain BS/EP" only for new technologies with a rationale in the annex)	
24	4.3	Clarify the application of IEC 62304 (PEMS, software) in the61 IEC 60601 series (clarify how type testing is applied on PEMS and medical software in ME systems, reduce SW process requirements in IEC 60601-1 by removing 14.1-14.12, retaining 14.13 or moving it to technical documentation section, include type test aspects of PEMS and SW in MES into type test clause 5, add iin the introduction clause as correlation of type test standards with process standards including IEC 62304)	
25	4.4	Clarify the application of IEC 62366-1(usability) in the IEC 60601 series (reference to IEC 62366-1 only in the general standard, only in the very first clauses like 4.2 of Ed.3.2 for risk management process, only addressing review of design output)	
26	5	Clarification of scope of the IEC 60601 series	See new scope and supporting definitions
27	5.1	Patients (especially particular standards need to identify in their scope coverage with respect to different patient groups and types of animals, with specific considerations in the main part for allowable values, IEC 60601-1 can also be used for some animals)	
28	5.2	Intended operators (consider the intended operator/user who can be a lay, a professional, a patient)	

No.	Goal No.	Goal in 62/348/Q	Implementation in 60601-1 Ed. 4 project
29	5.3	Medical environments (specify specific care environments, mainly "healthcare facilities" with subgroups "basic care, intermediate care, critical care" environments, "home" healthcare environment, "emergency" healthcare environment, "assisted living facilities")	
30	5.4	Medical systems, equipment, accessories, sub-assemblies, and components (define in IEC 60601-1: "component", "non-medical sub-assembly", "medical sub-assembly", "medical accessory", "associated part" as specified in 5.5.4.3 of 62/348/Q; consider them in the safety concepts; differentiate "normal use" during "operation", "service" and "any other" mode of use)	
31	5.5	Maintenance of medical electrical equipment/medical electrical systems – the lifecycle of safety (address aspects for maintaining MEE/MES during the lifecycle, especially in the accompanying documents)	
32	5.6	Concept to clarify medical electrical system requirements (overcome problems with unclear and mixed MEE/MES requirements, clearly segregate MEE requirements from MES requirements in all clauses; add a general requirement for MEE that is intended / optionally intended to be integrated into MES as listed in 5.5.6.4 of 62/348/Q including accompanying information about use of functional connections / environmental operating conditions / verification of distributable essential performance; include verification method for large systems or systems difficult to be tested as complete by practicable subgroup verification)	
33	5.7	Clarify the relationship between the terms IT-network, SIP/SOP, network/data coupling and functional connection (delineate those terms by appropriate more precise definitions, functional connection not only including but also covering data connections, SIP/SOP referring to data connections to equipment external of the MEE only, network/data coupling referring to data transfer to/from other equipment, IT-network used for a system of data-connected equipment)	
34	6	Establish a policy relating requirement of the IEC 60601 series to the IMDRF essential principles and labelling principles	Annex planned to support those mappings

No.	Goal No.	Goal in 62/348/Q	Implementation in 60601-1 Ed. 4 project
35	6.1	International Medical Devices Regulatory Forum (IMDRF) (decrease cost of gaining regulatory compliance and allow patient earlier access to new technologies in considering some of the IMDRF essential principles and labelling principles during standard development)	
36	6.2	Relationship to the essential principles and labelling principles of the IMDRF (include goals for coverage of the applicable IMDRF principles in the project document for each new/updated standard, include a statement in the introduction clause of the standard as given in 5.6.2.4 of 62/348/Q, add informative mapping annex like Annex B of 62/348/Q, indicate which IMDRF principles are covered by which requirement)	
37	7	Establish a policy for scheduled release and stability dates	Task of the TC and SC officers
38	7.1	Synchronize the release of the standards in the IEC 60601 series (establish lasting and stable rules & structures for synchronized release of standards in the IEC 60601 series, reference 62/348/Q and its stability policy / synchronized mode concept of 5.7 in the documents of the 60601 series)	
39	7.2	Address very urgent safety gaps (in very urgent safety gap cases, exception has to be confirmed by SC62A & TC62 with consultation of SC62B, 62C, 62D and a quick return to stability rules)	
40	8	Establish training for authors of documents developed by IEC/TC 62	Task of the editing team
41	8.1	Develop training modules (available for leaders and members of TC62 and its SC, its MTs; WGs, JWGs, member of ISO counterparts, National Committee members)	
42	8.2	Develop IEC 60601 series specific training (on the architecture for convenors and experts to become involved in the development of next ed. of IEC 60601 series, including the TC62 safety concept, the differences in the structure of next ed. of the series, the numbering structure, the relationship to other important IEC/ISO standards, the use of the IEC 60601 template, the relationship to IMDRF essential principles and possible use of input from regulatory bodies)	