INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ARCHITECTURAL SPECIFICATION FOR SAFETY STANDARDS OF MEDICAL ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEMS, AND SOFTWARE USED IN HEALTHCARE

Version 3.0

Remarks from the Secretariat:

For approval of this document see 62/350/RQ. The document was approved by a simple majority of P-Members.
Comments received are annexed at the end of this document.

2020-05-05
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CONTENTS

1 Scope

This document establishes an architectural concept for the IEC 60601 SERIES, which is a series of safety standards for medical electrical equipment, medical electrical systems and software used in healthcare.

This document is primarily intended to be used by:

a) those who prepare the design specification of the next edition[1] of the IEC 60601 SERIES, and

b) those who prepare standards for the design, installation, use, maintenance, refurbishment and repair of medical electrical equipment, medical electrical systems and software used in healthcare.

NOTE The architecture concept presented in this document is intended to apply not only to the next edition of the IEC 60601 SERIES but also to safety standards produced by IEC/TC 62, its subcommittees or liaisons.

2 Normative references

The following documents are referred to in the text in such a way that all or some of their contents constitute requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Directives Part 2, *Principles and rules for the structure and drafting of ISO and IEC documents*

ISO/IEC GUIDE 50, *Safety aspects – Guidelines for child safety in standards and other specifications*

ISO/IEC GUIDE 63, *Guide to the development and inclusion of safety aspects in International Standards for medical devices*

ISO/IEC GUIDE 71, *Guide for addressing accessibility in standards*

IEC GUIDE 104, *The preparation of safety publications and the use of basic safety publications and group safety publications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE The terms used in this document are defined hereafter. Terms defined in the IEC 60601 SERIES have not been used.

[1] The “next edition of the IEC 60601 SERIES” means the 4th edition of IEC 60601-1 and those publications of IEC or ISO based on and following the rules specified in the 4th edition of IEC 60601-1.

3.1
GENERAL STANDARD
Standard within the IEC 60601 SERIES covering safety aspects common to all medical electrical equipment and medical electrical systems

3.2
COLLATERAL STANDARD
Standard of the IEC 60601 SERIES covering safety aspects not addressed in the GENERAL STANDARD, common to a subgroup of or covering a specific aspect of medical electrical equipment and medical electrical systems

3.3
PARTICULAR STANDARD
Standard of the IEC 60601 SERIES specifying requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to specific types of medical electrical equipment and medical electrical systems

Note 1 to entry: For example, defibrillators or anaesthetic workstations.

3.4
IEC 60601 SERIES
set of publications of IEC or ISO based on, and following the rules specified in IEC 60601-1

Note 1 to entry: For historical reasons, some PARTICULAR STANDARDS based on IEC 60601-1 are numbered differently, such as:

IEC 80601-2-59, *Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*,

ISO 80601-2-12, *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators, and*

ISO 11197, *Medical Supply Units*

Note 2 to entry: IEC TR 60513:1994 clause 19.4 provides additional information.

3.5
AUTHORITY HAVING JURISDICTION
REGULATORY AUTHORITY
governmental agency or office assigned to oversee the regulation of a regulated product within a country, jurisdiction, or assigned territory

[SOURCE: ISO 16142-1:2016, 3.1]

3.6
ESSENTIAL PRINCIPLES
ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE
fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

3.7
LABELLING PRINCIPLES
fundamental high-level requirements specifying the general content and format of medical device and IVD medical device labelling in paper, electronic, or marking format

4 General concepts for the next edition of the IEC 60601 SERIES

4.1 The safety concept for the IEC 60601 SERIES

4.1.1 Correlation with documents internal and external to the IEC 60601 SERIES

The safety concept of the IEC 60601 SERIES mirrors the correlation between the requirements of:

a) the GENERAL STANDARD, which will include the formerly separate COLLATERAL STANDARDS;

b) the PARTICULAR STANDARDS;

c) process standards such as ISO 14971, IEC 62304, IEC 62366-1;

d) the ISO/IEC Guides.

4.1.2 Guidance on application of risk management

The safety concept includes guidance for the authors of type test standards (product standards) on how to apply the techniques of risk management and usability engineering. It also includes guidance on reducing the number of references to the risk management process in product standards. It is preferred that requirements in PARTICULAR STANDARDS are specific and measureable and only refer to the risk management process for issues such as “comparative safety” and “innovative technologies.” The GENERAL STANDARD should refer to the need for risk management, software lifecycle management and usability in a general clause.

NOTE A type test is a test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of the IEC 60601 SERIES.

The risk management process is used in addition to the requirements of the standard in order to address those hazards and hazardous situations that are associated with the medical electrical equipment but that are not completely addressed in the GENERAL STANDARD and the PARTICULAR STANDARDS. The risk management process is also used to justify alternative risk control measures (comparative safety) in accordance with 4.5 of IEC 60601-1:2005 + AMD1:2012.

4.1.3 Dealing with new technologies

For new technologies, the safety concept provides instruction on how to apply safety standards developed outside of the IEC/TC 62 responsibility in an appropriate way.

4.1.4 Dealing with different patient groups

As noted by the inclusion of IEC Guide 50 and IEC Guide 71, it is important that the next edition address any reasonably foreseeable risks of medical electrical equipment, medical electrical systems and software used in healthcare related to different patient groups like children, adults, or elderly persons. These concepts are mentioned in some parts of the IEC 60601 SERIES today. However, it is recognized that there can be areas where they should be more specifically addressed. See 5.5.1.

4.1.5 Incorporating the safety concept into the design specification for the next edition of the IEC 60601 SERIES

The complete safety concept will be part of the confirmed architecture for the IEC 60601 SERIES to define the design specification for the next edition of the IEC 60601 SERIES. Parts of the safety concept (overview of the correlations, instructions for application of type test standards to new technologies) might also become part of the introduction of IEC 60601-1.

4.2 Overview of the structure of the IEC 60601 SERIES

4.2.1 Overview of the architecture

The IEC 60601 SERIES is a collection of related documents developed by several IEC and ISO technical committees working independently or collaboratively through joint working groups.

The third edition of the IEC 60601 SERIES was based on an architecture described in IEC/TR 60513:1994 and illustrated in Figure 1.

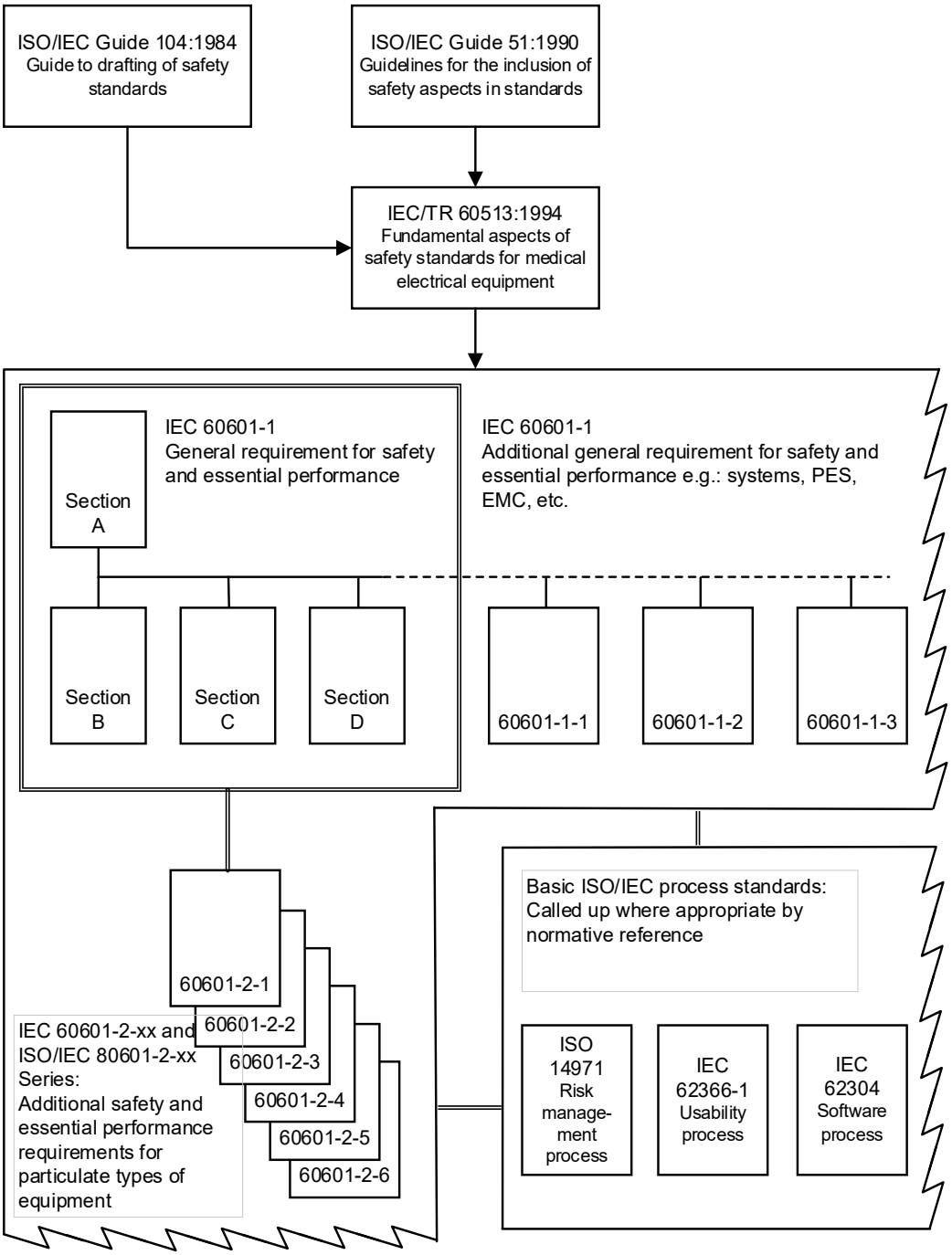
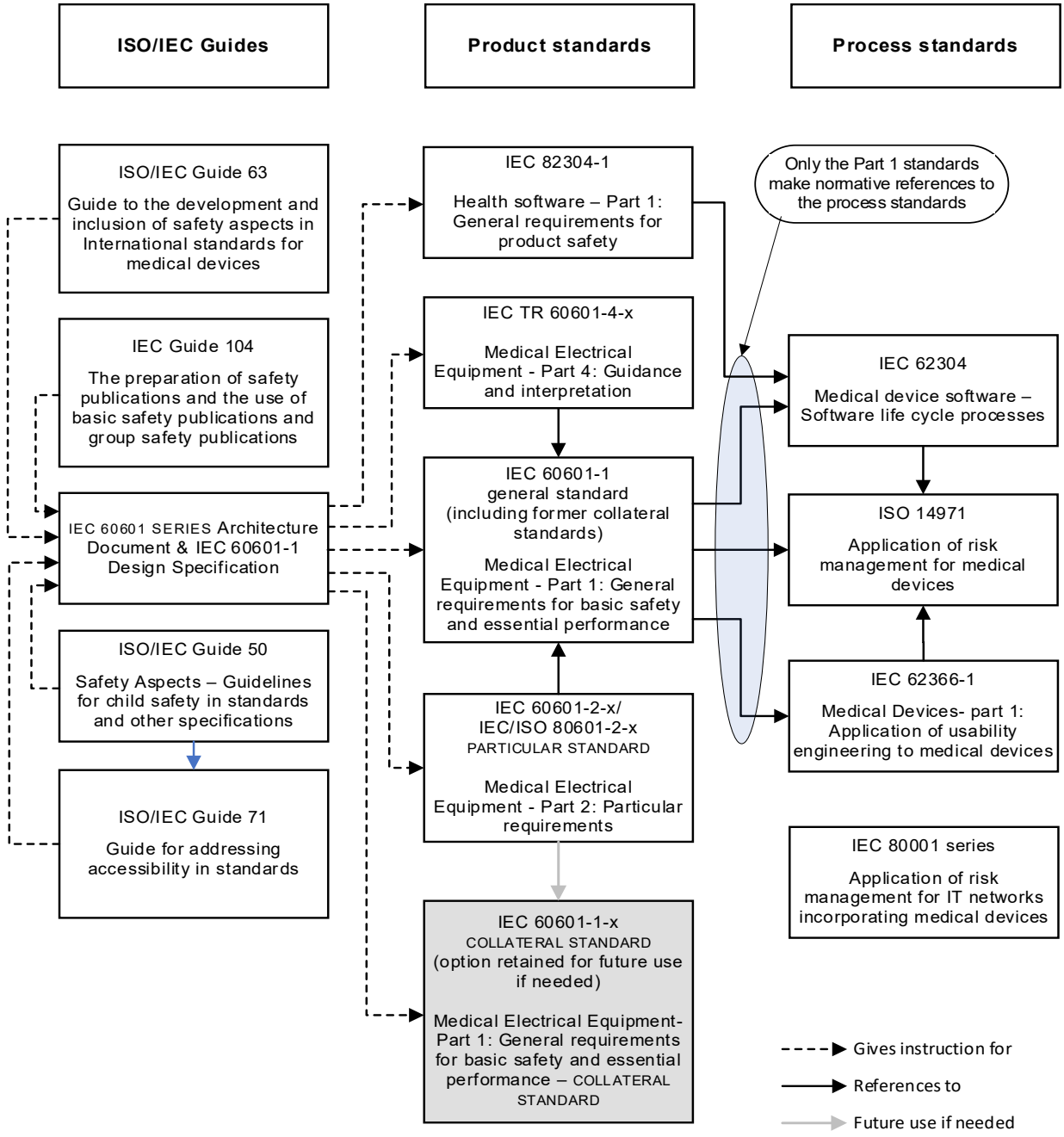


Figure 1 – Architecture of the third edition of the IEC 60601 SERIES

The IEC 60601 SERIES has grown to over 100 documents with interrelationships that makes them challenging for stakeholders to implement and makes ongoing maintenance difficult for the standards committees. The proposed streamlined architecture described in this document and

illustrated in Figure 2 is intended to help streamline the process of developing and maintaining standards in the next edition of the IEC 60601 SERIES as well as make the documents more user-friendly for the stakeholder communities.



NOTE Currently no link between IEC 60601 SERIES and IEC 80001 series exists; this could change in the future.

Figure 2 – Proposed streamlined architecture for the next edition of the IEC 60601 SERIES

IEC/TC 62 has established a set of high-level goals it expects to accomplish during the development of the design specification and subsequent implementation of the architecture illustrated in Figure 2. These goals are listed in Clause 5.

4.2.2 Processes within the IEC (and ISO) that impact the architecture implementation

IEC and ISO are jointly developing a new technology platform for creating, maintaining and publishing standards including a new online authoring tool to replace the usage of Microsoft

Word®. Undoubtedly there will be significant modifications to the drafting rules in the ISO/IEC Directives Part 2 and in the form in which deliverables (standards, amendments, technical reports, etc.) will be generated. It is anticipated that this new platform will be in full operation by the time work begins on implementing the architecture described in this document and will be used for drafting the next edition of the IEC 60601 SERIES.

Although many of the details are yet to be finalized, early indications are that the new platform will substantially alter the way technical committees work to create and maintain standards and other deliverables. The architecture described in this document anticipates some of the process changes based on early briefings that the leaders of IEC/TC 62 have received from IEC Central Office.

4.2.3 Organizational changes within IEC/TC 62 needed to implement the architecture

The processes in and structure of IEC/TC 62 need to be adapted to implement the architecture within the capabilities and limitations of the platform and drafting rules imposed by the IEC. The following organizational changes need to be implemented by IEC/TC 62 in order to develop publications in the IEC 60601 SERIES that are aligned with this architecture:

a) Establish an *ad-hoc* group to develop the format and text modules to be used in the standards to describe the alignment structure. These items can be made available at the IEC website and in the online authoring tool.

b) Establish an editing committee in IEC/TC 62 to monitor the documents in the IEC 60601 SERIES to ensure that they are in alignment with the architecture.

c) Establish an *ad-hoc* group to develop training for the technical experts writing the standards of the IEC 60601 SERIES. Such training can be made available at the IEC website.

5 Goals for the next edition of IEC 60601 SERIES

5.1 Goal 1—Sharpen the focus on basic safety and essential performance

5.1.1 Clarify the basic safety and essential performance concept

5.1.1.1 Safety is a constituent requirement on the design and use of medical electrical equipment, medical electrical systems and software used in healthcare.

5.1.1.2 The documents of the IEC 60601 SERIES address important aspects of safe design of medical electrical equipment, medical electrical systems and software used in healthcare, providing technical specifications for design and type testing as “product standards” (ISO/IEC Guide 63) in the GENERAL STANDARD and the PARTICULAR STANDARDS. Those aspects are “basic safety” and “essential performance.”

5.1.1.3 The term “basic safety” is the safety aspects related to physical hazards of the design, other than clinical functions, that need to be effective even in case of a single fault condition.

5.1.1.4 The term “essential performance” includes safety aspects of clinical functions that need to be effective even in case of a single fault condition.

5.1.1.5 In some documents of the IEC 60601 SERIES, e.g. in guidance documents, further aspects of design and use, such as effectiveness of clinical performance, can be addressed, as appropriate. This is what is meant when claiming a “focus” on basic safety and essential performance within the IEC 60601 SERIES. Further requirements, are, for instance, effectiveness of clinical performance, data protection, or environmentally conscious design. Those requirements are not necessarily related to safety and are outside the scope of the IEC 60601 SERIES, but can be considered in guidance documents or other standards.

5.1.2 Streamline the approach for safe use of new technologies

5.1.2.1 The sequence of assessments before publication or update of a standard of the IEC 60601 SERIES for medical electrical equipment or medical electrical systems involving new technologies, should utilize the following stages.

5.1.2.2 Assess the impact of the new technology on the safety of patients, operators, service personnel and bystanders in normal condition and single fault condition, including normal use and reasonably foreseeable misuse (assess impact on safety under aspects such as risk management, usability engineering).

5.1.2.3 For safety aspects related to operators, check which IEC or ISO safety standards (including those outside of the IEC 60601 SERIES) already include appropriate safety specifications.

5.1.2.4 If other IEC or ISO standards already include appropriate safety specifications for safety aspects related to operators, allow technical design solutions for medical electrical equipment, medical electrical systems and software used in healthcare based on any of the other IEC or ISO standards. For example, IEC 62368-1 is generally accepted as providing an appropriate level of safety for non-patient users of medical electrical equipment. Camera-based safety provisions might become another example.

5.1.2.5 Appropriate specifications for patient safety aspects should be evaluated carefully and sometimes require a higher degree of safety.

5.1.2.6 For safety aspects related to patients and operators for which no appropriate safety specifications in IEC or ISO standards yet exist, it is recommended to follow these steps:

1) For patient safety aspects, seek tight collaboration with clinicians to evaluate an appropriate acceptance level (not higher and not lower than necessary for safe use) and consult manufacturers of the new technologies to assess technical feasibility / practicability of new draft safety requirements.
2) Follow the applicable requirements of ISO/IEC Guide 63 when specifying additional product requirements in a clear and type testable way within the IEC 60601 SERIES, with testable acceptance criteria that are as specific as possible.
3) Seek additional collaboration with IEC/ISO standardization groups that work on safety specifications for the new technologies for users that are not patients.
4) If additional process requirements are really needed, check if they can be integrated into existing process standards outside of the IEC 60601 SERIES.

5.1.2.7 If there are more than one applicable safety standard, do not exclude one of them as being unsuitable for components. Medical electrical equipment, systems or software used in healthcare may be compliant with any one of these standards.

5.1.3 Include protection goals (rationale) for each of the safety requirements

5.1.3.1 Goals and rationales for each safety requirement need to be provided **f**or:

a) better understanding of each safety requirement;
b) better correlation with regulatory requirements;
c) better assessment of whether an alternative safety solution is satisfactory; and
d) better reviews to determine if the standard requirements still reflect the generally acknowledged state of the art.

5.1.3.2 More than one safety requirement can refer to the same protection goal. Assumptions why a requirement is sufficient to achieve a goal and evidence for it should be included in the rationales, as appropriate. Whether the best location for this is an informative annex, or whether such informative annex becomes a separate guidance document, may be decided separately, however, the preferred way is an informative annex in the same document. This is something that may be determined by the new online authoring tool capabilities.

5.1.3.3 Goals and rationales are informative and shall not contain a specific technical requirement. Also, they shall not conflict with the corresponding normative requirement. The informative text should primarily support the explanation of requirement goals, compliance criteria information and test method rationale.

5.1.3.4 In order to achieve the above consistently, start each subclause entry of Annex A (e.g., in IEC 60601-1 Annex A.4) that deals with a “requirement subclause” with a protection goal statement. The following are examples (here for IEC 60601-1 Annex A.4).

Example 1 Subclause 8.7, leakage currents and patient auxiliary currents:

> “The protection goal of this subclause is the limitation of electrical currents that may flow through the body of a patient, of an operator or through an operator and a patient in series in normal condition, single-fault condition and some foreseeable special conditions. The limits take into account that sometimes patients do not have intact skin or may even have invasive contact with parts of the electrical equipment and can sometimes not react to electrical currents in the way a healthy and awake person can.
>
> The limits for patients are categorized into different protection classes, applied parts B, BF, CF, each with or without defibrillation protection class. The limits for touch currents flowing through operators are specified lower than those in nonmedical safety standards because the operator, in a certain patient vicinity, can touch the medical equipment or system and the patient simultaneously, such that the current may flow via the operator to a patient, and operator and patient have to be protected together by appropriate touch current limits. The current limits are intended to ensure that the probability of:
>
> a) a ventricular fibrillation or pump failure is not increased to a higher probability than that for an everyday mechanical stimulation;
>
> b) a tissue necrosis by longer applied small currents is negligible; and
>
> c) a skin burn is also negligible.
>
> For more details, see additional explanations for subclause 8.7.3.”

Example 2 Subclause 12.4.3 Accidental selection of excessive output values:

> “The protection goal of this subclause is a sufficient protection against excessive (too low, too high) output values that might be hazardous for patients, operators or bystanders, when selected accidently by use error.”

5.1.4 Include, where appropriate, explanatory rationale for test methods and the selected pass/fail criteria

5.1.4.1 Test methods are specified, as appropriate, in order to get reproducible, undisputable results for the verification of design related to safety. Reproducible test results can require test conditions that differ from real use scenarios and may include a “worst case” scenario. Therefore, it is not always obvious to the reader why certain test methods have been selected in the documents of the IEC 60601 SERIES. Consequently, it might become difficult in certain cases for users of the documents to judge if a selected test condition or test setup really mirrors the intent of a technical requirement.

5.1.4.2 For improved usability, the documents of the IEC 60601 SERIES shall include an explanatory rationale for specified tests methods and pass/fail criteria, where appropriate. Appropriate means the reader should understand in short sentences the idea of the test concept and acceptance criteria but not all details that are typically known to skilled testing experts. They should understand how a test method contributes to achieving conformance with the test requirement.

5.1.4.3 The rationale(s) are mainly to be addressed in the annexes of the document, in order to keep the normative sections with technical requirements and compliance paragraphs as slim as possible.

5.1.5 Justify changes, to make it clear, if they are improvements, safety gap closures or for other important reasons (e.g., changing technology)

5.1.5.1 Changes to all deliverables (standards, technical reports or technical specifications) or new work items should always add value for the user of the IEC/TC 62 documents by maintaining a clear focus on basic safety and essential performance.

5.1.5.2 Each additional requirement creates additional effort and cost, which eventually ends up being passed on either directly to the patient or to healthcare funders, health insurances and their members.

5.1.5.3 Increasing cost for medical electrical equipment and medical electrical systems have a direct impact on the availability of such equipment and systems around the world, especially in developing countries.

5.1.5.4 The following information should be included in the justification section of the new work item proposal or whatever document is used to authorize work on the proposed revision of a standard:

a) The important basic safety or essential performance gap(s) that are intended to be closed with the specific change or addition, including revised normative references to standards.

b) The important new identified hazardous situations that are intended to be covered by the specific change or addition, including revised normative references to standards.

c) An indication and explanation of the added value of those changes and additions for the users of the documents, such as test houses and manufacturers, which includes for example:

   1) for reading, understanding and identifying affected medical electrical equipment, medical electrical systems and software used in healthcare;

   2) for design change of each affected medical electrical equipment, medical electrical system and software used in healthcare;

   3) for updating technical documentations for each affected medical electrical equipment, medical electrical system and software used in healthcare;

   4) for testing, verification, validation and release of each affected medical electrical equipment, medical electrical system and software used in healthcare;

   5) for updating of each affected IEC test report; or

   6) for medical device notification or registration-update worldwide of each affected medical electrical equipment, medical electrical system and software used in healthcare.

d) A list of recommended changes that are deemed basic safety and essential performance gaps for legacy products (i.e., for products completely designed before publication of the revised standard and verified based on the preceding edition or revision of the standard).

5.1.5.5 The officers of the respective drafting committees shall ensure that this information is introduced into the cover page or in an additional annex of the proposal.

5.1.5.6 A summary of the justification should also be provided to the users of the IEC 60601 SERIES (manufacturer, testing institutes, national authorities, etc.) in the IEC marketing form and in the introduction or foreword of the published version of each standard, to ensure that the users have a better understanding of the intention of the new or revised standard.

5.1.5.7 The summary should include:

a) the important basic safety or essential performance gap(s) that have been closed;

b) the important new identified hazardous situation(s) that have been addressed;

c) an explanation of the added value in relation to additional effort and costs; and

d) an identified list of recommended changes that are deemed basic safety and essential performance gaps for legacy products (i.e., for products completely designed before publication of the revised standard and verified based on the preceding edition or revision of the standard).

5.1.6 Improve the correlation between the IEC 60601 SERIES, applicable ISO/IEC guides and process documents, including risk management, usability evaluations and software lifecycle process

5.1.6.1 ISO/IEC Guide 51 [8] was the base for the development of the third edition of IEC 60601-1 (see Figure 1). The next edition of IEC 60601 SERIES will be based on ISO/IEC Guide 63, which is specifically developed to adapt ISO/IEC Guide 51 to the needs of the medical device sector (see Figure 2).

5.1.6.2 The GENERAL STANDARD will normatively refer to the process standards in Figure 2. The following additional clarification should be introduced into the Scope clause of IEC 60601-1:

> "For application of all standards of the IEC 60601 SERIES, it is anticipated that the manufacturer has implemented and follows the process standards ISO 14971, IEC 62304 and IEC 62366-1. However, these process standards are not part of type tests within IEC 60601 SERIES. If the output of those processes is used to demonstrate compliance with IEC 60601 SERIES, that specific output (not the processes according to ISO 14971, IEC 62304 and IEC 62366-1) are part of type tests within the IEC 60601 SERIES."

5.1.7 Establish a policy for using post-production information to review the standards

5.1.7.1 The project leaders and conveners of documents of the IEC 60601 SERIES shall evaluate public post-production information (feedback loop) for new or revised documents within the IEC 60601 SERIES.

5.1.7.2 Several REGULATORY AUTHORITIES provide public post-production information as safety medical alerts. This information should be used to review the safety impact on the existing medical standard. Medical alerts or voluntary recalls could also be used to address the hazards found in the medical field. These are helpful to identify new safety information sometimes not addressed or adequately addressed in existing standards.

5.1.7.3 Links to REGULATORY AUTHORITY websites where references can be found are listed in the bibliography:

a) U.S. FDA, MedWatch, Safety Alerts for Human Medical Products [11], [12], [13].

b) Health Canada - Advisories, Warnings and Recalls – Drugs and health products [16].

c) European Safety Alerts for Medical Devices (exemplarily) [9], [14], [15], [19], [21].

d) Therapeutic Goods Administration (TGA), Australia, Safety Information of Medical Devices (including newsletter), Adverse Events & Recall [22], [23], [24], [25].

The above list of examples is not complete. Other sources can also be used. Further sources might be the US Consumer Product Safety Commission (CPSC) or European Rapid Information Exchange System for Products (RAPEX).

5.1.7.4 ISO/IEC Guide 63 and IEC Guide 104 give additional general instruction on how to deal with post-production information.

5.1.8 Include where appropriate information to be communicated to support safe interoperability

5.1.8.1 Interoperability requires medical electrical equipment to be capable of exchanging data and/or control functionality with other medical or non-medical equipment or systems. In many cases, it requires the capability to exchange data and/or control functionality with equipment not originally known to the manufacturer of the medical electrical equipment or medical electrical system. Therefore, safety aspects of interoperability shall be taken into account in the design of medical electrical equipment that are intended to support interoperability. A concept of safe interoperability also includes aspects of IT security, as far as they contribute to safety.

5.1.8.2 In the architecture of the IEC 60601 SERIES, the GENERAL STANDARD shall address the general safety requirements for this feature, based on already available standards and

documents for communication of medical devices, such as ISO/IEEE 11073, while the PARTICULAR STANDARDS should add specific safety aspects, where applicable.

5.1.8.3 Writers of the GENERAL STANDARD should determine if those aspects are to be included into the clause for PEMS, or if a new clause is required.

5.2 Goal 2—Reconcile requirements to a single statement

5.2.1 Understand the user need

Users of the standard need to be able to identify and uniquely reference each individual requirement in the standard. Therefore, each requirement shall be placed into a uniquely identified paragraph of the standard.

NOTE See Annex A for a checklist of requirement attributes.

5.2.2 Utilize standardized file format

XML and other possible publication formats of IEC publications will be provided by IEC and facilitate the goal of preparing standards with uniquely identified requirements.

5.3 Goal 3—Simplify the structure of the IEC 60601 SERIES

5.3.1 Integrate the COLLATERAL STANDARDS

5.3.1.1 The COLLATERAL STANDARD concept

The concept of COLLATERAL STANDARDS was introduced in 1997 shortly after the publication of the second amendment to IEC 60601-1:1988 and was carried forward into IEC 60601-1:2005. COLLATERAL STANDARDS were intended to specify basic safety and essential performance requirements applicable to:

– a subgroup of medical electrical equipment (e.g., radiological equipment and equipment utilizing physiological closed loop control); or

– for medical electrical systems; or

– a specific characteristic of medical electrical equipment not fully addressed in the GENERAL STANDARD (e.g., electromagnetic disturbances, programmable electrical medical systems (PEMS), usability and alarms).

Following the publication of IEC 60601-1:2005, the application of COLLATERAL STANDARDS expanded to include:

– use environments not fully addressed in the GENERAL STANDARD (e.g., the home healthcare environment and the emergency medical services environment); and

– ancillary functions related to the design of medical electrical equipment (e.g., environmentally conscious design).

A total of ten COLLATERAL STANDARDS have been published by IEC/TC 62. Two COLLATERAL STANDARDS (IEC 60601-1-1 and IEC 60601-1-4) were withdrawn after their technical content was incorporated into IEC 60601-1:2005.

An approach to publishing separate documents for basic safety and essential performance requirements applicable at the "GENERAL STANDARD" level was thought to be efficacious in that it would:

– allow development of new requirements to address a specific need more quickly that revising the GENERAL STANDARD; and

– permit more frequent revisions to accommodate changes in technology.

Experience since the publication of IEC 60601-1:2005 has shown that while the concept of COLLATERAL STANDARDS met the original design intention, the approach has generated significant

challenges for stakeholders as well as the technical committees charged with developing PARTICULAR STANDARDS. Publishing the documents on different schedules and at different revision levels has led to confusion among the stakeholders as to which version of a COLLATERAL STANDARD applies at any moment in time. Similarly, those committees responsible for developing PARTICULAR STANDARDS struggled to keep up with a “platform” consisting of nine documents each on its own revision schedule.

5.3.1.2 Integrate the existing COLLATERAL STANDARDS

5.3.1.2.1 IEC/TC 62 decided at the Kobe meeting in 2015 that the GENERAL STANDARD and the COLLATERAL STANDARDS would be placed on a common maintenance schedule beginning with Amendment 2 to IEC 60601-1:2005. The intent is to publish any revisions to the GENERAL STANDARD and the COLLATERAL STANDARDS on the same date or as close as feasible given any constraints imposed by the IEC process.

5.3.1.2.2 Given the Kobe decision, the perceived benefits of the approach to publishing separate documents have largely disappeared. Therefore, the existing COLLATERAL STANDARDS, except for IEC 60601-1-9 which deals with environmentally conscious design, will be integrated with the next edition of the GENERAL STANDARD. The contents of IEC 60601-1-9 will be transferred to a new document within the scope of IEC/TC 62 but outside the IEC 60601 SERIES.

5.3.1.3 Retain the COLLATERAL STANDARD concept

5.3.1.3.1 The possibility of developing a new COLLATERAL STANDARD will be retained within the architecture so a medium is available if National Committees agree there is an urgent need to address some new aspect of basic safety and essential performance between revisions of the GENERAL STANDARD. It is anticipated that any COLLATERAL STANDARDS would be incorporated into the GENERAL STANDARD at the next revision.

5.3.1.3.2 However, when a requirement or test is covered in the GENERAL STANDARD it should not be addressed in a COLLATERAL STANDARD, i.e. neither referenced nor modified, and vice versa.

5.3.2 Rationalize the organization of the documents in the IEC 60601 SERIES

5.3.2.1 Internal structure

Modifying the internal structure of the IEC 60601 SERIES has a significant impact on all the stakeholders and involves modifications of PARTICULAR STANDARDS. Therefore, the intent is to retain the existing basic clause/subclause structure to the extent possible while addressing the other high-level goals.

5.3.2.2 Numbering of documents in the IEC 60601 SERIES

5.3.2.2.1 The GENERAL STANDARD and any future COLLATERAL STANDARDS are developed in IEC/TC 62 or its subcommittees.

5.3.2.2.2 Publications developed in IEC committees are numbered “IEC 60601-x-y”.

5.3.2.2.3 Publications developed jointly by IEC and ISO committees are numbered “IEC 80601-x-y”, if under IEC technical lead, or “ISO 80601-x-y”, if under ISO technical lead.

5.3.2.3 Numbering of clauses within the GENERAL STANDARD

5.3.2.3.1 The GENERAL STANDARD will establish the rules for clause numbers in the IEC 60601 SERIES.

5.3.2.3.2 The structure and contents of introductory Clauses 1, 2 and 3 shall follow the outline specified in the ISO/IEC Directives, Part 2.

5.3.2.3.3 The introductory clauses will be followed by one or more general clauses specifying requirements that are applicable to all medical electrical equipment or medical electrical systems (e.g., basic conditions, requirements for testing, classification, etc.).

5.3.2.3.4 The general clauses will be followed by technical clauses related to aspects of basic safety or essential performance (e.g., electrical safety, mechanical safety, etc.). To the extent possible, all requirements related to an aspect will be kept in a single major clause. For example, all electrical safety requirements for medical electrical equipment will appear in the same major clause.

5.3.2.4 Numbering of clauses within PARTICULAR STANDARDS

5.3.2.4.1 PARTICULAR STANDARDS refer to clauses of the GENERAL STANDARD using the clause number of the GENERAL STANDARD.

NOTE Because it is intended to integrate COLLATERAL STANDARDS into the GENERAL STANDARD, PARTICULAR STANDARDS will no longer need numbers such as 201, 202, 203. etc. to differentiate between clauses in the GENERAL STANDARD and those in the COLLATERAL STANDARDS.

5.3.2.4.2 PARTICULAR STANDARD clauses that are in addition to those of the GENERAL STANDARD shall be numbered starting with 101 and continuing with 102, 103, etc**.**

5.3.2.5 Reference number to assist identification of revisions

In the header of the GENERAL STANDARD and each PARTICULAR STANDARD, a reference number can assist to identify the associated revisions of the different parts of these standards.

EXAMPLE For next edition beginning 2024 or later:

– IEC 60601-1: Identifier 4.0 relates to Edition 4, identifier 4.1 relates to Edition 4 with Amendment 1.

– The Introduction and Clause 2 of each PARTICULAR STANDARD shall explain which edition of the GENERAL STANDARD it includes.

5.3.3 Reduce cross-referencing within documents of the IEC 60601 SERIES

5.3.3.1 Cross-referencing within a document can diminish readability and increase complexity. At worst, cross-referencing can result in cascading of cross-references leading to circular requirements. On the positive side, judicious cross-referencing can reduce duplication and prevent different parts of a document from applying divergent requirements/test methods to the same hazard or hazardous situation.

5.3.3.2 A cross-reference to an identifiable requirement or test method shall not be made, unless:

a) the referenced text includes a single testable requirement; and

b) the referenced text does not include any further cross references (prevent reference cascades).

5.3.4 Reduce referencing between documents of the IEC 60601 SERIES

5.3.4.1 References between documents of the IEC 60601 SERIES should be avoided. References from PARTICULAR STANDARDS to the GENERAL STANDARD (and to optional future COLLATERAL STANDARDS) are permissible.

5.3.4.2 References between PARTICULAR STANDARDS shall not be made, unless:

a) the referenced text includes a single testable requirement; and

b) the referenced text does not include any further references (to prevent reference cascades).

5.3.5 Streamline the use of terminology in the IEC 60601 SERIES

5.3.5.1 Rationalize the terminology used in the IEC 60601 SERIES

The rational use of defined terms within the IEC 60601 SERIES can improved the overall usability of the series. In some cases, the current parts of the IEC 60601 SERIES use common terms but assign different or additional meanings. For the next edition, a goal is to improve consistency by establishing a firm policy for creating and using defined terms.

5.3.5.2 Establish a policy for creating and using defined terms

5.3.5.2.1 The GENERAL STANDARD establishes the defined terms in a generic way to cover the whole field of medical electrical equipment and medical electrical systems. Terms that are not generally applicable should be avoided.

5.3.5.2.2 PARTICULAR STANDARDS will use defined terms from the GENERAL STANDARD that are applicable for their field of application without modification. If needed, an additional adjective may be used followed by the defined term. PARTICULAR STANDARDS can add additional definitions for their field of application. However, every effort should be made to use existing definitions from similar PARTICULAR STANDARDS when they are appropriate.

5.3.5.2.3 If COLLATERAL STANDARDS are created in the future, they can define terms within their specific field of application. COLLATERAL STANDARDS shall not modify definitions from the GENERAL STANDARD and shall not use unique definitions from PARTICULAR STANDARDS.

5.3.6 Reduce normative references to external standards

5.3.6.1 Normative references

5.3.6.1.1 A normative reference is created when an external standard is cited in the text of a document in such a way that some or all of that standard's content constitutes requirements of the document. For the convenience of the document user, all normative references are listed in Clause 2. However, it is how the standard is cited in the body of the document that makes it normative. Clause 15 of the ISO/IEC Directives, Part 2:2018 specifies the minimum rules for normative reference clause.

5.3.6.1.2 A normative reference is usually made to a document published by IEC or ISO. However, in the absence of an appropriate IEC or ISO document, those published by other bodies may be listed as a normative reference provided the five conditions specified in 10.2 of the ISO/IEC Directives, Part 2:2018 have been met. The complete citation of any normative reference is included in Clause 2 of the document.

5.3.6.1.3 The current IEC 60601 SERIES makes extensive use of normative references. Some stakeholders have suggested the usefulness of the series would be enhanced by reducing the number of normative references to some practical minimum without leaving gaps in the IEC 60601 SERIES. For details, see 5.3.6.2 to 5.3.6.4.

5.3.6.2 Informative references

5.3.6.2.1 An informative reference, such as would appear in a note or in an informative annex, directs the user to pertinent information intended to assist in the understanding or use of the document. An informative reference cannot provide information that is essential to the application of a document. An informative reference can be made to any type of document and may either be dated or undated (see 5.3.7). As with normative references, informative references shall be precise. The complete citation for any informative reference is listed in the Bibliography.

5.3.6.2.2 Where the reference is used to establish a specific safety requirement, the safety requirement shall be stated and an informative reference to at least one appropriate external standard shall be provided.

EXAMPLE

"Opto-couplers complying with an appropriate international safety standard are considered equivalent to solid insulation which forms supplementary insulation or reinforced insulation.

NOTE See IEC 60747-5-5."

5.3.6.2.3 Where the external standard is used to establish a general requirement where conformance cannot be verified within the constraints of a type test, the requirement should be stated in non-specific terms and an informative reference to one or more appropriate external standards provided.

EXAMPLE

"The MANUFACTURER shall assess and document the biocompatibility of ME EQUIPMENT and their parts or ACCESSORIES intended to come into contact with biological tissues, cells or body fluids using an appropriate method.

NOTE See ISO 10993-1 for general principles governing the biological evaluation of medical devices within a risk management process.

Conformance is checked by inspection of the documentation required by the method selected by the MANUFACTURER."

5.3.6.3 Include the relevant concept from the referenced standard

Small sections from the external standard should be integrated into the IEC 60601 SERIES document. The integrated text should generally be limited to not more than one subclause from the external standard. Where the purpose of the reference is to describe a single fixture, jig, or tool (e.g., the standard test finger), the information can be integrated into the IEC 60601 SERIES document. The source of the material can be cited as an informative reference in a note.

5.3.6.4 Use normative references to introduce testable requirements

Normative references should only be used to introduce a type testable requirement or a specific test method into IEC 60601 SERIES documents.

EXAMPLE

"PATIENT-COUPLED cables shall be considered interconnecting cables in accordance with the requirements of CISPR 11:2015."

5.3.7 Clarify the IEC/TC 62 policy for the use of dated and undated references

5.3.7.1 Normative reference

5.3.7.1.1 It is the policy of IEC/TC 62 that all normative references shall be dated.

5.3.7.1.2 When constructing a dated reference to specific elements in a standard, such as definitions, an amendment is only referenced if the amendment modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

5.3.7.1.3 Subsequent revisions (new editions or amendments) can be accepted in substitution of the referenced document provided the manufacturer can demonstrate the hazard or hazardous situation addressed in the normative reference is adequately resolved in the subsequent revision. This allowance has to be stated in all applicable documents of the IEC 60601 SERIES so that it is known to the readers of the document.

5.3.7.2 Informative reference

Informative references may be dated or undated as seem most appropriate in a given circumstance.

NOTE Subclause 10.5 of the ISO/IEC Directives, Part 2:2018 requires that a reference to specific elements (e.g., clauses or subclauses, tables and figures) is a dated reference.

5.4 Goal 4—Increase separation of type testing and process requirements

5.4.1 Reduce process requirements in the IEC 60601 SERIES to the extent feasible

The objective of this goal is to reduce the process requirements in the type test standards of the IEC 60601 SERIES and collect them in process standards (in particular, ISO 14971, IEC 62304 and IEC 62366-1).

5.4.2 Clarify the application of ISO 14971 (risk management) in the IEC 60601 SERIES

5.4.2.1 General approach to applying risk management in the IEC 60601 SERIES

5.4.2.1.1 Risk management is an essential aspect of product development. The approach described in this document does not replace risk management for risks not addressed in the IEC 60601 SERIES. It also cannot replace risk assessment and risk control if a manufacturer chooses alternative risk control measures. Risk management is also needed for new technologies for which the experts in a standard committee have not yet established adequate requirements and/or testable pass / fail criteria. The technical requirements in the IEC 60601 SERIES provide state-of-the-art solutions that achieve acceptable residual risks. As such, the results of applying the IEC 60601 SERIES will feed into the risk management process of ISO 14971 in a similar way as the usability engineering process of IEC 62366-1.

5.4.2.1.2 When establishing acceptance criteria for type tests, the experts preparing the standard are expected to follow the risk-based approach for developing standards set out in ISO/IEC Guide 63. The type test requirements in the IEC 60601 SERIES will then reflect having achieved an acceptable level of residual risk that is consistent with having applied generally acknowledged state of the art risk control measures related to the specific aspects addressed in the IEC 60601 SERIES.

5.4.2.2 Applying risk management with type testing

5.4.2.2.1 The requirements in the IEC 60601 SERIES are safety related product requirements. Ideally, evidence of conformance to a standard is provided by a type test. The type test consists of one or more individual tests in a specified order, according to specified test methods and with specified acceptance criteria. The requirements can be considered as state-of-the-art solutions and compliance with the type tests can be considered to achieve acceptable residual risk, unless there is objective evidence to the contrary.

5.4.2.2.2 In most cases, the goal is to specify compliance criteria for type tests that are unambiguous with either:

a) limits with measurable values, or

b) a detailed description of observable product behaviour.

5.4.2.2.3 In some cases, the acceptance criteria can only refer to specific hazardous situations that are intended not to arise during or after performing the specified tests, (i.e., simulation of rough handling or single fault conditions). This is not the preferred method to specify the type test acceptance/compliance criteria. However, at the time of publication, it has not always been possible for the experts developing standard in the IEC 60601 SERIES to specify limits or provide a detailed description of acceptable product behaviour.

5.4.2.2.4 In all cases, the requirement should be clear about the hazard and hazardous situation that is being addressed in combination with what is expected (not) to occur.

5.4.2.3 Applying risk management when acceptance criteria cannot be identified

5.4.2.3.1 Clauses in the standards of the IEC 60601 SERIES that cannot provide specific acceptance test limits and performance criteria may rely on assessment of outputs from the ISO 14971 risk management process as the compliance criteria. However, references to risk management process outputs should be reduced as far as practicable. For example, if the occurrence of a specific failure mode results in an unacceptable risk. Addressing these outputs is less clear than a specific type test. However, they do provide evidence that the manufacturer has considered the hazardous situation and taken steps to reduce the risk(s). Manufacturers

and applicable REGULATORY AUTHORITIES can then make a reasoned assessment of the risk reductions implemented in the product design.

5.4.2.3.2

The requirement to "maintain basic safety and essential performance" should be clearly explained in the rationale and should only be used for new technologies for which

a) a test method or acceptance criteria cannot be specified; or

b) the technology is so product specific that the IEC 60601 SERIES cannot specify a ~~specific~~ test method and acceptance criteria.

When possible, future revisions should replace these requirements with specific type tests and acceptance criteria.

5.4.2.4 Specific guidance for the next edition of IEC 60601-1

5.4.2.4.1 The requirement for a risk management process and the reference to unacceptable risk in the general clause (Clause 4 of IEC 60601-1:2005) are acceptable in principle. However, compliance statements will require updating to implement the goals of this document. References to risk management and unacceptable risks in Subclause 4.3 to 4.9 of IEC 60601-1:2005 are considered appropriate, but compliance statements will require updating to implement the goals of this document.

5.4.2.4.2 Instructions to address a particular risk using the risk management process with references to unacceptable risk need to be reviewed throughout the standard to see if they can be replaced with a type tests in line with 5.4.2.2.

5.4.3 Clarify the application of IEC 62304 (PEMS, software) in the IEC 60601 SERIES

5.4.3.1 **General approach to applying software process requirements in the IEC 60601 SERIES**

The next edition of the IEC 60601 SERIES needs to clarify how type testing will be applied to programmable electrical medical systems (PEMS) and medical software designed to operate on general computing platforms, e.g., in medial electrical systems.

5.4.3.2 Specific guidance for the next edition of IEC 60601-1

The following are examples of options to reduce software process requirements in IEC 60601-1:

a) Add to the introduction clause of IEC 60601-1, a general overview about the correlation of type test standards within the IEC 60601 SERIES with process standards including software lifecycle processes in IEC 62304.

b) Remove subclauses 14.1 to 14.12 from IEC 60601-1:2005. Subclauses 14.2 to 14.12 exclusively include process related aspects by citing IEC 62304 (aspects already covered by IEC 62304) or quoting a validation process (14.11). Subclause 14.1 can be removed because it only includes two references of:

   - 14.2 to 14.12 (which will be removed) and
   - 14.13 (the reference is not needed any longer when 14.2 to 14.12 are removed).

c) Retain the current subclause 14.13 with type testable requirements (clear technical description requirements, not process requirements) within Clause 14, or move it to subclause 7.9.3 ("Technical description") or, if operator related, to subclause 7.9.2.

d) Include type testable parts of the PEMS validation (subclause 14.11). PEMS validation into Clause 5 of the GENERAL STANDARD, as this is a general task and can be done only with the complete product combining the embedded software with its hardware environment.

5.4.4 Clarify the application of IEC 62366-1(usability) in the IEC 60601 SERIES

5.4.4.1 General approach to applying usability process requirements in the IEC 60601 SERIES

IEC 62366-1 as a process standard should be referenced only in IEC 60601-1, and only in the very first clauses, only addressing review of design output of the usability process where needed for compliance.

5.4.4.2 Specific guidance for the next edition of IEC 60601-1

5.4.4.2.1 Clauses 4 and 5 of IEC 60601-1:2005 and AMD1:2012 and AMD2:— on usability engineering need to be incorporated into a new subclause 4.x in the next edition of the IEC 60601 SERIES referring to IEC 62366-1 directly, in a similar construction as 4.2 of IEC 60601-1:2005 and AMD1:2012 and AMD2:— relating to risk management and referring to ISO 14971. Some defined terms may need to be incorporated as well.

5.4.4.2.2 References to IEC 60601-1-6 occur in Clauses 2, 7.9.1, 12.2, 15.1 and Annex A.4 (on 1.3, 7.9.2.1, 12) of IEC 60601-1:2005 and AMD1:2012 and AMD2:—.

5.4.4.2.3 References to IEC 62366 occur in Clauses 3.136, 3.137, 3.146, 3.147 and Annex A.4 (on 11.6.3) of IEC 60601-1:2005 and AMD1:2012 and AMD2:—. Reference needs to be included in the Bibliography (this was erroneously not included in Amendment 1:2012).

5.5 Goal 5—Clarification of scope of the IEC 60601 SERIES

5.5.1 Patients

In the current edition, patients include animals. Because of the large range of dimensions, weight and physiological vital signs of patients (including human beings: adult, elderly, adolescent, children, infants, neonates, and premature babies and different types of animals), PARTICULAR STANDARDS need to identify their coverage with respect to patients (e.g., human beings of specific age groups, sex, ethnicity, size (anthropometry) and strength (biomechanics), and different types of animals) in their scope. Considerations include allowable maximum temperature, mechanical pressure, or contacted tissues. Internal tissues are more sensitive than the skin surface.

NOTE IEC 60601-1 can be used for some animals, e.g., veterinarian medical electrical equipment or medical electrical system.

5.5.2 Intended operators

The intended operator or user (lay, professional) needs to be considered. The patient can be the operator. The term “operator” is currently used in the IEC 60601 series, while other standards use the term “user”.

5.5.3 Medical environments

5.5.3.1 Medical electrical equipment or medical electrical systems are used in different types of medical environments. The IEC 60601 SERIES, especially the PARTICULAR STANDARDS should use the following specific environments in which different types of medical electrical equipment or medical electrical systems are used.

NOTE Understanding the medical environments will help medical manufacturers to design medical electrical equipment and systems in accordance with the intended medical environment usage. This will ensure the appropriate scaling (up/down) of the functions and features of the medical electrical equipment / medical electrical system as per the specific medical environment.

EXAMPLE

> “A medical electrical equipment bed intended to be used (designed) for a basic care environment would not have the CPR and Trendelenburg features and functions, while a medical electrical equipment bed intended to be used (designed) for a critical care environment would.”

5.5.3.2 **Healthcare facilities**— Some standards in the IEC 60601 SERIES distinguish between patient care environments. The following are examples:

NOTE In North America, these medical environments are defined in NEC/CEC NFPA99 [20] and CSA Z32 [10]. Other regions can distinguish different medical environments.

5.5.3.2.1 Basic care environment—a patient care environment where body contact between a patient and medical electrical equipment is neither frequent nor usual.

EXAMPLE

- patient examination rooms;
- patient rooms in a long-term care facility; and
- patient rooms in general, specialty, and rehabilitation hospitals where body contact between a patient and medical electrical equipment is neither frequent nor usual.

5.5.3.2.2 Intermediate care environment—a patient care environment where body contact between a patient and medical electrical equipment is frequent or normal.

EXAMPLE

- Treatment wards and examination rooms in general, specialty, and rehabilitation hospitals;
- renal dialysis units;
- areas for non-invasive electrodiagnosis (ECG, EEG, EMG);
- patient preparation areas;
- physiotherapy departments;
- ultrasound suites;
- dental clinics;
- chiropractic clinics;
- physicians' offices; and
- patient bedrooms.

5.5.3.2.3 Critical care environment—a patient care environment where the induction and maintenance of general anaesthesia routinely occurs in connection with the examination or treatment of patients, or where cardiac contact between a patient and medical electrical equipment is frequent or normal.

EXAMPLE

- angiographic laboratories;
- cardiac catheterization laboratories;
- cardiac care units;
- emergency trauma units;
- intensive care units;
- intensive care neonatal units;
- operating rooms; and
- burn units.

5.5.3.3 **Home** (outside healthcare facilities, except for the emergency environment)—The requirements of the previous edition of IEC 60601-1-11 for medical electrical equipment and medical electrical systems used in the home healthcare environment apply.

EXAMPLE

Nursing homes

5.5.3.4 **Emergency** (outside of a professional healthcare facility or during professional transport to a professional healthcare facility or between professional healthcare facilities)—

The requirements of the previous edition of IEC 60601-1-12 for medical electrical equipment and medical electrical systems used in the emergency medical services environment apply.

5.5.3.5 **Assisting Living facilities**—Medical electrical equipment and medical electrical systems used in assisting living facilities are covered under the home environment (see 5.5.3.3).

5.5.4 Medical systems, equipment, accessories, sub-assemblies and components

5.5.4.1 This section explains the concept of components, non-medical sub-assemblies, medical sub-assemblies, medical accessories and associated parts in the context of a modularity approach (see Figure 3).

NOTE A modularity approach has been requested by the medical healthcare administrators to enable interconnectivity and interactions between medical electrical equipment and medical electrical system manufacturers.

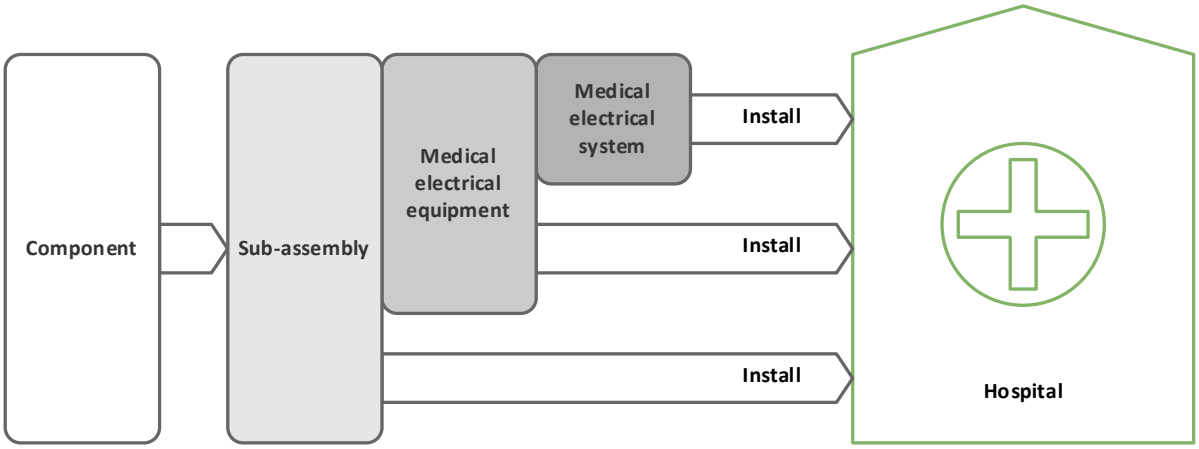


Figure 3 – Product structure in a modularity approach

5.5.4.2 The current concept of IEC 60601-1 edition 3.1 contains the following:

a) Component (could also define medical electrical components)—refer to subclause 4.8 of the IEC 60601-1:2005.

b) Accessory (refer to definition 3.3 of the IEC 60601-1:2005). An accessory is an additional part for use with equipment in order to:

   1) achieve the intended use;

   2) adapt it for some special use;

   3) facilitate its use;

   4) enhance its performance; or

   5) enable its function to be integrated with those of other equipment.

c) Medical electrical equipment (ME EQUIPMENT)—refer to definition 3.63 of the IEC 60601-1:2005.

d) Medical electrical systems (ME SYSTEM)—refer to definition 3.64 of the IEC 60601-1:2005. A Medical electrical system is a combination of at least one medical electrical equipment and can include non-medical electrical equipment, with the associated accessories, cables, sub-assemblies, components and applied parts.

e) The third edition of IEC 60601-1 does not define assembly or sub-assembly. However, IEC 60601-2-28 [2], which deals with X-ray tube assemblies, address sub-assemblies although in some countries, legislation defines X-ray tube assemblies as medical device. The next edition of the IEC 60601 SERIES should also address medical and non-medical sub-assemblies as well as components and accessories.

5.5.4.3 Providing the following definitions in the next edition IEC 60601-1 would facilitate the modularity approach between different medical electrical equipment and medical electrical systems.

a) A component is a singular product and rarely has a specific medical purpose (e.g., a fuse, capacitor, resistor, integrated circuit, wire, cable, etc..). A component cannot practically be decomposed any further.

b) A non-medical sub-assembly consists of multiple components assembled together providing a general function that is not specifically intended for a medical purpose (e.g., IT processor board sub-assembly or mechanical support sub-assembly). Sub-assemblies have a recognizable function of their own.

c) A medical sub-assembly consists of multiple components assembled together providing a medical function where some may have a medical purpose. (e.g., X-ray tube sub-assembly, SPO2 PC-board assembly).

d) A medical accessory enables an intended use of medical electrical equipment or a medical electrical system. A medical accessory can be a component or a combination of multiple components or a medical electrical equipment (e.g., SpO2 sensor, temperature sensor, ECG Trunk Cable, ECG Cable, ECG Lead-set, ECG electrodes, Defibrillator paddles/pads, humidifier for a critical care ventilator, etc.).

e) An associated part is any support item that is not part of the medical electrical equipment itself. An associated part can be a component, a combination of multiple components or an item of electrical equipment, e.g., a bar code scanner that connects to medical electrical equipment or a printer connected to a medical electrical equipment.

5.5.4.4 Usage of medical electrical equipment/medical electrical systems

Normal use includes service and maintenance. Because hazardous situations can be different during operation and service, there needs to be a term for each. The next edition of the IEC 60601 SERIES needs to define:

a) Normal use during operation mode of use.

b) Normal use during service mode of use.

c) Normal use during any other mode of use as defined by the manufacturer.

5.5.5 Maintenance of medical electrical equipment/medical electrical systems – the life cycle of safety

5.5.5.1 Service personnel ensures ongoing safety (life cycle) of medical electrical equipment or medical electrical systems with the appropriate sequence of planned maintenances/calibration schedules. The medical electrical equipment or medical electrical systems will need to be maintained and calibrated based on the manufacturer's maintenance manuals, which are part of the accompanying documents. Not only essential performances are considered during planned maintenance, but all performances prescribed by the medical manufacturer. Basic safety and essential performance are typically maintained by adequate maintenances schedules and appropriate calibrations meeting the technical specification as prescribed by the medical manufacturer.

5.5.5.2 Standards of the next edition of the IEC 60601 SERIES shall address aspects necessary for maintaining medical electrical equipment or medical electrical system during the lifecycle.

5.5.6 Concept to clarify medical electrical system requirements

5.5.6.1 This concept is intended to overcome reported problems with often unclear and mixed medical electrical equipment and medical electrical system requirements in the IEC 60601 SERIES. The reported problems include non-feasible or non-matching requirements in cases where the responsible organization is the legal manufacturer of the medical electrical

system, or where a manufacturer of only a part of a medical electrical system becomes the legal manufacturer of the medical electrical system.

5.5.6.2 General rule:

a) Do not address medical electrical equipment requirements in Clause 16 (or 201.16 in PARTICULAR STANDARDS), and

b) address testable medical electrical system requirements only in Clause 16 (or 201.16 in PARTICULAR STANDARDS).

5.5.6.3 In all clauses with testable requirements, except the clauses dealing specifically with medical electrical systems (Clause 16 / 201.16), the words “medical electrical equipment and/or medical electrical system” shall be replaced with “medical electrical equipment”.

5.5.6.4 A general requirement shall be added in each standard for all clauses addressing medical electrical equipment requirements, such as:

> "If the medical electrical equipment is intended or optionally intended to be integrated into a medical electrical system, as labelled by the ME EQUIPMENT manufacturer, the connection requirements for its system interfaces shall be specified in the accompanying documents of the medical electrical equipment so that the resulting medical electrical system will be safe. The connection requirements shall include any necessary configuration and test instructions.
>
> System interfaces might be electrical, mechanical, pneumatic or data interfaces, or any other functional interfaces. The connection requirements in the accompanying documents shall be verified with a connection representing the worst case of normal use (e.g. no tilt when the mechanical connection is made with a load as specified).
>
> Essential performance and clinical performance (IMDRF definition 3.10) may be distributed in a medical electrical system instead of integrated into one piece of medical electrical equipment, provided that the connection requirements for the medical electrical equipment are specified and verified accordingly."

5.5.6.5 The clause dealing with medical electrical systems (Clause 16 / 201.16) shall be reworked accordingly. The following general aspects shall be addressed in the medical electrical systems clause:

5.5.6.5.1 Functional connections of each medical electrical equipment to other equipment, which include IT-network connections.

5.5.6.5.2 Environmental operating conditions for each medical electrical equipment.

5.5.6.5.3 Verification requirements of essential performance that is distributed on multiple medical electrical equipment or non-medical electrical equipment.

5.5.6.6 In the clause dealing with medical electrical systems (Clause 16 / 201.16), delete all requirements which refer to other parts of the standard without a specific medical electrical system aspect.

5.5.6.7 Medical electrical systems which are very difficult to be tested as a complete, e.g., due to large dimensions, hazardous output, or similar justifiable reasons, may be verified in practicable portions (subgroups) provided that all functional connections are sufficiently included into the verification activities.

5.5.7 Clarify the relationship between the terms IT-network, SIP/SOP, network/data coupling and functional connection

5.5.7.1 The terms IT-network, SIP/SOP, network/data coupling and functional connection have a relationship to data transfer. Therefore, it is important to define the different uses of these terms more precisely in the next edition of the IEC 60601 SERIES.

5.5.7.2 The term “functional connection” is not restricted to data connections. It includes electrical connections (e.g., via a supply mains socket outlet), mechanical connections (e.g., via a fixation clamp) or pneumatic connections (e.g., via a gas supply hose). Functional connections

also include connections for data transfer (e.g., connections via an RS232 or USB connector or via a wireless service).

5.5.7.3 The term “SIP/SOP” is a part of medical electrical equipment that allows network/data coupling. It does not include data coupling to internal parts of the medical electrical equipment, such as applied parts or data connections to a display unit that is a part of the medical electrical equipment. The term “SIP/SOP” refers to the specific part(s) of a medical electrical equipment used for data transfer, while network/data coupling means the functionality for sending/receiving data to/from other equipment.

5.5.7.4 The term “network/data coupling” is a type of functional connection used for data transfer to or from other equipment (e.g., local area network (LAN) connections). It is a subgroup of functional connections. However, it does not include data connections internal to medical electrical equipment (e.g., data connections to an applied part), or data connections to other parts of the same medical electrical equipment (e.g., data connection to a display unit belonging to the medical electrical equipment).

5.5.7.5 The term “IT-network” is used for a system of wired or wireless connected equipment. A network/data coupling between medical electrical equipment and other equipment results in an IT-network. The medical electrical equipment is participating in the corresponding IT-network. The IT-network, however, extends externally beyond the medical electrical equipment. IT-networks of the responsible organization can be built without any medical electrical equipment; however, often medical electrical equipment is also involved (e.g., in case of distributed information systems or distributed alarm systems).

NOTE When medical electrical equipment is part of an IT-network, IEC 80001-1:2010 (definition 2.16) also uses the term “medical IT-network”.

5.6 Goal 6—Establish a policy relating requirement of the IEC 60601 SERIES to the IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES

5.6.1 International Medical Devices Regulatory Forum (IMDRF)

5.6.1.1 The IMDRF is a voluntary group of medical device regulators from around the world who come together to discuss future directions in medical device regulatory harmonization in order to accelerate international harmonization and convergence. IEC/TC 62 has a liaison relationship with the IMDRF.

5.6.1.2 The IMDRF has developed guidance documents on ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE [17] and LABELLING PRINCIPLES [18] for medical devices and IVD medical devices.

5.6.1.3 The purpose of the IMDRF guidance documents on ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES is to harmonize the documentation and procedures that are used to assess whether a medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance from the various AUTHORITIES HAVING JURISDICTION and allows patients earlier access to new technologies and treatments.

5.6.1.4 The principles set out in the IMDRF guidance documents should be considered during development of documents in the IEC 60601 SERIES. Depending on the particular medical electrical equipment or medical electrical system within the scope of the standard under development, some of the ESSENTIAL PRINCIPLES or LABELLING PRINCIPLES will not apply.

5.6.2 Relationship to the ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES of the IMDRF

5.6.2.1 The requirements in many of the standards in the IEC 60601 SERIES are intended to fulfil some of the principles set out in the IMDRF guidance documents. To facilitate the usage of the documents in the IEC 60601 SERIES for conformity assessment purposes by the AUTHORITIES HAVING JURISDICTION, it is important to clearly indicate which IMDRF principles are covered by which requirements in a standard in the IEC 60601 SERIES.

5.6.2.2 It is the policy of IEC/TC 62 to include an informative annex mapping the relationship to the IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES in each of the standards of the IEC 60601 SERIES. See Annex B for an example of such an informative annex.

5.6.2.3 Goals for the coverage of the IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES are to be included in the document establishing the project to develop a new or updated standard IEC 60601 SERIES (e.g., new work item proposal or whatever document is used to authorize work on the proposed revision of a standard).

5.6.2.4 In the Introduction of each standard of the IEC 60601 SERIES, a statement shall describe that the standard has been developed to provide coverage for some of the IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES. Suggested language appears below. Brackets indicate alternate suggested words.

> "During the preparation of this document, the committee [or committees for documents prepared by joint working groups] used IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES guidance documents to guide its development. Annex [XX] indicates the extent of coverage (fully or partially) of the ESSENTIAL PRINCIPLES and labelling requirements of the IMDRF by the requirements of this standard."

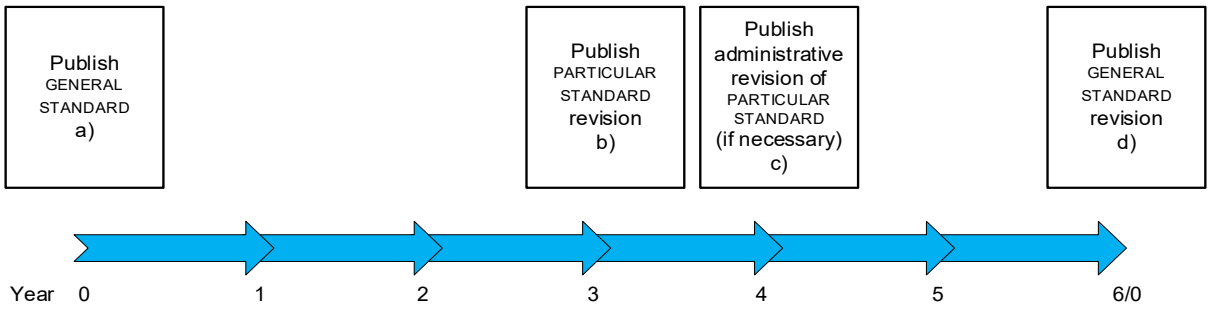
5.7 Goal 7—Establish a policy for scheduled release and stability dates

5.7.1 Synchronize the release of the standards in the IEC 60601 SERIES

The application of standards in the IEC 60601 SERIES by REGULATORY AUTHORITIES creates a need for stability and predictability among the stakeholders. Lasting and stable rules and structures for synchronized release of the standards in the IEC 60601 SERIES should be established.

In order to achieve that goal, IEC/TC 62 and other technical committees responsible for documents in the IEC 60601 SERIES should adhere to the following policy and reference this document within their deliverables.

New editions or amendments of standards of the IEC 60601 SERIES will be initiated and published only in a “synchronized mode” as follows (see Figure 4).



Key:

a) Year “0”: The GENERAL STANDARD is published, including all materials from the existing collaterals folded into the GENERAL STANDARD.

NOTE The contents of IEC 60601-1-9 will be transferred to a new document within the scope of IEC/TC 62 but outside the IEC 60601 SERIES (see 5.3.1.2.2).

b) Year “3”: All PARTICULAR STANDARDS are intended to be published with inclusion of references to the GENERAL STANDARD, plus modifications, additions, and further updates as appropriate.

c) Year “4”: If the responsible maintenance team has not been able to publish a revision of a PARTICULAR STANDARD, the Secretaries of IEC/TC 62 and the corresponding subcommittees will publish an administrative revision of the PARTICULAR STANDARDS that includes a reference to the GENERAL STANDARD.

d) Year “6”: Next time slot for publication of a synchronized bundle of the GENERAL STANDARD and any COLLATERAL STANDARDS developed during the cycle (see 5.3.1.3.1).

Figure 4 – Synchronized mode release schedule

NOTE 1 Stability dates are not limited by this synchronization. It is possible to determine longer stability dates than 6 years (e.g. 12 years) in accordance with ISO/IEC Directive 1. It is not advisable to apply stability dates shorter than one regular release circle according to this concept.

NOTE 2 According to this policy, a PARTICULAR STANDARD would typically be published three years after publication of the GENERAL STANDARD (year “3”, year “9”, etc.), and in case of a limited technical revision also up to 1 year later (years “3” to “4”, years “9” to “10”, etc.).

5.7.2 Address very urgent safety gaps

If a very urgent safety gap were to be detected in the GENERAL STANDARD, a deviation of the stability rules described in 5.7.1 is possible provided the urgency is confirmed by both IEC/SC 62A and IEC/TC 62 after consultation with subcommittees 62B, 62C and 62D. The lowest possible impact on PARTICULAR STANDARDS and a quick return to the stability rules in 5.7.1 have to be specified in this case.

NOTE In the case of a very urgent safety gap, an interim document—possibly an interpretation sheet (limited to this safety gap)—is acceptable for all standards in the IEC 60601 SERIES.

5.8 Goal 8—Establish training for authors of documents developed by IEC/TC 62

5.8.1 Develop training modules

Training modules need to be developed for leaders and expert members of IEC TC 62 and its subcommittees, including all maintenance teams, working groups and joint working groups. These modules should also be available to leaders and members of the ISO counterparts as well as the National Committee Members. The content of these modules should be strictly focused on aspects of the IEC 60601 SERIES.

NOTE 1 The IEC Academy is developing a role-based training module that will provide reference to the essential information and resources related to IEC technical work and the standards development process. All relevant stakeholders in IEC TC 62 shall be directed to these training modules.

NOTE 2 - IEC has developed training modules that address some of the topics listed above. https://www.iec.ch/academy/?ref=menu

5.8.2 Develop IEC 60601 SERIES specific training

5.8.2.1 IEC/TC 62 and its subcommittees will develop specific training on the architecture of the fourth edition of the IEC 60601 SERIES for those conveners and expert members who will be involved in the development of that edition.

5.8.2.2 The IEC/TC 62 safety concept, which is based on IEC horizontal standards (e.g. IEC 60479-1) and IEC / ISO guides (e.g. ISO/IEC Guides 50, 63, 71 and IEC Guide 104).

5.8.2.3 The main differences in the structure of the third edition and the next edition of the IEC 60601 SERIES.

5.8.2.4 The numbering structure of the IEC 60601 SERIES (part 1s, part 2s, part 4s, IEC/ISO 80601, etc.).

5.8.2.5 The relationship to other important IEC/ISO standards (e.g. ISO 13485, ISO 14971, IEC 62304, IEC 62366 series, IEC 62368-1, ISO 10933 series, IEC 62353, ISO 16142, ISO 20417).

5.8.2.6 The use of the IEC 60601 template including use of title, scope, defined terms, normative references, terminology, graphic symbols, annexes, shall, should, may, italics, notes, copyright and patents (the ISO/IEC Directives, Part 2).

NOTE 1 The IEC collaboration platform site or the IEC/TC 62 homepage can be used to disseminate this training material.

NOTE 2 Such training should be available before the development of the next edition of the IEC 60601 SERIES starts.

5.8.2.7 The relationship to IMDRF and its ESSENTIAL PRINCIPLES, and possibly use of input from regulatory bodies.

Annex A

Requirement attribute checklist

Each requirement statement in the next edition of the IEC 60601 SERIES shall have the following attributes:

a) Implements a requirement that clearly relates to basic safety or essential performance.

b) Addresses one or more of the IMDRF ESSENTIAL PRINCIPLES or LABELLING PRINCIPLES.

c) Can be clearly identified.

d) Is uniquely referenceable.

e) Does not contradict other requirements.

f) Is expressed in terms that avoid ambiguity.

g) Include clear compliance criteria.

h) Contains a verification method that is distinguishable from the requirement and presented in clear technical language.

i) Does not have multiple cross references.

j) Is supported by explanatory rationale (protection goal description).

Annex B

IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES checklist

B.1 Figure B.1 provides an example of the introductory text and tables that can be used to document the relationship of the requirements of a standard to the IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES.

Annex A
(informative)

Reference to the IMDRF *essential principles* and *labelling principles* guidance

This document has been prepared to support the *essential principles of safety and performance* and labelling requirements of [indicate the type – MEDICAL ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEM, specific type of MEDICAL ELECTRICAL EQUIPMENT] as a medical device according to IMDRF/GRRP WG/N47:2018 [17] and IMDRF/GRRP WG/N52:2019 [18]. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* requirements of IMDRF/GRRP WG/N47:2018 [17] and *labelling principles* requirements of IMDRF/GRRP WG/N52:2019 [18]. Other means are possible. Table A.1 maps the clauses and subclauses of this document with the *essential principles* of IMDRF/GRRP WG/N47:2018. Table A.2 maps the clauses and subclauses of this document with the *labelling principles* of IMDRF/GRRP WG/N52:2019.

Table A.1 — Correspondence between this document and the *essential principles*

***ESSENTIAL PRINCIPLE* of IMDRF/GRRP WG/N47: 2018 [17]**	**Corresponding clause(s)/sub-clause(s) of this document**	**Qualifying remarks/Notes**
[List the covered principles, only one per row in numerical order here]	[List the requirements of the standard that fulfil the principle]	[Indicate any explanation needed to clarify the coverage, e.g. partial coverage]

Table A.2 — Correspondence between this document and the *labelling principles*

Labelling principle of IMDRF/GRRP WG/N52: 2019 [18]	**Corresponding clause(s)/sub-clause(s) of this document**	**Qualifying remarks/Notes**
[List the covered principles, only one per row in numerical order here]	[List the requirements of the standard that fulfil the principle]	[Indicate any explanation needed to clarify the coverage, e.g. partial coverage]

Figure B.1 – Example of an IMDRF ESSENTIAL PRINCIPLES and LABELLING PRINCIPLES guidance annex

Bibliography

[1] ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

[2] IEC 60601-2-28 *Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*

[3] IEC 62304, *Medical device software – Software life cycle processes*

[4] IEC 62366-1, *Medical devices – Part 1: Application of usability engineering to medical devices*

[5] IEC TR 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*

[6] IEC 80001-1, *Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities*

[7] IEC TR 80002-1, *Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software*

[8] ISO/IEC GUIDE 51, *Safety aspects – Guidelines for their inclusion in standards*

[9] Agence nationale de sécurité du médicament et des produits de santé (ANSM), France, *https://www.ansm.sante.fr/S-informer/Informations-de-securite-Retraits-de-lots-et-de-produits#dm*

[10] CSA Z32, *Electrical Safety And Essential Electrical Systems In Health Care Facilities*

[11] FDA, U.S. Food & Drug Administration, *Medical Device Safety Communications*, https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices

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[14] Federal Institute for Drugs and Medical Devices (BfArM), Germany, *Field Corrective Actions, https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html?nn=4527724*

[15] Federal Institute for Drugs and Medical Devices (BfArM), Germany, *BfArM Recommendations, https://www.bfarm.de/EN/MedicalDevices/RiskInformation/Recommendations/_functions/_node.html*

[16] Health Canada, *Advisories, Warnings and Recalls – Drugs and health products*, *https://www.canada.ca/en/health-canada/services/drugs-health-products/advisories-warnings-recalls*

[17] IMDRF/GRRP WG/N47:2018, *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*, Available at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf.

[18] IMDRF/GRRP WG/N52:2019, *Labelling Principles for Medical Devices and IVD Medical Devices*, Available at: http://www.imdrf.org/documents/documents.asp.

[19] Medicines and Healthcare products Regulatory Agency, United Kingdom, *Alerts and recalls for drugs and medical devices, https://www.gov.uk/drug-device-alerts?*

[20] NFPA 99: *Health Care Facility Code*

[21] Swiss Agency for Therapeutic Products, Switzerland,
List of Field Safety Corrective Actions (FSCA) and recalls,
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/fsca.html

[22] Therapeutic Goods Administration (TGA), Australia *General safety information for health professionals including alerts warnings and other publications,*
https://www.tga.gov.au/safety-information-health-professionals

[23] TGA, *TGA quarterly newsletter for Medical Device Safety Update (MDSU),*
https://www.tga.gov.au/publication/medical-devices-safety-update

[24] TGA, *System for Australian Recall Actions (SARA),*
https://apps.tga.gov.au/PROD/SARA/arn-entry.aspx

[25] TGA, *Device Adverse Event Notifications (DAEN),*
https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx

Annex: Comments received from the National Committees

Document of: BE

BE-01				ge	The Belgian NC approves the attached document with the (mainly editorial) comments mentioned below.		
BE-01	322	5.1.3.1		te	Writing that a rationale is necessary to see if alternative safety solutions are satisfactory, leaves the door open for not implementing the standard. It also opens the door for interpretation and hence differences in interpretation between Notified body's or test houses..	Remove the line 322	
BE-02	606	5.3.5.1		ed	"…the IEC 60601 SERIES can improved the overall …"	"…the IEC 60601 SERIES can **improve** the overall …"	
BE-03	752-753	5.4.2.3.2		ed	Why are some of these terms underlined.	Remove the underlining if there is no particular reason for this.	corrected
BE-04	764	5.4.3		te	Will the information and other requirements for the process standards for PEMS then be moved to these process standards in order to make sure that no safety issue measures are lost ?		
BE-05				ed	The use of bold or not bold sub-clause numbering is not consistent. Please adjust to make it consistent. Some examples Line 586 & 591 : subclause number is not bold whilst line 571 & 576 the numbering is bold Line 604 & 736 & 765 & 834 &871 & 876: number not bold, title is Line 746 : sub-clause number mentioned alone whilst for other sub-clauses the text starts after the sub-clause number	Please revise document and make the use of bold in sub-clause numbering consistent.	
BE-06	838, 845, 858	5.5.3.2.1 to 5.5.3.2.3		ed	Why are the titles underlined and not just bold like for the other environment. It are sub-classes of the healthcare facilities, but just writing them in bold would give a more consistent overview.	Change underline into bold.	corrected
BE-07	881			ed	The reference number is not correct.	Replace 5.5.2.3 by 5.5.3.3	corrected
BE-08	1125	5.8.2		ed	Subclauses 5.8.2.2 till 5.8.2.7 are grammatically incorrect in comparison to the subclause 5.8.2.1 where the subclause is a full sentence.	Replace "5.8.2.1 IEC/TC 62 and its subcommittees will develop specific training on the architecture of the fourth edition of the	

					By moving the first part of the sentence of 5.8.2.1 in front of the 5.8.2.1 sub-clause the rest of the sub-clauses become also grammatically correct.	IEC 60601 SERIES for those conveners and expert members who will be involved in the development of that edition. “ By “IEC/TC 62 and its subcommittees will develop specific training on : 5.8.2.1 The architecture of the fourth edition of the IEC 60601 SERIES for those conveners and expert members who will be involved in the development of that edition. “	

Document of: CN

SAC	140	3.3	n/a	ge	This definition doesn’t address that the requirements of particular standard take priority over the general standard.	Standard of the IEC 60601 SERIES specifying requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE, taking priority over the general standard, applicable to specific types of medical electrical equipment and medical electrical systems	
SAC	156	3.4	n/a	ge	Clause 19.4 of IEC/TR 60513 didn’t talk about old structure of IEC 60601-1 family, nothing else is related to IEC 80601-2-XX or ISO 80601-2-XX.	IEC/TR 60513 is quite old document, somewhat it is too obsolete to explain the new structure as current IEC 60601 series extend, to avoid misunderstanding, just delete Note 2 to entry in 3.4.	
SAC	204	4.1.4	n/a	ed	The first sentence “it is important that the next edition address any…..”	Should be “ it is important that the next edition addresses any….”	
SAC	216	4.2.1	Figure 2	te	The figure 2 states that “only the part 1 standards make normative references to the process standards”. This statement is not very clear enough, for which reason why a process standard cannot be normatively referenced by a particular standard? In the reality, the essential performance for some home-healthcare devices are directly related with the usability, in this case, why the IEC 62366-1 cannot be referenced in this sort of particular standard?	Redesign the figure 2 if possible	

SAC	370	5,1,4,2	n/a	ge	The first sentence says that for improved usability, the documents of….. The word “USABILITY” (3.136 in IEC 60601-1) is actually a defined term which has been adapted by the general standard to indicate the characteristic of the operator interface, which somewhat is not the meaning of 5.1.4.2 intends to explain for.	Recommend to use “Readability or other appropriate word” to replace “USABILITY”	
SAC	606	5.3.5.1	n/a	ed	The first sentence: The rational use of defined terms within the IEC 60601 SERIES can improved the overall usability of the series. Two words above seem to be revised. As said above, the term USABILITY is a defined one in the general standard, it shall avoid using this term repeatedly in this document to cause confusion	1. Improved -> improve 2. Usability -> feasibility?	
SAC	680	5.3.7.1.1	n/a	te	This clause says that It is the policy of IEC/TC 62 that all normative references shall be dated. This statement is controversial. In fact, it is not strictly followed in many standards. For example, even the general standard didn’t date all normative standards in clause 2.	Change “ shall” to “should”	
802	802	5.4.4.2.3	n/a	Ed	Not correct standard number	Change 62366 to 62366-1	

Document of: DE

DE1				ge	The German national committee approves the architecture specification for the future IEC 60601 series. However, we strongly favour that some aspects become be clarified when working with this document. Those aspects are listed in the following comments.	Our vote: YES, with additional comments.	
DE2				ge	During the work of MTs/ WGs/JWGs on the next edition series of IEC 60601 and IEC/ISO 80601	Fix the following implementation rules:	

					standards, two aspects should be monitored and, if needed, an intervention should be possible. Note: Nobody can foresee future new situations which might justify or even require a necessary modification/adaption of a specification in the architecture document. In order to avoid that TC62 becomes incapable of acting in those cases, a certain – qualified – flexibility under supervision of TC62 makes sense.	a) All groups working on the next editions of the IEC 60601 and IEC/ISO 80601 series should follow the architecture document as accurately as possible. b) If parts of the architecture document cannot be followed, by reasons not foreseeable today, a request for modification / adaption of the affected architectural specification(s) can be requested. It is granted if a 2/3 majority of the NCs votes for that modification / adaption.	
DE3				ge	The integration of collateral standards into the general standard brings benefits as denoted in the architecture document. However, especially the integration of IEC 60601-1-2 (electromagnetic disturbances) might also result in new problems which should be avoided by appropriate and early provisions.	a) The database format of IEC 60601-1 should be granted before or with publication of the 4th edition of IEC 60601-1, as otherwise, the increased size of the standard will bring new usability problems. Also, size reduction of large collateral standards should be taken into account, e.g. in focussing on the requirements (plus their protection goals) in the future IEC 60601-1. b) The decision to integrate the collaterals including IEC 60601-1-2 should not automatically result in a change of requirement contents of IEC 60601-1-2. It is important to maintain reverse compatibility of contents as much as possible. c) Test labs and test engineers for general safety and for EMC are often not identical. So, one single test report template (TRF) for the future general safety standard could make problems. It should be granted that separate TRFs for portions of the general standard, especially for EMC, are granted and elaborated by IECEE early enough. d) In support of the previous aspect, the EMC requirements should remain bundled in one clause which allows to reference them completely and easily. e) The inclusion of IEC 60601-1-2 into the general standard should be balanced via 5.1.5 (Justify changes) in the upcoming documentation. f) The acceptance of integrated EMC requirements into the general standard by authorities having jurisdiction should be checked carefully in advance. g) In order to maintain flexibility for unforeseeable new technologies and gap closures, suitable tools (interpretation sheets? TS? TR? WG14 recommendations?) should be determined and	

						available on time without a longer determination in SC62A which tools are practicable for this.	

Document of: GB

GB	176	4.1.1		Ed	Capitalisation	'IEC 60601 SERIES' all in small caps	
GB			Fig 1	Ed	Suggest top right section of the figure should read as proposed	IEC 60601-1-xx Additional general requirement for safety and essential performance e.g.: systems, PES, EMC, etc.	
GB			Fig 2	Ed	For consistency with the title of this document, suggest the central left-hand box should read …	IEC 60601 SERIES Architecture Document Architectural Specification & IEC 60601-1 Design Specification	
GB			Fig 2	Ed	In the central IEC 60601-1 box …	'general standard' should be in small caps: general standard … or capitalised as 'General Standard'	
GB	329	5.1.3.2		Ed	'… the preferred way is an informative annex in the same document…' Suggest this is strengthened. To have this information in a separate document will compound the existing difficulty of encouraging/insisting that users of the Standard read the informative annex as well as the normative text.	'… the strongly preferred way is an informative annex in the same document …'	
GB	785	5.4.3.2.d)		Ed	Regarding: 'Include type testable parts of the PEMS validation (subclause 14.11). PEMS validation into Clause 5 …' Suggest there is a missing word.	'Include type testable parts of the PEMS validation (subclause 14.11). Move PEMS validation into Clause 5 …'	
GB	838-870	5.5.3.2.1 to 5.5.3.2.3		Ed/Tech	At an appropriate point in one of these subclauses, 'non-interventional radiology suites' & 'interventional radiology suites' should be included.	Suggest inclusion of 'non-interventional radiology suites' & 'interventional radiology suites' in 5.5.3.2.2 & 5.5.3.2.3 respectively.	
GB	843-844	5.5.3.2.1		Ed/Tech	Suggest an amendment to the text: 'Many patients in a basic care environment are in beds or on treatment couches. Most of these are MEE these days and patients come into contact with	'… where body contact between a patient and medical electrical equipment (other than electrically operated treatment couches or beds) is neither frequent nor usual.'	

					the MEE.'		
GB	881	5.5.3.5		Ed	The pointer to 5.5.2.3 is an error. This subclause does not exist.	'(see 5.5.3.3)'	
GB	924	5.5.4.3.c)		Ed/Tech	Suggest adding to the examples of medical sub-assemblies.	Adding '… power supply providing two means of patient protection …'	
GB	1071	5.6.2.4		Ed	Is there a reason for using term 'labelling requirements' at this point?	'… labelling principles …'	
GB		5.7		General	How will TC62 and its sub-committees ensure that ISO 80601-2-xx particular standards that are outside of its control adopt and stick to these goals? There have been examples for ISO 806-1-2-x standards being developed without sufficient MEE experts involved.		
GB		Annex B	Fig B.1	General	Per comment on 5.6.2.4 at line 1071 – is there a reason for using term 'labelling requirements' at this point?	'… labelling principles …'	

Document of: JP

JP				vote	**Question** Do you approve the document attached to 62/348/Q? --> Yes, Japanese National Committee of IEC TC62 does.		
JP1				ed	The format of the subclause numbers varies between bold and normal character. For example, 5.1.4.2 is normal but 5.4.1.3 is bold.	The subclause number should be bold.	
JP2	746			ed	There is unnecessary line feed in the line 746.	Please correct.	
JP3	904			ed	The first character of the line 946 is small capital. (M)	Please correct. Medical --> (medical)	

Document of: NL

NL	-	-	-	Ge	The Netherlands generally support the document 62/348/Q and cast a positive vote. We have some concerns for consideration of the IEC/TC 62 leadership in the development of IEC 60601, Edition 4.		

NL	5.3.1	490	-	Ge	Size of the general standard. On the one hand, we see the advantages of simultaneously updating the general and all collateral standards. This has proven effective in preparing Amendment 2. On the other hand, we are in doubt about integrating the general and collateral standards. This creates a huge document, to be purchased at a higher price, while containing several clauses that do not apply to specific types of medical electrical equipment. This will increase costs for manufacturers.		
NL	5.3.1	490	-	Ge	Character of collateral standards. Not all collateral standards have a general character. Only IEC 60601-1-2 (EMC) and 1-6 (Usability engineering) apply to all types of medical electrical equipment. The integration could be limited to these two collaterals. Other collaterals (3, 8, 10, 11, 12) have specific scope and do not apply to all medical electrical equipment. We agree to transfer IEC 60601-1-9 outside of the series.		
NL	361 700	5.1.4 5.4.2	-	Ge	Pass/fail criteria. Several countries have their own requirements, e.g. for radiation protection, which can be different. The pass/fail criteria must be defined with great care to avoid any conflicts.		

Document of: US

US				ge	**Advantages:** • Incorporating all the collateral standards could make it easier to understand the relationships for those well-versed in interpreting the standard • Could provide a more comprehensive easier-to-use reference for manufacturer if executed properly • May reduce confusion about which standards are applicable. • Closer integration between the general and collateral committees should streamline the standard. • Single requirements per subclause	These comments are offered merely as reinforcement for aspects of the specification that are viewed positively.	

					thereby making conformity assessment traceability absolutely clear • Plan for machine readable content • Rationale for every subclause • Heavy emphasis on streamlining and clarity • Merging collaterals into main standard • Increased awareness for addressing reasonably foreseeable risks to different patient *groups* and *interoperability* • Explicit callouts via normative references to ISO 14971, IEC 62366-1, and IEC 62304 (including clarifications on how to apply these 3 standards) • They make it clear that with "over 100 documents with interrelationships that makes them challenging for stakeholders to implement and makes ongoing maintenance difficult for the standards committees" – this by itself is the biggest reason for consolidating everything. • 5.1.1 – clarifying what "Basic Safety and Essential Performance" *actually* means! • 5.1.2.2 – "Assessing the impact of the new technology on the safety of patients, operators, service personnel and bystanders in normal condition and single fault condition, including normal use and reasonably foreseeable misuse (assess impact on safety under aspects such as risk management, usability engineering)." – making it more clear to think about as many potential persons scenarios as possible. • 5.3.7 – clarifying the use of *dated* and *undated* references – this was a constant point of confusion during EMC testing when 60601-1-2:2014 was released. • 5.5 – clarification of the actual *scope* (patients, intended operations, environments, different types of facilities, etc.) and addressing both medical and non-medical sub-assemblies as well as components and accessories. • 5.5.5 – more information on *maintenance*, life cycle of safety, service personnel, considering Essential		

					Performance during planned maintenance, etc. • 5.5.7 – clarifying the relationship between the terms IT-network, SIP/SOP, network/data coupling and functional connection; this too was a constant point of confusion during EMC testing. • 5.7.1 – synchronizing the release of all new standards (this is a must if consolidating) • 5.8.2 – new specific training being developed •		
US				ge	**Disadvantages:** • Huge general document • Will contain large sections not applicable to many products • May cause users to lose focus on electrical safety aspects if additional material, references and requirements are confusing • Larger checklists, more “testing”, larger reports. • We don’t see how this document won’t be in a constant state of flux. How can changes to collateral standards that are now internal to the main document be made without changing the top-level version every time? Has the management of this aspect been discussed? • Major disruption for manufacturer’s documentation for conformity assessment. This cannot be overstated- the revision will have an enormous cost impact associated with revision of all submission documents, templates, test reports, databases, etc.	• Consider ways to minimize impact of the revision through deployment of tools that assist the user of the standard in sorting, filtering, and generally reading. The normative content should be absolutely compatible with off the shelf requirements management tools so that users can import the standard in a way that makes creation of traceability reports easy and concise. • The 4th ED should factor in ISO 20417 (currently in FDIS?), as the purpose of that document is to house all generic labeling requirements in one standard rather than the current jumble where requirements are duplicated and scattered across many standards. This should allow many of these generic requirements to be removed entirely from 60601, leaving only those specific to MEE. That may require a rewrite of Goal 6 – labeling. • Explain how revisions to various topical areas that are now handled by separate WGs and MTs will be incorporated. In other words, what will revision control look like? • Provide a guidance document that clearly maps the 3rd to 4th edition requirements	
US				General	The architecture described in this document should not be mandatory and the inclusion of 1-2 should be discussed further.		

US		Entire document	Subclause numbers	Editorial	Bolding of subclause numbers is inconsistent.	Either bold all subclause numbers or establish a consistent format.	
US	15-16	Contents	4.1.3	Editorial	The link to the subclause is broken.	Replace "Error! Bookmark not defined" with the correct link.	corrected
US	83	Contents	5.8.2	Editorial	The link to the subclause is broken.	Replace "Error! Bookmark not defined" with the correct link.	corrected
US	273, 275, etc.	5.1.1.3, 5.1.1.4, etc.		Technical	The concept of single fault condition is obsolete. Multiple faults can occur, and better ways are needed for preventing unacceptable risk.	At a minimum, include the concept of multiple simultaneous faults.	
US	318	5.1.3 & 5.1.4		General	Providing the specified information will greatly facilitate usability of the standard. In some cases, the protection goal statements and test method rationales could be accompanied by explanatory illustrations (figures). Kudos for including this guideline and examples.	n/a	
US	435	5.1.6.2		Technical	Neither the process nor its outputs should be considered a part of type tests in IEC 60601, except perhaps those portions of the process output that constitute objective information. The output of a risk management process, for example, is often an argument concerning the acceptability of risk. While they may be supported in part by objective evidence from testing, such arguments are often ultimately subjective in nature and should not be considered as a part of type testing. Rather, these arguments may be presented by the manufacturer in support of a safety claim, and independently judged by regulators, purchasers, or other stakeholders.	In the final analysis, bodies assessing conformity to IEC 60601 should not be placed in the position of making judgments concerning the acceptability of risk, or more generally, the validity of any subjective claim. This needs to be made clear using plain language. One of the major weaknesses of the current edition, from a regulatory perspective, is its lack of clarity on this point.	
US	441	5.1.6.2	Second paragraph	Editorial	"SERIES" in this line appears smaller than in other lines in the paragraph.	Check the formatting of "SERIES" in line 441 and correct it as necessary.	
US	465	5.1.8.2		Technical	1. Restricting to known standards that currently exist is problematic. a. This also applies to constraining to the 11073 standards b. Current standards are too limiting. New standards are being develop for new applications. c. They are incomplete and are being expanded to address new clinical	Strike the need to limit to existing/available standards. Delete: "*based on already available standards and documents for communication of medical devices, such as ISO/IEEE 11073"* and replace with: "based on a generalized safety model, for example the types of safety information specified in ISO 80601-2-61:2017 (oximeters) Annex HH."	

					scenarios. 2. In particular, the standards used as examples are communication standards that instruct HOW to send data and information, not WHAT to send or WHY. a. The manufacturer should consider what information should be communicated based on the clinical application of the device. b. This has been referred to as a Medical Device Interface Data Sheet in scientific publications and related standards (e.g. AAMI Interoperability Work Group) c. Examples include ISO 80601-2-61 :2017 (oximeters) Annex HH, which defines the following categories: – **Parameters and units of measurement:** Parameters and units of measurement used within the PULSE OXIMETER EQUIPMENT – **Equipment identification:** Information identifying the PULSE OXIMETER EQUIPMENT – **Equipment settings:** Settings relating to the control and operation of the PULSE OXIMETER EQUIPMENT – **Equipment configuration:** EQUIPMENT SETTINGS that can be remotely configured – **Equipment specifications:** Relevant specifications to be transmitted **Service monitoring:** Indicators relating to preventative or corrective maintenance of the PULSE OXIMETER EQUIPMENT and its ACCESSORIES		
US	482 - 484	5.2.1	First paragraph	Technical	The immunity requirements of IEC 60601-1-2:2014 are specified in a per port basis and harmonized with the format of other EMC	Allow for requirements to be presented in a concise way, e.g. in tables.	

					standards, e.g. the IEC 61000-6-X series. EMC test labs are familiar with this format, and placing each requirement in a separate paragraph would not present the requirements in a concise way.		
US	525 - 534	5.3.1.2 - 5.3.1.3	First paragraph	Technical	Subclause 5.3.1.2 (line 525) proposes to integrate the existing collateral standards into the General Standard. Subclause 5.3.1.3 argues that the collateral standard approach should be retained to address new aspects of basic safety and essential performance that arise between revisions of the general standard. However, maintaining the collaterals as separate documents permits them to be revised more nimbly than the General Standard. Merging the collateral standards into the general standard would take away this nimbleness. It is felt that this issue alone was important enough to warrant a “no” vote on the architecture document. This issue is important enough to warrant further discussion by the committee.	There is much to like about the architecture document as a whole, and it should not be rejected on the basis of this one issue, if a way can be found to resolve the concern. A couple of points can be made. First, the document proposes that the entire series be updated on a six-year cycle. Should that objective be realized, it renders the issue moot. However, past history suggests that the six-year revision cycle is optimistic (in the extreme). Even the EMC collateral by itself – a prime example of an area requiring nimbleness – required more than six years to revise on its last revision (2007 to 2014). Also the transition period (1-3 years) needed for users to make system changes to adapt to the new standard would possibly add onto the adoption time. Appropriate transition time for the new version may be needed to put into development consideration as well. One possible resolution is for TC62 to commit to developing a process that can actually achieve the objective of a six-year revision cycle. Another approach is to broaden 5.3.1.3 to allow for collateral standards under two circumstances – either when new safety aspects arise, as presently stated, or when technologies are evolving so rapidly that new safety aspects are likely to arise. EMC is arguably one such area, as ubiquitous personal and embedded wireless devices are proliferating while using ever higher frequencies, posing new threats to coexistence with medical devices. Cybersecurity might be another such area where the nimbleness of a collateral standard might remain beneficial.	
US	600	5.3.4.2		Technical	A testable requirement can be restated citing the source, eliminating the need for users to purchase the additional standard just to access one or a small number of clauses or subclauses. Annex A, when necessary, can shed further light on the rationale for incorporating material from another standard to facilitate long-term maintenance.	Allow references to and between particular standards.	
US	606	5.3.5.1	First paragraph	Editorial	In the first line of the paragraph, "improved" should be "improve".	Change "improved" to "improve".	

US	619	5.3.5.2.3		Technical	The subclause as written prohibits the use of a unique definition from a particular standard in a collateral standard. This might be too strong. Just because a definition was used first in a particular standard does not mean it doesn't have general utility.	Perhaps the subclause could be amended to permit such use only when the definition from a particular standard is determined to have general utility and use in the collateral standard does not conflict with its use in the source standard.	
US	621	5.3.5.2.3	First paragraph	Technical	Not allowing collateral standards to use definitions from particular standards would be problematic. For example, there are unique issues with regard to electromagnetic disturbances from HF surgical equipment. It is essential to be able to draft specifications or recommendations that use the defined term HF surgical equipment.	Delete "and shall not use unique definitions from PARTICULAR STANDARDS" or change it to "or from PARTICULAR STANDARDS."	
US	664	5.3.6.2.3		Technical	This is a great example of a requirement that is ambiguous. Given that *inspection* is defined in ISO 17000 as "examination of [an object] and determination of its conformity with … requirements," the wording of the example leaves open to interpretation how to make the determination, since no objective criteria are given. The requirement in this example is for the manufacturer to "assess and document the biocompatibility of ME Equipment … using an appropriate method." Conformance is checked by "inspection of the documentation …" Part of the problem is that this requirement is directed toward the manufacturer, not the MEE, so it is not amenable to type testing. The requirement could perhaps be improved by specifying objective characteristics of the biocompatibility testing documents that must be observed during the inspection. And it must be clear from context what competence the conformity assessment body – typically a testing laboratory having an IEC 60601 scope of accreditation – must have in order to carry out these inspections.	There are multiple places in the architecture document where the principle of ensuring that requirements are testable are invoked. Perhaps that could be broadened to state that when the requirement is to inspect or evaluate a document or other object, the acceptability criteria should be explicit and objective. There are many examples in the IEC 60601 series where this is already the case.	
US	672	5.3.6.4		Editorial	This subclause appears to be misplaced.	Consider whether it would fit better under 5.3.6.1.	
US	737	5.4.2.3.1		Technical	The sentence beginning with "For example …" in this subclause appears to be incomplete. Perhaps it was intended to be joined with the following sentence by a comma or "if" should be deleted. More importantly, if the occurrence of a failure mode results in an unacceptable risk, then it would seem that this is either a matter of basic safety or essential performance, either of which should be describable in objective terms. Is there	Please address the concerns raised in the comment.	

					a third option? The statement that “Manufacturers and applicable regulatory authorities can then make a reasoned assessment of the risk reductions implemented” should be used with caution This is true for the manufacturer, but the regulatory authority will likely never be aware of hazardous situations that are addressed by the IEC 60601 series since conformity with its requirements is presumed to provide evidence of safety. However, so long as the acceptance test limits are framed in terms of essential performance, there is no issue, as regulatory authorities typically review the essential performance specified by the manufacturer to the testing laboratory.		
US	822 - 881	5.5.3	Entire subclause	Technical	While the environments listed can have implications for electromagnetic disturbances, there can be various electromagnetic environments within the medical environments listed. For example, the electromagnetic environment of the home healthcare environment can be very different in residences and in retail locations or commercial aircraft. The electromagnetic environment can be different in different areas of healthcare facilities, e.g. close to active HF surgical equipment.	Allow for other types of environments within the medical environments listed, such as electromagnetic environments.	
US	874 - 875	5.5.3.3	Example	Technical	In the US, there are healthcare professionals present in nursing homes.	Give another example for the home environment. Move nursing homes to an example of the professional healthcare facility environment.	
US	876	5.5.3.4		Technical	Other terms might include “pre-hospital care environment” and “medical transport environment.” Pre-hospital care is more or less synonymous with the emergency environment. Patient transport often occurs in non-emergency situations. Such transports may be of long duration and involve multiple forms of transportation as well as handoffs between caregivers. This can have implications for MEE safety.	Consider modifying the term or adding a new category for medical transport environment.	
US	883-940	5.5.4		Technical	The concept of interconnecting cables as part of MEE and MES is needed. For example, interconnecting cables should be tested for immunity to induced RF disturbances.	Define interconnecting cables within MEE and MES.	
US	912	5.5.4.3		General	I’m sure the intent was to consider developing definitions similar to the ones provided here. It is a mistake to presume that these definitions should be adopted without further discussion. However, any progress in clarifying the	Consider changing the language to present the accompanying definitions as suggestions rather than "finished business."	

					distinctions between these terms would be welcome!		
US	941	5.5.5		General	IEC 60601 has never been intended to be a total product life cycle standard. It focuses on the design of the MEE. To the extent that features of the MEE design impact its ability to be serviced in ways that ensure its continued safety, those aspects are appropriate for inclusion. Assessing the adequacy of service manuals, procedures, and tools will exceed the scope of the standard.	This section might need additional clarification.	
US	961	5.5.6.2		Editorial	It has already been stated that there will be no 201.xx clauses in the future.	Substitute generic terminology such as “corresponding clauses.”	
US	1013	5.5.7.3		Editorial	In the past, SIP/SOP referred to connections “intended to deliver or receive signals to or from other electrical equipment.” This includes analog signals as well as digital data. In the sentence, “The term “SIP/SOP” refers to the specific part(s) of a medical electrical equipment 1013 used for data transfer …”, the language suggests that SIP/SOP connections are used only for transferring (digital) data.	Please use language similar to the existing definition to make clear that SIP/SOP includes both analog and digital signals.	