

Medical device software — Software life-cycle processes

ICS 11.040.01; 35.080; 35.240.80

National foreword

This British Standard is the UK implementation of EN 62304:2006+A1:2015, incorporating corrigendum November 2008. It is identical to IEC 62304:2006, incorporating amendment 1:2015. It supersedes BS EN 62304:2006, which will be withdrawn on 31 July 2018.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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31 May 2011	Implementation of CENELEC corrigendum November 2008; modification of CENELEC Foreword and addition of Annex ZZ
30 November 2015	Implementation of IEC amendment 1:2015 with CENELEC endorsement A1:2015.

English version

**Medical device software -
Software life-cycle processes
(IEC 62304:2006)**

Logiciels de dispositifs médicaux -
Processus du cycle de vie du logiciel
(CEI 62304:2006)

Medizingeräte-Software -
Software-Lebenszyklus-Prozesse
(IEC 62304:2006)

This European Standard was approved by CENELEC on 2006-06-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62A/523/FDIS, future edition 1 of IEC 62304, prepared by a joint working group of SC 62A, Common aspects of electrical equipment used in medical practice, of IEC technical committee 62, Electrical equipment in medical practice, and ISO Technical Committee 210, Quality management and corresponding general aspects for medical devices, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62304 on 2006-06-01.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2007-03-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2009-06-01 |

In this standard the following print types are used:

- requirements and definitions: in roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- terms used throughout this standard that have been defined in Clause 3 and also given in the index: IN SMALL CAPITALS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives 93/42/EEC, 90/385/EC and 98/79/EC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

The contents of the corrigendum of November 2008 have been included in this copy.

Endorsement notice

The text of the International Standard IEC 62304:2006 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

The text of document 62A/1007/FDIS, future IEC 62304:2006/A1, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62304:2006/A1:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2016-05-01
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-07-31
standards conflicting with the
document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, 98/79/EC, 90/385/EEC see informative Annex ZZ, included in EN 62304:2006/corrigendum Nov. 2008.

Endorsement notice

The text of the International Standard IEC 62304:2006/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

Replace the existing references with the following:

IEC 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006.
IEC 60601-1:2005/AMD1:2012	NOTE	Harmonized as EN 60601-1:2006/A1:2013.
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996.
IEC 60601-1-4:1996/AMD1:1999	NOTE	Harmonized as EN 60601-1-4:1996/A1:1999.
IEC 60601-1-6	NOTE	Harmonized as EN 60601-1-6.
IEC 61508-3	NOTE	Harmonized as EN 61508-3.
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010.
ISO 9000:2005	NOTE	Harmonized as EN ISO 9000:2005.
ISO 9001:2008	NOTE	Harmonized as EN ISO 9001:2008.
ISO 13485:2003	NOTE	Harmonized as EN ISO 13485:2003.
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015.
IEC 82304-1	NOTE	Harmonized as EN 82304-1 ¹⁾

1) At draft stage.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 14971	- 1)	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000 2)

1) Undated reference.

2) Valid edition at date of issue.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directives 93/42/EEC, 90/385/EC and 98/79/EC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 62304 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice and ISO Technical Committee 210, Quality management and corresponding general aspects for MEDICAL DEVICES. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

It is published as a dual logo standard.

The text of this standard is based on the following documents:

FDIS	Report on voting
62A/523/FDIS	62A/528/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 23 P-members out of 23 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- requirements and definitions: in roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- terms used throughout this standard that have been defined in Clause 3 and also given in the index: in small capitals.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under “<http://webstore.iec.ch>” in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A1 NOTE The attention of National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication. **A1**

INTRODUCTION

Software is often an integral part of MEDICAL DEVICE technology. Establishing the SAFETY and effectiveness of a MEDICAL DEVICE containing software requires knowledge of what the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable RISKS.

This standard provides a framework of life cycle PROCESSES with ACTIVITIES and TASKS necessary for the safe design and maintenance of MEDICAL DEVICE SOFTWARE. This standard provides requirements for each life cycle PROCESS. **[A1]** Each life cycle PROCESS consists of a set of ACTIVITIES, with most ACTIVITIES consisting of a set of TASKS. **[A1]**

As a basic foundation it is assumed that MEDICAL DEVICE SOFTWARE is developed and maintained within a quality management system (see 4.1) and a RISK MANAGEMENT system (see 4.2). The RISK MANAGEMENT PROCESS is already very well addressed by the International Standard ISO 14971. Therefore IEC 62304 makes use of this advantage simply by a normative reference to ISO 14971. Some minor additional RISK MANAGEMENT requirements are needed for software, especially in the area of identification of contributing software factors related to HAZARDS. These requirements are summarized and captured in Clause 7 as the software RISK MANAGEMENT PROCESS.

Whether software is a **[A1]** contributing factor to a HAZARDOUS SITUATION **[A1]** is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. **[A1]** HAZARDOUS SITUATIONS **[A1]** that could be indirectly caused by software (for example, by providing misleading information that could cause inappropriate treatment to be administered) need to be considered when determining whether software is a contributing factor. The decision to use software to control RISK is made during the RISK CONTROL ACTIVITY of the RISK MANAGEMENT PROCESS. The software RISK MANAGEMENT PROCESS required in this standard has to be embedded in the device RISK MANAGEMENT PROCESS according to ISO 14971.

The software development PROCESS consists of a number of ACTIVITIES. These ACTIVITIES are shown in Figure 1 and described in Clause 5. Because many incidents in the field are related to service or maintenance of MEDICAL DEVICE SYSTEMS including inappropriate software updates and upgrades, the software maintenance PROCESS is considered to be as important as the software development PROCESS. The software maintenance PROCESS is very similar to the software development PROCESS. It is shown in Figure 2 and described in Clause 6.

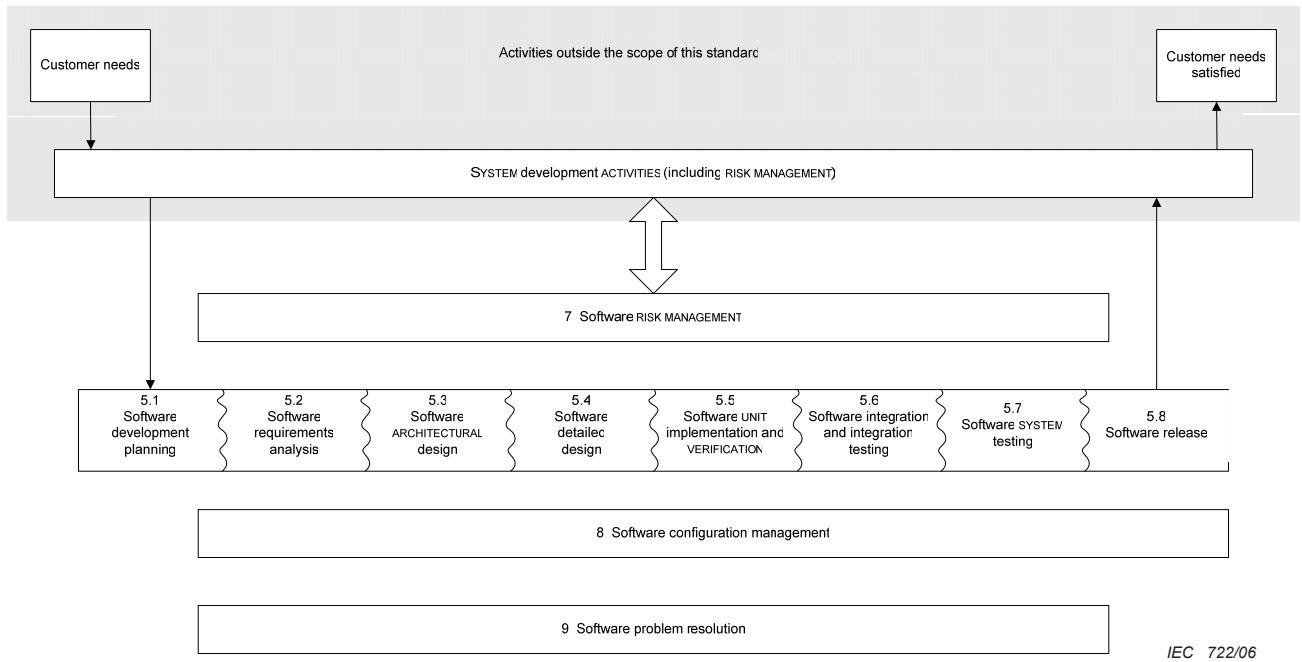


Figure 1 – Overview of software development PROCESSES and ACTIVITIES

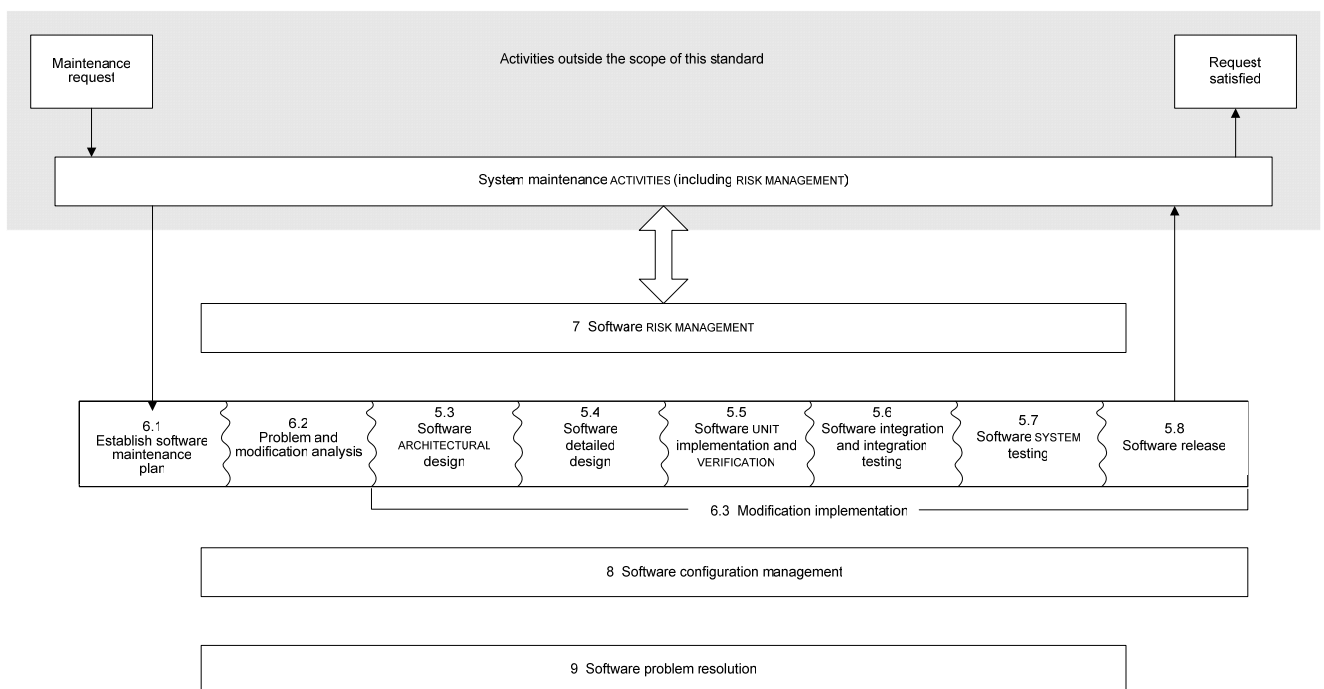


Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES IEC 723/06

This standard identifies two additional PROCESSES considered essential for developing safe MEDICAL DEVICE SOFTWARE. They are the software configuration management PROCESS (Clause 8) and the software problem resolution PROCESS (Clause 9).

A1 Amendment 1 updates the standard to add requirements to deal with LEGACY SOFTWARE, where the software design is prior to the existence of the current version, to assist manufacturers who must show compliance to the standard to meet European Directives. Software safety classification changes include clarification of requirements and updating of the software safety classification to include a risk-based approach. **A1**

This standard does not specify an organizational structure for the MANUFACTURER or which part of the organization is to perform which PROCESS, ACTIVITY, or TASK. This standard requires only that the PROCESS, ACTIVITY, or TASK be completed to establish compliance with this standard.

This standard does not prescribe the name, format, or explicit content of the documentation to be produced. This standard requires documentation of TASKS, but the decision of how to package this documentation is left to the user of the standard.

This standard does not prescribe a specific life cycle model. The users of this standard are responsible for selecting a life cycle model for the software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this standard onto that model.

Annex A provides rationale for the clauses of this standard. Annex B provides guidance on the provisions of this standard.

For the purposes of this standard:

- “shall” means that compliance with a requirement is mandatory for compliance with this standard;
- “should” means that compliance with a requirement is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement;
- “establish” means to define, document, and implement; and
- where this standard uses the term “as appropriate” in conjunction with a required PROCESS, ACTIVITY, TASK or output, the intention is that the MANUFACTURER shall use the PROCESS, ACTIVITY, TASK or output unless the MANUFACTURER can document a justification for not so doing.

MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

1 Scope

1.1 * Purpose

This standard defines the life cycle requirements for MEDICAL DEVICE SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this standard establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.

1.2 * Field of application

A1 This standard applies to the development and maintenance of MEDICAL DEVICE SOFTWARE when software is itself a MEDICAL DEVICE or when software is an embedded or integral part of the final MEDICAL DEVICE.

NOTE 1 This standard can be used in the development and maintenance of software that is itself a medical device. However, additional development activities are needed at the system level before this type of software can be placed into service. These system activities are not covered by this standard, but can be found in IEC 82304-1¹ [22].

This standard describes PROCESSES that are intended to be applied to software which executes on a processor or which is executed by other software (for example an interpreter) which executes on a processor.

This standard applies regardless of the persistent storage device(s) used to store the software (for example: hard disk, optical disk, permanent or flash memory).

This standard applies regardless of the method of delivery of the software (for example: transmission by network or email, optical disk, flash memory or EEPROM). The method of software delivery itself is not considered MEDICAL DEVICE SOFTWARE.

This standard does not cover validation and final release of the MEDICAL DEVICE, even when the MEDICAL DEVICE consists entirely of software.

NOTE 2 If a medical device incorporates embedded software intended to be executed on a processor, the requirements of this standard apply to the software, including the requirements concerning software of unknown provenance (see 8.1.2).

NOTE 3 Validation and other development activities are needed at the system level before the software and medical device can be placed into service. These system activities are not covered by this standard, but can be found in related product standards (e.g., IEC 60601-1, IEC 82304-1, etc.). **A1**

1.3 Relationship to other standards

This MEDICAL DEVICE SOFTWARE life cycle standard is to be used together with other appropriate standards when developing a MEDICAL DEVICE. Annex C shows the relationship between this standard and other relevant standards.

1.4 Compliance

Compliance with this standard is defined as implementing all of the PROCESSES, ACTIVITIES, and TASKS identified in this standard in accordance with the software safety class.

NOTE The software safety classes assigned to each requirement are identified in the normative text following the requirement.

¹ In preparation.

Compliance is determined by inspection of all documentation required by this standard including the RISK MANAGEMENT FILE, and assessment of the PROCESSES, ACTIVITIES and TASKS required for the software safety class. ^{A1} *Text deleted* ^{A1}

NOTE 1 This assessment could be carried out by internal or external audit.

NOTE 2 Although the specified PROCESSES, ACTIVITIES, and TASKS are performed, flexibility exists in the methods of implementing these PROCESSES and performing these ACTIVITIES and TASKS.

NOTE 3 Where any requirements contain "as appropriate" and were not performed, documentation for the justification is necessary for this assessment.

NOTE 4 The term "conformance" is used in ISO/IEC 12207 where the term "compliance" is used in this standard.

^{A1} NOTE 5 For compliance of LEGACY SOFTWARE see 4.4. ^{A1}

2 * Normative references

The following referenced documents are indispensable for the application 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 14971, *Medical devices – Application of risk management to medical devices*.

3 * Terms and definitions

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

3.1

ACTIVITY

a set of one or more interrelated or interacting TASKS

3.2

ANOMALY

any condition that deviates from the expected based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experiences. ANOMALIES may be found during, but not limited to, the review, test, analysis, compilation, or use of ^{A1} MEDICAL DEVICE SOFTWARE ^{A1} or applicable documentation

^{A1} NOTE Based on IEEE 1044:1993, definition 3.1. ^{A1}

3.3

ARCHITECTURE

organizational structure of a SYSTEM or component

[IEEE 610.12:1990]

3.4

CHANGE REQUEST

a documented specification of a change to be made to a ^{A1} MEDICAL DEVICE SOFTWARE ^{A1}

3.5

CONFIGURATION ITEM

entity that can be uniquely identified at a given reference point

NOTE Based on ^{A1} ISO/IEC 12207:2008, 4.7 ^{A1}

3.6

DELIVERABLE

required result or output (includes documentation) of an ACTIVITY or TASK

3.7

EVALUATION

a systematic determination of the extent to which an entity meets its specified criteria

Ⓐ [ISO/IEC 12207:2008, 4.12] Ⓐ

3.8

HARM

physical injury, damage, or both to the health of people or damage to property or the environment

Ⓐ [ISO 14971:2007, 2.2] Ⓐ

3.9

HAZARD

potential source of HARM

Ⓐ [ISO 14971:2007, 2.3] Ⓐ

3.10

MANUFACTURER

natural or legal person with responsibility for designing, manufacturing, packaging, or labelling a MEDICAL DEVICE; assembling a SYSTEM; or adapting a MEDICAL DEVICE before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or by a third party on that person's behalf

Ⓐ [ISO 14971:2007, 2.8]

NOTE 1 Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

NOTE 2 For a definition of labelling, see ISO 13485:2003, definition 3.6. Ⓐ

3.11

MEDICAL DEVICE

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
- supporting or sustaining life,
- control of conception,
- disinfection of MEDICAL DEVICES,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

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

NOTE 1 This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15] (in ISO 13485:2003).

[ISO 13485:2003, definition 3.7]

NOTE 2 Some differences can occur in the definitions used in regulations of each country.

Ⓐ NOTE 3 In conjunction with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 the term "medical device" assumes the same meaning as ME EQUIPMENT or ME SYSTEM (which are defined terms of IEC 60601-1). Ⓐ

3.12

MEDICAL DEVICE SOFTWARE

[A1] SOFTWARE SYSTEM that has been developed for the purpose of being incorporated into the MEDICAL DEVICE being developed or that is intended for use as a MEDICAL DEVICE

NOTE This includes a MEDICAL DEVICE software product, which then is a MEDICAL DEVICE in its own right. **[A1]**

3.13

PROBLEM REPORT

a record of actual or potential behaviour of a **[A1]** MEDICAL DEVICE SOFTWARE **[A1]** that a user or other interested person believes to be unsafe, inappropriate for the intended use or contrary to specification

NOTE 1 This standard does not require that every PROBLEM REPORT results in a change to the **[A1]** MEDICAL DEVICE SOFTWARE **[A1]**. A MANUFACTURER can reject a PROBLEM REPORT as a misunderstanding, error or insignificant event.

NOTE 2 A PROBLEM REPORT can relate to a released **[A1]** MEDICAL DEVICE SOFTWARE **[A1]** or to a **[A1]** MEDICAL DEVICE SOFTWARE **[A1]** that is still under development.

NOTE 3 This standard requires the MANUFACTURER to perform extra decision making steps (see Clause 6) for a PROBLEM REPORT relating to a released product to ensure that regulatory actions are identified and implemented.

3.14

PROCESS

a set of interrelated or interacting ACTIVITIES that transform inputs into outputs

[ISO 9000:2000, definition 3.4.1]

NOTE The term "ACTIVITIES" covers use of resources.

3.15

REGRESSION TESTING

the testing required to determine that a change to a SYSTEM component has not adversely affected functionality, reliability or performance and has not introduced additional defects

[ISO/IEC 90003:2004, definition 3.11]

3.16

RISK

combination of the probability of occurrence of HARM and the severity of that HARM

[A1] [ISO 14971:2007, 2.16] **[A1]**

3.17

RISK ANALYSIS

systematic use of available information to identify HAZARDS and to estimate the RISK

[A1] [ISO 14971:2007, 2.17] **[A1]**

3.18

RISK CONTROL

PROCESS in which decisions are made and RISKS are reduced to, or maintained within, specified levels

[A1] [ISO 14971:2007, 2.19] **[A1]**

3.19

RISK MANAGEMENT

systematic application of management policies, procedures, and practices to the TASKS of analyzing, evaluating, and controlling RISK

[A1] [ISO 14971:2007, 2.22, modified – The phrase "and monitoring" has been removed] **[A1]**

3.20

RISK MANAGEMENT FILE

set of records and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS

Ⓐ₁ [ISO 14971:2007, 2.23] Ⓐ₁

3.21

SAFETY

freedom from unacceptable RISK

Ⓐ₁ [ISO 14971:2007, 2.24] Ⓐ₁

3.22

SECURITY

Ⓐ₁ protection of information and data so that unauthorized persons or systems cannot read or modify them an authorized persons or systems are not denied access to them.

NOTE Based on ISO/IEC 12207:2008, 4.39. Ⓐ₁

3.23

SERIOUS INJURY

injury or illness that Ⓐ₁ *text deleted* Ⓐ₁:

- a) is life threatening,
- b) results in permanent impairment of a body function or permanent damage to a body structure, or
- c) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

NOTE Permanent impairment means an irreversible impairment or damage to a body structure or function excluding trivial impairment or damage.

3.24

SOFTWARE DEVELOPMENT LIFE CYCLE MODEL

conceptual structure spanning the life of the software from definition of its requirements to its release Ⓐ₁ *text deleted* Ⓐ₁, which:

- identifies the PROCESS, ACTIVITIES and TASKS involved in development of a Ⓐ₁ MEDICAL DEVICE SOFTWARE Ⓐ₁,
- describes the sequence of and dependency between ACTIVITIES and TASKS, and
- identifies the milestones at which the completeness of specified DELIVERABLES is verified.

NOTE Based on ISO/IEC 12207:1995, definition 3.11

3.25

SOFTWARE ITEM

Ⓐ₁ any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items

NOTE 1 Three terms identify the software decomposition. The top level is the SOFTWARE SYSTEM. The lowest level that is not further decomposed is the SOFTWARE UNIT. All levels of composition, including the top and bottom levels, can be called SOFTWARE ITEMS. A SOFTWARE SYSTEM, then, is composed of one or more SOFTWARE ITEMS, and each SOFTWARE ITEM is composed of one or more SOFTWARE UNITS or decomposable SOFTWARE ITEMS. The responsibility is left to the MANUFACTURER to provide the granularity of the SOFTWARE ITEMS and SOFTWARE UNITS.

NOTE 2 Based on ISO/IEC 90003:2004, 3.14 and ISO/IEC 12207:2008, 4.41. Ⓐ₁

3.26

Ⓐ₁ *Not used* Ⓐ₁

3.27

SOFTWARE SYSTEM

integrated collection of SOFTWARE ITEMS organized to accomplish a specific function or set of functions

3.28

SOFTWARE UNIT

SOFTWARE ITEM that is not subdivided into other items

[A1] NOTE The granularity of SOFTWARE UNITS is defined by the MANUFACTURER (see B.3). **[A1]**

3.29

SOUP

software of unknown provenance (acronym)

SOFTWARE ITEM that is already developed and generally available and that has not been developed for the purpose of being incorporated into the MEDICAL DEVICE (also known as “off-the-shelf software”) or

[A1] SOFTWARE ITEM previously developed **[A1]** for which adequate records of the development PROCESSES are not available

[A1] NOTE A MEDICAL DEVICE SOFTWARE SYSTEM in itself cannot be claimed to be SOUP. **[A1]**

3.30

SYSTEM

integrated composite consisting of one or more of the PROCESSES, hardware, software, facilities, and people, that provides a capability to satisfy a stated need or objective

[A1] NOTE Based on ISO/IEC 12207:2008, 4.48. **[A1]**

3.31

TASK

a single piece of work that needs to be done

3.32

TRACEABILITY

degree to which a relationship can be established between two or more products of the development PROCESS

[IEEE 610.12:1990]

[A1] NOTE Requirements, architecture, risk control measures, etc. are examples of deliverables of the development PROCESS. **[A1]**

3.33

VERIFICATION

confirmation through provision of objective evidence that specified requirements have been fulfilled

NOTE 1 “Verified” is used to designate the corresponding status.

[ISO 9000:2000, definition 3.8.4]

NOTE 2 In design and development, VERIFICATION concerns the PROCESS of examining the result of a given ACTIVITY to determine conformity with the stated requirement for that ACTIVITY.

3.34

VERSION

identified instance of a CONFIGURATION ITEM

NOTE 1 Modification to a VERSION of **[A1]** MEDICAL DEVICE SOFTWARE **[A1]**, resulting in a new VERSION, requires software configuration management action.

[A1] NOTE 2 Based on ISO/IEC 12207:2008, 4.56.

3.35

HAZARDOUS SITUATION

circumstance in which people, property or the environment are exposed to one or more HAZARD(S)

[SOURCE: ISO 14971:2007, 2.4] **[A1]**

A1 3.36

LEGACY SOFTWARE

MEDICAL DEVICE SOFTWARE which was legally placed on the market and is still marketed today but for which there is insufficient objective evidence that it was developed in compliance with the current version of this standard

3.37

RELEASE

particular VERSION of a CONFIGURATION ITEM that is made available for a specific purpose

NOTE Based on ISO/IEC 12207:2008, definition 4.35.

3.38

RESIDUAL RISK

RISK remaining after RISK CONTROL measures have been taken

NOTE 1 Adapted from ISO/IEC Guide 51:1999, definition 3.9.

NOTE 2 ISO/IEC Guide 51:1999, definition 3.9 uses the term “protective measures” rather than “RISK CONTROL measures.” However, in the context of this International Standard, “protective measures” are only one option for controlling RISK as described in 6.2 [of ISO 14971:2007].

[SOURCE: ISO 14971:2007, 2.15].

3.39

RISK ESTIMATION

PROCESS used to assign values to the probability of occurrence of HARM and the severity of that HARM

[SOURCE: ISO 14971:2007 2.20]

3.40

RISK EVALUATION

PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007 2.21] **A1**

4 * General requirements

4.1 * Quality management system

The MANUFACTURER of MEDICAL DEVICE SOFTWARE shall demonstrate the ability to provide MEDICAL DEVICE SOFTWARE that consistently meets customer requirements and applicable regulatory requirements.

NOTE 1 Demonstration of this ability can be by the use of a quality management system that complies with:

- ISO 13485 [7]; or
- a national quality management system standard; or
- a quality management system required by national regulation.

NOTE 2 Guidance for applying quality management system requirements to software can be found in ISO/IEC 90003 [11].

4.2 * RISK MANAGEMENT

The MANUFACTURER shall apply a RISK MANAGEMENT PROCESS complying with ISO 14971.

4.3 * Software safety classification

- A1** a) The MANUFACTURER shall assign to each SOFTWARE SYSTEM a software safety class (A, B, or C) according to the RISK of HARM to the patient, operator, or other people resulting from a HAZARDOUS SITUATION to which the SOFTWARE SYSTEM can contribute in a worst-case-scenario as indicated in Figure 3.

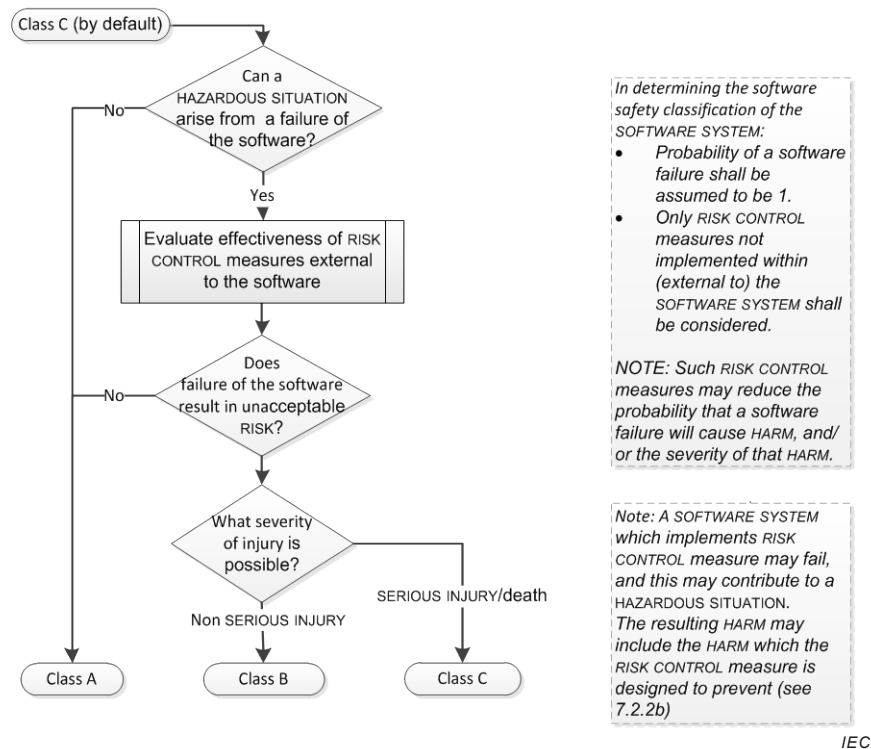


Figure 3 – Assigning software safety classification

The SOFTWARE SYSTEM is software safety class A if:

- the SOFTWARE SYSTEM cannot contribute to a HAZARDOUS SITUATION; or
- the SOFTWARE SYSTEM can contribute to a HAZARDOUS SITUATION which does not result in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM.

The SOFTWARE SYSTEM is software safety class B if:

- the SOFTWARE SYSTEM can contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is non-SERIOUS INJURY.

The SOFTWARE SYSTEM is software safety class C if:

- the SOFTWARE SYSTEM can contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is death or SERIOUS INJURY.

For a SOFTWARE SYSTEM initially classified as software safety class B or C, the MANUFACTURER may implement additional RISK CONTROL measures external to the SOFTWARE SYSTEM (including revising the system architecture containing the SOFTWARE SYSTEM) and subsequently assign a new software safety classification to the SOFTWARE SYSTEM.

NOTE 1 External RISK CONTROL measures can be hardware, an independent SOFTWARE SYSTEM, health care procedures, or other means to minimize that software can contribute to a HAZARDOUS SITUATION.

NOTE 2 See ISO 14971:2007 subclause 3.2, *Management Responsibilities*, for the definition of risk acceptability. **A1**

- A1** b) Not used. **A1**
- c) The MANUFACTURER shall document the software safety class assigned to each SOFTWARE SYSTEM in the RISK MANAGEMENT FILE.
- d) When a SOFTWARE SYSTEM is decomposed into SOFTWARE ITEMS, and when a SOFTWARE ITEM is decomposed into further SOFTWARE ITEMS, such SOFTWARE ITEMS shall inherit the software safety classification of the original SOFTWARE ITEM (or SOFTWARE SYSTEM) unless the MANUFACTURER documents a rationale for classification into a different software safety class **A1** (software safety classes assigned according to 4.3 a) replacing “SOFTWARE SYSTEM” with “SOFTWARE ITEM”) **A1**. Such a rationale shall explain how the new SOFTWARE ITEMS are segregated so that they may be classified separately.
- e) The MANUFACTURER shall document the software safety class of each SOFTWARE ITEM if that class is different from the class of the SOFTWARE ITEM from which it was created by decomposition.
- A1** f) For compliance with this standard, when applying this standard to a group of SOFTWARE ITEMS, the MANUFACTURER shall use the PROCESSES and TASKS which are required by the classification of the highest-classified SOFTWARE ITEM in the group unless the MANUFACTURER documents in the RISK MANAGEMENT FILE a rationale for using a lower classification. **A1**
- g) For each SOFTWARE SYSTEM, until a software safety class is assigned, Class C requirements shall apply.

A1 NOTE In the clauses and subclauses that follow, the software safety classes for which a specific requirement applies are identified following the requirement in the form of [Class . . .]. **A1**

A1 4.4 * LEGACY SOFTWARE

4.4.1 General

As an alternative to applying Clauses 5 through 9 of this standard, compliance of LEGACY SOFTWARE may be demonstrated as indicated in 4.4.2 to 4.4.5.

4.4.2 RISK MANAGEMENT ACTIVITIES

In accordance with 4.2 of this standard, the MANUFACTURER shall:

- a) assess any feedback, including post-production information, on LEGACY SOFTWARE regarding incidents and / or near incidents, both from inside its own organization and / or from users;
- b) perform RISK MANAGEMENT ACTIVITIES associated with continued use of the LEGACY SOFTWARE, considering the following aspects:
- integration of the LEGACY SOFTWARE in the overall MEDICAL DEVICE architecture;
 - continuing validity of RISK CONTROL measures, implemented as part of the LEGACY SOFTWARE;
 - identification of HAZARDOUS SITUATIONS associated with the continued use of the LEGACY SOFTWARE;
 - identification of potential causes of the LEGACY SOFTWARE contributing to a HAZARDOUS SITUATION;
 - definition of RISK CONTROL measures for each potential cause of the LEGACY SOFTWARE contributing to a HAZARDOUS SITUATION.

4.4.3 Gap analysis

Based on the software safety class of the LEGACY SOFTWARE (see 4.3), the MANUFACTURER shall perform a gap analysis of available DELIVERABLES against those required according to 5.2, 5.3, 5.7, and Clause 7.

- a) The MANUFACTURER shall assess the continuing validity of available DELIVERABLES.
- b) Where gaps are identified, the MANUFACTURER shall EVALUATE the potential reduction in RISK resulting from the generation of the missing DELIVERABLES and associated ACTIVITIES. **A1**

- A1** c) Based on this evaluation, the MANUFACTURER shall determine the DELIVERABLES to be created and associated ACTIVITIES to be performed. The minimum DELIVERABLE shall be SOFTWARE SYSTEM test records (see 5.7.5).

NOTE Such gap analysis should assure that RISK CONTROL measures, implemented in LEGACY SOFTWARE, are included in the software requirements.

4.4.4 Gap closure activities

- a) The MANUFACTURER shall establish and execute a plan to generate the identified DELIVERABLES. Where available, objective evidence may be used to generate required DELIVERABLES without performing ACTIVITIES required by 5.2, 5.3, 5.7 and Clause 7.

NOTE A plan on how to address the identified gaps can be included in a software maintenance plan (see 6.1).

- b) The plan shall address the use of the problem resolution PROCESS for handling problems detected in the LEGACY SOFTWARE and DELIVERABLES in accordance with Clause 9.
c) Changes to the LEGACY SOFTWARE shall be performed in accordance with Clause 6.

4.4.5 Rationale for use of LEGACY SOFTWARE

The MANUFACTURER shall document the VERSION of the LEGACY SOFTWARE together with a rationale for the continued use of the LEGACY SOFTWARE based on the outputs of 4.4.

NOTE Fulfilling 4.4 enables further use of LEGACY SOFTWARE in accordance with IEC 62304. **A1**

5 Software development PROCESS

5.1 * Software development planning

5.1.1 Software development plan

The MANUFACTURER shall establish a software development plan (or plans) for conducting the ACTIVITIES of the software development PROCESS appropriate to the scope, magnitude, and software safety classifications of the SOFTWARE SYSTEM to be developed. The SOFTWARE DEVELOPMENT LIFE CYCLE MODEL shall either be fully defined or be referenced in the plan (or plans). The plan shall address the following:

- a) the PROCESSES to be used in the development of the SOFTWARE SYSTEM (see Note 4);
- b) the DELIVERABLES (includes documentation) of the ACTIVITIES and TASKS;
- c) TRACEABILITY between SYSTEM requirements, software requirements, SOFTWARE SYSTEM test, and RISK CONTROL measures implemented in software;
- d) software configuration and change management, including SOUP CONFIGURATION ITEMS and software used to support development; and
- e) software problem resolution for handling problems detected in the **A1** MEDICAL DEVICE SOFTWARE **A1**, DELIVERABLES and ACTIVITIES at each stage of the life cycle.

[Class A, B, C]

NOTE 1 The SOFTWARE DEVELOPMENT LIFE CYCLE MODEL can identify different elements (PROCESSES, ACTIVITIES, TASKS and DELIVERABLES) for different SOFTWARE ITEMS according to the software safety classification of each SOFTWARE ITEM of the SOFTWARE SYSTEM.

NOTE 2 These ACTIVITIES and TASKS can overlap or interact and can be performed iteratively or recursively. It is not the intent to imply that a specific life cycle model should be used.

NOTE 3 Other PROCESSES are described in this standard separately from the development PROCESS. This does not imply that they must be implemented as separate ACTIVITIES and TASKS. The ACTIVITIES and TASKS of the other PROCESSES can be integrated into the development PROCESS.

NOTE 4 The software development plan can reference existing PROCESSES or define new ones.

NOTE 5 The software development plan may be integrated in an overall SYSTEM development plan.

5.1.2 Keep software development plan updated

The MANUFACTURER shall update the plan as development proceeds as appropriate. [Class A, B, C]

5.1.3 Software development plan reference to SYSTEM design and development

- a) As inputs for software development, SYSTEM requirements shall be referenced in the software development plan by the MANUFACTURER.
-  b) In the software development plan, the MANUFACTURER shall include or reference procedures for coordinating the software development with the system development necessary to satisfy 4.1 (such as system integration, verification, and validation). 

[Class A, B, C]

NOTE There might not be a difference between SOFTWARE SYSTEM requirements and SYSTEM requirements if the SOFTWARE SYSTEM is a stand alone SYSTEM (software-only device).

5.1.4 Software development standards, methods and tools planning

The MANUFACTURER shall include or reference in the software development plan:

- a) standards,
- b) methods, and
- c) tools

associated with the development of SOFTWARE ITEMS of class C. [Class C]

5.1.5 Software integration and integration testing planning

The MANUFACTURER shall include or reference in the software development plan, a plan to integrate the SOFTWARE ITEMS (including SOUP) and perform testing during integration. [Class B, C]

NOTE 1 It is acceptable to combine integration testing and SOFTWARE SYSTEM testing into a single plan and set of ACTIVITIES.

 NOTE 2 See 5.6. 

5.1.6 Software VERIFICATION planning

The MANUFACTURER shall include or reference in the software development plan the following VERIFICATION information:

- a) DELIVERABLES requiring VERIFICATION;
- b) the required VERIFICATION TASKS for each life cycle ACTIVITY;
- c) milestones at which the DELIVERABLES are VERIFIED; and
- d) the acceptance criteria for VERIFICATION of the DELIVERABLES.

[Class A, B, C]

5.1.7 Software RISK MANAGEMENT planning

The MANUFACTURER shall include or reference in the software development plan, a plan to conduct the ACTIVITIES and TASKS of the software RISK MANAGEMENT PROCESS, including the management of RISKS relating to SOUP. [Class A, B, C]

NOTE See Clause 7.

5.1.8 Documentation planning

The MANUFACTURER shall include or reference in the software development plan information about the documents to be produced during the software development life cycle. For each identified document or type of document the following information shall be included or referenced:

- a) title, name or naming convention;
- b) purpose;

 *Text deleted* 

- d) procedures and responsibilities for development, review, approval and modification.

[Class A, B, C]

 NOTE See Clause 8 for consideration of configuration management of documentation. 

5.1.9 Software configuration management planning

The MANUFACTURER shall include or reference software configuration management information in the software development plan. The software configuration management information shall include or reference:

- a) the classes, types, categories or lists of items to be controlled;
- b) the software configuration management ACTIVITIES and TASKS;
- c) the organization(s) responsible for performing A1 software configuration management ACTIVITIES A1;
- d) their relationship with other organizations, such as software development or maintenance;
- e) when the items are to be placed under configuration control; and
- f) when the problem resolution PROCESS is to be used.

[Class A, B, C]

A1 NOTE See Clause 8. A1

5.1.10 Supporting items to be controlled

The items to be controlled shall include tools, items or settings, used to develop the MEDICAL DEVICE SOFTWARE, which could impact the MEDICAL DEVICE SOFTWARE. [Class B, C]

NOTE 1 Examples of such items include compiler/assembler versions, make files, batch files, and specific environment settings.

A1 NOTE 2 See Clause 8. A1

5.1.11 Software CONFIGURATION ITEM control before VERIFICATION

The MANUFACTURER shall plan to place CONFIGURATION ITEMS A1 under configuration management A1 control before they are VERIFIED. [Class B, C]

A1 5.1.12 Identification and avoidance of common software defects

The MANUFACTURER shall include or reference in the software development plan a procedure for:

- a) identifying categories of defects that may be introduced based on the selected programming technology that are relevant to their SOFTWARE SYSTEM; and
- b) documenting evidence that demonstrates that these defects do not contribute to unacceptable RISK.

NOTE See Annex B of IEC TR 80002-1:2009 for examples of categories of defects or causes contributing to HAZARDOUS SITUATIONS.

[Class B, C] A1

5.2 * Software requirements analysis

5.2.1 Define and document software requirements from SYSTEM requirements

For each SOFTWARE SYSTEM of the MEDICAL DEVICE, the MANUFACTURER shall define and document SOFTWARE SYSTEM requirements from the SYSTEM level requirements. [Class A, B, C]

NOTE There might not be a difference between SOFTWARE SYSTEM requirements and SYSTEM requirements if the SOFTWARE SYSTEM is a stand alone SYSTEM (software-only device).

5.2.2 Software requirements content

As appropriate to the MEDICAL DEVICE SOFTWARE, the MANUFACTURER shall include in the software requirements:

a) functional and capability requirements;

NOTE 1 Examples include:

- performance (e.g., purpose of software, timing requirements),
- physical characteristics (e.g., code language, platform, operating system),
- computing environment (e.g., hardware, memory size, processing unit, time zone, network infrastructure) under which the software is to perform, and
- need for compatibility with upgrades or multiple SOUP or other device versions.

b) SOFTWARE SYSTEM inputs and outputs;

NOTE 2 Examples include:

- data characteristics (e.g., numerical, alpha-numeric, format)
- ranges,
- limits, and
- defaults.

c) interfaces between the SOFTWARE SYSTEM and other SYSTEMS;

d) software-driven alarms, warnings, and operator messages;

e) SECURITY requirements;

NOTE 3 Examples include:

- those related to the compromise of sensitive information,
 - authentication,
 - authorization,
 - audit trail, and
 - communication integrity.
- A1** – system security/malware protection.

f) user interface requirements implemented by software; **A1**

NOTE 4 Examples include those related to:

- support for manual operations,
- human-equipment interactions,
- constraints on personnel, and
- areas needing concentrated human attention.

NOTE 5 Information regarding usability engineering requirements can be found in **A1** IEC 62366-1 [21] among others (e.g., IEC 60601-1-6 [3]) **A1**.

g) data definition and database requirements;

NOTE 6 Examples include:

- form;
- fit;
- function.

h) installation and acceptance requirements of the delivered MEDICAL DEVICE SOFTWARE at the operation and maintenance site or sites;

i) requirements related to methods of operation and maintenance;

A1 j) requirements related to IT-network aspects;

NOTE 9 Examples include those related to:

- networked alarms, warnings, and operator messages;
- network protocols;
- handling of unavailability of network services. **A1**