American National Standard

ANSI/AAMI/ IEC 62304: 2006 & A1:2016

(Consolidated Text)

Medical device software—
Software life cycle processes

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

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Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

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Medical device software—Software life cycle processes

Approved 18 December 2015 by
AAMI

Approved 7 April 2016 by
American National Standards Institute, Inc.

Abstract: 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. 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.

Keywords: medical device, software, life cycle

AAMI Standard

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www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation
Software Work Group

The publication of ANSI/AAMI/IEC 62304:2006/A1 as a new American National Standard was initiated by the AAMI Information Technology Networks Work Group, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO) ISO/TC210 – IEC/SC62A JWG2. U.S. representatives from the AAMI Software Work Group participate as US experts on the ISO committee.

At the time this document was published, the **AAMI Software Work Group** had the following members:

Cochair:
Sherman Eagles, SoftwareCPR
John Murray, FDA/CDRH

Members:
Mark Adams, Steris Corporation
Michael Attili, Amaxo Inc
Michael Brendel, Spacelabs Healthcare
Frank Clay
Kimberly Colasanti, Welch Allyn Inc
Todd Cooper, Center for Medical Interoperability
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Rick Hampton, Premier Inc - Charlotte, NC
Ed Heierman, Abbott Laboratories
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Michelle Jump, Stryker Instruments Division
Jim Kainec, Steris Corporation
Patty Krantz-Zuppan, Medtronic Inc WHQ Campus
Alan Kusinitz, SoftwareCPR
Yimin Li, St Jude Medical Inc
Jared Mauldin, Integrated Medical Systems
Mary Beth McDonald, Mary Beth McDonald Consulting
Mulugeta Mideksa
Mark Miller, Covidien
Andrew O'Keeffe, Draeger Medical Systems Inc
Geoff Pascoe
Joe Petruzzelli, Mindray DS USA Inc
Dewey Phan, Becton Dickinson & Company
Jon Platt, 3M Healthcare
Frank Pokrop, CareFusion
Bryan Pourciau, Cyberonics Inc
Inhel Rekik, University of Maryland Medical System
Victor Rodrigues, Cochlear Ltd
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Miguel Rodriguez, Johnson & Johnson
Bill Roeca, CR Bard
Daniel Rubery, NxStage Medical Inc
Rick Schrenker, Massachusetts General Hospital
Ray Silkaitis, Amgen Inc
Chandresh Thakur, CareFusion
Donna-Bea Tillman, Biologics Consulting Group

Mark Walker, Focus Compliance & Validation Services
Janet Wickey, Bausch & Lomb Inc
Mike Willingham, Caradigm USA LLC
Daidi Zhong, Chongqing University

Alternates: Cheryl Carey, Medical Imaging & Technology Alliance a Division of NEMA
Kevin Crowe, Cochlear Ltd
Jean Desire, Hospira Worldwide Inc
Jeff Gilham, Spacelabs Healthcare
Jim Hempel, Covidien
Joshua Kim, Welch Allyn Inc
Don Lin
Don McAndrews, Philips Electronics North America
Andrew Northup, Medical Imaging & Technology Alliance a Division of NEMA
Susumu Nozawa, Becton Dickinson & Company
John Schmidt, Boston Scientific Corporation
Xianyu Shea, Stryker Medical Division
Diane Sheffer, Steris Corporation
Robert Smith, St Jude Medical Inc
Ferry Tamtoro, Amgen Inc
Ann Vu, Johnson & Johnson
Fei Wang, Fresenius Medical Care
J.S. Wiley, Draeger Medical Systems Inc
Xianyu Shea, Stryker Medical Division

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This Consolidated version of IEC 62304 bears the edition number 1.1. It consists of the first edition (2006-05) [documents 62A/523/FDIS and 62A/528/RVD] and its amendment 1 (2015-06) [documents 62A/1007/FDIS and 62A/1014/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

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.

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 the base publication and its amendment will remain unchanged until the stability 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.

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.

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. Each life cycle PROCESS consists of a set of ACTIVITIES, with most ACTIVITIES consisting of a set of TASKS.

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 contributing factor to a HAZARDOUS SITUATION is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. HAZARDOUS SITUATIONS 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.

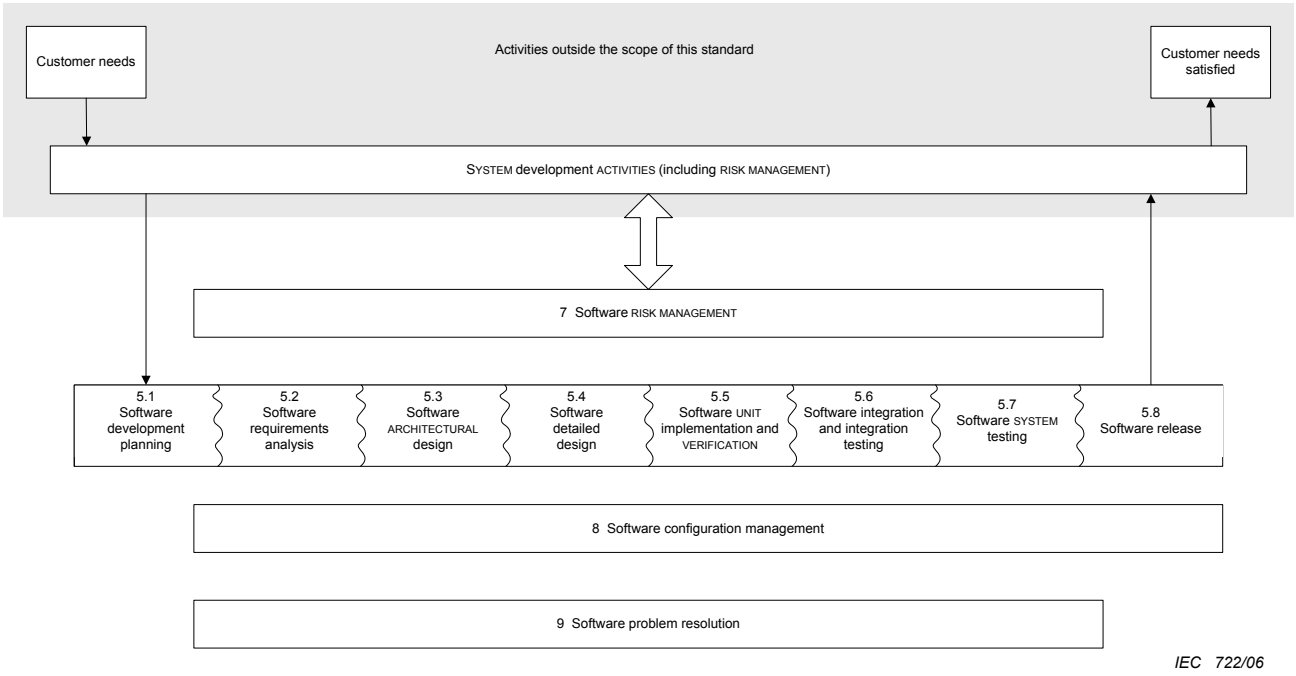

Figure 1 – Overview of software development PROCESSES and ACTIVITIES

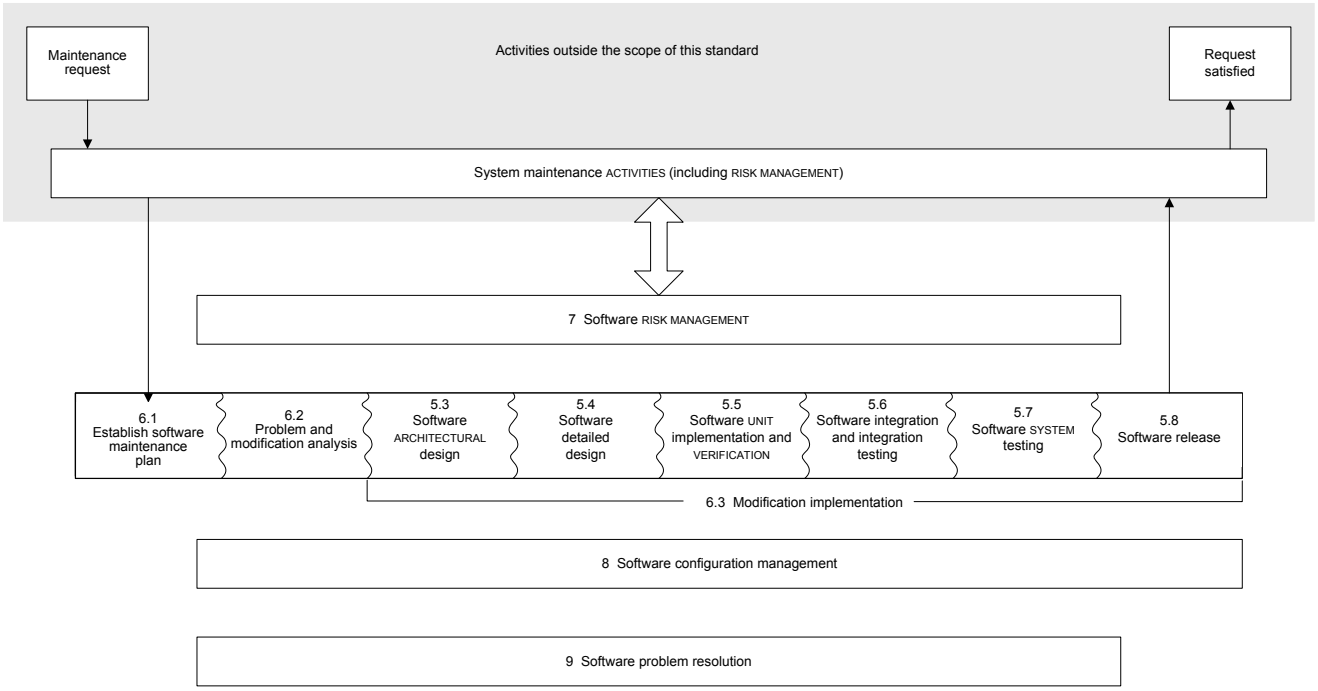

Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES

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).

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.

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.

Introduction to Amendment 1

The first edition of IEC 62304 was published in 2006. This amendment is intended 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 needed for this amendment include clarification of requirements and updating of the software safety classification to include a risk-based approach. Work is continuing in parallel to develop the second edition of IEC 62304.

Medical device software—Software life cycle processes

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

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 82304-1[1] [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.).

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.

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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.

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.

NOTE 5 For compliance of LEGACY SOFTWARE see 4.4.

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 MEDICAL DEVICE SOFTWARE or applicable documentation

NOTE Based on IEEE 1044:1993, definition 3.1.

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 MEDICAL DEVICE SOFTWARE

3.5
CONFIGURATION ITEM
entity that can be uniquely identified at a given reference point

NOTE Based on ISO/IEC 12207:2008, 4,7.

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

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.

[ISO 14971:2007, 2,8]

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
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.

3.13
PROBLEM REPORT
a record of actual or potential behaviour of a MEDICAL DEVICE SOFTWARE 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 MEDICAL DEVICE SOFTWARE. A MANUFACTURER can reject a PROBLEM REPORT as a misunderstanding, error or insignificant event.

NOTE 2 A PROBLEM REPORT can relate to a released MEDICAL DEVICE SOFTWARE or to a MEDICAL DEVICE SOFTWARE 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

[ISO 14971:2007, 2.16]

3.17
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

[ISO 14971:2007, 2.17]

3.18
RISK CONTROL
PROCESS in which decisions are made and RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2007, 2.19]

3.19
RISK MANAGEMENT
systematic application of management policies, procedures, and practices to the TASKS of analyzing, evaluating, and controlling RISK

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

3.20
RISK MANAGEMENT FILE
set of records and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS

[ISO 14971:2007, 2.23]

3.21
SAFETY
freedom from unacceptable RISK

[ISO 14971:2007, 2.24]

3.22
SECURITY
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.

3.23
SERIOUS INJURY
injury or illness that:

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, which:

– identifies the PROCESS, ACTIVITIES and TASKS involved in development of MEDICAL DEVICE SOFTWARE,

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

NOTE 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

3.26
Not used

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

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

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 SOFTWARE ITEM previously developed for which adequate records of the development PROCESSES are not available

NOTE A MEDICAL DEVICE SOFTWARE SYSTEM in itself cannot be claimed to be SOUP.