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.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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and A1:2016 (Consolidated Text)

Medical device software—Software life cycle processes

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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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Glossary of equivalent standards

International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

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:

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This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

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.

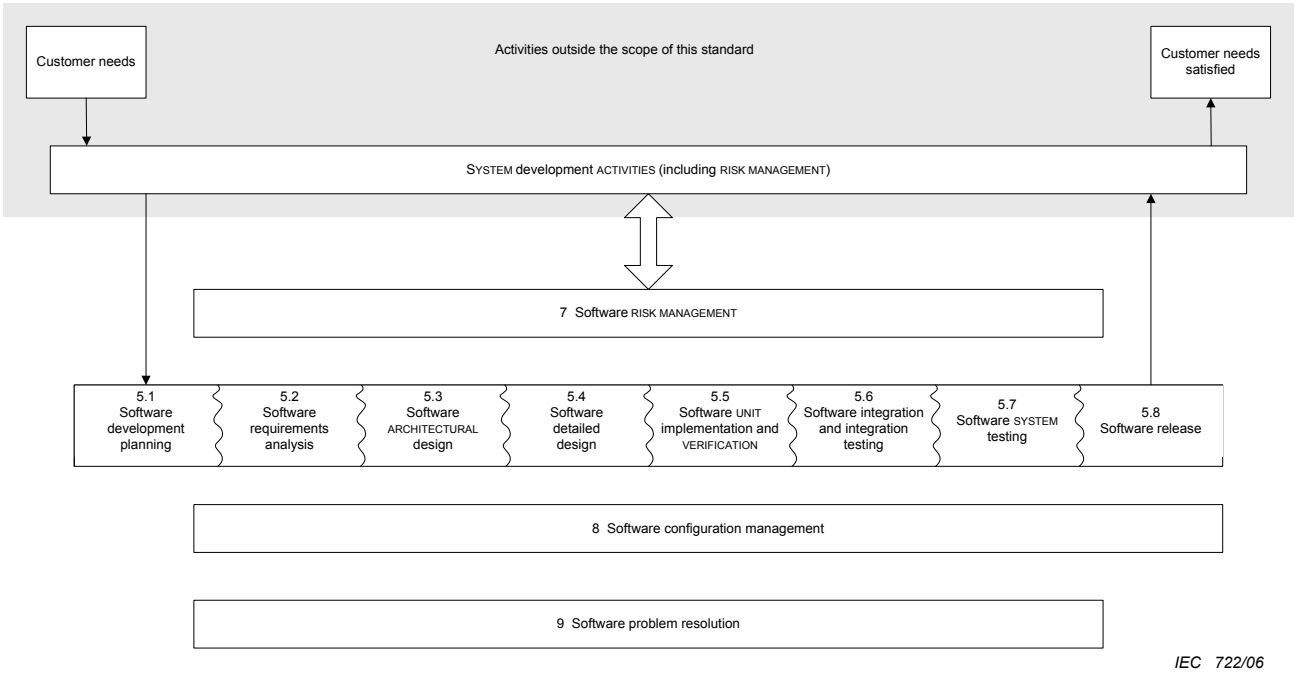

Figure 1 – Overview of software development PROCESSES and ACTIVITIES

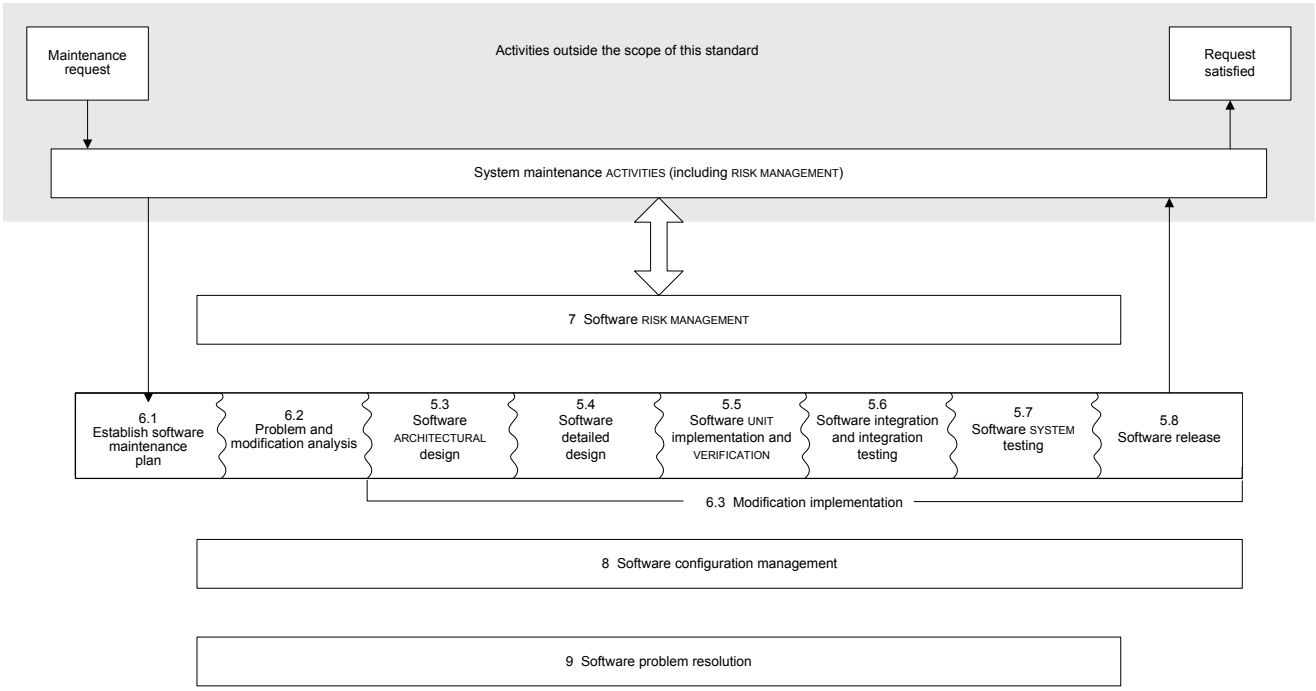

Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES

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.