

American National Standard

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Medical device software— Software life cycle processes

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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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Medical device software— Software life cycle processes

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Abstract: 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, with well-defined terminology that can be referenced by the medical device software industry.

Keywords: software, medical device, software life cycle process, software engineering

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Committee representation

Association for the Advancement of Medical Instrumentation

Medical Device Software Committee

This standard was developed by the AAMI Medical Device Software Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Medical Device Software Committee** had the following members:

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At the time this document was published, the **Executive Board of the AAMI Medical Device Software Committee** had the following members: Sherman Eagles, Brian Fitzgerald, Nancy George, Alan Kusnitz, Bernard Liebler, and John F. Murray.

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) published ISO/IEC 12207, *Information technology—Software life cycle processes* in August 1995. The ISO and IEC collaboration that produced this standard is known as Joint Technical Committee 1—Information Technology, Subcommittee 7, Software Engineering.

ISO/IEC 12207 was written as a software life cycle processes standard that could be used in any business sector (aerospace, automotive, medical, etc.). The standard as written contains a comprehensive set of software life cycle processes, activities, and tasks.

The Medical Device Software Committee of the Association for the Advancement of Medical Instrumentation (AAMI) has drafted a standard for use in the medical device business sector based on the framework established in ISO/IEC 12207.

This medical device software standard uses the framework for software life cycle processes established by ISO/IEC 12207 to describe the set of required processes, activities, and tasks necessary to convey this knowledge of intention and provide this demonstration of implementation. In general, this set is less comprehensive than the set defined in ISO/IEC 12207. However, where appropriate, the requirements of ISO/IEC 12207 have been added to and modified.

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
- “as appropriate” is defined to be “appropriate” unless the manufacturer can document justification otherwise.

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 fulfills those intentions without causing any unacceptable risks.

A minimum set of processes, activities, and tasks must be performed to enable a manufacturer to conduct a medical device risk analysis to determine whether the software can cause a hazard or mitigate a hazard. If the medical device risk analysis determines that the software can cause or mitigate a hazard, additional processes, activities, and tasks are required. See 1.3 of this medical device software standard for additional details.

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, with well-defined terminology that the medical device software industry can reference.

1.2 Field of application

This standard applies to the development and maintenance of medical device software.

This standard may be used when software is a stand-alone medical device or when software is an embedded or integral part of the final medical device.

Medical device development requires the execution of a number of system and subsystem life cycle processes. When a medical device contains software, the software comprises one or more of the subsystems of the medical device.

This standard provides requirements for the life cycle processes, activities, and tasks required for software subsystems of medical devices. It covers the life cycle of medical device software from assignment of system requirements to the software subsystem until the software is no longer in use.

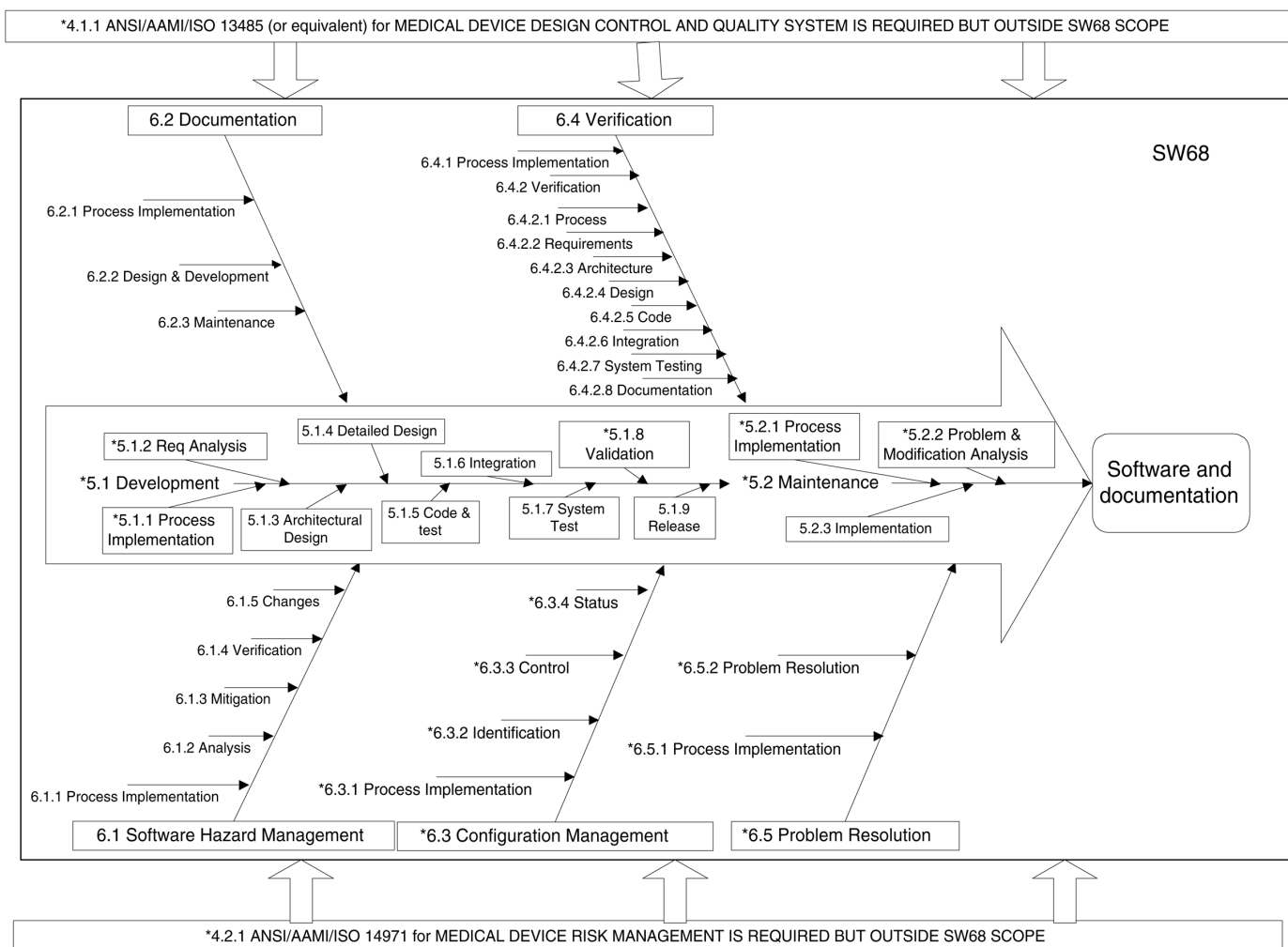
This standard groups software engineering activity into two primary life cycle processes (development and maintenance) and five supporting life cycle processes. Each life cycle process is further divided into a set of activities, with each activity further divided into a set of tasks.

A supporting life cycle process is designed to support another process as an integral part with a distinct purpose and contributes to the success and quality of the software project. A supporting process is used as needed during the execution of another process. For medical device software, the five supporting processes are:

- a) software hazard management;
- b) documentation;
- c) configuration management;
- d) verification; and
- e) problem resolution.

Activities and tasks required to conduct each of these primary and supporting processes are defined in this standard.

Figure 1 shows the relationship of the primary and supporting processes.



* Items marked with an asterisk are minimum requirements for low risk as defined by Section 1.3.2

Figure 1—Process and activity summary

1.3 Compliance

Whether software can cause a hazard is determined during the hazard identification activity of the risk management process. The decision to use software to control risk is made during the risk control activity of the risk management process. See ANSI/AAMI/ISO 14971 (normative reference 2.2).

Compliance with this standard is defined as performing all of the processes, activities, and tasks identified in this standard in accordance with 1.3.1 or 1.3.2. Hazards that may 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 to select compliance with 1.3.1 or with 1.3.2.

Although the specified processes, activities, and tasks shall be performed, flexibility exists in the methods of implementing these processes and performing these activities and tasks.

1.3.1 Compliance for software that can cause a hazard or that controls risk

For medical device software that can cause a hazard prior to risk control measures or is used to control risks, these processes and activities shall be performed:

- Processes and activities for a quality management system (4.1) and risk management (4.2).