American National Standard

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

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, reference 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 usually 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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

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.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

American National Standard ANSI/AAMI/IEC 62304:2006/A1:2016

AAMI

Advancing Safety in Healthcare Technology

Medical device software—Software life cycle processes

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

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

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This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

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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

Advancing Safety in Healthcare Technology

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
Conor Curtin, Fresenius Medical Care
Richard DeLaCruz, Silver Lake Group Inc
Theresa Dennis, Sterigenics International
Harsh Dharwad, Hospira Worldwide Inc
Plamena Entcheva-Dimitrov, Regulatory Consultant
Christie Evans, Hill-Rom Holdings
Chris Flahive, Chris Flahive Associates
Rick Hampton, Premier Inc - Charlotte NC
Ed Heierman, Abbott Laboratories
Jeremy Jensen, Boston Scientific Corporation
Clint Johnson, UC Davis Medical Cntr
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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
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Ann Vu, Johnson & Johnson
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Xianyu Shea, Stryker Medical Division

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

FOREWORD

This amendment 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.

This publication is published as a double logo standard.

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

FDIS	Report on voting
62A/1007/FDIS	62A/1014/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 30 P-members out of 30 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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.

A bilingual version of this publication may be issued at a later date.

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INTRODUCTION TO THE AMENDMENT

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.

FOREWORD

Add the following note at the end of the Foreword:

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

Replace, in the second paragraph, the existing third sentence with the following:

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

Replace, in the first sentence of the fourth paragraph, the phrase "contributing factor to a HAZARD" with " contributing factor to a HAZARDOUS SITUATION".

Replace, in the second sentence of the fourth paragraph, the term, "HAZARDS" with "HAZARDOUS SITUATIONS".

Add, after the existing sixth paragraph, the following new paragraph:

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.

1   Scope

1.2   * Field of application

Replace the entire existing text of this subclause with the following:

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].

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1   In preparation.