American National Standard

ANSI/AAMI/IEC 62304:2006

Medical device software—Software life cycle processes

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.

For a complete copy of this AAMI document, contact AAMI at (800) 332-2264, ext. 217 or visit www.aami.org.
The 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 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.

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 Manager for Technical Development. 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.
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.

Keywords: software, medical device, software life cycle processes, software engineering
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.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

For a complete copy of this AAMI document, contact AAMI at (800) 332-2264, ext. 217 or visit www.aami.org.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

© 2006 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1–57020–258–3
9.4 Use change control process ................................................................................................ 24
9.5 Maintain records .................................................................................................................. 24
9.6 Analyse problems for trends .............................................................................................. 24
9.7 Verify software problem resolution ...................................................................................... 24
9.8 Test documentation contents............................................................................................... 24

Annex A (informative) Rationale for the requirements of this standard ........................................ 25
Annex B (informative) Guidance on the provisions of this standard ............................................. 28
Annex C (informative) Relationship to other standards ........................................................................ 42
Annex D (informative) Implementation .......................................................................................... 63

Bibliography........................................................................................................................................... 65

Index of defined terms........................................................................................................................... 66

Table A.1 – Summary of requirements by software safety class .......................................................... 27
Table B.1 – Development (model) strategies as defined at ISO/IEC 12207......................................... 29
Table C.1 – Relationship to ISO 13485:2003..................................................................................... 43
Table C.2 – Relationship to ISO 14971:2000 .................................................................................... 44
Table C.3 – Relationship to IEC 60601-1 ......................................................................................... 47
Table C.4 – Relationship to IEC 60601-1-4 ..................................................................................... 52
Table C.5 – Relationship to ISO/IEC 12207 .................................................................................... 57
Table D.1 – Checklist for small companies without a certified QMS .................................................... 64

Figure 1 – Overview of software development PROCESSES and ACTIVITIES ........................................ xiii
Figure 2 – Overview of software maintenance PROCESSES and ACTIVITIES ........................................ xiii
Figure B.1 – Example of partitioning of SOFTWARE ITEMS ...................................................................... 32
Figure C.1 – Relationship of key MEDICAL DEVICE standards to IEC 62304........................................... 42
Figure C.2 – Software as part of the V-model....................................................................................... 45
Figure C.3 – Application of IEC 62304 with IEC 61010-1 ..................................................................... 55
Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

<table>
<thead>
<tr>
<th>International designation</th>
<th>U.S. designation</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC/TR 62348:200x¹</td>
<td>ANSI/AAMI/IEC TIR62348:2006</td>
<td>Identical</td>
</tr>
</tbody>
</table>

© 2006 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI/IEC 62304:2006
<table>
<thead>
<tr>
<th>International designation</th>
<th>U.S. designation</th>
<th>Equivalency</th>
</tr>
</thead>
</table>

¹In production
²Final approval pending
Committee representation

Association for the Advancement of Medical Instrumentation

Medical Device Software Committee

This standard was developed by the AAMI Medical Device Software Committee and the AAMI Quality Management 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:

**Cochairs:**
- Sherman Eagles
- John F. Murray, Jr.

**Secretary:**
- Nancy George

**Members:**
- Robert G. Britain, National Electrical Manufacturers Association (NEMA)
- David R. Christie, Spacelabs Medical Inc.
- Theresa Dennis, Sterigenics International
- Sherman Eagles, Medtronic Inc.
- Christine M. Flahive, Chris Flahive Associates, Belle Mead, NJ
- John J. Flynn, Hill-Rom Company
- Richard C. Fries, Baxter Healthcare Corporation
- Larry A. Fry, Draeger Medical
- Nancy George, Software Quality Management Inc., Towson, MD
- Ron Gerner, Abbott Laboratories
- Steve Gitelis, Guidant Corporation
- Lori Haller, Steris Corporation
- James P. Hempel, Tyco Healthcare
- Sam Jarrell, CerTech
- David R. Jones, Philips Medical Systems
- Marty J. King, Hospira Inc.
- Alan Kusinitz, Software CPR, Winchester, MA
- Bernie Liebler, Advanced Medical Technology Association (AdvaMed)
- Don Lin, PhD, Irvine, CA
- Steve Mallory, Welch Allyn Inc.
- Mark Maritch, Draeger Medical Infant Care
- Don McAndrews, Respironics
- Mary Beth McDonald, St. Jude Medical Inc.
- Dennis Mertz, Becton Dickinson
- Peter J. Mueller, Bausch & Lomb Inc.
- John F. Murray, Jr., U.S. Food and Drug Administration
- Harvey Rudolph, PhD, Underwriters Laboratories Inc.
- Richard A. Schrenker, Massachusetts General Hospital, Boston, MA
- Xianyu Shea, Stryker Instrument Corporation
- Carla Sivak, DePuy-Mitek
- Scott Thiel, Roche Diagnostics Corporation
- James H. Webb, Cardinal Health
- Gregory Whitney, CR Bard

**Alternates:**
- David Bauereis, Hill-Rom Company
- Matthias Buerger, Baxter Healthcare Corporation
- Christopher P. Clark, Bausch & Lomb Inc.
- Christopher D. Ganser, CR Bard
- Jeff Gilham, Spacelabs Medical Inc.
At the time this document was published, the AAMI Quality Management Committee had the following members:

Chair: Charles B. Sidebottom
Members: Leighton W. Hansel, Abbott Laboratories
Ed R. Kimmelman, BME, JD, Roche Diagnostics Corporation
Harvey Rudolph, Underwriters Laboratories
Charles B. Sidebottom, Medtronic Inc.
Kimberly A. Trautman, PhD, U.S. Food and Drug Administration
Alternates: Sherry Leichtweis, Abbott Laboratories
Ken Slickers, PhD, Roche Diagnostics Corporation

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.
Background on AAMI adoption of IEC 62304:2006

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this standard.

IEC 62304 is based on the American National Standard ANSI/AAMI SW68:2001 developed by AAMI. IEC 62304 was prepared by a Joint Working Group of Subcommittee (SC) 62A, Common aspects of electrical equipment used in medical practice, of IEC Technical Committee (TC) 62, Electrical equipment in medical practice, and ISO Technical Committee (TC) 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.

There are a few major differences between IEC 62304 and ANSI/AAMI SW68. The concept of software safety classification was added to IEC 62304. Three software safety classes are identified and manufacturers are required to assign a software safety class to each software system. Specific processes and tasks are required for each software safety class. A second difference is that there is no distinction in IEC 62304 between primary and supporting processes as there was in ANSI/AAMI SW68. And two processes that were included in ANSI/AAMI SW68 were removed from IEC 62304. These were the documentation process and the verification process. Some requirements that were in these processes were moved to other processes where they applied.


AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI Medical Device Software Committee, together with the U.S. Technical Advisory Groups for IEC/SC 62A and ISO/TC 210, reviewed IEC 62304 to formulate the U.S. position and comments while the document was being developed. As the U.S. Technical Advisory Group for IEC/SC 62A, the lead committee, AdvaMed granted AAMI permission to consider adoption of IEC 62304. First Edition, as an American National Standard. Following AAMI procedures, the AAMI Medical Device Software Committee voted to adopt the IEC standard as written.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page x, this American National Standard is identical to IEC 62304:2006.
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 Publications”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in their 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.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC provides no marking procedure to indicate its approval and cannot be held responsible for any equipment declared to be in conformity with an IEC Publication.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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:

<table>
<thead>
<tr>
<th>FDIS</th>
<th>Report on voting</th>
</tr>
</thead>
<tbody>
<tr>
<td>62A/523/FDIS</td>
<td>62A/528/RVD</td>
</tr>
</tbody>
</table>

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.
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 is further divided into a set of ACTIVITIES, with most ACTIVITIES further divided into 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 HAZARD is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. HAZARDS 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).

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

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

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.

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. See Annex D.

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.