Medical device software –
Software life cycle processes

This English-language version is derived from the original bilingual publication by leaving out all French-language pages. Missing page numbers correspond to the French-language pages.
INTERNATIONAL STANDARD

IEC 62304

First edition
2006-05

Medical device software –
Software life cycle processes

© IEC 2006 Copyright - all rights reserved

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11  Telefax: +41 22 919 03 00  E-mail: inmail@iec.ch  Web: www.iec.ch
CONTENTS

FOREWORD ....................................................................................................................... 7
INTRODUCTION .................................................................................................................. 11

1 Scope ................................................................................................................................ 17
  1.1 * Purpose .................................................................................................................. 17
  1.2 * Field of application .......................................................................................... 17
  1.3 Relationship to other standards ......................................................................... 17
  1.4 Compliance ........................................................................................................... 17

2 * Normative references .......................................................................................... 19

3 * Terms and definitions ......................................................................................... 19

4 * General requirements .......................................................................................... 27
  4.1 * Quality management system ........................................................................... 27
  4.2 * RISK MANAGEMENT ....................................................................................... 29
  4.3 * Software safety classification .......................................................................... 29

5 Software development PROCESS .............................................................................. 31
  5.1 * Software development planning ........................................................................ 31
  5.2 * Software requirements analysis ......................................................................... 35
  5.3 * Software ARCHITECTURAL design .................................................................. 39
  5.4 * Software detailed design ................................................................................... 41
  5.5 * SOFTWARE UNIT implementation and verification ........................................... 41
  5.6 * Software integration and integration testing ....................................................... 43
  5.7 * SOFTWARE SYSTEM testing ............................................................................. 47
  5.8 * Software release ................................................................................................ 49

6 Software maintenance PROCESS ............................................................................... 51
  6.1 * Establish software maintenance plan ............................................................... 51
  6.2 * Problem and modification analysis ................................................................... 51
  6.3 * Modification implementation ........................................................................... 53

7 * Software RISK MANAGEMENT PROCESS ........................................................... 55
  7.1 * Analysis of software contributing to hazardous situations ............................. 55
  7.2 RISK CONTROL measures .................................................................................. 57
  7.3 VERIFICATION of RISK CONTROL measures .................................................... 57
  7.4 RISK MANAGEMENT of software changes ......................................................... 59

8 * Software configuration management PROCESS ............................................... 59
  8.1 * Configuration identification ............................................................................. 59
  8.2 * Change control .................................................................................................. 61
  8.3 * Configuration status accounting ...................................................................... 61

9 * Software problem resolution PROCESS ............................................................ 61
  9.1 Prepare PROBLEM REPORTS ................................................................................ 61
  9.2 Investigate the problem ....................................................................................... 63
  9.3 Advise relevant parties ......................................................................................... 63
  9.4 Use change control process ................................................................................ 63
  9.5 Maintain records .................................................................................................. 63
  9.6 Analyse problems for trends ............................................................................... 63
  9.7 Verify software problem resolution ..................................................................... 65
  9.8 Test documentation contents ............................................................................... 65
INTERNATIONAL ELECTROTECHNICAL COMMISSION

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 Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this 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 rendered 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.
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.
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.
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.