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Medical device software

Part 3: Process reference model of medical device software life cycle processes (IEC 62304)

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MEDICAL DEVICE SOFTWARE –

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FOREWORD

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IEC TR 80002-3, which is a technical report, 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. It is published as a double logo standard.

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The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/918/DTR	62A/928/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table. In ISO, the technical report has been approved by 14 P members out of 16 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2 and in accordance with ISO/IEC 24774, *Systems and software engineering – Life cycle management – Guidelines for process description*.

A list of all parts of the IEC 80002 series, published under the general title *Medical device software,* can be found on the IEC website.

The committee has decided that the contents of this publication 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- withdrawn,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.

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

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INTRODUCTION

0.1 Background

Software is often an integral part of medical device technology. Establishing the safety and effectiveness of a medical device containing software requires well designed software that fulfils its purpose without causing any unacceptable risks. Following an internationally approved set of software development practices provides one way of achieving this.

This technical report (TR) provides a framework of life cycle processes supporting the safe design and maintenance of medical device software called the process reference model (PRM). The process descriptions in this PRM are fully compliant with the requirements of ISO/IEC 24774:2010, *Systems and software engineering – Life cycle management – Guidelines for process description*.

This TR presents the PRM for medical device software development as a result of integrating requirements from IEC 62304:2006 and from the international standard of software life-cycle processes ISO/IEC 12207:2008.

This TR is aimed at medical device software developers who can use it for realizing the set of requirements they have to achieve to be compliant with IEC 62304:2006 in the scope of the safety class of the medical device software they are developing. Each process outcome with a corresponding safety class is a requirement in IEC 62304:2006. The process outcomes without a corresponding safety class are based only on ISO/IEC 12207:2008. These process outcomes provide additions that are beneficial when achieving the purpose of the process and could be regarded as a valuable contribution to safety-critical software development. The PRM may also be used to provide a common basis for different models and methods for process assessment, ensuring that the results of the assessments can be reported in a common context. Assessors who are concerned with examining medical device software processes can use the PRM as an agreed list of IEC 62304 process outcomes to inform audit check listing and reporting.

The process descriptions in the PRM incorporate a statement of the purpose of the process which describes at a high level the overall objectives of performing the process, together with the set of outcomes which demonstrate the successful achievement of the process purpose. These process outcomes are the software life cycle process requirements – the statements of the overall goal of performing the process. In any process description, the set of process outcomes are necessary and sufficient to achieve the purpose of the process.

A manufacturer of a medical device software system is required to assign a software safety class (A, B, or C) according to the possible effects on the patient, operator, or other people resulting from a hazard to which the software system contributes, described in greater detail in IEC 62304:2006. The software safety classes are assigned based on severity as follows:

– Class A: no injury or damage to health is possible;
– Class B: non-serious injury is possible;
– Class C: death or serious injury is possible.

0.2 Organization of this technical report

This TR is organized to follow the structure of IEC 62304. Annex A describes the development of the TR in greater detail. Annex B provides a mapping from IEC 62304 clauses together with their safety classes to the corresponding ISO/IEC 12207:2008 processes. The life cycle processes of the PRM for medical device software development are described in terms of process name, process purpose and the corresponding process outcomes. The outcomes marked with an “[ISO/IEC 12207]” at the end of the outcome statement are derived from ISO/IEC 12207:2008, with no directly corresponding requirement in IEC 62304. Users of this PRM who wish to examine only the IEC 62304 requirements can elect to disregard the outcomes that are based only on ISO/IEC 12207:2008.

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MEDICAL DEVICE SOFTWARE –

Part 3: Process reference model of medical device software life cycle processes (IEC 62304)

1 Scope

This part of IEC 80002, which is a technical report (TR), provides the description of software life cycle processes for medical devices. The medical device software life cycle processes are derived from IEC 62304:2006, with corresponding safety classes. They have been aligned with the software development life cycle processes of ISO/IEC 12207:2008 and are presented herein in full compliance with ISO/IEC 24774:2010. The content of these three standards provides the foundation of this TR.

This TR does not address:

– areas already covered by existing related standards, e.g. the international standards that relate to the four standards used to build this TR (see Bibliography);
– FDA guidance documents; or
– software development tools.

This TR describes the PRM for medical device software development and is limited in scope to the life cycle processes described in IEC 62304:2006. The process names correspond to those of IEC 62304:2006. The mappings provided in Annex B are essential for the alignment between IEC 62304:2006 (which is based on ISO/IEC 12207:1995) and ISO/IEC 12207:2008, developed to address the detailed normative relationship between the two standards.

This technical report is not intended to be used as the basis of regulatory inspection or certification assessment activities.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 62304:2006, *Medical device software – Software life cycle processes*

ISO/IEC 12207:2008, *Systems and software engineering – Software life cycle processes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 62304:2006 apply.

NOTE To be consistent with the requirements for developing a PRM, the guidelines set forth in ISO/IEC 24774 were followed. Having a dedicated software risk management process enables the software developers to realize the set of requirements they have to adhere to when developing software for medical devices. This PRM also enables the medical device software developers to determine the requirements necessary to develop software for a specific safety class. The PRM presented in this TR includes only the software risk management requirements of ISO 14971 that are a part of IEC 62304. The software risk management terminology is therefore derived directly from ISO 14971. For the purposes of this TR, the software development-related terms and definitions used are inherited from IEC 62304.

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4 Medical device software life cycle processes

4.1 Software development process

4.1.1 Software development planning

4.1.1.1 Purpose

The purpose of software development planning (IEC 62304, 5.1) is to establish a plan for conducting the activities of the software development processes.

4.1.1.2 Outcomes

The successful implementation of software development planning shall ensure that:

a) a software development plan is established for the software development appropriate to the scope, magnitude, and software safety classification of the software system. [Classes A, B, C];

NOTE 1 The software development plan includes the description of the development processes, the deliverables from the processes (including documentation), software configuration and change management (including SOUP configuration items and software used to support development), and software problem resolution.

b) the software development plan addresses how traceability between system requirements, software requirements, software system test and risk control measures is established [Classes A, B, C];

c) the software development plan is maintained throughout the software life cycle [Classes A, B, C];

d) the software development plan references system design and development [Classes A, B, C];

e) the software development plan includes or references the standards, methods and tools associated with the development of software items for Class C [Class C];

f) the software development plan includes or references an integration strategy for software units, including SOUP [Classes B, C];

g) the software development plan includes or references a verification strategy [Classes A, B, C];

NOTE 2 Verification strategy includes ensuring that all activities and tasks are complete along with all the associated documentation.

h) the software development plan includes or references a risk management plan, including the plan to manage risks relating to SOUP [Classes A, B, C];

i) the software development plan includes or references a strategy identifying the documentation to be produced during the software development life cycle, and the standards to be applied for the development of the software documentation [Classes A, B, C];

j) the software development plan includes or references a configuration management plan [Classes A, B, C];

NOTE 3 The software configuration management plan includes or references:

i) the classes, types, categories or lists of items to be controlled;

ii) the software configuration management activities and tasks;

iii) the organization(s) responsible for performing software configuration management and activities;

iv) their relationship with other organizations, such as software development or maintenance;

v) when the items are to be placed under configuration control;

vi) when the problem resolution process is to be used;

vii) software configuration items that include other software products or entities such as SOUP.

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k) the software development plan includes or references the supporting items or settings used to develop medical device software requiring control [Classes B, C];

l) The software development plan includes the plan to place configuration items under documented configuration management control before they are verified [Classes B, C].

4.1.2 Software requirements analysis

4.1.2.1 Purpose

The purpose of software requirements analysis (IEC 62304, 5.2) is to establish the requirements of the software elements of the system.

4.1.2.2 Outcomes

A successful implementation of software requirements analysis shall ensure that:

a) the requirements allocated to the software system and their interfaces are defined [Classes A, B, C];

b) software requirements are analyzed for correctness and testability [Classes A, B, C];

c) the impact of software requirements on the operating environment are understood [Classes A, B, C];

d) consistency and traceability are established between the software requirements and system requirements [Classes A, B, C];

e) prioritization for implementing the software requirements is defined [ISO/IEC 12207];

f) the existing requirements, including system requirements, are updated as appropriate as a result of software requirements analysis [Classes A, B, C];

g) changes to the software requirements are evaluated for cost, schedule and technical impact [ISO/IEC 12207];

h) the software requirements are baselined and communicated to all affected parties [ISO/IEC 12207];

i) risk control measures implemented in software for hardware failures and potential software defects are included in the software requirements [Classes B, C];

NOTE 1 Software architecture implements the defined risk management requirements.

NOTE 2 Software safety class is assigned to software items based on the possible effects of the hazard.

j) medical device risk analysis is re-evaluated and updated as appropriate when software requirements are established [Classes A, B, C].

4.1.3 Software architectural design

4.1.3.1 Purpose

The purpose of software architectural design (IEC 62304, 5.3) is to provide a design for the software that implements and can be verified against the requirements.

4.1.3.2 Outcomes

A successful implementation of software architectural design shall ensure that:

a) a software architectural design is developed and baselined that describes the software items, including SOUP, that will implement the software requirements [Classes B, C];

b) in the case of SOUP items, all functional and performance requirements shall be specified, including hardware and software requirements of the system [Classes B, C];

NOTE 1 Examples include processor type and speed, memory type and size, system software type, communication and display software requirements.

c) internal and external interfaces of each software item are defined [Classes B, C];

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