PD ISO/TR 80002-2:2017

BSI Standards Publication

Medical device software

Part 2: Validation of software for medical device quality systems

National foreword

This Published Document is the UK implementation of ISO/TR 8000-2:2017.

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2017

ISBN 978 0 580 76425 7

ICS 35.240.80; 11.040.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 October 2017.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TR 80002-2:2017

TECHNICAL REPORT

ISO/TR 80002-2

First edition
2017-06

Medical device software —

Part 2: Validation of software for medical device quality systems

Logiciels de dispositifs médicaux —

Partie 2: Validation des logiciels pour les systèmes de qualité des dispositifs médicaux

Reference number
ISO/TR 80002-2:2017(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO should not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62A, *Common aspects of electrical equipment used in medical practice*, in accordance with ISO/IEC mode of cooperation 4.

A list of all parts in the ISO 80002 series can be found on the ISO website.

Introduction

This document has been developed to assist readers in determining appropriate activities for the validation of process software used in medical device quality systems using a risk-based approach that applies critical thinking.

This includes software used in the quality management system, software used in production and service provision, and software used for the monitoring and measurement of requirements, as required by ISO 13485:2016: 4.1.6, 7.5.6 and 7.6.

This document is the result of an effort to bring together experience from medical device industry personnel who deal with performing this type of software validation and who are tasked with establishing auditable documentation. The document has been developed with certain questions and problems in mind that we all go through when faced with validating process software used in medical device quality systems such as the following: What has to be done? How much is enough? How is risk analysis involved? After much discussion, it has been concluded that in every case, a set of activities (i.e. the tools from a toolbox) was identified to provide a level of confidence in the ability of the software to perform according to its intended use. However, the list of activities varied depending on factors including, among others, the complexity of the software, the risk of harm involved and the pedigree (e.g. quality, stability) of vendor-supplied software.

The intention of this document is to help stakeholders, including manufacturers, auditors and regulators, to understand and apply the requirement for validation of software included in ISO 13485:2016, 4.1.6, 7.5.6 and 7.6.

Medical device software —

Part 2: Validation of software for medical device quality systems

1 Scope

This document applies to any software used in device design, testing, component acceptance, manufacturing, labelling, packaging, distribution and complaint handling or to automate any other aspect of a medical device quality system as described in ISO 13485.

This document applies to

— software used in the quality management system,

— software used in production and service provision, and

— software used for the monitoring and measurement of requirements.

It does not apply to

— software used as a component, part or accessory of a medical device, or

— software that is itself a medical device.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and ISO 13485 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Software validation discussion

4.1 Definition

The term “software validation” has been interpreted both broadly and narrowly, from just testing to extensive activities including testing. This document uses the term software validation to denote all of the activities that establish a level of confidence that the software is appropriate for its intended use and that it is trustworthy and reliable. The chosen activities, whatever they might be, should ensure that the software meets its requirements and intended purpose.

4.2 Confidence-building activities: Tools in the toolbox

The tools in the toolbox (see Table A.1 to Table A.5) include activities completed during the life cycle of software that reduce risk and build confidence.

4.3 Critical thinking

This document promotes the use of critical thinking to determine which activities should be performed to adequately validate specific software. Critical thinking is a process of analysing and evaluating various aspects of software, as well as the environment in which it will be used, to identify the most meaningful set of confidence-building activities to be applied during validation. Critical thinking avoids an approach that applies a one-size-fits-all validation solution without thoroughly evaluating the solution to determine if it indeed results in the desired outcome. Critical thinking recognizes that validation solutions can vary greatly from software to software and also allows for different validation solutions to be applied to the same software in a similar situation. Critical thinking challenges proposed validation solutions, to ensure that they meet the intent of the quality management system requirements, and considers all key stakeholders and their needs. Critical thinking is also used to re-evaluate the validation solution when characteristics of the software change, when the software's intended use changes or when new information becomes available.

Critical thinking results in a validation solution that establishes compliance for a manufacturer, ensures that the software is safe for use, results in documented evidence that is deemed appropriate and adequate by reviewers, and results in a scenario in which individuals performing the validation work feels that the effort adds value and represents the most efficient way to reach the desired results.

Annex C presents example studies demonstrating how critical thinking can be applied to software validation of software used in medical device quality systems in a variety of situations, including different complexities, pedigrees and risk levels.

5 Software validation and critical thinking

5.1 Overview

Throughout the life cycle of software for medical device quality systems, appropriate controls need to be in place to ensure that the software performs as intended. Incorporation of critical thinking and application of selected confidence-building activities result in establishing and maintaining a validated state of the software. Figure 1 depicts a conceptual view of typical activities and controls that are part of the life cycle from the moment the decision is made to automate a process until the software is retired or is no longer used for medical device quality systems. Although Figure 1 depicts a sequential model, in reality, the process is of an iterative nature as elements are defined, risks are identified and critical thinking is applied.

When developing software for use in the medical device quality system, a fundamental confidence-building activity to be selected from the toolbox is the choice of software development life-cycle model. The model chosen should include critical thinking activities that enable the selection of other appropriate tools during various life-cycle activities. The results of the analyses and evaluations used drive the selection of the most meaningful set of confidence-building activities to ensure that the software performs as intended. This document does not mean to imply or prescribe the use of any particular software development model. For simplicity, however, the remainder of this document explains the concepts of critical thinking within the context of a waterfall development model using generic names for the phases. Other software development models (e.g. iterative, spiral) can certainly be used as long as critical thinking and the application of appropriate tools are incorporated into the model.

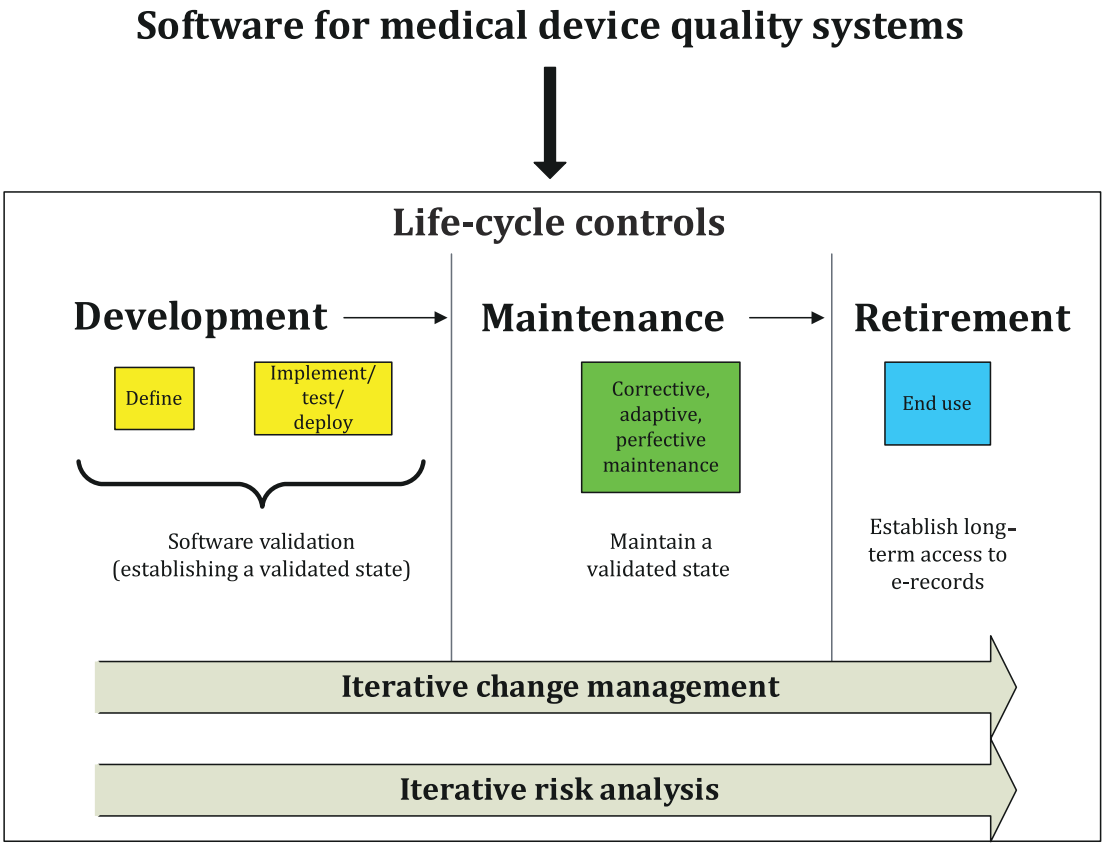

Figure 1 — Life-cycle controls

When considering using software in a process, one should identify whether the proposed software is used as part of a medical device quality system process through an investigation of its intended use. If so, then the software should be validated for its intended use. Although this document describes an approach to validating software for medical device quality systems, the same approach is also good practice for software to evaluate whether it fulfils defined requirements. The most critical part of software validation is developing/purchasing the right software tool to be able to support processes as intended by the manufacturer. This implies that requirements should be determined accurately to evaluate whether the developed/purchased software is suitable to fulfil the requirements of the intended use. Technical requirements suitable for verification, as well as process requirements suitable for validation, are equally important. When considering using software in a process, the software can interact or can have interfaces with other software.

During the development phase of the life cycle, risk management and validation planning tasks are performed to gather information and drive decisions in the following four areas:

— level of effort applied and scrutiny of documentation and deliverables;

— extent of content in the documentation and deliverables;

— selection of tools from the toolbox and methods for applying the tools;

— level of effort in applying the tools.

The primary drivers for decisions in the four areas are process risk and software risk. However, other drivers can influence decisions, including the complexity of the software and process, the type of software and the software pedigree.

The validation planning process consists of two distinct elements. The first validation planning element involves determining the level of rigor in the documentation and the scrutiny to be applied to the review of the resulting deliverables. The decisions in this element are primarily driven by the results