

This is a preview of "ISO/TR 80002-2:2017". [Click here to purchase the full version from the ANSI store.](#)

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)

© ISO 2017

This is a preview of "ISO/TR 80002-2:2017". [Click here to purchase the full version from the ANSI store.](#)



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

This is a preview of "ISO/TR 80002-2:2017". [Click here to purchase the full version from the ANSI store.](#)

## Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Software validation discussion</b> .....	<b>1</b>
4.1 Definition.....	1
4.2 Confidence-building activities: Tools in the toolbox.....	1
4.3 Critical thinking.....	2
<b>5 Software validation and critical thinking</b> .....	<b>2</b>
5.1 Overview.....	2
5.2 Determine if the software is in scope.....	6
5.2.1 Document a high-level definition of the process and use of the software.....	6
5.2.2 Regulatory use assessment.....	6
5.2.3 Processes and software extraneous to medical device regulatory requirements...	6
5.3 Development phase.....	7
5.3.1 Validation planning.....	7
5.3.2 Define.....	7
5.3.3 Implement, test and deploy.....	11
5.4 Maintain phase.....	13
5.4.1 Entering the maintenance phase.....	13
5.4.2 Planning for maintenance.....	14
5.4.3 Types of maintenance within the maintain phase.....	15
5.4.4 Process changes: Change to risk control measures.....	15
5.4.5 Emergency change.....	15
5.4.6 Maintaining for intended use.....	16
5.5 Retirement phase.....	16
<b>6 Documentation</b> .....	<b>16</b>
<b>7 Prerequisite processes</b> .....	<b>17</b>
<b>Annex A (informative) Toolbox</b> .....	<b>18</b>
<b>Annex B (informative) Risk management and risk-based approach</b> .....	<b>24</b>
<b>Annex C (informative) Examples</b> .....	<b>28</b>
<b>Bibliography</b> .....	<b>84</b>

## 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](http://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](http://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](http://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.

This is a preview of "ISO/TR 80002-2:2017". [Click here to purchase the full version from the ANSI store.](#)

## 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.