
Guide to the development and inclusion of aspects of safety in International Standards for medical devices

*Guide pour l'élaboration des aspects de sécurité et leur incorporation
dans des Normes internationales relatives aux dispositifs médicaux*

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO/IEC Guide 63:2019](https://standards.iteh.ai/catalog/standards/iso/af9c8c7b-7e3c-49b3-883a-7cf6b0ca7be5/iso-iec-guide-63-2019)

<https://standards.iteh.ai/catalog/standards/iso/af9c8c7b-7e3c-49b3-883a-7cf6b0ca7be5/iso-iec-guide-63-2019>



Reference number
ISO/IEC GUIDE 63:2019(E)

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO/IEC Guide 63:2019

<https://standards.iteh.ai/catalog/standards/iso/af9c8c7b-7e3c-49b3-883a-7cf6b0ca7be5/iso-iec-guide-63-2019>



COPYRIGHT PROTECTED DOCUMENT

© ISO/IEC 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Use of the terms “safety”, “safe”, “effective”, and “effectiveness”	4
4.1 Safety.....	4
4.2 Safe.....	5
4.3 Effective.....	5
4.4 Effectiveness.....	5
5 Principles for including aspects of safety in medical device standards	5
5.1 Scope of medical device standards that include aspects of safety.....	5
5.2 Objective of medical device standards that include aspects of safety.....	6
5.3 Types of standards.....	6
5.3.1 Product standards.....	6
5.3.2 Process standards.....	6
5.3.3 Installation and environmental standards.....	7
5.3.4 In-service standards.....	7
5.4 Taking a practical view of safety.....	7
5.5 Coordination of medical device standards.....	7
5.6 Implications of the regulatory or legal use of standards.....	8
6 The nature of risk	8
6.1 The elements of risk.....	8
6.2 Systematic or random nature of risks.....	9
6.2.1 Types of causes of risks.....	9
6.2.2 Risks arising from systematic causes.....	10
6.2.3 Risks arising from random causes.....	10
7 Risk-based process for developing a medical device standard that includes aspects of safety	10
7.1 General.....	10
7.2 Preparatory work.....	11
7.2.1 Identifying the need for a new or revised standard including aspects of safety... 11	11
7.2.2 Establishing the risk management framework under which the standard will be developed.....	11
7.2.3 Risk acceptability criteria.....	12
7.3 Drafting.....	14
7.3.1 General.....	14
7.3.2 Iterative process of managing risk.....	14
7.3.3 Intended use and characteristics that can influence safety.....	16
7.3.4 Identification of hazards and hazardous situations.....	17
7.3.5 Risk estimation.....	18
7.3.6 Risk evaluation.....	19
7.3.7 Identification of risk controls.....	19
7.3.8 Verification of effectiveness.....	22
7.3.9 Assessment of residual risks.....	22
7.3.10 Impact of introduced risk control measures.....	22
7.3.11 All identified hazards and hazardous situations considered.....	22
7.4 Validation of the standard.....	22
7.5 Conclusion.....	22
8 Overview of the application of medical device standards including aspects of safety in a risk management framework	22

Annex A (informative) Product and process safety standards	24
Annex B (informative) Risk information	25
Bibliography	26

iTeh Standards
(<https://standards.itih.ai>)
Document Preview

[ISO/IEC Guide 63:2019](https://standards.itih.ai/catalog/standards/iso/af9c8c7b-7e3c-49b3-883a-7cf6b0ca7be5/iso-iec-guide-63-2019)

<https://standards.itih.ai/catalog/standards/iso/af9c8c7b-7e3c-49b3-883a-7cf6b0ca7be5/iso-iec-guide-63-2019>

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 and IEC shall 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) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

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

For an explanation of 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 www.iso.org/iso/foreword.html.

ISO/IEC Guide 63 was prepared by a Joint Working Group of ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

This third edition cancels and replaces the second edition (ISO/IEC Guide 63:2012), which has been technically revised.

The main changes compared with the previous edition are as follows:

- restructuring of content to more closely follow the structure of ISO/IEC Guide 51:2014;
- revision of clause numbering, including the inclusion of [Clause 2](#) on normative references, in order to respect the fixed clause structure for the first three clauses specified in the ISO/IEC Directives, Part 2;
- updating of defined terms in [Clause 3](#), with many derived from ISO/IEC Guide 51:2014, and the definitions of “manufacturer” and “medical device” now based on the GHTF guidance documents GHTF/SG1/N055:2009 and GHTF/SG1/N071:2012;
- addition of new content in [Clause 4](#) to provide guidance on the use of the terms “safety”, “safe”, “effective” and “effectiveness”;
- reorganization of existing content into [Clause 5](#) discussing the principles, [Clause 6](#) discussing the nature of risk, [Clause 7](#) focusing on the process for developing standards that include aspects of safety, and [Clause 8](#) providing an overview of the application of medical device standards;
- revision of [Figure 1](#) to better illustrate how a sequence of events can transform a hazard into a hazardous situation that can lead to harm;
- addition of [Figure 2](#) to illustrate the iterative process of risk management.