GUIDE 63

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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

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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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides practical guidance to standards writers on how to include safety aspects in the development of medical device standards, including management system standards related to medical devices. This document is based on risk management principles and ISO/IEC Guide 51:2014 to address the needs of the medical device sector.

The concept of safety, as described in this document, is closely related to protecting patients who are the subjects of medical care, as well as those persons who provide the care and other potentially affected persons. Safety is also related to harm to property or the environment.

The approach described in this document aims to reduce the risk arising during the life cycle of a medical device, including design, production, distribution, installation, use, service, maintenance, and destruction or disposal. The complete life cycle of a medical device (including both the intended use and the reasonably foreseeable misuse) is considered. The goal is to achieve acceptable risk for people, property and the environment.

As different circumstances warrant different approaches to ensuring safety, it is impossible to provide precise requirements and recommendations that apply to every case. Examples of such differences are the development of standards for manufacturers of medical devices and standards for health care providers and institutions. However, this document, when followed on a judicious "use when applicable" basis, will help in developing standards that include aspects of safety which are consistent with the generally acknowledged state of the art.

NOTE The term "standard" used throughout this document includes International Standards, Technical Specifications, Publicly Available Specifications, Technical Reports and Guides developed by ISO or IEC.

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

1 Scope

This document provides requirements and recommendations to writers of medical device standards on the inclusion of aspects related to safety in International Standards, based on well-established risk management concepts and methodology.

This document is applicable to any aspect related to the safety of people, property, the environment, or a combination of these.

In this document, the term "product" includes a medical device or a system consisting of one or more medical devices, possibly combined with non-medical devices.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.2
hazard
potential source of *harm* (3.1)

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.3
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.2)

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.4
intended use
use for which a product, process or service is intended according to the specifications, instructions and information provided by the *manufacturer* (3.6)

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.