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 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.

3.5
life cycle
series of all phases in the life of a *medical device* (3.7), from the initial conception to final decommissioning and disposal

3.6
manufacturer
natural or legal person with responsibility for design and/or manufacture of a *medical device* (3.7) with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture" can include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the *intended use* (3.4) of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: GHTF/SG1/N055:2009, 5.1, modified - The words "may include" have been replaced with "can include" in Note 3 to entry.]

3.7
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (3.6) to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which can be assisted in its intended function by such means

Note 1 to entry: Products which can be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal and/or human tissues,

— devices for in-vitro fertilization or assisted reproductive technologies.

[SOURCE: GHTF/SG1/N071:2012, 5.1, modified — The words "may be assisted" have been replaced with "can be assisted" in the definition, and the words "may be considered" have been replaced with "can be considered" in Note 1 to entry.]

3.8
reasonably foreseeable misuse
use of a product or system in a way not intended by the *manufacturer* (3.6), but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO/IEC Guide 51:2014, 3.7, modified — The word “supplier” has been replaced with “manufacturer”, the example in Note 1 to entry has been modified, and Note 2 to entry has been replaced with a new Note to entry.]

3.9
residual risk
risk (3.10) remaining after *risk control* (3.12) measures have been implemented

[SOURCE: ISO/IEC Guide 51:2014, 3.8, modified — The words “risk reduction measures” have been replaced with “risk control measures”.]

3.10
risk
combination of the probability of occurrence of *harm* (3.1) and the *severity* (3.17) of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a *hazardous situation* (3.3) and the possibility to avoid or limit the harm.

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified — The words "the occurrence of a hazardous event" have been removed from Note 1 to entry.]

3.11
risk analysis
systematic use of available information to identify *hazards* (3.2) and to estimate the *risk* (3.10)

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

3.12
risk control
process in which decisions are made and measures implemented by which *risks* (3.10) are reduced to, or maintained within, specified levels

3.13
risk estimation
process used to assign values to the probability of occurrence of *harm* (3.1) and the *severity* (3.17) of that harm

3.14
risk evaluation
process of comparing the estimated *risk* (3.10) against given risk criteria to determine the acceptability of the risk

3.15
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.10)

3.16
safety
freedom from unacceptable *risk* (3.10)

3.17
severity
measure of the possible consequences of a *hazard* (3.2)

3.18
state of the art
developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the "generally acknowledged state of the art".

[SOURCE: ISO/IEC Guide 2:2004, 1.4, modified — Note 1 to entry has been added.]

3.19
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

4 Use of the terms "safety", "safe", "effective", and "effectiveness"

4.1 Safety

The use of the term "safety" in medical device standards should be as a noun rather than as a descriptive adjective. As an adjective, it is likely to be misinterpreted as an assurance of freedom from risk. The recommended approach is to replace, wherever possible, the terms "safety" with an indication of the objective.

EXAMPLE "Protective helmet" instead of "safety helmet"; "protective impedance device" instead of "safety impedance".

