GUIDE 63

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

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC Guide 63 was prepared jointly by 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*, in a Joint Working Group, *Application of risk management to medical devices*.

This second edition cancels and replaces the first edition (ISO/IEC Guide 63:1999), which has been technically revised.

Introduction

ISO/IEC Guide 51 was the first of a series of guides intended to provide a harmonized approach to the concept of safety when preparing International Standards. ISO/IEC Guide 51 anticipated the need for sectoral guides such as this Guide. Consistent with ISO/IEC Guide 51, additional guidance might be needed for sectors within the broad category of medical devices.

The concept of safety, including safety-related performance and usability, is closely related to safeguarding the integrity of the patients who are the subjects of medical care, as well as that of those persons who are giving the care and any other persons. As medical devices and medical systems have become more complex, the diligence required to ensure their safety has similarly increased.

As different circumstances warrant different approaches to ensuring safety, it is impossible to provide precise requirements and recommendations that apply to every case. However, these guidelines, when followed on a judicious “use when applicable” basis, will help in developing reasonably consistent standards.

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

1 Scope

This Guide provides guidance to standards writers on how to include safety aspects in the development of medical device safety standards intended to be used within the risk management framework established in ISO 14971. It expands on the concepts developed in ISO/IEC Guide 51 to include safety-related performance and usability.

This Guide is intended to be read in conjunction with ISO/IEC Guide 51 and ISO 14971.

2 Terms and definitions

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

2.1
accompanying document
document accompanying a medical device and containing information for those accountable for the installation, use and maintenance of the medical device, the operator or the user, particularly regarding safety

[ISO 14971:2007, definition 2.1]

2.2
harm
physical injury or damage to the health of people, or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.3]

2.3
hazard
potential source of harm

NOTE The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

[ISO/IEC Guide 51:1999, definition 3.5]

2.4
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazards

[ISO/IEC Guide 51:1999, definition 3.6]

2.5
intended use
intended purpose
use for which a product, process, or service is intended according to the specifications, instructions and information provided by the manufacturer

[ISO 14971:2007, definition 2.5]

2.6
life cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

[ISO 14971:2007, definition 2.7]

2.7
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

NOTE 1 Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

NOTE 2 For a definition of labelling, see ISO 13485:2003, definition 3.6.

[ISO 14971:2007, definition 2.8]

2.8
medical device
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific 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 for medical purposes by means of *in vitro* examination of specimens derived from the human body,

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

NOTE 1 This definition has been developed by the Global Harmonization Task Force (GHTF).

NOTE 2 Products, which could be considered to be medical devices in some jurisdictions, but for which there is not yet a harmonized approach, are

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices,
- disinfection substances,
- devices incorporating animal and human tissues which can meet the requirements of the above definition but are subject to different controls.

NOTE 3 Adapted from ISO 13485:2003, definition 3.7, and ISO 14971:2007, definition 2.9.

2.9
residual risk
risk remaining after risk control measures have been taken

NOTE 1 ISO/IEC Guide 51:1999, definition 3.9, uses the term “protective measures” rather than “risk control measures”.

NOTE 2 Adapted from ISO 14971:2007, definition 2.15.

2.10
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51:1999, definition 3.2]

2.11
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[ISO/IEC Guide 51:1999, definition 3.10]

NOTE Risk analysis includes the examination of different sequences of events that can produce hazardous situations and harm.

2.12
risk control
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

[ISO 14971:2007, definition 2.19]

2.13
risk estimation
process used to assign values to the probability of occurrence of harm and the severity of that harm

[ISO 14971:2007, definition 2.20]

2.14
risk evaluation
process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

[ISO 14971:2007, definition 2.21]

2.15
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

[ISO 14971:2007, definition 2.22]

2.16
safety
freedom from unacceptable risk

[ISO/IEC Guide 51:1999, definition 3.1]

2.17
severity
measure of the possible consequences of a hazard

[ISO 14971:2007, definition 2.25]

2.18
usability
characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction

[IEC 62366:2007, definition 3.17]

2.19
use error
act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user

NOTE 1 Use error includes slips, lapses, and mistakes.

NOTE 2 See also IEC 62366:2007, Annex B and D.1.3.

NOTE 3 An unexpected physiological response of the patient is not in itself considered use error.

[IEC 62366:2007, definition 3.21]

2.20
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

- performing alternative calculations,
- comparing a new design specification with a similar proven design specification,
- undertaking tests and demonstrations, and
- reviewing documents prior to issue.

[ISO 9000:2005, definition 3.8.4]

3 Principles for preparing medical device safety standards

3.1 General considerations

The goal of medical device safety standards is to support the development and production of medical devices with a predictable, consistent level of safety.

To achieve this goal, medical device safety standards should

a) assist manufacturers in the design and production of safe and effective medical devices,

b) assist manufacturers, certification bodies, testing laboratories or test houses, and regulatory authorities in assessing compliance with legal and market requirements, and

c) assist health care providers in managing risks associated with the use of medical devices.

To produce medical device safety standards that are well suited to assisting the stakeholders listed above, the standards writers are encouraged to employ a risk-based framework (see Clause 4).

3.2 Scope of safety standards

The planning and development of medical device safety standards require a global approach that includes manufacturers, users, regulatory authorities and other stakeholders. Close coordination within and among committees responsible for different medical devices is necessary to create a coherent approach to the treatment of safety in the preparation of standards. Defining the scope of safety standards will ensure that each standard is restricted to specific aspects and makes reference to standards of wider application for all other relevant aspects. Such a hierarchy is built on:

— **basic safety standards**, including fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products, processes and services (basic safety standards are sometimes referred to as horizontal standards);

— **group safety standards**, including safety aspects applicable to several, or a family of, similar products, processes or services dealt with by two or more technical committees or subcommittees, making reference, as far as possible, to basic safety standards;

— **product safety standards**, including all necessary safety aspects of a specific, or a family of, product(s), process(es), or service(s) within the scope of a single technical committee or subcommittee, making reference, as far as possible, to basic safety standards and group safety standards (product safety standards are sometimes referred to as vertical standards).

This hierarchy is set out in ISO/IEC Guide 51:1999, 7.1.

Safety requirements for medical devices may be incorporated in different types of standards (see 3.3) that may be found at any appropriate level in the hierarchy described above.

3.3 Types of standards

3.3.1 Product standards

These can be

— standards that state safety or performance parameters and include reference test methods that can be used to demonstrate conformance to those parameters, or

— disclosure and test method standards where adherence to declared pass/fail criteria are necessary for safety and performance.

See Clause A.1 for a discussion of how product standards can contribute to the safety and the effectiveness of medical devices.

3.3.2 Process standards

These can be

a) quality system standards that establish a framework within which the manufacturer is able to design, develop and produce medical devices that consistently meet specifications, or

b) standards that establish a framework within which the manufacturer is able to design and develop medical devices of consistent safety and effectiveness, or

c) standards for processes used for the design, development or production of safe and effective medical devices (e.g. sterilization, biological evaluation, clinical investigation).

See Clause A.2 for a discussion of how process standards can contribute to the safety and the effectiveness of medical devices.

Some types of standards cannot be easily allocated to one of these categories since they combine properties of product standards and process standards. Examples are described in 3.3.3 and 3.3.4.