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Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

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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).

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. 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).

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.

This document was prepared by Technical Committee 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 14971:2007), which has been technically revised. The main changes compared to the previous edition are as follows:

— A clause on normative references has been included, in order to respect the requirements for fixed in Clause 15 of ISO/IEC Directives, Part 2:2018.

— The defined terms are updated and many are derived from ISO/IEC Guide 63:2019. Defined terms are printed in italic to assist the reader in identifying them in the body of the document.

— Definitions of *benefit*, *reasonably foreseeable misuse* and *state of the art* have been introduced.

— More attention is given to the *benefits* that are expected from the use of the *medical device*. The term *benefit-risk* analysis has been aligned with terminology used in some regulations.

— It is explained that the *process* described in ISO 14971 can be used for managing *risks* associated with *medical devices*, including those related to data and systems security.

— The method for the evaluation of the overall *residual risk* and the criteria for its acceptability are required to be defined in the *risk management* plan. The method can include gathering and reviewing data and literature for the *medical device* and for similar *medical devices* and similar other products on the market. The criteria for the acceptability of the overall *residual risk* can be different from the criteria for acceptability of individual *risks*.

— The requirements to disclose *residual risks* have been moved and merged into one requirement, after the overall *residual risk* has been evaluated and judged acceptable.

— The review before commercial distribution of the *medical device* concerns the execution of the *risk management* plan. The results of the review are documented as the *risk management* report.

— The requirements for production and *post-production* activities have been clarified and restructured. More detail is given on the information to be collected and the actions to be taken when the collected information has been reviewed and determined to be relevant to *safety*.

— Several informative annexes are moved to the guidance in ISO/TR 24971, which has been revised in parallel. More information and a rationale for the requirements in this third edition of ISO 14971 have been provided in Annex A. The correspondence between the clauses of the second edition and those of this third edition is given in Annex B.

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

The requirements contained in this document provide *manufacturers* with a framework within which experience, insight and judgment are applied systematically to manage the *risks* associated with the use of *medical devices*.

This document was developed specifically for *manufacturers* of *medical devices* on the basis of established principles of *risk management* that have evolved over many years. This document could be used as guidance in developing and maintaining a *risk management process* for other products that are not necessarily *medical devices* in some jurisdictions and for suppliers and other parties involved in the *medical device life cycle*.

This document deals with *processes* for managing *risks* associated with *medical devices*. *Risks* can be related to injury, not only to the patient, but also to the user and other persons. *Risks* can also be related to damage to property (for example objects, data, other equipment) or the environment.

Risk management is a complex subject because each stakeholder can place a different value on the acceptability of *risks* in relation to the anticipated *benefits*. The concepts of *risk management* are particularly important in relation to *medical devices* because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of the public.

It is generally accepted that the concept of *risk* has two key components:

— the probability of occurrence of *harm*; and

— the consequences of that *harm*, that is, how severe it might be.

All stakeholders need to understand that the use of a *medical device* involves an inherent degree of *risk*, even after the *risks* have been reduced to an acceptable level. It is well known that in the context of a clinical *procedure* some *residual risks* remain. The acceptability of a *risk* to a stakeholder is influenced by the key components listed above and by the stakeholder's perception of the *risk* and the *benefit*. Each stakeholder's perception can vary depending upon their cultural background, the socio-economic and educational background of the society concerned and the actual and perceived state of health of the patient. The way a *risk* is perceived also takes into account other factors, for example, whether exposure to the *hazard* or *hazardous situation* seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from a poorly understood cause, or directed at a vulnerable group within society.

As one of the stakeholders, the *manufacturer* reduces *risks* and makes judgments relating to the *safety* of a *medical device*, including the acceptability of *residual risks*. The *manufacturer* takes into account the generally acknowledged *state of the art*, in order to determine the suitability of a *medical device* to be placed on the market for its *intended use*. This document specifies a *process* through which the *manufacturer* of a *medical device* can identify *hazards* associated with the *medical device*, estimate and evaluate the *risks* associated with these *hazards*, control these *risks*, and monitor the effectiveness of the controls throughout the *life cycle* of the *medical device*.

The decision to use a *medical device* in the context of a particular clinical *procedure* requires the *residual risks* to be balanced against the anticipated *benefits* of the *procedure*. Such decisions are beyond the scope of this document and take into account the *intended use*, the circumstances of use, the performance and *risks* associated with the *medical device*, as well as the *risks* and *benefits* associated with the clinical *procedure*. Some of these decisions can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.

For any particular *medical device*, other standards or regulations could require the application of specific methods for managing *risk*. In those cases, it is necessary to also follow the requirements outlined in those documents.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);

— "can" is used to express possibility and capability; and

— "must" is used to express an external constraint that is not a requirement of the document.

Medical devices — Application of risk management to medical devices

1 Scope

This document specifies terminology, principles and a *process* for *risk management* of *medical devices*, including software as a *medical device* and *in vitro diagnostic medical devices*. The *process* described in this document intends to assist *manufacturers* of *medical devices* to identify the *hazards* associated with the *medical device*, to estimate and evaluate the associated *risks*, to control these *risks*, and to monitor the effectiveness of the controls.

The requirements of this document are applicable to all phases of the *life cycle* of a *medical device*. The *process* described in this document applies to *risks* associated with a *medical device*, such as *risks* related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

The *process* described in this document can also be applied to products that are not necessarily *medical devices* in some jurisdictions and can also be used by others involved in the *medical device life cycle*.

This document does not apply to:

— decisions on the use of a *medical device* in the context of any particular clinical *procedure*; or

— business *risk management*.

This document requires *manufacturers* to establish objective criteria for *risk* acceptability but does not specify acceptable *risk* levels.

Risk management can be an integral part of a quality management system. However, this document does not require the *manufacturer* to have a quality management system in place.

NOTE Guidance on the application of this document can be found in ISO/TR 24971[9].

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
accompanying documentation
materials accompanying a *medical device* (3.10) and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the *medical device* (3.10), particularly regarding safe use

Note 1 to entry: The *accompanying documentation* can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: *Accompanying documentation* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

3.2
benefit
positive impact or desirable outcome of the use of a *medical device* (3.10) on the health of an individual, or a positive impact on patient management or public health

Note 1 to entry: *Benefits* can include positive impact on clinical outcome, the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public health.

3.3
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:2019, 3.1]

3.4
hazard
potential source of *harm* (3.3)

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.5
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.4)

Note 1 to entry: See Annex C for an explanation of the relationship between hazard and hazardous situation.

[SOURCE: ISO/IEC Guide 63:2019, 3.3, modified — Note 1 to entry added.]

3.6
intended use
intended purpose
use for which a product, *process* (3.14) or service is intended according to the specifications, instructions and information provided by the *manufacturer* (3.9)

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*.

[SOURCE: ISO/IEC Guide 63:2019, 3.4]

3.7
in vitro diagnostic medical device
IVD medical device
device, whether used alone or in combination, intended by the *manufacturer* (3.9) for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1:2009, 3.27, modified — NOTE deleted.]

3.8
life cycle
series of all phases in the life of a *medical device* (3.10), from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:2019, 3.5]

3.9
manufacturer
natural or legal person with responsibility for the design and/or manufacture of a *medical device* (3.10) with the intention of making the *medical device* (3.10) available for use, under his name, whether or not such a *medical device* (3.10) is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: The 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 (RA) 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" may 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* 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 authorised 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: ISO/IEC Guide 63:2019, 3.6]

3.10
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* (3.9) 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* (3.10),

— 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 may be assisted in its 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 reproduction technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7]

3.11
objective evidence
data supporting the existence or verity of something

Note 1 to entry: *Objective evidence* can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 9000:2015, 3.8.3, modified — Note 2 to entry deleted.]

3.12
post-production
part of the *life cycle* (3.8) of the *medical device* (3.10) after the design has been completed and the *medical device* (3.10) has been manufactured

EXAMPLE Transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning and disposal.

3.13
procedure
specified way to carry out an activity or a *process* (3.14)

Note 1 to entry: *Procedures* can be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5]

3.14
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a *process* is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a *process* are generally the outputs of other *processes* and outputs of a *process* are generally the inputs to other *processes*.

Note 3 to entry: Two or more interrelated and interacting *processes* in series can also be referred to as a *process*.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 4, 5 and 6 are deleted.]

3.15
reasonably foreseeable misuse
use of a product or system in a way not intended by the *manufacturer* (3.9), 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 63:2019, 3.8]

3.16
record
document stating results achieved or providing evidence of activities performed

Note 1 to entry: *Records* can be used, for example, to formalize traceability and to provide evidence of *verification*, preventive action and corrective action.

Note 2 to entry: Generally *records* need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

3.17
residual risk
risk remaining after *risk control* (3.21) measures have been implemented

[SOURCE: ISO/IEC Guide 63:2019, 3.9]

3.18
risk
combination of the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that *harm* (3.3)

[SOURCE: ISO/IEC Guide 63:2019, 3.10, modified — Note 1 to entry deleted.]

3.19
risk analysis
systematic use of available information to identify *hazards* (3.4) and to estimate the *risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.11]

3.20
risk assessment
overall *process* (3.14) comprising a *risk analysis* (3.19) and a *risk evaluation* (3.20)

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.21
risk control
process (3.14) in which decisions are made and measures implemented by which *risks* (3.18) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2019, 3.12]

3.22
risk estimation
process (3.14) used to assign values to the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that harm

[SOURCE: ISO/IEC Guide 63:2019, 3.13]

3.23
risk evaluation
process (3.14) of comparing the estimated *risk* (3.18) against given *risk* (3.18) criteria to determine the acceptability of the *risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.14]

3.24
risk management
systematic application of management policies, *procedures* (3.13) and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.15]