INTERNATIONAL STANDARD

ISO 14971

Third edition
2019-12

Medical devices — Application of risk management to medical devices

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

Reference number
ISO 14971:2019(E)

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.

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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.