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Medical devices — Application of risk management to medical devices

AMENDMENT 1: Rationale for requirements

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

AMENDEMENT 1: Justification des exigences

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Foreword

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

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard 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.

Amendment 1 to ISO 14971:2000 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

At the time of publication of ISO 14971:2000, it was anticipated that maintenance of the standard would be required within a few years. IEC/SC 62A has already anticipated that a revision may be needed in about 2005. In anticipation of the maintenance process, ISO/TC 210-IEC/SC 62A Joint Working Group 1, *Application of risk management to medical devices*, developed this Amendment to document its reasoning for establishing the various requirements contained in ISO 14971. Those who make future revisions to the standard can use this Amendment, along with experience gained in the use of the standard, to make the standard more useful to manufacturers, regulatory bodies, and health care providers.

The material in this Amendment is purely informative. It does not alter in any way the requirements of ISO 14971 or modify any of the other informative material.

Introduction

A standard for the application of risk management to medical devices became important largely because of the increasing recognition by regulators that the manufacturer should apply risk management to medical devices. No medical device risk management standard existed, and ISO 14971 was written to fill that gap. ISO/TC 210 Working Group 4 was formed to develop the new standard. Almost simultaneously, drafters of the third edition of IEC 60601-1 planned to have risk management included in the standard then under development. They saw the need for a separate risk management activity and formed Working Group 15 of IEC/SC 62A. Recognizing that the efforts of these two working groups overlapped, IEC and ISO formed the Joint Working Group 1 (JWG 1) on Risk Management combining the membership of both working groups. This collaboration resulted in the publication of ISO 14971 with both an ISO and an IEC logo. The dual logo signifies that both ISO and IEC recognize ISO 14971 as the International Standard covering the application of risk management to medical devices.

When JWG 1 started its discussions on the international risk management standard, there was no satisfactory standard in place to address risk management for medical devices. Crucial features of risk management needed to be addressed such as the process of risk evaluation, as well as the balancing of risks and benefits for medical devices. Manufacturers, regulatory bodies, and health care providers had recognized that “absolute safety” in medical devices was not achievable. In addition, the risks that derive from the increasing diversity of medical devices and their applications cannot be completely addressed through product safety standards. The recognition of these facts and the consequent need to manage risks from medical devices throughout their life cycle led to the decision to develop ISO 14971.

The JWG 1’s original plan was to write ISO 14971 in several parts, each dealing with a specific aspect of risk management. ISO 14971-1:1998, covering risk analysis, was intended as the first part of an overall risk management standard. Later, the JWG 1 decided that it was better to develop a single document that would include all aspects of risk management. The main reason for this was that it was apparent that risk management would be mandated by several regulatory regimes in the world, including Europe. It was therefore no longer useful or necessary to have a separate standard on risk analysis available. Also, making one risk management standard instead of having several parts would much better show the coherence between the several aspects of risk management.

In this Amendment, the numbering parallels the numbering of the clauses and subclauses of ISO 14971:2000.

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Annex H
(informative)

Rationale for requirements

H.1 Rationale for Clause 1, Scope

As explained in the Introduction, a risk management standard applying to all medical devices is required. Risks exist throughout the product life cycle, and risks that become apparent at one point in the life cycle may be managed by action taken at a completely different point in the life cycle. For this reason, this International Standard is intended to be a complete life cycle standard. This means that it instructs manufacturers to apply risk management principles to a medical device from its initial conception until its ultimate decommissioning and disposal.

This International Standard is not intended to be applicable to clinical decision making. The decision to embark upon a clinical procedure utilizing a medical device requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgements should take into account the intended use/intended purpose, performance, and risks associated with the medical device as well as the risks and benefits associated with the clinical procedure or the circumstances of use. Some of these judgements may be made only by a qualified health care professional with knowledge of the state of health of an individual patient and the patient's own opinion.

Although there has been significant debate over what constitutes an acceptable level of risk, this International Standard does not specify acceptability levels. Specifying a single level for acceptable risk would be inappropriate because

— the wide variety of devices and situations covered by this International Standard would make a single level meaningless, and

— local laws, customs, and values are more appropriate for defining risk acceptability for a particular culture or region of the world.

Because not all countries require a quality system for medical device manufacturers, a quality system is not required in this International Standard. However, a quality system is extremely helpful in managing risks properly. Because of this and because most medical device manufacturers do employ a quality system, this International Standard is constructed so that it can easily be incorporated into the quality system that they use. The relationship with ISO 13485:1996 is shown in Table G.2 in Annex G.

H.2 Rationale for Clause 2, Terms and definitions

It was not intended to invent a host of new and possibly unfamiliar terms and so this International Standard is intentionally built upon the wealth of risk management information both in standards and in the literature. Existing definitions were used wherever possible. The primary sources for the definitions were ISO/IEC Guide 51:1999 and ISO 8402:1994[1)].

It was known that risk management would be made mandatory, either explicitly or implicitly, by the European Union (EU), the United States, and other countries and regions of the world. Therefore definitions were used that would be widely acceptable in a regulatory sense. For example, the term “manufacturer” (2.6) while based on the medical device directive in the EU, is consistent with the definition used in the United States. The term “medical device” (2.7) was taken from ISO 13485 where a similar consideration for local regulations had also been applied. The combined term “intended use/intended purpose” (2.5) was used because there was no consensus on which term to use. The Medical Device Directive uses “intended purpose,” whereas the United States regulations use “intended use.” Both terms have essentially the same definition. It was decided to use the combined term along with a definition that is similar to that used in both the EU and the United States.

Only three terms in this International Standard are not based on definitions in other standards. These are “risk control” (2.16), “risk management” (2.18), and “risk management file” (2.19). The definition for “risk control” was provided to be consistent with the definitions of “risk analysis” and “risk evaluation” given by ISO/IEC Guide 51. The definition for “risk management” emphasizes the use of a systematic approach and the need for management overview. The concept of a “risk management file” was originally expressed in IEC 60601-1-4, but the definition was changed because the definition in IEC 60601-1-4 refers to quality records, which need not exist for compliance with ISO 14971.

H.3 Rationale for Clause 3, General requirements for risk management

Although risk management activities are highly individual to the device being evaluated, there are basic elements that need to be included in the risk management process. This clause satisfies that need. This clause also allows for some differences in the requirements for meeting this standard, based on local differences in regulatory approaches.

H.3.1 National or regional regulatory requirements

Worldwide applicability of this International Standard is important despite differing regional regulatory requirements. This subclause was needed so that both Europe and the United States (as well as other countries and regions) could use this International Standard in their regulatory programmes. In Europe, manufacturers do not need to have a certified quality system in place to meet the essential requirements necessary for applying a CE mark to their product. In the United States, a quality system is always required to market a device (unless the device is specifically exempted). Subclauses 3.3 and 3.4 closely follow quality system requirements. This subclause enables manufacturers to apply 3.3 and 3.4 in conjunction with a quality system, when required by their local regulatory authorities.

H.3.2 Risk management process

This subclause requires each manufacturer to establish a risk management process as part of the design of a medical device. This is required so that the manufacturer can systematically ensure that the required elements are in the process. Risk analysis, risk evaluation and risk control are commonly recognised as essential parts of risk management. In addition to these elements, it was necessary to emphasize, however, that the risk management process does not end with the design and manufacturing of a medical device, but continues on into the post-production phase. Therefore, the gathering of post-production information was identified as a required part of the risk management process. When a manufacturer employs a quality system, the risk management process should be fully integrated into that quality system.

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1) ISO 8402:1994 has been replaced by ISO 9000:2000. However, the definitions of terms such as “objective evidence” in ISO 14971:2000 were taken from ISO 8402:1994.