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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

Reference number
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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.

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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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Medical devices — Application of risk management to medical devices

AMENDMENT 1: Rationale for requirements

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Add the following annex before the Bibliography.

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.

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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.

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H.3.3 Management responsibilities

The commitment of a manufacturer's management is critical for an effective risk management process. These individuals should take responsibility for overall guidance of the risk management process. Therefore, this subclause was included to emphasize that role. In particular, the following was concluded.

a) Because this International Standard does not define acceptable risk levels, the manufacturer has to decide what criteria to apply, taking account of relevant factors.

b) In the absence of adequate resources, risk management activities would be less effective, even if complying with the letter of the other requirements of this International Standard.

c) Risk management is a specialized discipline and requires the use of individuals trained in risk management techniques (see H.3.4).

d) Risk management is an evolving process and periodic review of the risk management activities is needed to ascertain whether they are being carried out correctly, to rectify any weaknesses, to implement improvements, and to adapt to changes.

H.3.4 Qualification of personnel

It is essential to get qualified people to perform risk management tasks. Risk management processes require people who know

— how the device is constructed,

— how the device works,

— how the device is intended, or likely, to be used, and

— how to apply the risk management process.

In general, this will require several experts, each contributing their specialist knowledge. Records of the appropriate qualifications are required to provide objective evidence. For confidentiality reasons, this International Standard does not require these records to be kept in the risk management file.

H.3.5 Risk management plan

A risk management plan is required because

— an organized approach is essential for good risk management,

— the plan provides the roadmap for risk management, and

— the plan encourages objectivity and helps prevent essential elements being forgotten.

A plan is also beneficial for reuse of the process for subsequent risk management programmes. Elements a) to e) are required for the following reasons.

a) There are two distinct elements in the scope of the plan. The first identifies the intended medical device or accessory; the other identifies the phases of the life cycle covered by the plan. By defining the scope, it can be seen if any part of the device is not included and if parts of the life cycle have to be covered by another plan.

b) Verification is an essential activity and is required by 6.3. Planning this activity helps ensure that essential resources are available when required. If verification is not planned, important parts of the verification could be neglected.

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c) The allocation of responsibilities is needed to ensure that no responsibility is omitted.

d) This point is included as a generally recognised responsibility of management.

e) The criteria for risk acceptability are fundamental to risk management and should be decided upon before risk analysis begins. This helps make the process in Clause 5 objective.

The requirement to keep a record of changes is to facilitate audit and review of the process.

H.3.6 Risk management file

This International Standard uses this term to signify where the manufacturer can locate or find the locations of all the records applicable to risk management. This facilitates the risk management and enables more efficient auditing to this International Standard.

H.4 Rationale for Clause 4, Risk analysis

ISO 14971-1:1998, *Medical devices — Risk management — Part 1: Application of risk analysis*, was used as the basis for this clause. ISO 14971-1 was the ISO version of EN 1441 on medical device risk analysis. EN 1441 was written under a mandate of the European Commission, and it gives the presumption of conformance with the requirements for risk analysis of the European medical device regulations[2)].

In this and subsequent clauses of this International Standard, the requirements are keyed to the steps of the flow diagram in Figure 2. Figure 2 was provided to give the user an overview of the risk management process. Providing a key (in the form of step numbers) between the figure and the actual requirements in the text would prove a useful aid. This is an expansion of the mechanism provided in ISO 14971-1. As indicated in Figure 2, the process needs to be iterative, covering each risk in turn, and returning to earlier steps if risk control measures introduce new hazards or if new information becomes available.

H.4.1 Risk analysis procedure

The risk analysis procedure is described in 4.2, 4.3 and 4.4.

A note was added on how to deal with the availability of a risk analysis for a similar medical device to inform users of this International Standard that when adequate information already exists it can and should be applied to save time, effort and other resources. Users of this International Standard need to be careful, however, to assess systematically their previous work for applicability to the current risk analysis.

Note that details required by a), b) and c) form the basic minimum data set for ensuring traceability and are important for management reviews and for subsequent audits. The requirement in a) also helps clarify what is in the scope of the analysis and verify completeness.

H.4.2 Intended use/intended purpose and identification of characteristics related to the safety of the medical device

This step forces the manufacturer to think about all the characteristics that could affect safety of the medical device. This analysis should include “reasonably foreseeable misuse.” Devices are frequently used in situations other than those intended by the manufacturer and in situations other than those foreseen when a device is first conceived. It is important that the manufacturer tries to look into the future to see the hazards due to potential uses of their device.

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2) EN 1441 was ratified on 13 September 1997 and its reference number published in the European Community’s Official Journal of 9 May 1998.

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Annex A is intended to be helpful in describing the characteristics of the medical device and the environments in which it is used. It cannot be emphasized too strongly that this list is not exhaustive. Every manufacturer should be creative in determining the relevant safety characteristics for the medical device under investigation. The list in Annex A was originally taken from ISO 14971-1:1998, with some additions made as a result of comments on drafts of that standard. The list ought to stimulate thinking of "where can things go wrong?" Annex B on *in vitro* devices and Annex C on toxicological hazards have been taken from Annex A and Annex B, respectively, of ISO 14971-1:1998 with only minor changes.

H.4.3 Identification of known or foreseeable hazards

This step requires that the manufacturer be systematic in the identification of potential hazards. The manufacturer should list "known or foreseeable hazards" based upon the safety characteristics identified in 4.2. A risk can only be assessed and managed once a hazard has been identified. Listing the hazards allows this to be done systematically.

Annex D was provided to give examples of "possible hazards and contributing factors." This terminology was used because it may not always be clear whether something is a "hazard" or a "contributing factor." This is especially true when there is a sequence of events that in the end may lead to a hazardous situation. The manufacturer should recognise these sequences of events to address risk properly. Whether a specific element of this sequence is called a hazard or a contributing factor is unimportant.

Again the list as given in Annex D is non-exhaustive and is not intended as a checklist, but rather to stimulate creative thinking.

Annex F is provided as guidance on common risk analysis techniques that may be helpful in the identification of hazards.

H.4.4 Estimation of the risk(s) for each hazard

This is the final step of risk analysis. The difficulty with this step is that estimation of risk is different for every hazard that is under investigation as well as for every device. It was therefore decided to write the text of this subclause generically. Because hazards can occur both when the device functions normally and when the device malfunctions, one should look closely at both situations. In practice, both components of risk, probability and consequence, should be analysed separately. When a manufacturer uses a systematic way of categorizing the severity or probability estimate levels, it should define the categorization scheme and record it in the risk management file. This enables the manufacturer to treat equivalent risks repeatably and serves as evidence that the manufacturer has done so.

Frequently, good quantitative data are not readily available. Therefore the suggestion that estimation of risk should be done in a quantitative way has been avoided.

Annex E (E.1 to E.2) has been added as helpful guidance on risk analysis. The information originates from several sources, including IEC 60300-3-9. The information in that standard was adapted to make it useful for all medical devices. Annex E does not require the construction of a "risk chart" showing the relationship between probability and severity and acceptability of risk. When risk charts are used for establishing the acceptability of a particular risk, their use and interpretation should be explained for the particular application.

H.5 Rationale for Clause 5, Risk evaluation

Decisions have to be made about the acceptability of risk. A decision was placed at this point because this is the first occasion that the required information is available. Manufacturers can use the recently estimated risks and evaluate them using the criteria for risk acceptability defined in the risk management plan. They can screen the risks to determine which ones need to be reduced. Clause 5 was written in this way to allow the user to avoid unnecessary work.

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H.6 Rationale for Clause 6, Risk control

H.6.1 Risk reduction

Steps 6.2 to 6.7 make up a logical sequence of stages. This systematic approach is important since it ensures that relevant information is available when required.

H.6.2 Option analysis

Often there will be more than one way to reduce a risk. The three mechanisms listed are

— inherent safety by design,

— protective measures in the medical device itself or in the manufacturing process, and

— information for safety.

These are standard risk reduction measures and are derived from ISO/IEC Guide 51. The priority order listed is important. This principle is found in several places, including IEC/TR 60513 and local or regional regulations (e.g. the European Medical Device Directive). If practicable, the device should be designed to be inherently safe. If this is not practicable, then protective measures such as barriers or audible alarms are appropriate. The least preferred protective measure is a written warning or contra-indication.

It was recognised that one possible result of the option analysis could be that there is no practicable way for reducing the risk to acceptable levels according to the pre-established criteria for risk acceptability. For example, it could be impractical to design a life-supporting device with such an acceptable residual risk. In this case, a risk/benefit analysis may be carried out as described in 6.5 to determine whether the benefit of the device to the patient outweighs the residual risk. This option is included at this point in this International Standard to make sure that every effort was first made to reduce risks to the pre-established acceptable levels.

H.6.3 Implementation of risk control measure(s)

Two distinct verifications were included. The first verification is required to make sure that, provided the measure is implemented, the risk is reduced. The second verification is required to ensure that the measure has been implemented in the final design.

H.6.4 Residual risk evaluation

A check was introduced here to determine whether the implemented measures have made the risk acceptable. If the risk is not less than the criteria established in the risk management plan, manufacturers are instructed to assess additional risk control measures. This iterative process should be continued until the risk is reduced to within the acceptability levels established in the risk management plan.

The requirement to provide the user with relevant information on residual risks was included so that the user can make informed decisions. This requirement is consistent with the approach taken in many countries and regions, including the United States and the European Union.

H.6.5 Risk/benefit analysis

There will be some occasions where the risk associated with a medical device is greater than would be generally accepted. This subclause was included to enable the manufacturer to provide a high-risk device for which they have done a careful evaluation and can show that the benefit of the device outweighs the risk.

H.6.6 Other generated hazards

This subclause was included because it was recognised that risk control measures alone or in combination might introduce a new and sometimes quite different hazard.

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H.6.7 Completeness of risk evaluation

At this stage, the risk of all the hazards should have been evaluated. This check was introduced to ensure that no hazards were left out in the intricacies of a complex risk analysis.

H.7 Rationale for Clause 7, Overall residual risk evaluation

During the process defined by Clauses 4 to 6, manufacturers identify hazards, evaluate the risks, and implement risk control measures in their design one at a time. This is the point where the manufacturer has to step back, consider the combined impact of the individual residual risks, and make a decision as to whether to proceed with the device. It is possible that the overall residual risk can exceed the manufacturer's criteria for acceptable risk, even though individual residual risks do not. This is particularly true for complex systems and devices with a large number of risks. Even if the overall residual risk exceeds the criteria in the risk management plan, the manufacturer has one last opportunity to do an overall risk-benefit evaluation to determine whether a high risk, but highly beneficial, device should be marketed.

H.8 Rationale for Clause 8, Risk management report

The risk management report is a crucial part of the risk management file. It is intended to be a summary of what was done in the risk management process. The risk management report should contain pointers to the respective details in the risk management file. The report serves as the high level document for all kinds of questions about risks associated with the device.

Completeness is very important in risk management. An incomplete task can mean that the risk of a hazard is not controlled and harm to someone may be the consequence. The problem can result from incompleteness at any stage of risk management (e.g. unidentified hazards, risks not assessed, unspecified risk control measures, or risk control measures not implemented). The risk management report is a tool that allows completeness to be judged. It does this by requiring that traceability be demonstrated for the implementation of all risk control measures required to achieve an acceptable residual risk for each hazard.

H.9 Rationale for Clause 9, Post-production information

It cannot be emphasized too often that risk management does not stop when the device goes into production. Risk management is an imperfect process because it is based on an idea with no physical manifestation of the device. Risk estimates can be refined throughout the design process and made more accurate when a functioning prototype is built. However, no amount of modelling can substitute for an actual device in the hands of actual users. This is where all the potential hazards become real. Because of this, manufacturers should monitor post-market information for things that may affect their risk estimates and, therefore, their risk management decisions. With this post-production information, the risk management process truly becomes a repetitive closed-loop process.

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