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**Medical devices — Risk management
— Part 1: Application of risk analysis**

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Reference number : JIS Q 14971-1 : 2001 (E)

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Ministers of Health, Labour and Welfare and Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from the Japan Federation of Medical Devices Associations (JFMDA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Medical devices — Risk management — Part 1: Application of risk analysis

Introduction

This Japanese Industrial Standard has been prepared based on ISO 14971-1 *Medical devices—Risk management—Part 1: Application of risk analysis* published in 1998 without modifying the technical contents.

Judgements relating to safety, including the acceptability of risks, are necessary in order to determine the suitability of a medical device for its intended use. Factors influencing the perception of safety include the socio-economic and educational background of the society concerned, and the actual and projected situation and status of the patient. Such judgements must take into account the intended use, performance, risks and benefits of the device, and the risks and benefits associated with the clinical procedure.

The overall process for the control of risks is referred to as "risk management". This part of JIS Q 14971 describes techniques for risk analysis based on quantitative or qualitative estimation of the probability of possible consequences of a postulated event relating to the application of a medical device. Risk analysis is the initial step in the overall process referred to as risk management. Elements of risk evaluation and risk control are included in the flow diagram (figure 1) for purposes of completeness. The relationship between risk analysis, risk evaluation and risk control is illustrated in annex E. Further work is under consideration.

Portions underlined with dots are the matters not stated in the original International Standard.

1 Scope

This part of JIS Q 14971 specifies a procedure for investigating, using available information, the safety of a medical device, including *in vitro* diagnostic devices (IVD) or accessories, by identifying hazards and estimating the risks associated with the device. It may be or particular assistance in areas where relevant standards are not available or not used.

This part of JIS Q 14971 does not stipulate levels of acceptability because these are determined by a multiplicity of factors that cannot be set down in such a standard.

This part of JIS Q 14971 is not intended to give guidance on all aspects of management of risks. Furthermore, it is not intended to cover decision-making processes regarding assessment of the indications and contra-indications for the use of a particular device.

NOTE The International Standard corresponding to this Standard is as follows.

In addition, Symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

ISO 14971-1:1998 *Medical devices—Risk management—Part 1: Application of risk analysis (IDT)*

2 Definitions

For the purposes of this part of JIS Q 14971, the following definitions apply.

2.1

harm

physical injury and/or damage to health or property
[ISO/IEC Guide 51]

Information: The harm also includes death, etc.

2.2

hazard

potential source of harm
[ISO/IEC Guide 51]

2.3

risk

probable rate of occurrence of a hazard causing harm and the degree of severity of the harm
[ISO/IEC Guide 51]

2.4

risk analysis

investigation of available information to identify hazards and to estimate risks

NOTE 1 See annex E.

NOTE 2 Examples of sources of information are given in note 3 in subclause 3.4.

2.5

safety

freedom from unacceptable risk of harm
[ISO/IEC Guide 51]

3 Procedure

3.1 General

The risk analysis procedure described in 3.2 to 3.9 and illustrated in the flow diagram given in figure 1 shall be followed. A record of the conduct and results of the risk analysis procedure shall be documented and maintained by the manufacturer.

NOTE 1 Risk analysis can be carried out as part of a quality system.

NOTE 2 The documentation of the conduct and results of the risk analysis procedure should include at least the following:

- a) a complete description and identification of the device or accessory under consideration;
- b) a list of possible hazards as identified under 3.3;
- c) an indication of the methods by which risks have been reduced to acceptable levels;
- d) identification of which party carried out the risk analysis.

3.2 Identification of qualitative and quantitative characteristics related to medical devices

For the particular device or accessory being considered, all those characteristics that could affect its safety and, where appropriate, their defined limits should be listed.

NOTE 1 Additional guidance on risk analysis techniques for IVDs is given in annex A.

NOTE 2 Additional guidance on risk analysis techniques for toxicological hazards is given in annex B.

The following questions can serve as a useful guide in drawing up such a list.

a) What is the intended use and how is the device to be used?

Factors that should be considered include the intended user, the required skill and training of the user, ergonomic aspects, the environment(s) in which it is to be used, by whom it will be installed, and whether the patient can control or influence the use of the device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a device.

b) Is the device intended to come into contact with the patient or other persons?

Factors that should be considered include intended contact, surface contact, invasive contact, implantation and, respectively, period and frequency of contact.

c) What materials and/or components are incorporated in the device or are used?

Factors that should be considered include whether characteristics relevant to safety are known.

d) Is energy delivered to and/or extracted from the patient?

Factors that should be considered include the type of energy transferred and its control, quality, quantity, and time function.

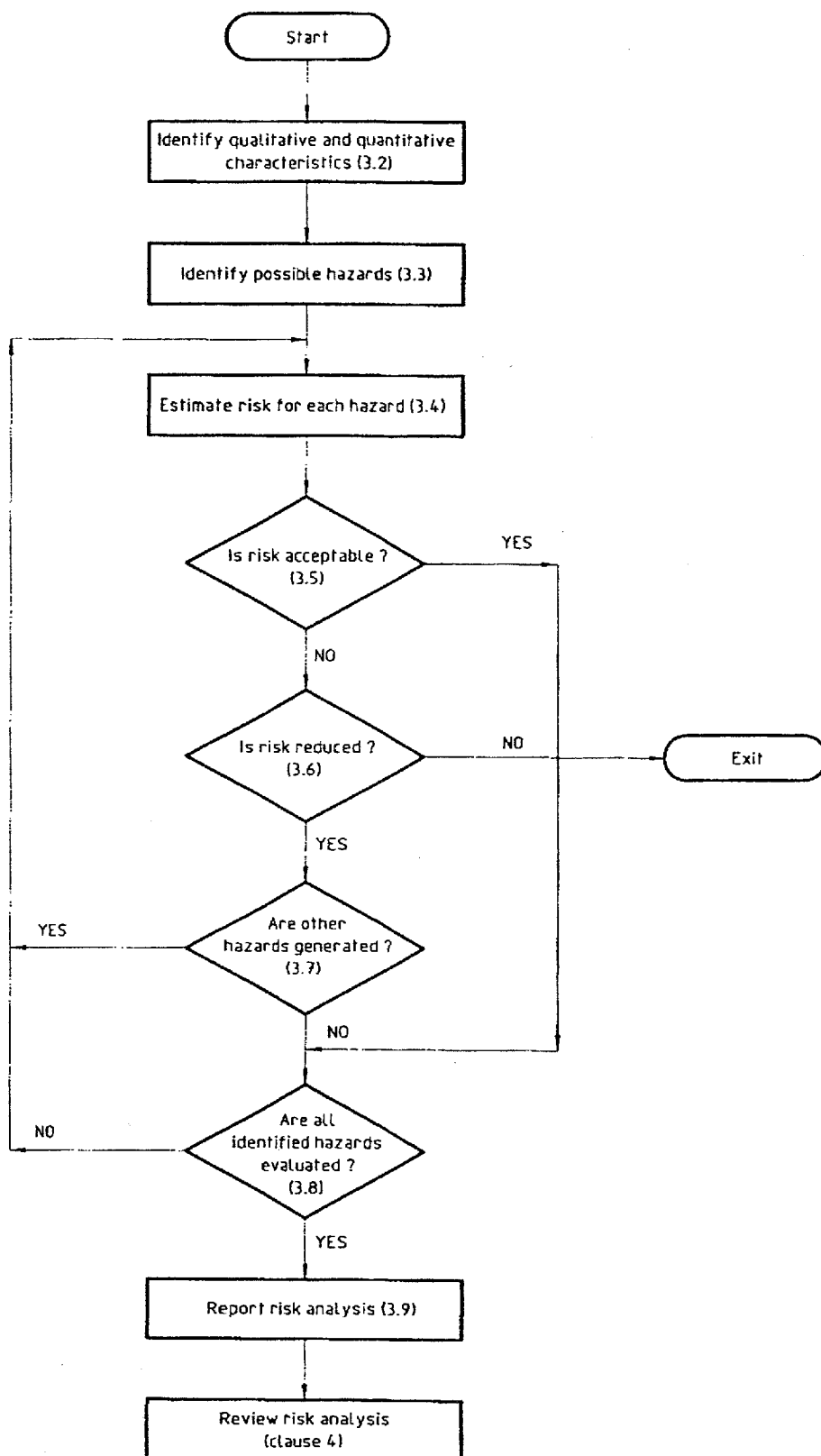


Figure 1 — Flow diagram of risk analysis procedure