SLOVENSKI STANDARD
SIST EN 1441:2000

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Medical devices - Risk analysis

Medical devices - Risk analysis

Medizinprodukte - Risikoanalyse

Dispositifs médicaux - Analyse des risques

Ta slovenski standard je istoveten z: **EN 1441:1997**

ICS:

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English version

Medical devices - Risk analysis

Dispositifs médicaux - Analyse des risques

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This European Standard was approved by CEN on 13 September 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Contents

Foreword

This European Standard has been prepared by BTS 3 /WG 1 "Risk assessment of medical devices" of CEN/CS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1998, and conflicting national standards shall be withdrawn at the latest by April 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative annex ZA which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A, B, C, D and E are informative.

Introduction

Judgements relating to safety, including the acceptability of risks, are necessary in order to determine the suitability for use of a medical device. 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 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 risk is referred to as risk management. During the design phase of a medical device a manufacturer will need to analyse the hazards and risks associated with the use of a device. This standard addresses that phase of the risk management process.

Relevant standards mentioned within this standard include harmonized European standards, the references of which has been published in the Official Journal of the European Communities.

1 Scope

This standard specifies a procedure for the manufacturer to investigate, using available information, the safety of a medical device, including in vitro diagnostic devices or accessories, by identifying hazards and estimating the risks associated with the device. It is of particular assistance in areas where relevant standards are not available or not used.

This standard does not stipulate levels of acceptability, which because they are determined by a multiplicity of factors, cannot by their nature be set down in such a standard.

This standard is not intended to give detailed guidance on 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.

2 Definitions

For the purposes of this standard, the following definitions apply:

2.1 harm: Physical injury and/or damage to health or property. [ISO/IEC Guide 51:1990]

2.2 hazard: A potential source of harm. [ISO/IEC Guide 51:1990]

2.3 risk: The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm. [ISO/IEC Guide 51:1990]

2.4 risk analysis: The investigation of available information to identify hazards and to estimate risks.

2.5 safety: Freedom from unacceptable risk of harm. [ISO/IEC Guide 51:1990]

3 Procedure

3.1 General (step 1 of figure 1)

The risk analysis procedure, as described in 3.2 to 3.9 and illustrated in the flow diagram given in figure 1 shall be followed and 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 devices or accessory under consideration;

b) a list of possible hazards as identified under 3.3;

c) an indication of the way in which the risk has been reduced to acceptable levels;

d) identification of which party carried out the risk analysis.

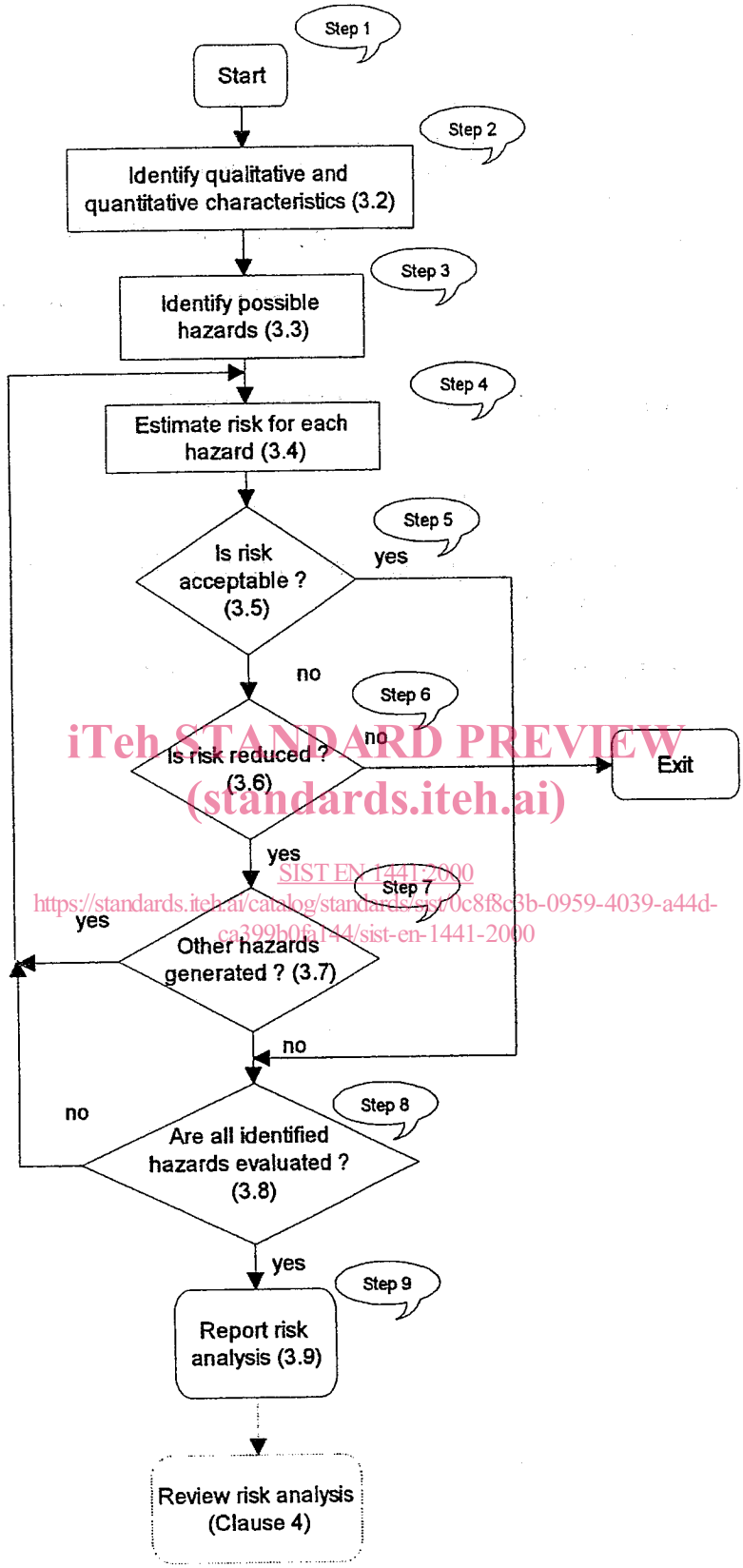

Figure 1: Flow diagram of risk analysis procedure

3.2 Identification of qualitative and quantitative characteristics related to medical devices (step 2 of figure 1)

For the particular device or accessory being considered, list all those characteristics that can affect its safety and, where appropriate, list their defined limits.

NOTE 1: Additional guidance on risk analysis procedures for in vitro diagnostic devices is given in annex A.

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

NOTE 3: 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 who is the intended user, the required skill and training of the user, in which environment it is to be used, by whom it will be installed and whether the patient can influence the use of the device. Special attention should be paid to users with special needs like 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 contact 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.

e) Are substances delivered to and/or extracted from the patient?

Factors that should be considered include whether the substance is delivered or extracted, whether it is a single substance or range of substances, the maximum and minimum transfer rates and control thereof.

f) Are biological materials processed by the device for subsequent re-use?

Factors that should be considered include the type of process and substance(s) processed (e.g. auto-transfusion, dialyzers).

g) Is the device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable?

Factors that should be considered include whether the device is intended for single-use or to be re-usable, any packaging, the shelf-life and any limitation on the number of re-use cycles or type of sterilization process to be used.

h) Is the device intended to modify the patient environment?
Factors that should be considered include temperature, humidity, atmospheric gas composition and pressure.

i) Are measurements made?

Factors that should be considered include the variables measured and the accuracy and the precision thereof.

j) Is the device interpretative?

Factors that should be considered include whether conclusions are presented by the device from input or acquired data, the algorithms used and confidence limits.

k) Is the device intended to control or to interact with other devices or drugs?

Factors that should be considered include identifying other devices and drugs which can be involved and the potential problems associated with such interactions.

l) Are there unwanted outputs of energy or substances?

Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing and ultra-violet/visible/infra-red radiation), contact temperatures, leakage currents and electrical and/or magnetic fields.

Substance-related factors that should be considered include discharge of chemicals, waste products and body fluids.

m) Is the device susceptible to environmental influences?

Factors that should be considered include the operational, transport and storage environment, including spillage, and power and cooling supplies.

n) Are there essential consumables or accessories associated with the device?

Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.

o) Is maintenance and/or calibration necessary?

Factors that should be considered include whether maintenance and/or calibration are to be carried out by the operator or user or by a specialist.

p) Does the device contain software?

Factors that should be considered include whether software is intended to be installed, modified or exchanged by the user and/or operator.

q) Does the device have a restricted "shelf-life"?

Factors that should be considered include labelling or indicators and the disposal of such devices.

r) Possible delayed and/or long term use effects?

Factors that should be considered include ergonomic and cumulative effects.

s) To what mechanical forces will the device be subjected?

Factors that should be considered include whether the forces to which the device will be subjected are under the control of the user or controlled by interaction with other persons.

t) What determines the lifetime of the device?

Factors that should be considered include ageing.

u) Is the device intended for single use or re-use?

3.3 Identification of possible hazards (step 3 of figure 1)

Using the examples of possible hazards listed in Annex C as an aide-memoire, compile a list of potential hazards associated with the device in both normal and fault conditions.

3.4 Estimation of the risks for each hazard (step 4 of figure 1)

For each of the possible hazards identified under 3.3, estimate the risks in both normal and fault conditions using available information/data.

NOTE 1: In order to better analyse risks, their components, i.e. consequences and probability should be analysed separately. This includes answering the following questions:

- does the hazard occur in the absence of a failure?
- does the hazard occur in a failure mode?
- does the hazard occur only in a multiple failure condition?

Annex D gives information on some risk analysis techniques that can be used.