**EN ISO 14971:2000**

**3 General requirements for risk management**

3.2 Risk management process

The manufacturer shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. This process shall be documented and shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control; and

— post-production information.

Where a documented product design/development process exists, it shall incorporate the appropriate parts of the risk management process.

NOTE 1 A documented product design/development process can be used to deal with safety in a systematic manner, in particular to enable the early identification of hazards in complex systems and environments.

NOTE 2 A schematic representation of the risk management process is shown in Figure 1.

NOTE 3 See the bibliography.

Compliance is checked by inspection of the risk management file.

3.3 Management responsibilities

The manufacturer shall

a) define the policy for determining acceptable risk, taking into account relevant International Standards, and national or regional regulations,

b) ensure the provision of adequate resources,

c) ensure the assignment of trained personnel (see 3.4) for management, performance of work and assessment activities, and

d) review the results of risk management activities at defined intervals to ensure continuing suitability and the effectiveness of the risk management process.

The above shall be documented in the risk management file.

Compliance is checked by inspection of the risk management file.

2.13

**risk**

combination of the probability of occurrence of harm and the severity of that harm

2.14

**risk analysis**

systematic use of available information to identify hazards and to estimate the risk

[ISO/IEC Guide 51 :1999, definition 3.10]

2.15

**risk assessment**

overall process comprising a risk analysis and a risk evaluation

[ISO/lEG Guide 51:1999, definition 3.12]

2.16

**risk control**

process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

2.17

**risk evaluation**

judgement, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society

NOTE Based on ISO/lEG Guide 51:1999, definitions 3.11 and 3.7.

2.18

**risk management**

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk

2.19

**risk management file**

set of records and other documents, not necessarily contiguous, that are produced by a risk

management process
2.20
**safety**
freedom from unacceptable risk
[ISO/lEG Guide 51:1999, definition 3.1]
**2.21**
**severity**
measure of the possible consequences of a hazard
2.22
**verification**
confirmation by examination and provision of objective evidence that specified requirements have been fulfilled NOTE In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the stated requirement for that activity.
[ISO 8402:1994, definition 2.17]
**2.5**
**intended use/intended purpose**
use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer
2.6
**manufacturer**
natural or legal person with responsibility for the design, manufacture, packaging or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party
**2.7**
**medical device**
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[ISO 13485:1996, definition 3.1]
**2.8**
**objective evidence**
information which can be proven true, based on facts obtained through observation, measurement, test or other means
[ISO 8402:1994, definition 2.19]
**2.9**
**procedure**
specific way to perform an activity
[ISO 8402:1994, definition 1.3]
2.10
**process**
set of inter-related resources and activities which transform inputs into outputs

[ISO 8402:1994, definition 1.2]

**2.11**
**record**
document which furnishes objective evidence of activities performed or results achieved
[ISO 8402:1994, definition 3.15]

**2.12**
**residual risk**
risk remaining after protective measures have been taken