AS/NZS 4810.1:2000
ISO 14971-1:1998

Australian/New Zealand Standard™

Medical devices—Risk management

Part 1: Application of risk analysis

Standards Australia

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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Australian Council on Health Care Standards
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Health Standards Coordination Group, under the responsibility of the Multitechnics Standards Policy Board.

The Standard is identical with, and has been reproduced from ISO 14971-1:1998, *Medical devices—Risk management*, Part 1: *Application of risk analysis*.

The objective of this Standard is to determine the safety of a medical device by identifying hazards and estimating the risks associated with the use of the device.

Users of this Standard should also be aware of AS/NZS 4360, *Risk management* which was developed by the Joint Standards Australia/Standards New Zealand Committee OB/7, and provides a generic guide for the establishment and implementation of the risk management process involving establishing the context and the identification, analysis, evaluation, treatment, communication and ongoing monitoring of risks. Risk management is an integral part of good management practice, decision making and improvement which may be applied at all stages in the life of an activity, function, project or asset, and often involves a multi-disciplinary approach.

The decision to follow Standards policy by this adoption without modification of the International Standard ISO 14971-1:1998 will assist in the development of a common methodology and understanding of the process of applying risk analysis. However, it introduces a difference in application between this Standard and AS/NZS 4360 in that this Standard does not address the full process of risk management described in AS/NZS 4360, as can be understood by contrasting Annex E of this Standard with Figures 3.1 and 4.1 of AS/NZS 4360.

As this Standard is reproduced from an International Standard, the following applies:

(a) Its number does not appear on each page of the text and its identity is shown only on its cover and title page.

(b) In the source text, ‘this part of ISO 14971’ should read ‘this Australian/ New Zealand Standard’.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

INTRODUCTION

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 ISO 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.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical devices — Risk management

Part 1:
Application of risk analysis

1 Scope

This part of ISO 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 of particular assistance in areas where relevant standards are not available or not used.

This part of ISO 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 ISO 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.

2 Definitions

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

2.1
harm
physical injury and/or damage to health or property
[ISO/IEC Guide 51]

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.