

AS/NZS 4513:1995

IEC 513:1994

Australian/New Zealand Standard

Medical electrical equipment— Fundamental aspects of safety standards

[IEC title: Fundamental aspects of safety standards for medical
electrical equipment]

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND



Documents

Document Sharing Hub

AS/NZS 4513:1995

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/15, Medical Electrical Equipment—General Safety Aspects. It was approved on behalf of the Council of Standards Australia on 13 February 1995 and on behalf of the Council of Standards New Zealand on 13 March 1995. It was published on 5 June 1995.

The following interests are represented on Committee HT/15:

Australasian College of Physical Scientists and Engineers in Medicine
 Australian and New Zealand College of Anaesthetists
 Australian Federation for Medical and Biological Engineering
 Australian Private Hospitals Association
 Canterbury Area Health Board, New Zealand
 Department of Defence, Australia
 Department of Health, New South Wales
 Department of Health, Western Australia
 Department of Human Services and Health, Australia
 Department of Veterans Affairs, Australia
 Institute of Biomedical Engineering, Australia
 Medical Industry Association of Australia
 Ministry of Commerce, New Zealand
 Monash Medical Centre, Victoria
 Public Works Department, New South Wales
 Queensland Health
 Society for Medical and Biological Engineering
 Wellington Area Health Board, New Zealand

Review of Standards. To keep abreast of progress in industry, Joint Australian/New Zealand Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto.

Full details of all Joint Standards and related publications will be found in the Standards Australia and Standards New Zealand Catalogue of Publications; this information is supplemented each month by the magazines 'The Australian Standard' and 'Standards New Zealand', which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.

Suggestions for improvements to Joint Standards, addressed to the head office of either Standards Australia or Standards New Zealand, are welcomed. Notification of any inaccuracy or ambiguity found in a Joint Australian/New Zealand Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

AS/NZS 4513:1995

Australian/New Zealand Standard

Medical electrical equipment— Fundamental aspects of safety standards

PUBLISHED JOINTLY BY:

STANDARDS AUSTRALIA
1 The Crescent,
Homebush NSW 2140 Australia

STANDARDS NEW ZEALAND
Level 10, Standards House,
155 The Terrace,
Wellington 6001 New Zealand

ISBN 0 7262 9711 9



Documents

Document Sharing Hub

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/15 on Medical Electrical Equipment—General Safety Aspects. This Standard is identical to and has been reproduced from IEC 513: *Fundamental aspects of safety standards for medical electrical equipment*.

Under arrangements made between Standards Australia, Standards New Zealand and the IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover and title page.

For the purposes of this Standard the IEC text should be modified as follows:

- (a) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.
- (c) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		Australian/New Zealand Standard	
IEC		AS	
50	International Electrotechnical Vocabulary—	1852	International Electrotechnical Vocabulary
50.191	Chapter 191: Dependability and quality of service	—	
Guide 104	Guide to the drafting of s safety Standards	—	
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment
601-1	Part 1: General requirements for safety	3200.1 NZS 6150	Part 1: General requirements for safety
		AS/NZS	
601-1-XX	Part 1.XX: Series of Collateral Standards	3200-X.XX	Part X.XX: Series of Collateral Standards
601-2.XX	Part 2.XX: Series of particular Standards	3200-2	Part 2.XX: Series of particular Standards
ISO/IEC			
Guide 51:	Guidelines for the inclusion of safety aspects	—	
ISO		AS/NZS	
8402	Quality management and quality assurance—Vocabulary	ISO 8402	Quality management and quality assurance—Vocabulary
		AS/NZS	
9001	Quality systems—Model for quality assurance in design, development, introduction, installation and servicing	ISO 9001	Quality systems—Model for quality assurance in design, development, introduction, installation and servicing

AS		AS/NZS	
9004	Quality management and quality systems elements Part 1: Guidelines	ISO 9004.1	Quality management and quality systems elements Part 1: Guidelines

© Copyright – STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Users of Standards are reminded that copyright subsists in all Standards Australia and Standards New Zealand publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia or Standards New Zealand may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia or Standards New Zealand. Permission may be conditional on an appropriate royalty payment. Australian requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia. New Zealand requests should be directed to Standards New Zealand.

Up to 10 percent of the technical content pages of a Standard may be copied for use exclusively in-house by purchasers of the Standard without payment of a royalty or advice to Standards Australia or Standards New Zealand.

Inclusion of copyright material in computer software programs is also permitted without royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia or Standards New Zealand at any time.

CONTENTS

	Section 1: General	Page
1	Scope	1
2	Concepts	1
	2.1 Basic safety	1
	2.2 Effectiveness	2
	2.3 Efficacy	2
	2.4 Essential performance	2
	2.5 Essential requirements	2
	2.6 Fitness for use	3
	2.7 Hazard	3
	2.8 Quality assurance	3
	2.9 Risk	3
	2.10 Risk level	3
	2.11 Safety	3
	2.12 Safety integrity level	4
	2.13 Severity level	4
	2.14 User/operator	4
	 Section 2: Safety and standards	
3	Hazards	5
	3.1 Causes of hazards	5
	3.2 Patient related hazards	6
	3.3 Operator hazards	6
4	Factors affecting safety	7
5	Measures to achieve safety	7
6	Goal of standards	7
7	Types of standards	8
	7.1 Product standards	8
	7.2 Process standards	8
	7.3 Installation and environmental standards	8
	7.4 Application standards	9
8	Acceptable risk levels	9
9	Developing safety and essential performance requirements	11
	9.1 Hazard identification	11
	9.2 Severity level	12
	9.3 Deciding on acceptable risk levels	13
	9.4 Fault avoidance and control	15

	<i>Page</i>
9.5 Integrity levels	17
9.6 Achieving acceptable risk levels	17
9.7 Surpassing specified requirements	18
9.8 Treatment of risk in the IEC 601 series	18
9.9 Fault conditions	19
9.10 Single fault philosophy	19
9.11 Integrity levels implied in IEC 601-1	21
9.12 Acceptable risk levels according to IEC 601	22
10 Equipment accessories	22
11 Standardization	23
12 Coordination of standards	23
12.1 Overall approach to safety	23
12.2 Overall planning in the development of standards	24
13 Standards and the law	24
14 Role of standards	24
15 Accidents	24
16 Maintenance of standards	25

**Section 3: Guide to the development of
future product standards**

17 Identification of problems	25
18 Priority	25
19 Format and structure	26
19.1 Titles	26
19.2 Scope and rationale	26
19.3 Form of specification	26
19.4 Structure	26
20 Specifying safety and essential performance requirements	27
20.1 General	27
20.2 Specific test requirements vs assessment of design process	30
21 Testing requirements	31
21.1 General	31
21.2 "Single fault condition" and "safety hazard"	31
21.3 Protective devices	31
21.4 High reliability components	32
21.5 Safety factors	32
21.6 Test methods	32
21.7 Basic safety standards	33
21.8 Marking and labelling	33

	Page
21.9 Warning notices	34
21.10 Other information to be provided	34
22 Design verification	34
23 Clinical trials and similar assessment	35
24 Performance requirements	35
24.1 General	35
24.2 Essential performance requirements	35
24.3 Essential disclosure requirements	36
24.4 "Non-essential" performance requirements	36
Annexes	
A Classification of applied parts	37
B The role of standards in the assessment and approval of medical electrical equipment	43
C Improving overall safety	45
D Safety factors	49
E History of IEC 513, 1st edition and IEC 601 series	51
Figures	
1 Flow diagram for risk management	11
2 Structure of the IEC 601 series under the third edition of IEC 601-1	29
C.1 Overall safety	47
Tables	
1 Risk classification of accidents	14
2 Interpretation of risk level	15
3 Third edition of IEC 601-1 and its collateral standards	28
B.1 Hazards and causes	43
B.2 Role of standards in overall safety	44

First published as AS/NZS 4513:1995.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment—Fundamental aspects of safety Standards**Section 1: General****1 Scope**

This report identifies fundamental considerations to be taken into account in developing standards to ensure the safety of medical electrical equipment.

NOTE - This report follows closely recommendations of ISO/IEC Guide 51* and expands on matters which are unique to, or critical in, the application of medical electrical equipment.

This report is primarily intended to be used by:

- those who prepare standards for the design, installation and use of medical electrical equipment;
- health care regulatory authorities, test houses and other organizations responsible for implementing standards for medical electrical equipment;
- manufacturers of medical electrical equipment;
- those who assemble systems which include medical electrical equipment.

This report may also be of assistance to:

- users or operators of medical electrical equipment;
- hospital administrators;
- non-technical personnel involved in the procurement of medical electrical equipment;
- educators and students.
- hospital and clinical engineers responsible for the construction of patient care facilities or for the procurement or maintenance of medical electrical equipment;

2 Concepts

The following material is not intended to introduce new definitions. It is a general discussion on the terminology and concepts used in this report. Where a particular term is defined in an international publication, the definition is reproduced after the relevant discussion herein.

2.1 Basic safety

Basic safety provides protection against direct physical hazards when medical electrical equipment is used under normal or other reasonably foreseeable conditions, (e.g. mechanical strength, leakage current and fire safety).

* ISO/IEC Guide 51: 1990, *Guidelines for the inclusion of safety aspects in standards*.

2.2 Effectiveness

The effectiveness of an item of medical electrical equipment is its ability to perform as specified, (e.g. the accuracy of the delivered energy from a cardiac defibrillator).

This term is defined in IEC* as follows:

Effectiveness (performance): The ability of an item to meet a service demand of given quantitative characteristics.

2.3 Efficacy

The efficacy of an item of medical electrical equipment is its ability to achieve the expected result in assisting diagnosis or treatment, (e.g. the ability of a cardiac defibrillator to revert fibrillation).

2.4 Essential performance

This concept is less widely understood than basic safety. Many items of medical electrical equipment are life-sustaining or critical for correct diagnosis. Medical electrical equipment which does not perform properly can present an unacceptable risk, and hence it may be unsafe. For example, most people would consider a defibrillator that will not discharge to be unsafe. Likewise, incorrect diagnosis resulting from equipment malfunction can lead to incorrect treatment.

For medical electrical equipment, the distinction between safety and performance standards is often unclear, and the concept of essential performance arises.

Typically, essential performance requirements limit or establish critical parameters such as the frequency response of a diagnostic electrocardiograph and the output energy of a cardiac defibrillator. However, in some cases essential performance can best be addressed through disclosure requirements.

2.5 Essential requirements

No complete distinction can be made between safety, efficacy and effectiveness of medical electrical equipment. Successful diagnosis and treatment, and even the patient's life, may be jeopardized by a device which:

- a) is physically dangerous;
- b) does not perform as specified by the manufacturer; or
- c) is incorrectly used.

Accordingly, this report identifies "essential requirements" as the combination of "basic safety" (see 2.1) and "essential performance" (see 2.4).

* IEC 50(191): 1990, *International Electrotechnical Vocabulary – Chapter 191: Dependability and quality of service*. (191-02-01).

2.6 *Fitness for use*

Some aspects of performance which do not affect essential performance may determine fitness for use. Fitness for use may include matters relating to efficiency or reliability and require the disclosure of enough information to allow the consumer to rate design suitability for the intended application.

2.7 *Hazard*

Normally the word hazard refers to a source of risk or danger. In this report the word hazard is generally used to describe a situation of potential harm to people or property, (i.e. a condition, situation, procedure, object or material which is capable of causing harm).

Hazard is defined in ISO/IEC Guide 51 as: *"A potential source of harm."*

2.8 *Quality assurance*

Quality assurance (QA) includes good manufacturing practice (GMP) and quality control (QC).

Quality assurance is defined in ISO 8402* as: *"All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality."*

Quality control is defined in ISO 8402* as: *"The operational techniques and activities that are used to fulfill requirements for quality."*

2.9 *Risk*

The application of medical electrical equipment can result in "direct" risks when inadequate design, equipment failure or misuse result in physical harm to the patient, the operator, the equipment or the environment. Other "indirect" risks resulting from inadequate equipment performance can adversely affect the patient, (e.g. failure of life-support systems and mis-diagnosis).

Risk is defined in ISO/IEC Guide 51 as: *"The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm."*

2.10 *Risk level*

Risk level is a qualitative measure of risk (see tables 1 and 2).

2.11 *Safety*

Normally the word safety means a freedom from danger or risk. Absolute safety is therefore a complete freedom from conditions and circumstances which may result in harm.

* ISO 8402: 1986, *Quality – Vocabulary*.

As discussed below, it is impractical to expect absolute safety in the use of medical electrical equipment. In this report, the word safety generally refers to freedom from unacceptable risk.

"Safety" was used in the first and second editions of IEC 601-1 to mean "basic" safety associated with "direct" risks when inadequate design or use, or equipment failure, results in physical harm to the patient, the operator, the equipment or the environment.

However, "safety" is also used in this report in association with a broader range of "indirect" risks in which the patient can be adversely affected by equipment malfunction or by equipment which is inadequate for the intended purpose. It is intended that "safety" will be used in this broader sense in future editions of IEC 601- 1.

Safety is defined as follows in ISO/IEC Guide 51: "*Freedom from unacceptable risk of harm*", (see also explanatory notes in Guide 51).

2.12 Safety integrity level

Safety integrity level is a measure of the level of assurance that a component or system will function as intended or, if it malfunctions, will do so in a safe manner. Integrity is concerned with hazardous malfunctions and takes account of non-stochastic aspects such as design errors as well as stochastic aspects such as component failures.

2.13 Severity level

Severity level is a qualitative measure of the possible consequences of a hazardous event. With medical electrical equipment it is generally unnecessary to distinguish more than four levels:

- catastrophic, if it has the potential of resulting in multiple deaths of serious injuries;
- critical, if it has the potential of resulting in death or serious injury;
- marginal, if it has the potential of resulting in injury; and
- negligible, if it has little or no potential to result in injury.

2.14 User/operator

These terms are defined as follows in IEC 601-1 (1988) to differentiate between the person who (or the organization which) is responsible for the equipment, and the person who actually handles it during normal operation:

USER: *Authority responsible for the use and maintenance of EQUIPMENT* (subclause 2.12.13).

OPERATOR: *Person who handles EQUIPMENT* (subclause 2.12.17).

Section 2: Safety and standards

3 Hazards

3.1 Causes of hazards

The application of medical electrical equipment may introduce hazards due to a number of causes including the following:

- a) failure of a device to perform its intended function, (e.g. failure of a lung ventilator to ventilate the patient, failure of an apnoea monitor to give an alarm);
- b) incorrect function, (e.g. excessive drug delivery by an an infusion pump, excessive temperature in a baby incubator, inaccurate measurement of a physiological parameter);
- c) energies delivered when functioning normally, e.g.:
 - leakage current or functional current flowing from a cardiac defibrillator or from high frequency surgical equipment unit through unintended pathways in the patient or operator;
 - exposure to radiation of an unintended part of the patient or operator;
 - exposure of the patient or operator to ultrasonic energy or accelerated elementary particles;
 - excessive heating or cooling of the patient;
- d) equipment faults, e.g.:
 - fire, electric shock, explosion, expelled parts;
 - excessive ionizing or non-ionizing radiation resulting from equipment malfunction, leakage or over exposure;
 - excessive temperatures of accessible surfaces leading to burns;
- e) fire or explosion resulting from ignition of flammable material within the vicinity of the medical electrical equipment;
- f) mechanical failures in normal and fault conditions;
- g) incorrect installation of medical electrical equipment, e.g.:
 - inadequate earthing of an item of Class I medical electrical equipment;
 - dangerous surfaces, corners or edges;
 - physical instability;
- h) incorrect selection of medical electrical equipment, (e.g. the use of medical electrical equipment having a Type BF or Type B applied part to carry out an intracardiac procedure);
- i) incorrect use of medical electrical equipment, (e.g. selection of an incorrect energy scale while using an internal cardiac defibrillator);
- j) electromagnetic interference, (e.g. interference of an ECG display by high frequency surgical equipment, generation of interference with adjacent medical electrical equipment by strong magnetic fields emanating from a display);
- k) release of corrosive, poisonous or hot liquids or gases, or contact with biologically unsafe materials;

- l) disposal of material and byproducts resulting from the use of medical electrical equipment, (e.g. the disposal of radioactive substances used in nuclear medicine).

3.2 Patient related hazards

Some hazards are specific to medical electrical equipment and are introduced or exacerbated by the following circumstances:

- a) inability of the patient or operator to detect the presence of certain potential hazards, such as ionizing or high-frequency radiation;
- b) absence of normal reactions by the patient, who may be ill, unconscious, anaesthetized, under the effect of muscle relaxing drugs, immobilized, etc.;
- c) absence of protection to electric current normally provided by the resistance of the patient's skin, if this is penetrated or treated to obtain low skin resistance;
- d) application of electric circuits via low impedance connections to the patient. This hazard exists at quite low current levels when the equipment is connected directly to the patient's heart;
- e) deposition of metal ions into the patient's skin by the passage of direct current or current having a d.c. component, which may result in tissue necrosis even at quite low current levels if the current flows for more than a limited time;
- f) unreliability or failure of equipment used to support or replace vital body functions;
- g) simultaneous connection of more than one item of medical electrical equipment to the patient;
- h) combination of high-frequency equipment and low-signal equipment, often in ad-hoc combinations;
- i) environmental conditions in patient treatment areas, which may present a combination of humidity, moisture and/or fire or explosion hazards caused by air, oxygen or nitrous oxide combined with anaesthetic media and cleaning agents.

3.3 Operator hazards

Operators of medical electrical equipment may be exposed to hazards in the form of substances, energies and ionizing or non-ionizing radiation which exceed the levels permitted for the general public, e.g.:

- a) workers in areas such as nuclear medicine, radiology and radiotherapy may be exposed to radiation levels which are greater than those which are allowed for the general public;
- b) many health professionals are exposed to the possibility of electrocution or burning from the high voltage output of equipment such as cardiac defibrillators and HF surgical equipment, whereas users of most general purpose electrical equipment are protected from exposure to voltages above extra-low voltage.

However these levels shall still be restricted to acceptable limits which should be as low as reasonably achievable, and shall sometimes be restricted to lower limits than those allowed for the patient.

4 Factors affecting safety

The safe use of medical electrical equipment depends on a number of factors, including:

- a) design of the equipment, which must take into account and incorporate means for avoiding hazards;
- b) adequate validation of design, both hardware and software, prior to initiating equipment production;
- c) application of good manufacturing practices during equipment production;
- d) choice of appropriate equipment for the particular procedure;
- e) operator understanding of the equipment and its application, which may depend on training, or on equipment markings and manufacturers' instructions;
- f) use of accessories which are compatible with the equipment;
- g) connection of the equipment to appropriate supplies, (e.g. electrical supply mains, compressed gas lines);
- h) preventive equipment maintenance;
- i) use of specified parts during equipment repairs.

5 Measures to achieve safety

The safety of medical electrical equipment often requires an integrated approach in which manufacturers and users implement a combination of measures involving:

- a) requirements incorporated into the design of the equipment;
- b) additional measures such as installation requirements, formal commissioning, routine maintenance and safety testing; and
- c) measures requiring the users to be aware of the need for particular precautions in the use of certain types of medical electrical equipment or in certain procedures.

To achieve overall safety, consideration should be given to whether there is a need for formal standards in each of the above areas.

6 Goal of standards

The goal of safety and essential performance standards for medical electrical equipment is to improve safety in the use of such equipment. This goal should be achieved by developing standards which assist:

- a) manufacturers in designing and assembling safe and effective products;
- b) manufacturers, test houses and regulatory authorities in assessing compliance with requirements; and
- c) health care professionals in managing risks associated with the use of these products.

7 Types of standards

Product standards for the safety and essential performance of medical electrical equipment may fall into one or more of the following categories (see 19.4).

7.1 *Product standards*

These standards relate to a specific product or group of products and include:

- a) safety standards, comprising safety requirements which are necessary for, and applicable to, the intended use of the product, (e.g. IEC 601-1 and its associated collateral and particular standards for medical electrical equipment);
- b) essential performance standards, which include requirements which:
 - are necessary to ensure effective performance of the product;
 - are necessary for many users who would be unable to identify or specify them without reference to a suitable standard, or assess them without specialized laboratory facilities; and
 - can be specified in fully testable engineering terms through reproducible compliance tests or assessment of design process;

NOTE - For medical electrical equipment, requirements described in a) and b) are often published as part of the same standard.

- c) non-essential performance standards, which include matters which do not fall within the area discussed in a) or b). These standards include performance requirements or test methods which assist the manufacturer or user in specifying fitness for use.

Disclosure standards including associated test methods may be developed, where adherence to marked or claimed performance is to be standardized.

7.2 *Process standards*

A number of types of standards fall within this category, including:

- a) quality assurance (QA) standards, (e.g. standards for good manufacturing practice (GMP) and quality control (QC), which are part of the quality system and are applied where maintenance of type approved requirements or process-unique performance is critical);
- b) other standards which require assessment of "evidence of process", (e.g. standards for programmable electronic systems, sterility and ergonomics).

7.3 *Installation and environmental standards*

These standards include:

- a) construction and installation standards, (e.g. X-ray shielding, electrical wiring rules);
- b) systems standards, (e.g. critical requirements for correct interfacing and interaction), such as:
 - IEC 601-1-1, the collateral standard for medical electrical systems;
 - standards for medical picture archival computer systems (PACS);
 - standards for a medical information bus (MIB).

- c) commissioning standards, where safety can be improved by carrying out design evaluation or checking the correct installation and adjustment of equipment immediately prior to initial use;
- d) standards which limit the likely effect of the equipment on its environment or the effect of external influences on the equipment, (e.g. standards relating to electromagnetic compatibility).

7.4 *Application standards*

These standards include:

- a) routine in-service testing standards, where safety can be jeopardized by wear and tear of the equipment or the installation, (e.g. proposed IEC in-service testing standards for cardiac defibrillators and HF surgical equipment);
- b) constancy and calibration standards, where safety depends on confirmed equipment function and accuracy;
- c) explanatory guidelines providing information about the hazards associated with particular types of equipment and procedures, together with appropriate safety recommendations;
- d) user guidelines providing information about the safety classification systems used in associated product standards.

8 **Acceptable risk levels**

ISO/IEC Guide 51 states that safety is a balance between freedom from risk and the other demands on a product, process or service, including utility, suitability and cost. If safety is defined as freedom from any risk, there can be no absolute safety in the use of medical electrical equipment; its application can only be relatively safe or relatively unsafe. The requirements of society, and therefore the acceptable degree of safety or risk, are subject to social changes.

Very few things are perfectly safe, which would be the complete absence of risk. The realistic expectation must be that risks are kept as low as possible, taking into account the cost which would be incurred in further reducing risk and the benefits resulting from the use of a product, process or service.

Society (including the users of medical electrical equipment, patients, manufacturers, regulatory authorities and the general public) may desire or even expect medical electrical equipment to be physically safe, perform as specified and produce appropriate results. However, in developing appropriate product standards, the balance between risk and cost must take into account the adverse effect of failure to use the product. A medical device which saves a thousand lives and injures one person may be preferable to a device which saves a hundred lives and injures no one. An associated consideration is the difference (which is not easily evaluated) between on the one hand injuring a patient and on the other hand failing to save a life.

One function of medical electrical equipment product standards is to define an acceptable level of risk in the foreseeable use, or even misuse of the equipment. In this respect, the design and assessment of product safety depends on four complementary activities:

- a) identifying the hazards which need to be considered;
- b) evaluating the risks arising from these hazards;
- c) establishing the level of safety required and obtaining agreement on acceptable risk levels;
- d) specifying safety requirements to eliminate or minimize these hazards and achieve an acceptable risk level.

According to circumstances, these activities may be performed by the same or different people, at the same or different times.

All these activities are carried out in developing product standards. However, the designer or assessor of the product will also need to perform a further iteration to ensure that the product does not introduce additional hazards besides those covered in the standard. Activity c) is also a political and social activity involving a wide range of interests.

Product standards should therefore specify requirements and tests which relevant organizations may use for the assessment of a finished product, or of the processes by which the product is designed and manufactured. However it is often desirable for manufacturers to be permitted to adopt different solutions from those specified in a standard, provided they can demonstrate that an equivalent level of safety is achieved. Figure 1 is a flow diagram for identifying risk, establishing acceptable risk levels and developing safety and essential performance requirements.

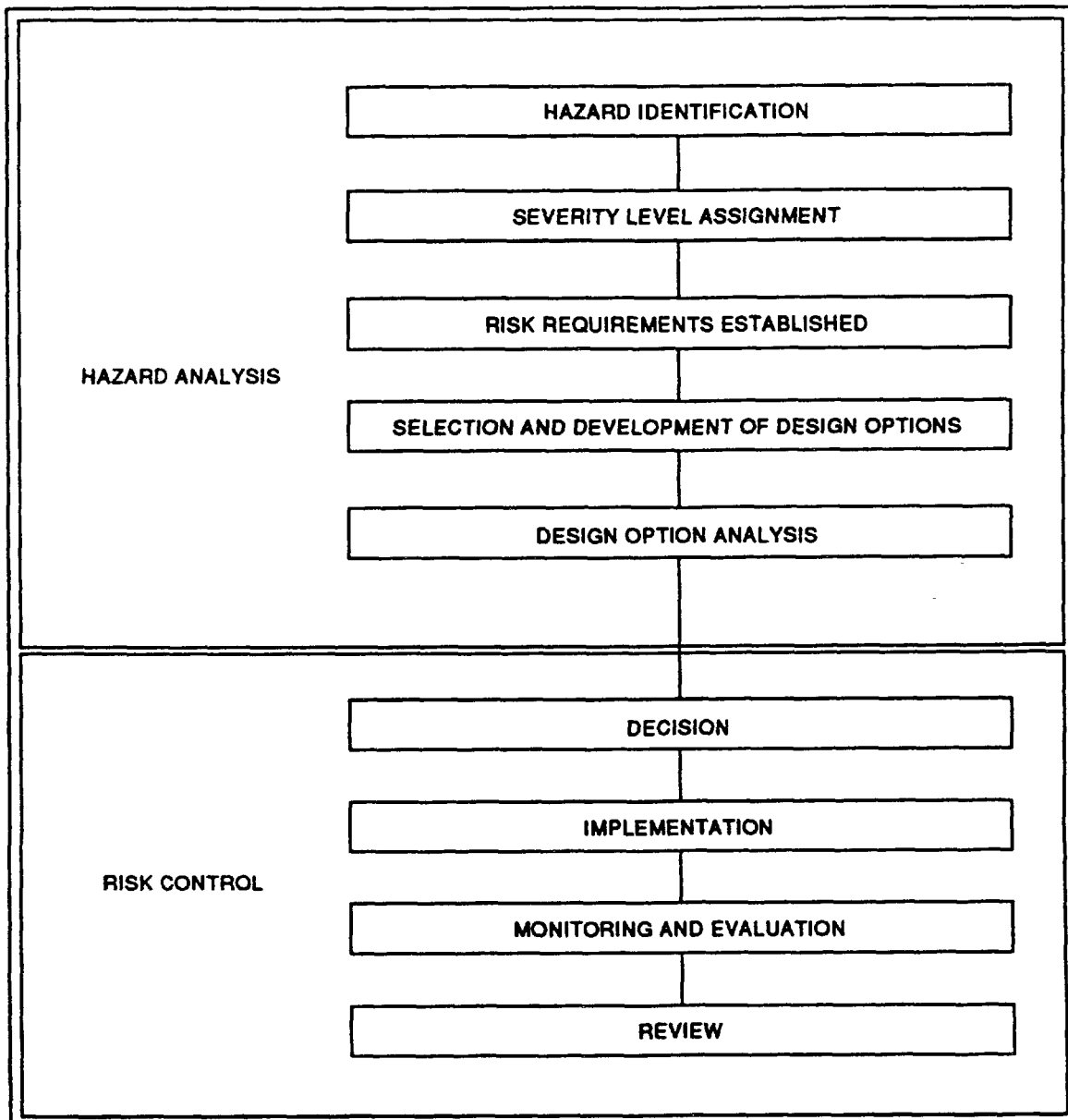


Figure 1 – Flow diagram for risk management

9 Developing safety and essential performance requirements

9.1 Hazard identification

Before developing safety and essential performance requirements, the hazards associated with a particular kind of equipment have to be identified.

A particular item of medical electrical equipment may be capable of causing or contributing to a variety of hazards (see 3.1). IEC 601-1 also lists hazards according to a series of categories, which should be used as a basis for the risk analysis for each particular kind of equipment.

An essential function of a particular standard is to list the hazards which are characteristic of the particular type of equipment and need to be avoided or minimized, thus identifying more precisely the general hazards which are addressed in IEC 601-1.

For example, clause 51 of the second edition of IEC 601-1 identifies the need for protection against hazardous outputs. However the general standard only specifies general requirements, and a particular device may have several important output characteristics. For example, the output of an infusion pump is the rate of delivery of solution, and any of the following specific output characteristics may cause a hazard:

- a) error in average rate relative to set rate in normal operation;
- b) variation in instantaneous rate with time in normal operation;
- c) errors in total delivered volume, with or without an alarm, in the event of a fault.

Generally the use of a new technology (such as that employed in programmable electronic systems) will not affect the range of hazards associated with a particular kind of equipment, although it may introduce additional failure mechanisms which result in the same hazards. Appropriate requirements for new technologies are usually associated with essential performance, rather than with protection against basic safety hazards such as fire and electric shock.

9.2 *Severity level*

Another function of a particular standard is the assessment of each identified hazard to determine its severity level.

Even if acceptable risk cannot be defined precisely, the process of systematically listing hazards and assigning their severity level ensures that each hazard receives an appropriate degree of consideration during the design of a product.

There may be more than one way in which the same hazard can arise, with different levels of concern. For example, a potential hazard in an infusion pump could be failure to stop infusing when the desired volume has been delivered. This could occur because of pump malfunction or through an error by the operator in setting the desired volume. The severity level is the same in both cases, but the measures for dealing with the risk, and the effectiveness of those measures, may differ. The probability of delivering an excessive volume due to equipment malfunction should be low, because this problem can be addressed in the design. However the best that can be done to avoid operator error may be to require the equipment to give a clear indication of the volume which has been set.

The severity of a hazard may not only depend on the equipment design. For example, the effect on the patient of an excessive flow rate from an infusion pump depends on what fluid is being delivered, how long the excess rate continues, and the patient's health. Thus the same hazard may have different severity levels under different circumstances. If the circumstances are unpredictable, the severity level should be determined from the worst plausible case.