

Fundamental aspects of safety standards for medical electrical equipment

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Contents

	Page
Committees responsible	Inside front cover
National foreword	iii
Foreword	1
Section 1. General	
1 Scope	4
2 Concepts	4
Section 2. Safety and standards	
3 Hazards	8
4 Factors affecting safety	10
5 Measures to achieve safety	10
6 Goal of standards	10
7 Types of standards	11
8 Acceptable risk levels	12
9 Developing safety and essential performance requirements	14
10 Equipment accessories	25
11 Standardization	26
12 Coordination of standards	26
13 Standards and the law	27
14 Role of standards	27
15 Accidents	27
16 Maintenance of standards	28
Section 3. Guide to the development of future product standards	
17 Identification of problems	28
18 Priority	28
19 Format and structure	29
20 Specifying safety and essential performance requirements	30
21 Testing requirements	34
22 Design verification	37
23 Clinical trials and similar assessment	38
24 Performance requirements	38
Annexes	
A Classification of applied parts	40
B The role of standards in the assessment and approval of medical electrical equipment	46
C Improving overall safety	48
D Safety factors	52
E History of IEC 513, 1st edition and IEC 601 series	54

Figures

1	Flow diagram for risk management	14
2	Structure of the IEC 601 series under the third edition of IEC 601-1	32
C.1	Overall safety	50

Tables

1	Risk classification of accidents	17
2	Interpretation of risk level	18
3	Third edition of IEC 601-1 and its collateral standards	31
B.1	Hazards and causes	46
B.2	Role of standards in overall safety	47

National foreword

This Published Document has been prepared under the direction of the Health Care Standards Policy Committee and is identical with IEC TR 513 : 1994 *Fundamental aspects of safety standards for medical electrical equipment* prepared within Technical Committee 62, 'Electrical equipment in medical practice' of the International Electrotechnical Commission (IEC) with the active participation of the UK.

IEC TR 513 : 1994 is an IEC Technical Report type 3. This type of Technical Report is published when a technical committee has collected data of a different kind from that which is normally published as an International Standard.

In the first paragraph on the last page of the IEC foreword, reference is made to 'The proposed European Directive on medical devices'. This Directive has now been published, so the word 'proposed' should be deleted.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**FUNDAMENTAL ASPECTS OF
SAFETY STANDARDS FOR
MEDICAL ELECTRICAL EQUIPMENT**
FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.
- 3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

The main task of IEC technical committees is to prepare International Standards. In exceptional circumstances, a technical committee may propose the publication of a technical report of one of the following types:

- type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;
- type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;
- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

Technical reports of types 1 and 2 are subject to review within three years of publication to decide whether they can be transformed into International Standards. Technical reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

IEC 513, which is a technical report of type 3, has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this technical report is based on the following documents:

Committee draft	Report on Voting
62A(SEC)136	62A(SEC)148

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

The first edition of IEC 513: *Basic Aspects of the safety philosophy for electrical equipment used in medical practice*, was published in 1976 and provided the basis for developing:

- the first and second editions of IEC 601-1 (the parent safety standard for medical electrical equipment);
- the IEC 601-1-xx series of collateral standards for medical electrical equipment, and
- the IEC 601-2-xx series of particular standards for particular types of medical electrical equipment.

The original IEC approach was to prepare separate "safety" and "performance" standards for medical electrical equipment. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where basic physical safety is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context it has been said that, "The ability of an electric kettle to boil water is not critical to its safe use!"

It is now recognized that this is not the situation with many items of medical electrical equipment, and users have to depend on standards to ensure essential performance as well as basic safety. Medical authorities are equally concerned about the ability of the equipment to perform correctly and the prevention of other hazards.

Although the structure and content of the first and second editions of IEC 601-1 were restricted to basic safety issues, increasing clinical involvement in the preparation of the particular standards confirmed that, for many types of medical electrical equipment, the user has to depend on formal standards to ensure adequate performance as well as basic safety. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the patient, or processes and displays physiological data which will affect patient management.

Resulting from this recognition that separating "safety" and "performance" is somewhat inappropriate in addressing the hazards which result from inadequate design of medical electrical equipment, many particular standards in the IEC 601-2-xx series address a range of essential performance requirements which cannot be directly evaluated by the user without applying such standards. (However, the current IEC 601 series includes far less requirements for functional safety than for basic safety).

There is also a growing suggestion that all the safety and essential performance requirements for medical electrical equipment should be found within one set of international standards. The proposed European Directive on medical devices also highlights the need for a single series of standards covering essential requirements for all such products.

A history of IEC 513, 1st edition and IEC 601 series can be found in Annex E.

It is intended that this second edition of IEC 513 will provide guidance for developing the third edition of IEC 601-1, and for the further development of the IEC 601-1-xx and IEC 601-2-xx.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 601-2-xx, this second edition of IEC 513 includes two major changes:

- the first change is that the concept of "safety" has been broadened from the simple, basic safety considerations in the first and second editions of IEC 601-1, to include essential performance matters, (e.g. the accuracy of physiological monitoring equipment).
- the second change is that in specifying minimum safety requirements, provision is made for assessing the adequacy of the design process where this provides an appropriate alternative to the application of laboratory testing with specific pass/fail criteria, (e.g. in assessing the safety of new technologies such as programmable electronic systems).

This second edition cancels and replaces the first edition, published in 1976.

FUNDAMENTAL ASPECTS OF SAFETY STANDARDS FOR MEDICAL ELECTRICAL EQUIPMENT

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 IEV* 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 or 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 shall 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.

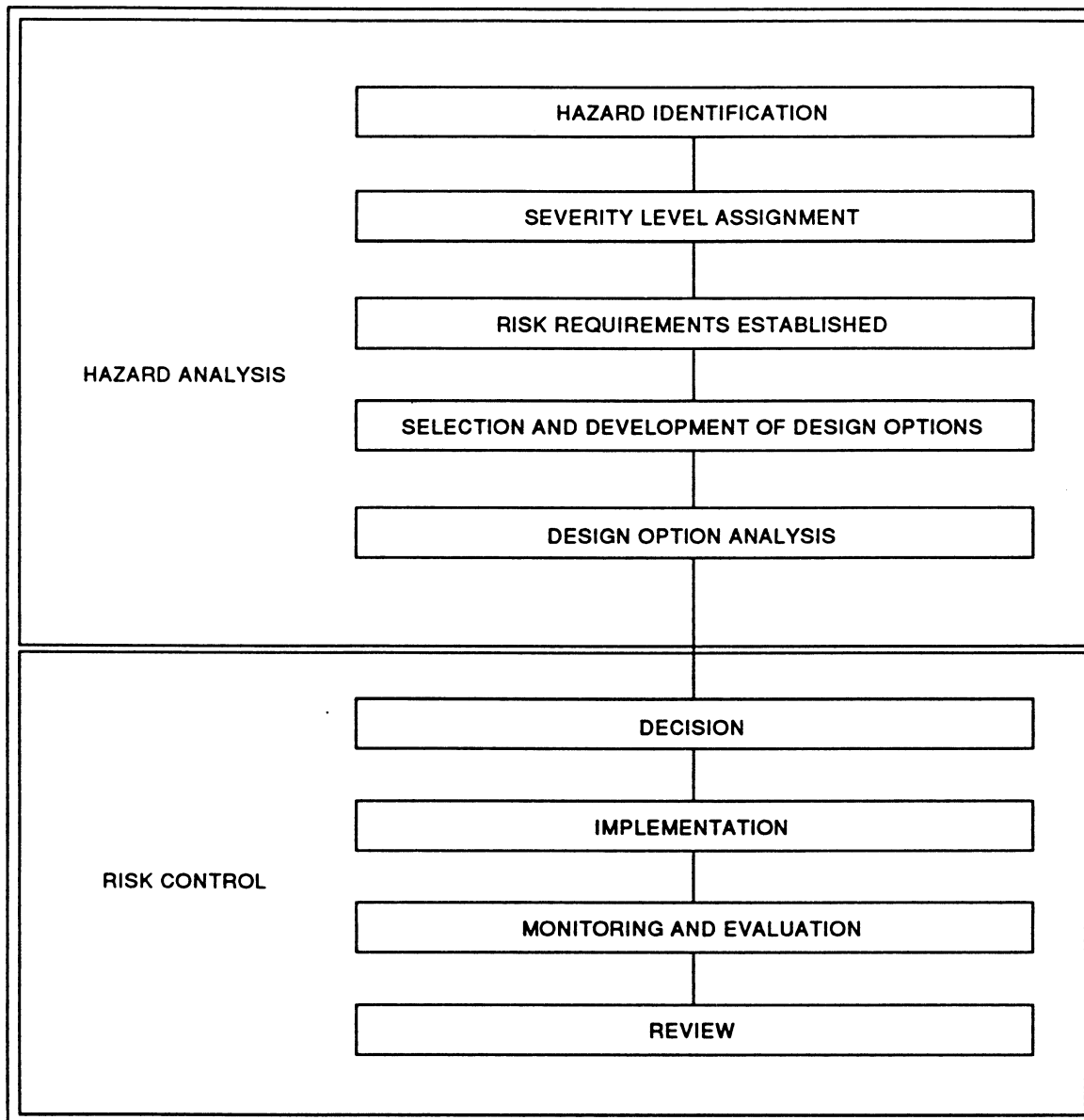


Figure 1 – Flow diagram for risk management

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.