GUIDE 63

Guide to the development and inclusion of safety aspects in International Standards for medical devices

First edition 1999

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

Guides are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

ISO/IEC Guide 63 was prepared by ISO/IEC Joint Technical Advisory Group 1 (JTAG 1), *Health care technology*, with the collaboration of ISO/TC 210, *Quality management and corresponding general aspects for medical devices.* The draft was agreed by the meeting of JTAG 1 on 20 April 1998.

Introduction

ISO/IEC Guide 51, *Guidelines for the inclusion of safety aspects in standards*, is the first of a series intended to provide a harmonized approach to the concept of safety when preparing International Standards. ISO/IEC Guide 51 anticipates the need for sectoral guides such as this Guide 63.

While safety is a key element of medical device standards, there is a need to address performance as well. Consistent with ISO/IEC Guide 51, additional guidance may be needed for sectors within the broad category of medical devices. Existing examples are IEC/TR 513, *Fundamental aspects of safety standards for medical electrical equipment* and ISO/TR 14283, *Implants for Surgery — Fundamental Principles.* The above-mentioned documents were among the sources used for the concepts described in this Guide.

The concept of safety is closely related to safeguarding the integrity of both the patients who are the subjects of medical care and those persons who are giving the care. As the complexity of medical devices and diagnostics devices and systems have become more complex, the diligence required to ensure their safety has similarly increased.

There can be no absolute safety. Even at the highest level of safety, a medical device can only be relatively safe. Medical practice involves protection of the patient's well-being while applying treatments that have some degree of inherent risk. It is incumbent on the designers and manufacturers of medical devices to ensure that the devices used in diagnosis, treatment or alleviation of handicap do not harm or present possibilities of harm to the patient that are not outweighed by the benefits offered by the device.

As different circumstances warrant different approaches to ensuring safety, it is impossible to provide precise provisions and recommendations that apply to every case. However, these guidelines, when followed on a judicious "use when applicable" basis, will help in developing reasonably consistent standards.

Guide to the development and inclusion of safety aspects in International Standards for medical devices

1 Scope

This Guide provides an approach to writing international standards for medical devices that takes into account the hazards of medical use, the role of standards in managing risk in relation to the medical need for the device and the use of standards in medical device design, manufacture and regulation.

This Guide will also help those who use medical device standards to understand what such standards are intended to accomplish. Among such users are:

— users of medical devices;

— hospital administrators;

— personnel involved in the procurement of medical devices;

— regulatory authorities;

— persons responsible for the design and construction of patient care facilities;

— persons responsible for the installation and maintenance of medical devices;

— manufacturers of medical devices;

— persons who assemble systems of medical devices from more than one manufacturer.

This sectoral Guide is intended to be read in conjunction with ISO/IEC Guide 51.

2 References

ISO 14971-1:1998, *Medical devices — Risk management — Part 1: Application of risk analysis.*

ISO/IEC *Directives, Part 2: Drafting and presentation of International Standards*, 1996.

ISO/IEC Guides.

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

3 Terms and definitions

For the purposes of this Guide, the following terms and definitions apply.

3.1
basic safety
freedom from unacceptable risk created by direct physical hazards when medical devices are properly used under normal or reasonably foreseeable conditions relating for example to mechanical strength, biocompatibility and sterility

3.2
harm
physical injury or damage to the health of people either directly or indirectly as a result of damage to property or to the environment

3.3
hazard
potential source of harm

3.4
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

NOTE 1 Regulatory authorities may use other definitions of the term medical device.

NOTE 2 A medical device may or may not be used under the direct or indirect supervision of a medical professional.

3.5
quality assurance
all the planning and systematic actions to be implemented, and demonstrated as needed, necessary to provide adequate confidence that an entity will satisfy given requirements for quality

3.6
risk
combination of the probability of occurrence of harm and the severity of that harm

3.7
safety
freedom from unacceptable risk

4 Risk

4.1 Taking a practical view of safety

Safety must be balanced against other demands on the product, process or service. These other demands include utility, suitability and cost. Since safety is defined as freedom from unacceptable risk, and absolute safety is unattainable, medical devices may only be considered as either relatively safe or relatively unsafe.

Although society would like all medical devices to be safe and to perform as intended, the reality is that no system is perfectly reliable and the risk is never zero. Although zero risk is an ideal to pursue, its attainment should not be expected. The more realistic expectation is to ensure that risks are kept as low as reasonably achievable. Evaluation of an acceptable level of risk shall take into account the incremental costs of lower risks and the magnitude of the corresponding benefit provided by the medical device both to the patient and to society.

In evaluating the safety of medical devices, it is also necessary to consider that certain devices, because of their means of operation or the circumstances of their use, carry with them an inherent risk that cannot be eliminated without degrading their effectiveness.

Since technologies and social values are subject to change over time and differences exist in medical and health practices among cultures, judgement of safety of medical devices and procedures also changes over time and among countries. In other words, the evaluation of risk is a subjective rather than an objective exercise. These issues can often be addressed by identifying the specific conditions under which a technical requirement applies. Requiring devices to include specific features or functions in addition to those critical to safety or to accomplishing the uses identified by the manufacturer in accompanying documents should be avoided whenever possible.

4.2 Managing risk

The risk management process includes:

a) identifying hazards;

b) estimating their frequency of occurrence;

c) estimating the probability of harm per occurrence;

d) establishing acceptable risk limits;

e) determining means to maintain each risk within the selected limits;

f) balancing between risks and benefits.

The risk analysis process is described more fully in ISO 14971-1.

Standards development should be based on hazard identification, and the process produce standards that recommend the actions and precautions needed to ensure that the acceptable level of risk is not exceeded.

These considerations should then be taken into account as the standards developer determines the appropriate requirements to be included in the standard.

5 Hazards

5.1 General

When preparing a safety standard for a medical device, the initial task is to identify the hazards associated with the use of the device. There are several types of hazard associated with the application of a medical device in the course of medical treatment.

5.2 Device-related hazards

To a great extent, the possible device-related hazards depend on the nature of the medical device. Since it is not possible to ensure that a medical device will not fail, the standard should recognize the potential hazards of the devices as they pertain to the condition and health of the patient and the safety and health of the user. The preferred result in the event of a failure is failure to a safe mode (fail-safe). Alternatively, when possible or practicable, the device should give warning prior to failure or at the time of failure. Warnings and alarms are more easily included on active devices, but are not impossible to include in many inactive devices. Some examples of device-related hazards are:

a) failure of a device to perform its intended function, e.g. failure of a defibrillator to deliver the proper energy, mechanical failure of a cardiac valve;

b) incorrect performance of a device, e.g. a defibrillator delivering less than indicated output;

c) for active medical devices, the hazards due to the energies involved in the proper functioning of the device, e.g. flow of current through an unintended path through the patient or user, excessive or inadequate heating or cooling of a patient or part of a patient;

d) for sterile medical devices, infections transmitted by a non-sterile device, e.g. caused by improper sterilization or failure of a sterile barrier;

e) hazards incidental to the function of the medical devices, e.g. fire resulting from the ignition of flammable materials in the vicinity of the medical device;

f) hazards arising from the incorrect reading of a device's output, e.g. misinterpretation of the results of an *in vitro* diagnostic test;

g) hazards arising from mechanical failure of a medical device or its ancillary equipment, e.g. collapse of a component of an X-ray table, failure of side-rails on a hospital bed;

h) hazards related to the toxicity of materials used in the device or leached from the device, or the lack of biocompatibility of the component materials of the device. These hazards may be immediate (occurring soon after initial use of the device) or long-term (arising only after prolonged exposure to the device);

i) hazards arising from the interconnection of incomptatible devices, e.g. connection of medical and possibly non-medical devices from different manufacturers.

5.3 Patient-related hazards

Some hazards are specifically related to the patient and the patient environment. Some examples are:

a) the inability of the patient or user to detect the presence of certain potential hazards, such as ionizing or high-frequency radiation;

b) the absence of normal reaction by the patient resulting from his or her physical condition, such as a patient who is ill, unconscious, sedated or anaesthetized;

c) a patient's decreased state of immunological resistance that may not be able to overcome infectious attack;

d) environmental conditions in patient areas that may present a combination of humidity and fire or explosion hazards related to the presence of pure oxygen, nitrous oxide and other anaesthetic media and cleaning agents;

e) patient allergy or other hypersensitivity to a material used in a device, e.g. latex.

5.4 User-related hazards

Some hazards are specifically related to the application of the medical device by the user. Some examples are:

a) hazards arising from the use of a device for the treatment of a condition for which it is contraindicated;

b) hazards arising from the use of the device when the user is confused, distracted or fatigued;

c) hazards arising from the use of a device by a non-expert user or by an untrained person, for example, home-use diagnostics.

5.5 Hazards to user

In the use of certain medical devices, the user may be subjected to hazardous chemicals or radiation, or other hazards beyond those acceptable for the general public. The risk to the user presented by these exposures must be limited.

6 General considerations for reducing risk

The next task is to consider the general methods available for reducing risk. These methods include:

a) proper design, taking into account potential risk and means for avoiding or reducing them;

b) manufacture of devices in accordance with an appropriate quality system, including controlled manufacturing processes;

c) choice of the appropriate device by the user, which in turn depend on the manufacturer's providing a clear description of the intended use of the device;

d) the user's understanding of the device, which may depend on training or appropriate and complete equipment marking instructions, and warnings provided by the manufacturer (this is particularly important in the case of home-use devices);

e) the identification and use of compatible accessories;

f) when necessary, the maintenance of the sterility of the medical device and of an appropriate sterile field for use of the medical device;

g) appropriate preventive maintenance and competent repair service.

These considerations are taken into account in planning and developing standards so that the standard can take an appropriate role in helping to mitigate the risks.

7 Principles for preparing international medical device safety standards

7.1 General

The goal of safety standards for medical devices is to encourage the development and production of devices with a predictable, consistent level of safety.

To achieve this goal, International Standards should:

a) assist manufacturers in the design and production of a safe and effective medical device;

b) assist manufacturers, certification bodies, testing laboratories or houses, and regulatory authorities in assessing compliance with legal and market requirements; and

c) assist health care providers in managing risks associated with the use of medical devices.

7.2 Hierarchy of standards

The planning and development of standards for medical devices requires a global approach including manufacturers, users, and other interests. Close coordination within and among committees responsible for different medical devices is necessary to create a coherent approach to the treatment of safety in the preparation of standards. The use of a hierarchy of standards will ensure that each specialized standard is restricted to specific aspects and makes reference to standards of wider application for all other relevant aspects. Such a hierarchy is built on:

- **basic safety standards**, including fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products, processes and services (basic safety standards are sometimes referred to as horizontal standards);

- **group safety standards**, including safety aspects applicable to several or a family of similar products, processes or services dealt with by two or more technical committees or subcommittees, making reference, as far as possible, to basic safety standards;

• **product safety standards**, including all necessary safety aspects of a specific, or a family of, product(s), process(es), or service(s) within the scope of a single technical committee or subcommittee, making reference, as far as possible, to basic safety standards and group safety standards.

Safety requirements for medical devices may be incorporated in different types of standard (see 7.3) that may be found at any appropriate level in the hierarchy described above.

7.3 Types of standard

7.3.1 Product standards

These may be:

a) standards that state safety or performance parameters and include reference test methods that can be used to demonstrate conformance to those parameters affecting safety;

b) disclosure and test method standards where adherence to declared performance is critical for safety.

7.3.2 Process standards

These may be:

a) quality systems standards that ensure that the manufacturer is able to produce medical devices of consistent quality;

b) standards for processes required for the production of safe and effective medical devices, for example sterilization, clinical trials.

7.3.3 Installation and environmental standards

These standards are generally appropriate for large systems and active devices:

a) construction and installation standards, for example X-ray shielding, electrical wiring;

b) systems standards that address the proper precautions and procedures for interconnection of multiple devices into a single system;

c) commissioning standards that address the proper testing and inspection procedures to apply to permanently installed equipment and systems prior to initial use;

d) environmental standards that address precautions and testing to ensure that a medical device does not negatively affect its environment and that the environment does not degrade or otherwise impair the performance of a medical device, for example electromagnetic compatibility standards.

7.3.4 In-service standards

These include:

a) routine in-service testing standards to ensure that the safety of active devices is maintained over the useful life of the equipment;

b) quality assurance and calibration standards to ensure the continued proper function and accuracy of devices for which those characteristics are essential.

7.4 Coordination of International Standards

The development of each new standard shall be viewed in the context of existing devices, standards, national, regional and international laws. New standards should make use of the body of existing standards, whenever relevant, either by reference or by reproduction of text where this is justified by convenience or clarity (see ISO/IEC Directives, Part 3, 6.6.6.).

7.5 Regulatory implications of International Standards

Safety and effectiveness of medical devices, whose sale and use is regulated in most countries, are of particular concern to regulatory authorities.

Standards are often cited in regulations and legislation, in which case the standards themselves become legally binding. Alternatively, there are systems in which standards have a “deemed to comply” status, meaning that a medical device that complies with a specified standard is “deemed to comply” with the regulations.

Standards may also be cited in litigation as what may reasonably be expected by society, and thus used to establish compliance with these expectations.

Standards developers should be aware of the possible legal and regulatory implications for the standard they develop.

7.6 Maintenance of standards

An important factor in maintaining standards is feedback to the standards-writing body. Medical device manufacturers and regulatory bodies investigate medical device failures and complaints relating to performance. The information that is gained from these investigations should be used to improve device design; national representatives to standards-writing bodies should seek such information. In this way the standards developers will obtain the information needed to ensure that device standards continue to reflect improvements in medical devices and practices.

8 Considerations when developing safety requirements for medical device standards

8.1 Rationale for safety requirements

It is advantageous for a standard to include detailed rationale for each requirement of the standard.

Developing and providing rationale helps those using the standard to understand the requirements and facilitates:

— interpretation;

— reference in other standards;

— application to changing technology;

— revision of the standard.

8.2 Form of safety requirements

8.2.1 Safety requirements

Wherever practical, requirements should be expressed in terms of specific inspection, test and procedure requirements, rather than by design requirements or descriptive characteristics.