



GUIDE 63

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

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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.

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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