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## GUIDE 63

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

This is a preview of "ISO/IEC Guide 63:201...". Click [here](#) to purchase the full version from the ANSI store.



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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC Guide 63 was prepared jointly by ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*, in a Joint Working Group, *Application of risk management to medical devices*.

This second edition cancels and replaces the first edition (ISO/IEC Guide 63:1999), which has been technically revised.

This is a preview of "ISO/IEC Guide 63:201...". [Click here to purchase the full version from the ANSI store.](#)

## Introduction

ISO/IEC Guide 51 was the first of a series of guides intended to provide a harmonized approach to the concept of safety when preparing International Standards. ISO/IEC Guide 51 anticipated the need for sectoral guides such as this Guide. Consistent with ISO/IEC Guide 51, additional guidance might be needed for sectors within the broad category of medical devices.

The concept of safety, including safety-related performance and usability, is closely related to safeguarding the integrity of the patients who are the subjects of medical care, as well as that of those persons who are giving the care and any other persons. As medical devices and medical systems have become more complex, the diligence required to ensure their safety has similarly increased.

As different circumstances warrant different approaches to ensuring safety, it is impossible to provide precise requirements 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.