GUIDE 63

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

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Contents

Page

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.

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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.

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.

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

1 Scope

This Guide provides guidance to standards writers on how to include safety aspects in the development of medical device safety standards intended to be used within the risk management framework established in ISO 14971. It expands on the concepts developed in ISO/IEC Guide 51 to include safety-related performance and usability.

This Guide is intended to be read in conjunction with ISO/IEC Guide 51 and ISO 14971.

2 Terms and definitions

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

2.1
accompanying document
document accompanying a medical device and containing information for those accountable for the installation, use and maintenance of the medical device, the operator or the user, particularly regarding safety

[ISO 14971:2007, definition 2.1]

2.2
harm
physical injury or damage to the health of people, or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.3]

2.3
hazard
potential source of harm

NOTE The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

[ISO/IEC Guide 51:1999, definition 3.5]

2.4
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazards

[ISO/IEC Guide 51:1999, definition 3.6]

2.5
intended use
intended purpose
use for which a product, process, or service is intended according to the specifications, instructions and information provided by the manufacturer

[ISO 14971:2007, definition 2.5]