TECHNICAL SPECIFICATION

ISO/TS 19218-2

First edition
2012-04-01

Medical devices — Hierarchical coding structure for adverse events —

Part 2: Evaluation codes

Dispositifs médicaux — Structure de codage pour la cause et le type d'événement défavorable —

Partie 2: Codes d'évaluation

Reference number
ISO/TS 19218-2:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

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

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 19218-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO/TS 19218-2, together with ISO/TS 19218-1, cancels and replaces ISO/TS 19218:2005, which has been technically revised.

ISO 19218 consists of the following parts, under the general title *Medical devices — Hierarchical coding structure for adverse events*:

— *Part 1: Event-type codes*

— *Part 2: Evaluation codes*

Introduction

It is envisaged that the adverse-event evaluation codes specified in this part of ISO 19218 will originate primarily from the manufacturer of the device concerned. This Technical Specification provides a structure by which adverse-event evaluations can be used to collect medical device surveillance information in the post-market phase. It will also enable this information to be easily exchanged on an international basis using the common codes.

It can be used by healthcare providers and other users of the devices; however, a number of the evaluation codes characterize the results of analyses or investigations conducted by the manufacturer or regulatory authorities, who can use it to

— recognize the results of analyses or investigations of adverse events by means of globally recognized evaluation codes, and

— apply these codes as part of a medical device surveillance or reporting system.

Annex A shows how adverse-event codes can be used in conjunction with other data elements in order to facilitate global data exchange between regulatory bodies.

Medical devices — Hierarchical coding structure for adverse events —

Part 2: Evaluation codes

1 Scope

This part of ISO 19218 specifies requirements for a hierarchical coding structure for characterizing the results of the analysis or evaluation of adverse events relating to medical devices. The codes are intended primarily for use by medical device manufacturers and regulatory authorities. They can also be used for coding the results of the analysis or evaluation of events other than those related to death or serious injury, as well as malfunctions that could lead to death or serious injury.

This part of ISO 19218 is not intended to be used to decide whether or not an incident is reportable.

2 Terms and definitions

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

2.1
adverse event
event associated with a medical device that has led to the death or serious injury of a patient, user or other person, or that might lead to the death or serious injury of a patient, user or other person if it were to reoccur

NOTE 1 This definition is consistent with guidance in GHTF/SG2/N54/R8:2006[5].

NOTE 2 It includes the malfunction or deterioration of a device which has not yet caused death or serious injury, but which could lead to death or serious injury.

NOTE 3 This definition is not intended to be used in determining if an event is reportable to a regulatory authority.

2.2
serious injury
serious deterioration in state of health that constitutes either

— a life threatening illness or injury, or

— a permanent impairment of a body function or permanent damage to a body structure, or

— a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

NOTE 1 “Permanent” here means irreversible impairment or damage, excluding minor impairment or damage.

NOTE 2 This definition is consistent with guidance in GHTF/SG2/N54/R8:2006[5].

2.3
intended use
intended purpose
objective intent of the manufacturer regarding the use of a product, as reflected in the specifications, instructions or information provided by the manufacturer

NOTE This definition is consistent with GHTF/SG1/N41/R9:2005[6].