TECHNICAL SPECIFICATION

ISO/TS 19218-1

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Medical devices — Hierarchical coding structure for adverse events —

Part 1: Event-type codes

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

Partie 1: Codes de type d'événement

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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

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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.

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 normative 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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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 19218-1 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

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

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

— *Part 1: Event-type codes*

The following part is under preparation:

— *Part 2: Evaluation codes*

Introduction

The adverse-event coding system specified in this part of ISO/TS 19218 envisages that medical device adverse-event reporting will originate from one of two sources: either the user or the manufacturer of the device concerned. In this context, users can be health care providers, but can also be the general public. This part of ISO/TS 19218 provides a structure by which an adverse-event type can be used to collect medical device surveillance information in the post-market phase. It also enables this information to be easily exchanged on an international basis using the common codes.

This part of ISO/TS 19218 can be used by the users, manufacturers and regulatory authorities in the following ways:

— users can report, to a manufacturer or a regulatory body, a code number to describe an adverse event that will be universally understood;

— manufacturers and regulatory authorities can easily recognize universally understood adverse-event types, which can be globally recognized by regulatory authorities;

— in addition, both users and manufacturers can apply these codes as part of a medical device surveillance or reporting system.

Medical devices — Hierarchical coding structure for adverse events —

Part 1: Event-type codes

1 Scope

This part of ISO/TS 19218 specifies requirements for a hierarchical coding structure for describing adverse events relating to medical devices. The codes are intended for use by medical device users, manufacturers, regulatory authorities, health care facilities and other organizations. The codes can be used for coding events that are not related to death or serious injury, or malfunctions that could lead to death or serious injury.

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

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 led to death or serious injury of a patient, user or other person, or that might lead to death or serious injury of a patient, user or other person if the event recurs

NOTE 1 This definition is consistent with guidance in GHTF/SG2/N54/R8:2006[7].

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

2.2
serious injury
serious deterioration in a 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 The term “permanent” means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.

NOTE 2 This definition is consistent with guidance in GHTF/SG2/N21/R8:1999[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[4].