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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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].

3 Adverse-event-type code requirements

The adverse-event-type code characterizes the observed use/malfunction/failure of the medical device at the time the event occurred. The code shall be a four-digit numerical code selected from Table 1.

NOTE 1 The single code that most closely describes the adverse event can be used. However, multiple codes can sometimes be necessary to fully describe an adverse event.

NOTE 2 The adverse-event-type code can be useful in describing the hazard presented by an adverse event. It can also be useful in "user reporting systems". When combined with the adverse-event evaluation code (from ISO/TS 19218-2), the adverse event is better characterized.

NOTE 3 The adverse-event-type codes chosen to describe the adverse event at the time of the event reflect the most up-to-date assessment of the adverse event and can take into account any additional information learned between occurrence of the event and submission of the report.

4 Adverse-event-type codes

Table 1 specifies adverse-event-type codes.

Table 1 — Adverse-event-type codes

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1000	Activation, Positioning or Separation	Issue associated with any deviations from device-documented performance specifications relating to the sequence of events for activation or positioning of the device or one of its components into a specific body location. NOTE 1 "Deployment" is synonymous with "activation".	1001	Difficult to Position	Issue associated with users experiencing difficulty or uneasiness to deploy a device, device component, or both, to a specified location.
			1002	Failure to Activate	Issue associated with the inability of a device or device component to be activated.
			1003	Failure to Separate	Issue associated with the failure of the device or one of its components to detach or separate as intended.
			1004	Premature Activation	Issue associated with an early and unexpected activation of the device, device component, or both, from the system.
			1005	Delayed Activation	Issue associated with a delayed and unexpected activation of the device, device component, or both, from the system.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1100	Computer Hardware	Issue associated with hardware that affects device performance or communication with another device.	1101	Hardware Issue	Issue associated with hardware that affects device performance.
			1102	Network Issue	Issue associated with the deviations from documented system specifications that affect overall system performance or the performance of an individual device or collection of devices connected to that system.
1200	Computer Software	Issue associated with written programs, codes or software system that affects device performance or communication with another device.	1201	Application Program Issue	Issue associated with the requirement for software to fulfil its function within an intended use or application.
			1202	Programming Issue	Issue associated with the written program code or application software used to satisfy a stated need or objective for functioning of the device, including incorrect software programming, dose, parameter and power calculations.
1300	Connection or Fitting	Issue associated with linking of device, device components, or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.	1301	Connection Issue	Issue associated with linking of a device, device component, or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.
			1302	Disconnection	Issue associated with a linked device, device component, or both, having a sufficient open space (disconnection) to prevent gas, liquid or electrical current flowing between connectors.
			1303	Failure to Disconnect	Issue associated with the linking of a device, device component, or both, whereby termination of the transfer of liquid, gas, electricity or information cannot be accomplished, or linking components do not come apart, or disconnect, when expected.

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
			1304	Fitting Problem	Issue associated with the connection of a device, device component, or both, whereby channels, switching systems and other functional units set up to provide means for a transfer of liquid, gas, electricity or information do not match or fit.
			1305	Loose or Intermittent Connection	Issue associated with the connection of a device or device component being loose or intermittent.
			1306	Misconnection	Issue associated with the improper connection of a device, device component or a connection not in accordance with device specifications.
1400	Electrical/ Electronic	Issue associated with a failure of the electrical or electronic circuitry or components of the device.	1401	Arcing	Issue associated with electrical current flowing through a gap between two conductive surfaces, typically resulting in a visible flash of light.
			1402	Circuit Failure	Issue associated with a failure of the internal network paths or electrical circuitry (i.e. electrical components, circuit boards, wiring).
			1403	Device Sensing Issue	Issue associated with device features that are designed to respond to a physical stimulus (temperature, illumination, motion, cardiac rhythms) that do not transmit a resulting signal for interpretation or measurement.
			1404	Power Source Issue	Issue associated with the internal power of the device (e.g. battery, transformer, fuel cell or other power sources).
			1405	Spark	Issue associated with the discharge of electricity between two bodies previously electrically charged (e.g. electrostatic discharge).

Table 1 (*continued*)

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition
1500	External Conditions	Issue associated with the surrounding conditions in which the device is being used or stored, such as temperature, noise, lighting, ventilation or power supply.	1501	Environmental Particulates	Issue associated with fine solids or liquid particles, such as dust, smoke, fumes or mist suspended in the immediate atmosphere in which the device is being used.
			1502	Fumes or Vapours	Issue associated with the visibility, odour or toxicity of an ambient vapour or gas which affects the operation of the device.
			1503	Inadequate Storage	Issue associated with inadequate or inappropriate storage of the device.
			1504	Loss of Power	Issue associated with the failure of primary power provided by the facility (e.g. electrical, gas, fluid pressure).
1600	Implantable Device Failure	The migration, malfunction or failure of an implanted device (active or non-active).	1601	Migration of Device or Device Component	Issue associated with an undesired movement of a device, device component, or both, related to its movement away from or dislodging from a source.
			1602	Osseo-disintegration Issue	Issue associated with interconnection between bone and an implanted device.
1700	Incompatibility	Issue associated with the device not being compatible with another device component, patient or substance (medication, body fluid, etc.) that it contains or transports.	1701	Component or Accessory Incompatibility	Issue associated with the incompatibility of any device, device component, or both, while being operated in the same use environment, thereby leading to a dysfunction between the device and its components.
			1702	Device-Device Incompatibility	Issue associated with the incompatibility of two or more devices while being operated in the same use environment, thereby leading to a dysfunction of more than one device.
			1703	Patient-Device Incompatibility	Issue associated with the interaction between the patient's physiology or anatomy and the device that affects the patient or device (e.g. biocompatibility or immunological issues).