TECHNICAL SPECIFICATION

ISO/TS 19218-2

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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

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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 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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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].

3 Adverse-event evaluation code requirements

The adverse-event evaluation code characterizes the latest conclusions of an analysis or investigation of the adverse event. The code shall be a five-digit numerical code selected from Table 1.

NOTE 1 Multiple codes can be necessary to fully describe the results of the evaluation of an adverse event.

NOTE 2 The adverse-event evaluation code can be useful for manufacturers and regulatory authorities when following up on reported adverse events. When combined with the adverse-event-type code, the characteristics of the adverse event are succinctly communicated.

NOTE 3 The latest conclusions characterize the event at any stage of an analysis or investigation.

4 Adverse-event evaluation codes

Table 1 specifies adverse-event evaluation codes.

Table 1 — Adverse-event evaluation codes

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
25000	Biological	Event relating to, caused by or affecting life or living organisms	25001	Abnormal or unexpected physiological response	Abnormal or unexpected physiological response such as hypersensitivity
			25002	Biocompatibility	Device causes cellular or tissue responses that elicit an undesirable local or systemic effect in the recipient or beneficiary of that therapy [see ISO 10993 (all parts)]
			25003	Biological material	Presence of biological material(s) in a device resulting in a reaction other than immediate hypersensitivity
			25004	Contamination by foreign material	Presence of extraneous material that renders a device impure or potentially harmful NOTE Excludes contamination during production (see level 2 code 26503).
			25005	Genotoxic problem	Device's ability to cause damage to genetic material, e.g. leading malignant tumours [see ISO 10993 (all parts)]
			25006	Hematologic problem	Device affects or impacts the blood or its components [see ISO 10993 (all parts)]
			25007	Endotoxin contamination	Undesirable presence of toxins associated with certain bacteria (e.g. gram negative bacteria)

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			25008	Microbiological contamination	Undesirable presence of microorganisms or microbes such as bacteria and fungi (yeasts and moulds)
			25009	Material or material leachate pyrogenic problem	Undesirable presence of pyrogens or fever-producing organisms resulting from materials that permeate through the device
25100	Counterfeiting	Event associated with the reproduction of a genuine medical device or the forging of labelling or product information with the intent to deceptively misrepresent the genuine medical product	25101	Counterfeit	Imitation of a genuine medical device with the intent to deceive
			25102	Forged product information	Product labelling or other information that is not provided or authorized by the company responsible for labelling the device
25300	Design	Event associated with the failure of a medical device to achieve its intended function due to inadequate design or development process	25301	Design deficiency	Failure of the device to achieve its intended function due to inadequate design, including inappropriate risk assessment
			25302	Development process deficiency	Failure of the device to achieve its intended function due to an inadequate development process
			25303	Packaging	Inadequate or inappropriate packaging
			25304	Safety measures	Inadequate or missing safety measures
			25305	Usability	Deficient or inadequate characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction NOTE Consistent with IEC 62366:2007, 3.17.
25500	Electrical	Event associated with an electrically powered device where an electrical malfunction results in a device failure (e.g. electrical circuitry, contact or component failed), even if the failure is intermittent	25501	Electrical component	Electrical or electronic component defect (e.g. resistor failure, capacitor failure, transformer failure, microprocessor failure) resulting in a device failure NOTE Excludes insulation breakdown (see level 2 code 25506).

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
			25502	Electrical circuitry	Malfunction of an electrical circuit resulting from events such as fluid penetration or overheating
			25503	Electrical contact	Electrical issue resulting in the malfunction of the device (e.g. make or break a contact, corrosion, high-resistance, thermal shock, or unintentional movement)
			25504	Energy storage system	Device problem related to the electrical energy storage system (e.g. rechargeable battery, charging system or capacitor) and including problems such as premature power source depletion and battery explosions
			25505	Improper construction	Device problem related to improper wire routing, breakage due to unexpected movement and other construction deficiencies
			25506	Insulation	Device that has inadequate or incorrect insulation material, resulting in exposure to hazardous voltage
			25507	Power source — loss of power	Failure of the mains power, causing a device to cease to operate
25600	Electromagnetic interference	Event associated with the malfunction of an active, electrically powered medical device, caused by electromagnetic disturbance, including radio-frequency interference (RFI)	25601	Electromagnetic immunity	Medical device performance degradation resulting from an electromagnetic disturbance
			25602	Electromagnetic emissions	Medical devices that unintentionally emit electromagnetic disturbances that affect radio services, other equipment or the performance of other medical devices or medical systems

Table 1 *(continued)*

Level 1			Level 2		
Code	**Term**	**Definition**	**Code**	**Term**	**Definition**
26000	Human factors	Event associated with the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations NOTE Consistent with AAMI HE75.	26001	Abnormal use	Act or omission of an act by the user or operator of the medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer, e.g. deliberate violation of instructions, procedures or use prior to completing installation, causing a device failure NOTE Consistent with IEC 62366:2007, 3.1.
			26002	Expiration date	Use of the medical device beyond the expiration date, resulting in a device failure
			26003	End of life	Device failure resulting from use beyond the intended useful life of the product
			26004	Inappropriate environment	Use of a device in an environment that results in a failure or malfunction
			26005	Incorrect calibration	Calibration performed incorrectly or not performed at all, resulting in inaccurate results provided by medical devices involved in measurements (e.g. temperature, weight, pH, IVD test results)
			26006	Installation problem	Device that malfunctions because incorrectly installed, set-up or configured
			26007	Maintenance	Failure or malfunction of a device resulting from inadequate routine or periodic maintenance
			26008	Non-hygienic condition	Device failure resulting from inadequate hygienic status of the user or locality of the user
			26009	Patient anatomy/ physiology	Device failure resulting from use inadequate or inappropriate for the anatomy/physiology of the patient involved
			26010	Patient condition	Failure or poor performance of a device resulting from the patient condition (possibly unexpected)
			26011	Sterilization, disinfection, cleaning	Failure of a device due to inadequate or inappropriate sterilization, disinfection, or cleaning