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Medical devices — Coding structure for adverse event type and cause

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

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Foreword

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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:

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— 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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

Introduction

The adverse event coding structure specified in this Technical Specification envisages that the reporting of medical device adverse events will originate from one of two sources, either the user or the manufacturer of the device concerned. Users, in this context, may be healthcare professionals, but may also be the general public. This Technical Specification provides a coding structure by which an adverse event type and/or the observable cause/effect can be used so as to collect medical device surveillance information. The observable cause/effect comes from an initial assessment of the adverse event. It also enables this information to be easily exchanged on an international basis using the common codes.

This Technical Specification can be utilized 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 by both.

— Manufacturers and regulatory authorities can easily recognize universally understood adverse event types, can assign understood initial assessment cause/effect codes which can be globally recognized by regulatory authorities.

— Both users and manufacturers can apply the use of these codes as part of a medical device surveillance or reporting system.

This Technical Specification is not intended for the purpose of taking a decision whether an incident is reportable or not.

Medical devices — Coding structure for adverse event type and cause

1 Scope

This Technical Specification specifies requirements for a coding structure for describing adverse events related to medical devices. This code is intended for use by medical device users, manufacturers and regulatory authorities.

2 Terms and definitions

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

2.1
serious injury
condition that

— results from life-threatening illness or injury;

— results in permanent impairment (2.2) of a body function or permanent damage (2.3) to a body structure;

— necessitates medical or surgical intervention to prevent permanent impairment (2.2) of a body function or permanent damage (2.3) to a body structure

NOTE 1 Serious injury is also known as serious deterioration in state of health.

NOTE 2 This definition is consistent with guidance in GHTF/N21R8:1999.

2.2
permanent impairment
irreversible impairment to a body structure or function, excluding minor impairment

2.3
permanent damage
irreversible damage to a body structure or function, excluding minor damage

2.4
adverse event
event associated with a medical device that leads to death or serious injury (2.1) of a patient, user or other person or might lead to death or serious injury of a patient, user or other person if the event recurs

NOTE This definition is consistent with guidance in GHTF/N21R8:1999.

3 Code system and requirements

3.1 Adverse event type code

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 three-digit numerical code selected from Table 1.

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

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

NOTE 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 cause code, the adverse event is better characterized.

Table 1 — Adverse event (AE) type

AE type code	AE type term	AE type description	Examples
100	Abnormal or unexpected biological response	An abnormal or unexpected biological response.	Allergic reaction to a device containing natural rubber latex (NRL), e.g. catheters, drains, or gloves.
110	Computer hardware	Any medical device using computer hardware, (e.g. internal hard disc, external disc drives) where any malfunction of the hardware results in a device failure.	Internal hard drive of the central monitoring system crashes causing the system to no longer function and also resulting in the loss of individual patient information.
120	Connection	An inappropriate capability for connection between: devices, parts, components, or joined elements; not intended to be joined together.	Patient lead is inserted into an electrical outlet.
130	Data output/readings	Data provided by the device or through the use of a device is deficient, e.g. observed aberrant test result possibly leading to inappropriate action or treatment.	Patient identification number is truncated on diagnostic device display unit.
140	Disconnection	The unintended separation of a connection or an unstable connection between two or more parts, (e.g. electrical, mechanical, tubing) resulting in a device failure.	Needles separating from hub. Suture wing separates from catheter.
150	Electrical	An event associated with an electromedical device where an electrical malfunction results in a device failure (e.g. electrical circuitry, contact or component failed) even if the failure is intermittent.	Overheating of electrical circuits, sparking of relays, break in instillation resulting in electrical shock. Overheating wires leading to a break in wire.
160	Environmental	Device function is adversely influenced by temperature, user hygiene, transportation, storage, etc.	Steam sterilization of hip prostheses results in surface roughening. Rubber or plastic materials become brittle due to extended high storage temperatures.

Table 1 (*continued*)

AE type code	AE type term	AE type description	Examples
170	Implantable device failure	The migration, malfunction or failure of an implanted device (active or non-active) resulting in an invasive procedure which may lead to explantation, e.g. breast implants, pacemakers, intraocular lenses.	Catheter for a venous access system becomes disconnected from the port. Two-piece orthopaedic device separates. Breast implant leaks.
180	Incompatibility	The lack of compatibility between items intended to function properly together; leading to dysfunction between two or more devices, parts, components, joined elements, or between a device and the substance (e.g. medicine, body fluid) it contains or transports. This type excludes disconnection.	Universal connector will not attach securely to ventilator connection.
190	Instructions for use/labelling deficiency	Inadequate, incorrect, instructions for use/labelling/packaging resulting in an event or device failure.	Hex head of a screwdriver included in a kit is too large to fit the heads of the bone screws also included. Labelled refractive power of a contact lens is not consistent with that of the lens in the package.
200	Intermittent malfunction	The intermittent malfunction of unidentified origin resulting in a device failure.	Monitor for a device periodically goes blank and then the image will reappear.
210	Material, component failure	An event where part of, or the entire device or component is manufactured using material(s) of limited durability, (e.g. insulation, rubber) resulting in a device failure.	Polymer coating on a reusable cable deforms during sterilization by user facility.
220	Mechanical component failure	A mechanical component defect, including moving parts or subassemblies resulting in a device malfunction (e.g. breakage, deformation, obstruction) resulting in device failure.	Missing component in the cassette of an infusion pump administration set results in free flow of the drug. Swivel base on a diagnostic device fails causing the unit to fall from its mounted position.
230	Medication overdose/under dose	An overdose/under dose of medication delivered to a patient associated with the use of a medical device.	In 2 h, infusion pump delivers medication that should have taken 5 h.
240	Other[a]	An event type not included in this table resulting in a device related event.	
250	Power source failure	A deviation in the power supply resulting in a device failure. This includes batteries that can provide power for the parent device or power to run auxiliary functions, e.g. alarms, memory.	Portable defibrillator does not recharge after a shock is delivered. Battery wires become loose and disconnect from the device being powered. Battery backup unit does not activate when power fails.
260	Protective measure	The failure of a protective measure including the failure of an alarm or the failure to transmit the alarm to a remote [device] [monitor].	A ventilator is intended to alarm when an obstruction in the patient airway causes reduced airflow to patient does not alarm.
270	Radiation	Unintended radiation overexposure/ underexposure due to a malfunction of a medical device.	Dental X-ray film is too dark to be read, due to the delivery of an incorrect amount of radiation. Laser activates and fires without being activated by user.