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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

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to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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