PD ISO/TS 20405:2018

BSI Standards Publication

Health informatics — Framework of event data and reporting definitions for the safety of health software

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National foreword

This Published Document is the UK implementation of ISO/TS 20405:2018.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2018

ISBN 978 0 580 99334 3

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2018.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 20405:2018

TECHNICAL SPECIFICATION

ISO/TS 20405

First edition
2018-05-18

Health informatics — Framework of event data and reporting definitions for the safety of health software

Informatique de santé — Cadre des données relatives aux événements et de compte-rendu des définitions pour la sécurité des logiciels de santé

Reference number
ISO/TS 20405:2018(E)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Patient safety is a major, worldwide concern in healthcare.

Individuals and organizations representing an array of roles, responsibilities, interests and relationships have become involved, including clinical professionals, academic researchers and patient advocates, as well as government and health regulatory authorities, and of course public and private sector corporations delivering healthcare.

Since 1999, patient safety has been a consistent focus of deliberation and action at national and international levels, including at ISO and IEC. Existing standards have been revised and new ones developed to incorporate recognized and emerging best practices in patient safety, in particular with respect to risk analysis, prevention and mitigation.

While these efforts have been supported by local, regional and global initiatives to improve patient safety, a consensus-based framework approach to the identification and reporting of incidents, near-misses and unsafe conditions with respect to the safety of health software has not been articulated. This is a significant gap when considering:

1) the rapidly increasing use of health information technology (HIT) in healthcare delivery,

2) the greater uptake and implementation of products on a more global basis, and

3) the rapidly expanding endeavour towards achieving greater interoperability, based on standards and specifications, of previously 'stand-alone' or otherwise heterogeneous health software systems.

Considering this gap, it is useful to return to the Institute of Medicine's report[[16]]which noted that improved surveillance mechanisms are needed to identify, capture, and investigate adverse events to continually improve the safety of HIT.

In the context of achieving a framework approach, it is important to understand that the use of the term “Identification” in this document refers to the capacity to describe health software safety events, in suitable quantitative and qualitative fashion through concepts, definitions, and processes, so as to provide the most useful information in support of current and future efforts to avoid or mitigate patient safety incidents.

Indeed several nations already have a variety of general and specific reporting regimes with respect to the safety of health software, including but not limited to the Agency for Healthcare Research and Quality's (AHRQ) common formats approach, the National Health Service (NHS) England's National Reporting and Learning System (NRLS), Japan's Medical Near-Miss/Adverse Event Reporting Project, among many others (see Annex A). Academic research in this area is also growing, including the classification for problems associated with IT systems in healthcare. These regimes as well as academic research have helped greatly in the preparation of this document.

This document is based upon a primary focus of patient safety. It is therefore principally concerned with setting out suitable definitions that describe data in most/all events where health software performs adversely (either in a stand-alone sense, or when interoperability is involved between distinct systems) and thereby poses a risk to patients.

Using this framework approach, it is anticipated that incidents, near-misses and unsafe conditions involving the safety of like or similar health software systems can better be defined, documented and compared, with the result being a greater, shared understanding of health software, systems safety risks and better informed actions to both mitigate future risks and respond when adverse actions occur. Use of incident data can have a broader relevance to the notification and response to events that results from any of the event classifications.

This document does not describe how learning from incidents should be managed. There might be a risk that separate analyses of incidents, complaints and other health software-related adverse events can result in fragmented solutions that do not address problems effectively. A combined analytical and

resolution framework approach, involving incident data along with data from other relevant sources, can therefore be considered.

Health informatics — Framework of event data and reporting definitions for the safety of health software

1 Scope

This document provides a model framework for improving the surveillance and reporting of events with respect to the safety of health software.

This document defines those data elements needed for identification of particular events including incidents, near-misses and unsafe conditions, as well as outlining good principles, relevant concepts and a process model for the recording, analysis and reporting of event-specific information related to the safety of health software.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.2
hazardous event
event that can cause harm

[SOURCE: ISO/IEC Guide 51:2014, 3.3]

3.3
health software
software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

[SOURCE: IEC 82304-1:2016, 3.6]

3.4
health software safety event
hazardous event involving, either directly or indirectly, the operation of health software that risks the safety of the patient