BS EN ISO 21549-2:2014

BSI Standards Publication

Health informatics — Patient healthcard data

Part 2: Common objects

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National foreword

This British Standard is the UK implementation of EN ISO 21549-2:2014. It supersedes BS EN ISO 21549-2:2004 which is withdrawn.

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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Health informatics - Patient healthcard data - Part 2: Common objects (ISO 21549-2:2014)

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This European Standard was approved by CEN on 13 December 2013.

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Foreword

This document (EN ISO 21549-2:2014) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2014, and conflicting national standards shall be withdrawn at the latest by August 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21549-2:2004.

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Endorsement notice

The text of ISO 21549-2:2014 has been approved by CEN as EN ISO 21549-2:2014 without any modification.

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Document Sharing Hub

Full document details: BS EN ISO 21549-2:2014

Contents

Page

Foreword ..... **iv**
Introduction ..... **vi**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Symbols and abbreviated terms **3**
5 Basic data object model for a healthcare data card - Patient healthcard data object structure **3**
6 Basic data objects for referencing **3**
6.1 Overview 3
6.2 Internal links 4
6.3 Coded data 4
6.4 Accessory attributes 6
7 Device and data security attributes **9**
7.1 General 9
7.2 Specific data cards' security services-related data objects 9
Annex A (normative) **ASN.1 data definitions** **13**
Bibliography **15**

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Document Sharing Hub
Full document details: BS EN ISO 21549-2:2014

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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 21549-2:2004), which has undergone a minor revision. The following changes have been made.

— Foreword: mention of CEN collaboration is removed.

— Scope: first paragraph is reworded.

— Normative references: references that are not cited normatively are moved to the Bibliography.

— Terms and definitions: unused terms are removed.

— Symbols and abbreviated terms: unused abbreviated terms are removed.

— Subclause 6.3.2, Table 2: data type of codeIdentifier is corrected to match ASN.1 definition.

— Clauses 5, 6, and 7: the figures and tables are renumbered sequentially, references to the figures and tables are added.

— Bibliography: dates from the references are removed where not applicable.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data*:

— *Part 1: General structure*

— *Part 2: Common objects*

— *Part 3: Limited clinical data*

— *Part 4: Extended clinical data*

— *Part 5: Identification data*

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— *Part 6: Administrative data*

— *Part 7: Medication data*

— *Part 8: Links*

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Introduction

This part of ISO 21549 provides data structures and definitions for limited clinical data for use within patient-held healthcare data cards.

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible data bases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized in three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card "de facto" has to contain device data and identification data and may in addition contain administrative, clinical, prescription and linkage data.

Device data is defined to include:

— identification of the device itself;

— identification of the functions and functioning capabilities of the device.

Identification data may include:

— unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include:

— complementary person(s)-related data;

— identification of the funding of healthcare, whether public or private, and their relationships i.e. insurer(s), contract(s) and policy(ies) or types of benefits;

— other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include:

— items that provide information about health and health events;

— their appraisal and labeling by a healthcare provider (HCP);

— related actions planned requested or performed.

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Because a data card essentially provides specific answers to definite queries while having at the same time a need to optimize the use of memory by avoiding redundancies, "high level" Object Modeling Technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

Data in the four categories above share many features. For instance, each may need to include ID numbers, names and dates. Some information may also have clinical as well as administrative uses. Therefore it has been considered inadequate to provide a simple list of items carried by healthcare data cards without applying a generic organization, based upon the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed; several such objects may also share attributes.

This part of ISO 21549 describes and defines the Common Data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

These data objects are utilized in all forms of healthcare data cards and are used to construct compound data objects as defined in Parts 3 to 8 of ISO 21549.

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