Irish Standard
I.S. EN ISO 21549-3:2014

Health informatics - Patient healthcard data -- Part 3: Limited clinical data (ISO 21549-3:2014)

I.S. EN ISO 21549-3:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

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English Version

Health informatics - Patient healthcard data -- Part 3: Limited clinical data (ISO 21549-3:2014)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 3: Données cliniques limitées (ISO 21549-3:2014)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 3: Kerndatensatz der klinischen Daten (ISO 21549-3:2014)

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

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 21549-3:2014) 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of an identical text or by endorsement, at the latest by August 2014, and conflicting national standards shall be withdrawn at the latest by August 2014.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 21549-3:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 21549-3:2014 has been approved by CEN as EN ISO 21549-3:2014 without any modification.

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I.S. EN ISO 21549-3:2014

INTERNATIONAL STANDARD

ISO 21549-3

Second edition
2014-02-15

Health informatics — Patient healthcard data —

Part 3: Limited clinical data

Informatique de santé — Données relatives aux cartes de santé des patients —

Partie 3: Données cliniques limitées

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 21549-3:2004), which has undergone a minor revision. The following changes have been made.

— Foreword: mention of CEN collaboration is removed.

— Scope:. first line is reworded.

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

— Clause 5: paragraph after Figure 1 is reworded.

— Subclause 7.1: last sentence before Figure 2 is reworded.

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

— Clause 7: the class ExtendedEmergencyData is moved from Part 4 to Part 3.

— 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*

— *Part 6: Administrative data*

— *Part 7: Medication data*

— *Part 8: Links*

Introduction

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 databases 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 caries 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 are 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 labelling by a healthcare provider (HCP);

— related actions planned requested or performed.

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 Modelling Technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

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

This part of ISO 21549 does not describe and define the common objects defined within ISO 21549-2 even though they are referenced and utilized within this part of ISO 21549.

Health informatics — Patient healthcard data —

Part 3: Limited clinical data

1 Scope

This part of ISO 21549 is applicable to situations in which limited clinical data are recorded on or transported by patient healthcards compliant with the physical dimensions of ID-1 cards defined by ISO/IEC 7810.

This part of ISO 21549 describes and defines the limited clinical data objects used in or referenced by patient healthcards using UML, plain text and abstract syntax notation (ASN.1).

This part of ISO 21549 specifies the basic structure of the data contained within the data object limited clinical data, but does not specify or mandate particular data sets for storage on devices. In particular the data contained within the data objects in limited clinical data are intended to aid the delivery of emergency care, while being by themselves neither intended, nor fit for purpose, for the total of information provision for the delivery of emergency care.

The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549, (although its structures can accommodate suitable data objects elsewhere specified):

— the encoding of free text data;

— security functions and related services which are likely to be specified by users for data cards depending on their specific application, for example: confidentiality protection, data integrity protection, and authentication of persons and devices related to these functions;

— access control services which may depend on active use of some data card classes such as microprocessor cards;

— the initialisation and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it according to this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

— physical or logical solutions for the practical functioning of particular types of data cards;

— how the message is processed further “downstream” of the interface between two systems;

— the form which data takes for use outside the data card, or the way in which such data are visibly represented on the data card or elsewhere.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21549-1, *Health informatics — Patient healthcard data — Part 1: General structure*

ISO 21549-2, *Health informatics — Patient healthcard data — Part 2: Common objects*