NSAI

Standards

Health informatics - Patient healthcard data - Part 5: Identification data (ISO 21549-5:2015)

I.S. EN ISO 21549-5:2016

Incorporating amendments/corrigenda/National Annexes issued since publication:

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NSAI 1 Swift Square, Northwood, Santry Dublin 9	T +353 1 807 3800 F +353 1 807 3838 E standards@nsai.ie W NSAI.ie	Sales: T +353 1 857 6730 F +353 1 857 6729 W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 21549-5:2016 is the adopted Irish version of the European Document EN ISO 21549-5:2016, Health informatics - Patient healthcard data - Part 5: Identification data (ISO 21549-5:2015)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21549-5

April 2016

ICS 35.240.80

Supersedes EN ISO 21549-5:2008

English Version

Health informatics - Patient healthcard data - Part 5: Identification data (ISO 21549-5:2015)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 5: Données d'identification (ISO 21549-5:2015)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 5: Identifikationsdaten (ISO 21549-5:2015)

This European Standard was approved by CEN on 2 April 2016.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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EN ISO 21549-5:2016 (E)

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European foreword

The text of ISO 21549-5:2015 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21549-5:2016 by 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 October 2016, and conflicting national standards shall be withdrawn at the latest by October 2016.

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 21549-5:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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 21549-5:2015 has been approved by CEN as EN ISO 21549-5:2016 without any modification.

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INTERNATIONAL STANDARD

ISO
21549-5

Second edition
2015-09-15

Health informatics — Patient healthcard data —

Part 5:
Identification data

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

Partie 5: Données d'identification

Reference number
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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).

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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 21549-5:2008), which has undergone a minor revision. The following changes have been made.

— Subclause 5.2, Table 1: condition of Sex optionality is added.

— Subclause 5.2, Table 1: optionality of National representation of the name is corrected to match ASN.1 definition and Figure 1.

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 funding institutions and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems. Administrative data objects may require linkage to external parties responsible for their own domains which are not within the scope of this part of ISO 21549. For instance, cross-border reimbursement of healthcare services are usually regulated by law and intergovernmental agreements which are not subject to standardization.

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 categorised 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" contains device data and identification data and may in addition contain administrative, clinical, medication 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 are defined to include:

— unique identification of the device holder (and not information of other persons).

Administrative data can 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;

— identification of other persons as a part of the insurance contract (e.g. a family contract);

— 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;

— related actions planned requested or performed.

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Medication data may include:

— a record of medications received or taken by the patient;

— copies of prescriptions including the authority to dispense records of dispensed medication;

— records of medication bought by the patient;

— pointers to other systems that contain information that makes up an electronic prescription and the authority to dispense.

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.

This part of ISO 21549 describes and defines the basic structure of the identification data objects held on healthcare 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.

INTERNATIONAL STANDARD

Health informatics — Patient healthcard data —

Part 5:
Identification data

1 Scope

This part of ISO 21549 describes and defines the basic structure of the identification data objects held on healthcare data cards, but does not specify particular data sets for storage on devices.

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):

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

— access control services;

— the initialization 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 card;

— the forms that data take 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 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

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

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

ISO/IEC 8824-1, *Information technology — Abstract Syntax Notation One (ASN.1): Specification of basic notation*

ISO/IEC 8825-1, *Information technology — ASN.1 encoding rules: Specification of Basic Encoding Rules (BER), Canonical Encoding Rules (CER) and Distinguished Encoding Rules (DER)*

ISO/IEC 10646:2014, *Information technology — Universal Coded Character Set (UCS)*

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