SLOVENSKI STANDARD
SIST EN ISO 21549-7:2008

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Zdravstvena informatika - Podatki o pacientu na zdravstveni kartici - 7. del: Podatki o zdravilih (ISO 21549-7:2007)

Health informatics - Patient healthcard data - Part 7: Medication data (ISO 21549-7:2007)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 7: Medikationsdaten (ISO 21549-7:2007)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 7: Données de médication (ISO 21549-7:2007)

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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 21549-7:2008 **en**

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English Version

Health informatics - Patient healthcard data - Part 7: Medication data (ISO 21549-7:2007)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 7: Données de médication (ISO 21549-7:2007)

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This European Standard was approved by CEN on 2 June 2007.

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Foreword

This document (EN ISO 21549-7:2007) 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of an identical text or by endorsement, at the latest by December 2007, and conflicting national standards shall be withdrawn at the latest by December 2007.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 21549-7:2007 has been approved by CEN as EN ISO 21549-7:2007 without any modifications.

INTERNATIONAL STANDARD

ISO 21549-7

First edition
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Health informatics — Patient healthcard data —

Part 7: Medication data

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

Partie 7: Données de médication

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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.

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 21549-7 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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*

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 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 benefit;

— 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;

Prescription data may include:

— a record of medications received by the patient;

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

— records of medications dispensed by the pharmacist to the patient;

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

Because a data card essentially provides specific answers to definite queries whilst 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.

Patient data cards may offer facilities to

a) communicate prescription information from one healthcare person to another healthcare person such as to a healthcare agent or healthcare organization;

b) provide indexes and/or authority to access prescription information held other than on the patient data card.

This part of ISO 21549 describes and defines the medication 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 part 2 of ISO 21549 even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 7: Medication data

1 Scope

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

This part of ISO 21549 specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data-sets for storage on devices.

The purpose of this part of ISO 21549 is for cards to provide information to other health professionals and to the patient or to their non-professional care giver.

It may also be used to carry a new prescription from the prescriber to the dispenser/pharmacy in the design of its sets.

Medication data includes the following four components:

— **medication notes**: the list of all medication for a patient;

— **medication prescriptions**: to carry a new prescription from the prescriber to the dispenser/pharmacy;

— **medication dispensed**: the records of medications bought by the patient;

— **medication references**: pointers to other systems that contain information that makes up a medication prescription and the authority to dispense.

In order to facilitate interoperability, whenever an application is built for use in the healthcare domain in compliance with this part of ISO 21549, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in Clauses 6 to 8. These shall then be used in conjunction with other data defined in other parts of this part of ISO 21549. 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 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 that may depend on active use of some data card classes such as microprocessor cards;

— 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;

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

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

It should be noted that not only the definition of “medicinal products” differs from country to country, but also the same name may relate to entirely different products in some countries. Therefore, special attention should be made for the safety of patient, when the card is used across borders

As a matter of course, exchange of prescription across borders must follow all laws, instructions, rules, terms and treaties between the said two countries.

2 Normative references

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

ISO 7810, *Identification cards — Physical characteristics*

ISO 7498-2, *Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture*

ISO/IEC 7826-1, *Information technology — General structure for the interchange of code values — Part 1: Identification of coding schemes*

ISO/IEC 7826-2, *Information technology — General structure for the interchange of code values — Part 2: Registration of coding schemes*

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

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

ENV 13607:2000, *Health informatics — Messages for the exchange of information on medicine prescriptions*

3 Terms and definitions

Please note that there are many different terms used to describe the basic concepts in healthcare for different purposes available from ISO, CEN, HL-7 and various national organizations. The following definitions are not meant to be universal in ISO work in health informatics, only to facilitate the understanding of this part of ISO 21549.

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

3.1
attribute
characteristic of an object or entity

3.2
audit trail
record of the resources that were accessed and/or used and by whom

NOTE This may involve a formal monitoring technique for comparison between the actual use of a medical information system and pre-established criteria.

3.3
authentication
process of reliably identifying security objects by securely associating an identifier and its authenticator

3.4
availability
property of being accessible and useable upon demand by an authorized entity

[ISO 7498-2, definition 3.3.11]

3.5
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance test requirements and produced during a defined validated process of manufacture

[EN 375:1992 E] [EN 376:1992 E]

3.6
clinical information

information about a subject of care, relevant to the health or treatment of that subject of care, which is recorded by or on behalf of a healthcare person

NOTE Clinical information about a subject of care can include information about the subject of care's environment or about related people where this is relevant.

[ENV 1613]

3.7
code meaning
element within a coded set

EXAMPLE “Paris Charles-de-Gaulle” which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

3.8
code value
result of applying a coding scheme to a code meaning

EXAMPLE “CDG” as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

3.9
coding scheme
collection of rules that maps the elements of one set on to the elements of a second set

3.10
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989, definition 3.3.16]