SLOVENSKI STANDARD
oSIST prEN ISO 21549-7:2014

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Zdravstvena informatika - Podatki o pacientu na zdravstveni kartici - 7. del: Podatki o zdravilih (ISO/DIS 21549-7:2014)

Health informatics - Patient healthcard data - Part 7: Medication data (ISO/DIS 21549-7:2014)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 7: Medikationsdaten (ISO/DIS 21549-7:2014)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 7: Données de médication (ISO/DIS 21549-7:2014)

Ta slovenski standard je istoveten z: **prEN ISO 21549-7**

ICS:

35.240.15	Identifikacijske kartice in sorodne naprave	Identification cards and related devices
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN ISO 21549-7:2014 **en,fr,de**

DRAFT INTERNATIONAL STANDARD
ISO/DIS 21549-7

ISO/TC **215** Secretariat: **ANSI**

Voting begins on: **2014-08-14**

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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

ICS: 35.240.80

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 21549-7:2014(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.

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*.

This second edition cancels and replaces the first edition (ISO 21549-7:2007). The following changes have been made.

— .Clause 1: medication notes definition is modified.

— Clause 3:. list of definitions is shortened, several definitions are corrected and clarified.

— Clause 4: list of abbreviation is shortened.

— Subclause 5.1: an explanation is added why MedicationData is modelled as a direct child of the PatietnHealthcardData.

— Subclause 6.2.3: "healthcare person" is replaced by "healthcare professional".

— Subclause 6.2.4: "factor of the quantity" is replaced by "Quantity units".

— Subclause 6.4: "medication history" is changed to "medication notes" in the title, an explanation of a major use is modified.

— Clause 7: All the names of attributes in the tables are harmonized with the class diagrams. Term "data object" is replaced by "class". Additional comments are included in the tables. For implementer's convenience the fragments of ASN.1 definitions are gathered together in the new Annex A.

— Subclause 7.2.1: explanation of MedicationNotes is modified.

— Subclause 7.2.2: Table 3: comments are modified.

— Subclause 7.2.3: Table 4: comments are modified.

— Subclause 7.2.4: Table 5: comments are modified.

— Subclause 7.2.5: Example is moved to informative Annex B.

— Subclause 7.3: Figures 7 and 8 are merged. Class “Prescriber” is defined as an attribute. The attribute “qualification” is replaced by the attribute “qualifier” having datatype “CodedData”. The attribute “medicinalProduct” is renamed as “prescribedMedicinalProduct”. The class “MedicinalProduct” is renamed as “PrescribedMedicinalProduct”. The class “ManufacturedMedicinalProduct” is renamed as “PrescribedManufacturedMedicinalProduct”. The class “MagistralMedicinalProduct” is renamed as “PrescribedMagistralMedicinalProduct”. Datatype of the attribute “strength” is replaced by “Strength”, the definition of this new datatype is added. Datatype of the attribute “quantityOfMedicinalProduct” is replaced by “Quantity”. Datatype of the attribute “amountOfIngredient” is replaced by “Amount”. The class “AmountOfIngredient” is replaced by the class “Amount”.

— Subclause 7.4: Figures 17 and 18 are merged. Class “Dispenser” is defined as an attribute. The attribute “dispensedMedicinalCode” is replaced by the attribute “dispensedMedicinalProduct” having new datatype “DispensedMedicinalProduct”. This new datatype is a generalization of the classes “DispensedManufacturedMedicinalProduct” and “DispensedMagistralMedicinalProduct”. The attributes “strength”, “form”, manufacturerOfMedicinalProduct” are moved from the class “ActualDispensedItem” to the class “DispensedManufacturedMedicinalProduct”. The attributes “batchIdentifier”, “genericSubstitution” are moved from the class “DispensingInformation” to the class “DispensedManufacturedMedicinalProduct”. Datatype of the attribute “quantityDispensed” is replaced by “QuantityToDispense”, so the class “QuantityDispensed” becomes unused and is deleted. The attributes “magistralMedicinalProductName” and “dispensedQuantity” are added to the class “DispensedMagistralMedicinalProduct”. The attribute “nameOfIngredient” is deleted from the class “DispensedIngredient”. Datatype of the attribute “quantityOfIngredient” is replaced by “Amount”. The attribute “nameOfContainerOrApplicationAid” is deleted from the class “DispensedContainerOrApplicationAid”.

— Subclause 7.5: Figures 26 and 27 are merged.

— Annex A: new ASN.1 definition is added.

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

This work is developed by ISO/TC 215 in collaboration with CEN/TC 251 under Vienna agreement with ISO in the lead.

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 Professional” 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 standardised 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 realise that a given healthcare data card "de facto" has to contain device data and identification data and may in addition contain administrative, clinical, medication 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 health care , 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;

Medication data may include:

- a record of medications purchased by the patient for self administration;
- copies of prescriptions including the authority to dispense records of dispensed medications;
- records of medications dispensed by a pharmacist to the patient;
- pointers to other systems that contain information that hold medication data - either medication history or prescribed medicines, (or both) and in the case of prescribed medicines, the authority to dispense.

Because a data card essentially provides specific answers to definite queries whilst having at the same time a need to optimise 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 professional to another healthcare professional such as to a healthcare agent or healthcare organisation;

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 this multipart standard even though they are referenced and utilised 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 is 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 standard is for cards to provide information to other health professionals and to the patient or its 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**, - additional information related to medication and the safe use of medicines by the patient such as medication history, sensitivities and allergies,;

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

— **medication dispensed**, the records of medications dispensed for the patient;

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

The following topics are 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 is 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, HL7 and various national organisations. 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

a characteristic of an object or entity

3.2

audit trail

record of the resources which were accessed and/or used 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

[ISO 7498 –2]

3.3

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]

3.4
coding scheme
a system of codes, descriptions, designations, properties and relationships

[ISO 27951:2009]

3.5

data object, information object

an instance of some information object class, being composed of a set of fields which conform to the field specifications of the class.

[ISO/IEC 8824-2, definition 3.4.9]

3.6

dispenser

a specialisation of a healthcare professional which is a representation of an individual . professionally responsible for filling / dispensing the prescription. This is usually the pharmacist but may be other individuals according to local jurisdiction

3.7

healthcare

provision of health related services

NOTE This includes more than performing procedures on subjects of care. It includes also e.g. the management of information about patients, their health status and their relationship with their healthcare framework

[ENV 13940:2001]

3.8

healthcare data card

a machine readable card conformant to ISO 7810 intended for use within the healthcare domain

3.9

healthcare organisation

organisation involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE 1 Groupings or subdivisions of an organisation, such as departments or sub-departments, may also be considered as organisations where there is need to identify them.

NOTE 2 Healthcare organisations is a subset of healthcare agents.

[ENV 13607] [ENV 1613, modified]

3.10

healthcare party

organisation or person involved in the direct or indirect provision of healthcare services to an individual or to a population

[ENV 13607]

3.11

healthcare professional

person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care

EXAMPLE Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk

[ENV 1613:1995]

3.12

immediate container

container that is in direct contact with the pharmaceutical product

[ENV 12610]

3.13 information object class

A set of fields, forming a template for the definition of a potentially unbounded collection of information objects, the instances of the class.

[ISO/IEC 8824-2, definition 3.4.10]

3.14

ingredient

substance included as a component in a product

NOTE In this context product refers to pharmaceutical product.

[ENV 13607]

3.15

magistral medicinal product;

extemporaneous medicinal product

medicinal product manufactured in a pharmacy or pharmacy department, which is based on a recipe and intended to be used for one and only one subject of care

NOTE 1 A magistral/extemporaneous medicinal product is also a pharmaceutical product.

[ENV 13607] [ENV 12610, modified]