SLOVENSKI STANDARD
SIST EN ISO 21549-4:2007

01-marec-2007

Zdravstvena informatika – Podatki o pacientu na zdravstveni kartici – 4. del: Razširjeni klinični podatki (ISO 21549-4:2006)

Health informatics - Patient healthcard data - Part 4: Extended clinical data (ISO 21549-4:2006)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 4: Klinische Daten - Erweiterter Datensatz (ISO 21549-4:2006)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 4: Données cliniques élargies (ISO 21549-4:2006)

Ta slovenski standard je istoveten z: **EN ISO 21549-4:2006**

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

SIST EN ISO 21549-4:2007 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21549-4

November 2006

ICS 35.240.80

English Version

Health informatics - Patient healthcard data - Part 4: Extended clinical data (ISO 21549-4:2006)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 4: Données cliniques élargies (ISO 21549-4:2006)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 4: Klinische Daten - Erweiterter Datensatz (ISO 21549-4:2006)

This European Standard was approved by CEN on 28 October 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 21549-4:2006: E

Foreword

This document (EN ISO 21549-4:2006) 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 May 2007, and conflicting national standards shall be withdrawn at the latest by May 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, 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 21549-4:2006 has been approved by CEN as EN ISO 21549-4:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 21549-4

First edition
2006-11-15

Health informatics — Patient healthcard data —

Part 4: Extended clinical data

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

Partie 4: Données cliniques élargies

Reference number
ISO 21549-4:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 21549-4 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: Electronic prescription (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, 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.

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: i) identification (of the device itself and the individual to whom the data it caries relates), ii) administrative and iii) 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, 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;
- 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 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.

This part of ISO 21549 describes and defines the Extended Clinical Data objects used within or referenced by patient held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1)[13].

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

Health informatics — Patient healthcard data —

Part 4: Extended clinical data

1 Scope

This part of ISO 21549 is applicable to situations in which such data are recorded on or transported by patient healthcare data cards 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 data object extended clinical data, but does not specify or mandate particular data-sets for storage on devices.

In order to facilitate interoperability, whenever an application is built for use in the healthcare domain in compliance with 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 and 7. These shall then be used in conjunction with other data defined in other parts 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 specified elsewhere):

- 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 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 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.