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Health informatics – Patient healthcard data – Part 2: Common objects (ISO 21549-2:2014)

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Denna standard ersätter SS-EN ISO 21549-2:2005, utgåva 1.

The European Standard EN ISO 21549-2:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 21549-2:2014.

This standard supersedes the Swedish Standard SS-EN ISO 21549-2:2005, edition 1.

**Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 21549-2:2014/
Relations to other parts under the same general title - Extract from the Foreword of
ISO 21549-2:2014**

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

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Denna standard är framtagen av kommittén för Hälso- och sjukvårdsinformatik, SIS/TK 334.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN ISO 21549-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Health informatics - Patient healthcard data - Part 2: Common objects (ISO 21549-2:2014)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 2: Objets communs (ISO 21549-2:2014)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 2: Gemeinsame Elemente (ISO 21549-2:2014)

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

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.

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Foreword

This document (EN ISO 21549-2:2014) 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.

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Endorsement notice

The text of ISO 21549-2:2014 has been approved by CEN as EN ISO 21549-2:2014 without any modification.

Introduction

This part of ISO 21549 provides data structures and definitions for limited clinical data for use within patient-held healthcare data cards.

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

Data in the four categories above share many features. For instance, each may need to include ID numbers, names and dates. Some information may also have clinical as well as administrative uses. Therefore it has been considered inadequate to provide a simple list of items carried by healthcare data cards without applying a generic organization, based upon the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed; several such objects may also share attributes.

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

These data objects are utilized in all forms of healthcare data cards and are used to construct compound data objects as defined in Parts 3 to 8 of ISO 21549.

Health informatics — Patient healthcard data —

Part 2: Common objects

1 Scope

This part of ISO 21549 establishes a common framework for the content and the structure of common objects used to construct data held on patient healthcare data cards. It is also applicable to common objects referenced by other data objects.

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/IEC 7810.

This part of ISO 21549 specifies the basic structure of the data, but does not specify or mandate 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):

- 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 is 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 21090:2011, *Health informatics — Harmonized data types for information interchange*

3 Terms and definitions

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