NSAI
Standards

Irish Standard
I.S. EN ISO 21549-1:2013

Health informatics - Patient healthcard data - Part 1: General structure (ISO 21549 -1:2013)

I.S. EN ISO 21549-1:2013

> *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

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English Version

Health informatics - Patient healthcard data - Part 1: General structure (ISO 21549-1:2013)

Informatique de santé - Données relatives aux cartes de santé des patients - Partie 1: Structure générale (ISO 21549-1:2013)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 1: Allgemeiner Aufbau (ISO 21549-1:2013)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 21549-1:2013) 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of an identical text or by endorsement, at the latest by December 2013, and conflicting national standards shall be withdrawn at the latest by December 2013.

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The text of ISO 21549-1:2013 has been approved by CEN as EN ISO 21549-1:2013 without any modification.

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INTERNATIONAL STANDARD

ISO
21549-1

Second edition
2013-06-15

Health informatics — Patient healthcard data —

Part 1:
General structure

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

Partie 1: Structure générale

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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.

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ISO 21549-1 was prepared by Technical Committee ISO/TC 215, *Health informatics.*

This second edition cancels and replaces the first edition (ISO 21549-1:2004), which has undergone a minor revision. The following changes have been made.

— Foreword: the title of Part 7 was changed to "Medication data".

— Scope: the restriction "This part does not apply to multi-application cards" was deleted and other wording was improved.

— Normative references: ISO 21549, Parts 2 to 8, were added.

— Clause 5: the title of ISO 21549-7 was changed to "Medication data" in the text and in Figure 1, and references to ISO 21549, Parts 2 to 7, were reworded to shorten them.

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 records, 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 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 categorized in three broad types: identification (of the device itself and the individual to whom the data it carries relate), 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 and clinical data.

Device data are 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 labelling by a healthcare provider (HCP);

— related actions planned, requested or performed.

Because a data card essentially provides specific answers to definite queries while at the same time there is 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.

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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.