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**Medizinische Informatik –
Patientendaten auf Karten im Gesundheitswesen –
Teil 2: Gemeinsame Elemente (ISO 21549-2:2004);
Deutsche Fassung EN ISO 21549-2:2004, Text Englisch**

Health informatics –
Patient healthcard data –
Part 2: Common objects (ISO 21549-2:2004);
German version EN ISO 21549-2:2004, text in English

Informatique de santé –
Données relatives aux cartes de santé des patients –
Partie 2: Objets communs (ISO 21549-2:2004);
Version allemande EN ISO 21549-2:2004, texte en anglais

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Normenausschuss Medizin (NAMed) im DIN

Die Europäische Norm EN ISO 21549-2:2004 hat den Status einer Deutschen Norm.

Nationales Vorwort

Diese Norm enthält unter Berücksichtigung des Präsidialbeschlusses 13/1983 die Englische Fassung der Internationalen Norm prEN ISO 21549-2:2004. Diese Norm wurde in der WG 5 „Health cards“ des ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem CEN/TC 251 „Health informatics“ erarbeitet. Der Fachbereich G „Medizinische Informatik“ und insbesondere die Mitarbeiter des Arbeitsausschusses G 5 „Karten“ des Normenausschusses Medizin (NAMed) im DIN haben an der Erarbeitung mitgewirkt.

Für die im Abschnitt 2 zitierte Internationale Norm wird im Folgenden auf die entsprechende Deutsche Norm hingewiesen:

ISO 3166-1 siehe DIN EN ISO 3166-1

Nationaler Anhang NA (informativ)

Literaturhinweise

DIN EN ISO 3166-1:1998-04, *Codes für die Namen von Ländern und deren Untereinheiten – Teil 1: Codes für Ländernamen (ISO 3166-1:1997); Deutsche Fassung EN ISO 3166-1:1997*

Deutsche Fassung

Medizinische Informatik - Patientendaten auf Karten
im Gesundheitswesen - Teil 2: Gemeinsame Elemente
(ISO 21549-2:2004)

Health informatics - Patient healthcard data - Part 2:
Common objects (ISO 21549-2:2004)

Informatique de santé - Données relatives aux cartes de
santé des patients - Partie 2: Objets communs
(ISO 21549-2:2004)

Diese Europäische Norm wurde vom CEN am 30. April 2004 angenommen.

Die CEN-Mitglieder sind gehalten, die CEN/CENELEC-Geschäftsordnung zu erfüllen, in der die Bedingungen festgelegt sind, unter denen dieser Europäischen Norm ohne jede Änderung der Status einer nationalen Norm zu geben ist. Auf dem letzten Stand befindliche Listen dieser nationalen Normen mit ihren bibliographischen Angaben sind beim Management-Zentrum oder bei jedem CEN-Mitglied auf Anfrage erhältlich.

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Vorwort

Dieses Dokument EN ISO 21549-2:2004 wurde vom Technischen Komitee CEN/TC 251 „Health informatics“, dessen Sekretariat vom SIS gehalten wird, in Zusammenarbeit mit dem Technischen Komitee ISO/TC 215 „Health informatics“ erarbeitet.

Diese Europäische Norm muss den Status einer nationalen Norm erhalten, entweder durch Veröffentlichung eines identischen Textes oder durch Anerkennung bis November 2004, und etwaige entgegenstehende nationale Normen müssen bis November 2004 zurückgezogen werden.

Entsprechend der CEN/CENELEC-Geschäftsordnung sind die nationalen Normungsinstitute der folgenden Länder gehalten, diese Europäische Norm zu übernehmen: Belgien, Dänemark, Deutschland, Estland, Finnland, Frankreich, Griechenland, Irland, Island, Italien, Lettland, Litauen, Luxemburg, Malta, Niederlande, Norwegen, Österreich, Polen, Portugal, Schweden, Schweiz, Slowakei, Slowenien, Spanien, Tschechische Republik, Ungarn, Vereinigtes Königreich und Zypern.

Anerkennungsnotiz

Der Text der Internationalen Norm ISO 21549-2:2004 wurde von CEN als Europäische Norm ohne irgendeine Abänderung genehmigt.

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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 21549-2 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)*
- *Part 8: Links*

At the time of publication of this part of ISO 21549, some of these parts were in preparation.

This work is being carried out by ISO/TC 215 in collaboration with CEN/TC 251, *Medical informatics*, under the Vienna Agreement, with ISO having the lead role. This new series of International Standards is intended to replace the European Prestandard ENV 12018 ratified by CEN in 1997.

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 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 into 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 and clinical 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-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 person (HCP);
- related actions planned, requested or performed.

Because a data card essentially provides specific answers to definite queries, whilst at the same time there is a need to optimize the use of memory by avoiding redundancies, a “high-level” object-modelling 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 in 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.