INTERNATIONAL STANDARD

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Health informatics — Patient healthcard data —

Part 8: Links

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

Partie 8: Liens

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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 21549-8 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: Medication data*

— *Part 8: Links*

Introduction

The ISO 21549 series of International Standards is intended to replace the European Prestandard ENV 12018 adopted by CEN in 1995. This series of International Standards provides data structures and definitions for data objects on patient data cards.

Healthcare becomes more and more integrated and is changing from having a local character to being regional and – with increasing mobility – even international. Typically, a patient's health history consists of many service episodes distributed over time and space. Sometimes patients are getting services from separate service providers at the same time. Each service provider such as hospital, health centre and physician has his own local patient record system. Thus the patient's health data is distributed more and more over specialities and space inside one country and also worldwide.

Patients can be better cared for if the health professional in charge has access to the patient's most recent data. Physicians at different locations have to be able to simultaneously see and edit a patient record from remote locations.

This requires on the one hand, information systems that are able to communicate and, on the other hand, standardized methods to locate the information. The Internet, which is able to distribute information to geographically-distant users, offers a securable technological solution for handling electronic patient records. However, it is necessary to access the data required in an easy and timely way. Not only does this mean that the relevant information has to be made available by its authors, but also that it has to be retrieved from a mass of irrelevant information whenever and wherever needed.

Patient data are especially sensitive and a secure basic infrastructure is absolutely necessary. Therefore, besides the secure transmission of data, the persons handling the record, for example health professionals and/or the patients have to be identified and authenticated. Further services like integrity and privacy protection, accountability, accessibility etc. need to be addressed as well.

Health cards can help to provide the necessary security in the sensitive health domain – including data integrity and data protection. They enable authentication for data on the card and can also provide links to several additional data objects stored elsewhere. Health cards may contain both a subset of critical clinical data stored on the card itself and links to data distributed nationally or worldwide over many medical information systems.

Health informatics — Patient healthcard data —

Part 8:
Links

1 Scope

This part of ISO 21549 defines a way to facilitate access to distributed patient records and/or administrative information using healthcards. It defines the structure and elements of “links” typically stored in healthcards and representing references to individual patients' records as well as to subcomponents of them. Access control mechanisms, data protection mechanisms, access methods and other security services are outside the scope of this part of ISO 21549.

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 21549-2, *Health informatics — Patient healthcard data — Part 2: Common objects*

ISO 21549-4, *Health informatics — Patient healthcard data — Part 4: Extended clinical data*

HL7v3, *Health Level Seven — Messaging Standard Version 3*, Normative Edition 2006

IETF RFC 3986, *Uniform Resource Identifier (URI): Generic Syntax*

3 Terms and definitions

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

3.1
reference
information that provides the unambiguous identification of a certain part of a distributed record

3.2
linkage information
data set that provides the complete information to locate the resource of a certain part of a distributed record

3.3
ISO OID organization code
unique worldwide organization code defined and managed following the ISO/IEC 9834 series of International Standards

3.4
Uniform Resource Identifier
compact sequence of characters which identifies an abstract or physical resource

3.5
Uniform Resource Locator
standardized address used for referring to resources by their location

3.6
Uniform Resource Name
location-independent standardized label identifying an object by its name serving as persistent, location-independent resource identifier

4 Abbreviated terms

OID Object Identifier

URI Uniform Resource Identifier

URL Uniform Resource Locator

URN Uniform Resource Name

XML eXtended Markup Language

5 Requirements

Typically, organizations are using internal data object identification systems for patient data records and images (e.g. DICOM numbering system consisting of an ISO OID organization code, a local archiving code and accumulative yearly number). The data object identifiers may be globally unique (as DICOM identifiers of studies, series and frames) or locally unique (as laboratory accession numbers). References to these data objects enable access to data objects that cannot be handled by use of the healthcard itself (e.g. for reasons of timing or storage capacity). The logical structure of these references should be compatible with the structure of references used in messages sent between healthcare information systems.

6 Structure

A link consists of the following data elements (see Figure 1).

— **URI** contains the physical reference (e.g. an internet/email address) and the unique ID (OID or proprietary ID) labelling the referenced data.

— **Description** gives a short characterization of the kind of data.

— **Accessory** specifies who stored the data and the date the link was created. Moreover it may contain the author and the date of collection of the data.

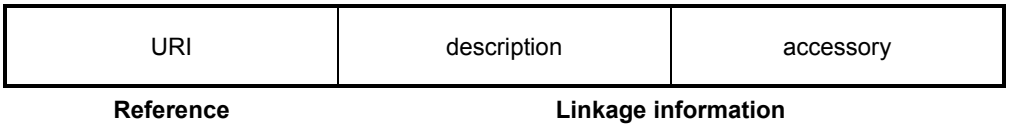

Figure 1 — Schematic representation of a link

URI represents the **Reference** part of a Link. Additional **linkage information** is provided by the optional sections, description and constraints. The constraints elements are used according to the specification for accessory attributes in ISO 21549-2.

The proposed structure of healthcard links data area intended for storage of internal and external references is shown below in Figure 2 as a UML class diagram.

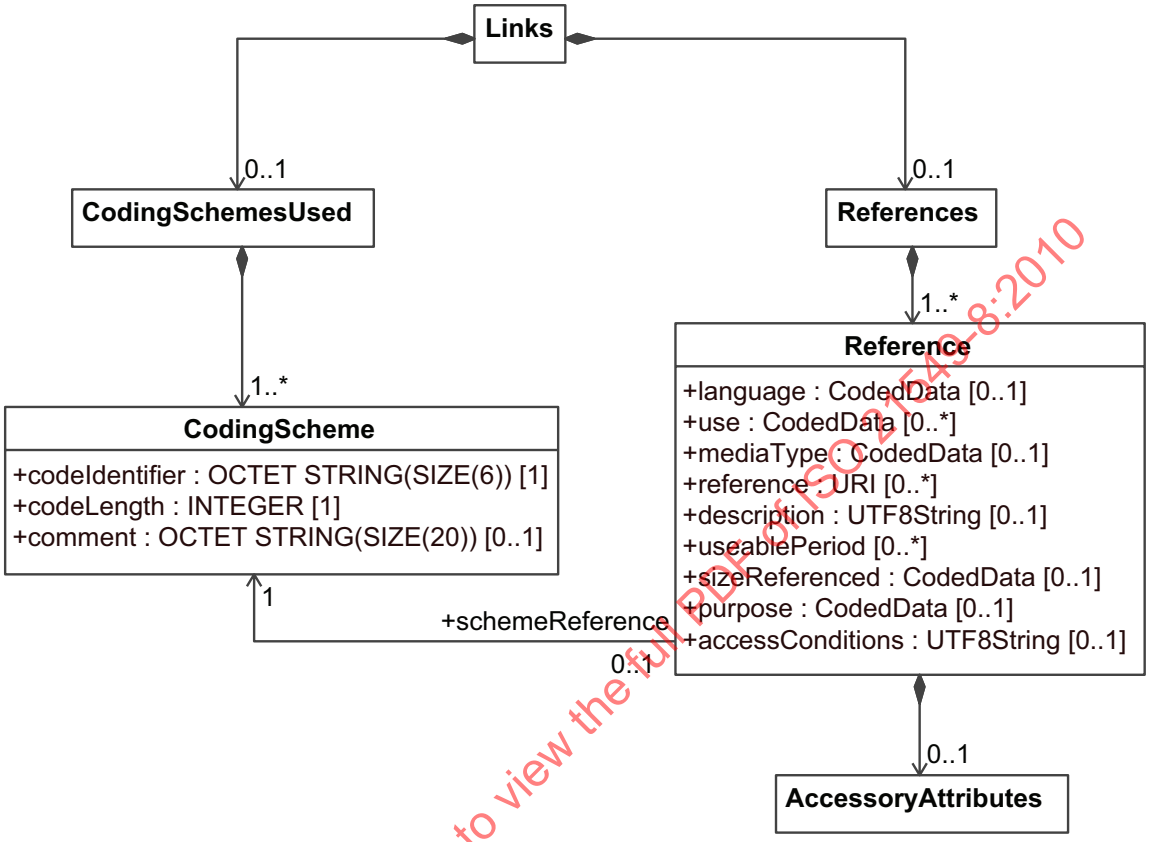

Figure 2 — Patient healthcard links data structure

This structure extends the structure of the object links defined in ISO 21549-2 with the following two optional objects.

— Object CodingSchemesUsed is defined in ISO 21549-2. It contains the identifiers and the short descriptions of the coding schemes used in the other parts of ISO 21549.

— Object References contains references to external data objects which may be complemented by a concise characterization of the kind of data and the AccessoryAttributes as specified in ISO 21549-2.

Due to the different usage, references can be divided into the two subtypes: **relay** and **standalone**.

Reference of type **relay** provides a kind of extension point for data objects stored on the healthcard itself. If there are additional data for a ClinicalEvent data object specified in ISO 21549-4 available from an external source, this can be referenced by use of an object Reference. A **standalone** reference is independent from other data objects on the healthcard and may be used discretely.

The structure of the object Reference is derived from data type Encapsulated Data defined in Health Level Seven Reference Information Model and used in Health Level Seven Clinical Document Architecture, Release Two. The attribute description is of type CWE (HL7 “**C**ode **W**ith **E**xception”) and allows to have code only, code with text or text only.

Table 1 — The specification of individual entities within object Reference

Object name	Object Type	Multiplicity	Comments
label	String	0..1	Information of the referenced data for display purposes (man-machine interface).
description	CWE	0..*n*	A short description of the kind of referenced data.
mediaType	CodedData	0..1	Identifies the type of the referenced data and identifies a method to interpret or render the data.
language	CodedData	0..1	For character-based information the language property specifies the human language of the text.
reference	URI	0..*n*	A unified resource identifier in accordance with IETF RFC 3986, such as a URL for HTTP or FTP provides the link to an external data object. Any identifier in this set points to the same data object and is used as an alternative way to receive access to these objects. May also contain identifiers intended for human use for example 'phone number of a patient's physician.
useablePeriod	TimeRange	0..*n*	Indicates that the external data may only be available for a limited period of time. Whether the reference is limited by a usablePeriod or not, the content of the reference is fixed for all time. Any application using the reference must always receive the same data. The reference cannot be re-used to send a different version of the same data or different data.
sizeReferenced	CodedData	0..1	Approximately the size of the referenced data ENUMERATED {<100kB(0), <1MB(1), <10MB(2), <100MB(3), <1GB(4), other(9)}
purpose	CodedData	0..1	purpose of the referenced data: ENUMERATED {expert opinion(1), second opinion(2), referral(3), single-point information(4), fragment of record(5)
accessConditions	UTF8string	0..1	constraints limiting sensitivity level (e.g. authorization, confidentiality code)

Annex A
(normative)

ASN.1 data definitions

```
Links DEFINITIONS ::= BEGIN
-- AccessoryAttributes, CodingSchemesUsed, CodedData, RefPointer are defined in ISO 21549-2
IMPORTS AccessoryAttributes, CodingSchemesUsed, CodedData, RefPointer FROM CommonDataTypes;
Links ::= SET
{
    codingSchemesUsed   [0] CodingSchemesUsed   OPTIONAL,
    references          [1] References          OPTIONAL
}
References ::= SEQUENCE
{
    label               [0] UTF8String          OPTIONAL,
    language            [1] CodedData           OPTIONAL,
    use                 [2] SET OF CodedData    OPTIONAL,
    mediaType           [3] CodedData           OPTIONAL,
    reference           [4] SET OF URI          OPTIONAL,
    description         [5] UTF8String          OPTIONAL,
    useablePeriod       [6] SET OF TimeRange    OPTIONAL,
    sizeReferenced      [7] CodedData           OPTIONAL,
    purpose             [8] CodedData           OPTIONAL,
    accessConditions    [9] UTF8String          OPTIONAL,
    schemeReference     [10] RefPointer         OPTIONAL, -- This is a pointer to a coding scheme referenced
    accessoryAttributes [11] AccessoryAttributes OPTIONAL
}
```

```
TimeRange ::= SEQUENCE
{
    value                   [0] OCTET STRING,   -- This is a representation of time range
        operator                [1] ENUMERATED {
                                    intersect (0),  -- Form the intersection with the value
                                    exclude (1),   -- Form the set-difference with this value, i.e.,
                                        -- exclude this element or set from the resulting set
                                    convexHull (2),     -- Form the convex hull with the value. The convex hull
                                        -- is defined over ordered domains and is the smallest
                                        -- contiguous superset (interval) of all the operand sets
                                    include (3),    -- Form the union with this value, i.e., include this
                                        -- element or set in the resulting set
                                    periodicHull (4)-- Form the periodic hull with the value. The periodic
                                        -- hull is defined over ordered domains and is the periodic set
                                        -- that contains all contiguous supersets of pairs
                                        -- of intervals generated by the operand periodic intervals
                                }   OPTIONAL
}
URI ::= UTF8String              -- This is a URI representation
END
```