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Health informatics — Harmonized data types for information interchange

Informatique de santé — Types de données harmonisées pour une interchangeabilité d'informations

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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 21090 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Assistance from the Infrastructure and Messaging Committee in HL7 and the support of Connecting for Health have been instrumental in the preparation of this International Standard, which is a shared document between Health Level Seven (HL7) and ISO, and has been produced according the terms of the agreement between HL7, CEN and ISO (JIC, see http://www.global-e-health-standards.org/), which ensures that the content is fully available through ISO, CEN and HL7 publication channels.

Health informatics — Harmonized data types for information interchange

1 Scope

This International Standard

— provides a set of datatype definitions for representing and exchanging basic concepts that are commonly encountered in healthcare environments in support of information exchange in the healthcare environment;

— specifies a collection of healthcare-related datatypes suitable for use in a number of health-related information environments;

— declares the semantics of these datatypes using the terminology, notations and datatypes defined in ISO/IEC 11404, thus extending the set of datatypes defined in that standard;

— provides UML definitions of the same datatypes using the terminology, notation and types defined in Unified Modelling Language (UML) version 2.0;

— specifies an XML (Extensible Mark-up Language) based representation of the datatypes.

The requirements which underpin the scope reflect a mix of requirements gathered primarily from HL7 Version 3 and ISO/IEC 11404, and also from CEN/TS 14796, ISO 13606 (all parts) and past ISO work on healthcare datatypes.

This International Standard can offer a practical and useful contribution to the internal design of health information systems, but is primarily intended to be used when defining external interfaces or messages to support communication between them.

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/IEC 4217, *Codes for the representation of currencies and funds*

ISO/IEC 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO/IEC 8824 (all parts), *Information technology — Abstract Syntax Notation One (ASN.1)*

ISO/IEC 11404:2007, *Information technology — General-Purpose Datatypes (GPD)*

ISO/TS 22220, *Health Informatics — Identification of subjects of health care*

IETF RFC 1738, *Uniform Resource Locators (URL)*

IETF RFC 1950, *ZLIB Compressed Data Format Specification version 3.3*

IETF RFC 1951, *DEFLATE Compressed Data Format Specification version 1.3*

IETF RFC 1952, *GZIP file format specification version 4.3*

IETF RFC 2045, *Multipurpose Internet Mail Extensions (MIME) Part One: Format of Internet Message Bodies*

IETF RFC 2046, *Multipurpose Internet Mail Extensions (MIME) Part Two: Media Types*

IETF RFC 2396, *Uniform Resource Identifiers (URI): Generic Syntax*

IETF RFC 3066, *Tags for the Identification of Languages*

IETF RFC 3966, *The tel URI for Telephone Numbers*[1)]

FIPS PUB 180-1, *Secure Hash Standard*

FIPS PUB 180-2, *Secure Hash Standard*[2)]

Open Group, CDE 1.1, *Remote Procedure Call specification, Appendix A*

HL7 V3 Standard, *Data Types — Abstract Specification (R2)*

Regenstrief Institute, Inc. and the UCUM Organization, *The Unified Code for Units of Measure*[3)]

W3C Recommendation, *XML Signature Syntax and Processing*[4)]

3 Terms and definitions

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

3.1
attribute
characteristic of an object that is assigned a name and a type

NOTE The value of an attribute can change during the lifetime of the object.

3.2
class
descriptor for a set of objects with similar structure, behaviour and relationships

3.3
code
concept representation published by the author of a code system as part of the code system, being an entity of that code system

1) Revision of IETF RFC 2806.

2) Revision of FIPS PUB 180-1.

3) Regenstrief Institute, Inc. and the UCUM Organization, Indianapolis, Indiana, USA [viewed 2010-08-23]. Available from: http://aurora.regenstrief.org/ucum.

4) World Wide Web Consortium (W3C) [viewed 2010-08-23]. Available from: http://www.w3.org/TR/xmldsig-core/.

3.4
code system
managed collection of concept identifiers, usually codes, but sometimes more complex sets of rules and references

NOTE They are often described as collections of uniquely identifiable concepts with associated representations, designations, associations and meanings.

EXAMPLES ICD-9, LOINC and SNOMED

3.5
concept
unitary mental representation of a real or abstract thing; an atomic unit of thought

NOTE 1 It should be unique in a given code system.

NOTE 2 A concept can have synonyms in terms of representation and it can be a primitive or compositional term.

3.6
conformance
fulfillment of a specified requirement; adherence of an information processing entity to the requirements of one or more specific specifications or standards

3.7
datatype
set of distinct values, characterized by properties of those values, and by operations on those values

3.8
enumeration
datatype whose instances are a set of user-specified named enumeration literals

NOTE The literals have a relative order, but no algebra is defined on them.

3.9
generalization
taxonomic relationship between a more general class, interface or concept and a more specific class, interface or concept

NOTE 1 Each instance of the specific element is also an instance of the general element. Thus, the specific element has all the features of the more general element.

NOTE 2 The more specific element is fully consistent with the more general element and contains additional information.

NOTE 3 An instance of the more specific element can be used where the more general element is allowed.

3.10
information processing entity
anything that processes information and contains the concept of datatype, including other standards, specifications, data handling facilities and services

3.11
inheritance
mechanism by which more specific elements incorporate structure and behaviour of more general elements

3.12
interface
specifier for the externally-visible operations of class, without specification of internal structure

3.13
invariant
rule about the features of a class which must always be true

3.14
operation
service that an instance of the class may be requested to perform

NOTE An operation has a name and a list of arguments with assigned names and types, and returns a value of the type specified.

3.15
specialization
taxonomic relationship between a more general class, interface or concept and a more specific class, interface or concept where the more specific entity adds new features or redefines existing features by constraining their possible behaviours

3.16
string character set
character set used in all string content throughout this International Standard

3.17
valueSet
that which represents a uniquely identifiable set of valid concept representations, where any concept representation can be tested to determine whether or not it is a member of the value set

NOTE A concept representation can be a single concept code or a post-coordinated combination of codes.

4 Abbreviated terms

For the purposes of this document, the following abbreviated terms apply.

CEN Comité Européen de Normalisation (European Committee for Standardization)

CNE Coded no exceptions

CWE Coded with exceptions

GPD General-Purpose Datatypes

HL7 Health Level Seven, Inc.

IETF Internet Engineering Task Force

OID Object Identifier

OMG Object Management Group

UML Unified Modelling Language

W3C World Wide Web Consortium

XML Extensible Mark-up Language

5 Conformance

5.1 General

An information processing product, system, element or other entity may conform to this International Standard either directly, by utilizing datatypes specified in this International Standard in a conforming manner, or indirectly, by means of mappings between internal datatypes used by the entity and the datatypes specified in this International Standard.

NOTE The term "information processing entity" is used as defined in 3.10, which is consistent with how it is used in ISO/IEC 11404:2007, Clause 4. Specifically, this definition includes applications and also other standards and specifications.

5.2 Direct conformance

5.2.1 Direct conformance definition

An information processing entity which conforms directly to this International Standard shall:

a) specify which of the datatypes specified in Clause 7 are provided by the entity and which are not;

b) define the value spaces of the healthcare datatypes used by the entity to be identical to the value spaces specified by this International Standard;

c) specify to what extent the value spaces of the datatypes are constrained for use within its own context;

d) to the extent that the entity provides operations other than movement or translation of values, define operations on the healthcare datatypes which can be derived from, or are otherwise consistent with, the characterizing operations specified by this International Standard;

e) represent these datatypes using the Extensible Mark-up Language (XML) representation described herein, when the datatypes are represented in XML;

f) optionally, publish a formal conformance profile making these statements clear, or reference one published by some other information processing entity.

The above-mentioned requirements prohibit the use of a type-specifier defined in this International Standard to designate any other datatype (but, see 6.3 concerning the scope of the datatype names). They make no other limitation on the definition of additional datatypes in a conforming entity. For instance, a directly conforming information processing entity could continue to use ISO/IEC 11404 general-purpose datatypes in addition to these healthcare datatypes.

Requirement d) does not require all characterizing operations to be supported and permits the provision of additional operations. The intention is to permit the addition of semantic interpretation to the datatypes, as long as it does not conflict with the interpretations given in this International Standard. A conflict arises only when a given characterizing operation could not be implemented or would not be meaningful, given the entity provided operations on the datatype.

Examples of entities that could conform directly are language definitions or healthcare specifications whose datatypes, and the notation for them, are those defined herein. In addition, the verbatim support by a software tool or application package of the datatype syntax and definition facilities herein should not be precluded.

Information processing entities claiming direct conformance with this International Standard do not always need to use the datatypes defined in this International Standard to represent the concepts, i.e. simply because an address datatype is defined does not mean that the address datatypes must always be used for representing addresses. However, the type defined within this International Standard shall be used where the context is interoperability using these datatypes.

Information processing entities claiming direct conformance with this International Standard may further constrain the value domain of any of the datatypes within their context of use. The conformance statement shall make clear how constraints are applied within the information processing entity and how values that do not conform to the imposed constraints are handled.

Consistency of characterizing operations specified by conforming entities may be assessed by these criteria. Where operations have the same name as the operation defined within this International Standard, they are consistent if the operation can be invoked with the same parameters to return the same result. Other parameters may be defined, but shall have default values or be defined using additional definitions of operations with the same name but other parameter lists.

Information processing entities claiming direct conformance are not required to call any or all of the types defined in this International Standard "types". Other terms such as "data structures" may be used.

5.2.2 Conformance statements

When an information processing entity claims direct conformance with this International Standard, it should make a conformance statement.

It is anticipated that other standards bodies would make conformance statements with regard to this International Standard both in a general sense and in the sense of adopting these datatypes for a particular standard. In addition, it is anticipated that certain countries publish profiles of these datatypes on either an advisory or a normative basis. Finally, vendors and purchasers of healthcare applications may well find use in creating, sharing and publishing these conformance statements.

This International Standard makes no rules about either the form of the statement or how it is published, but it should be clearly and formally presented and made available to all interested parties associated with the scope of the information processing entity.

In addition to specifying that conformance statements shall contain formal statements pertaining to 5.2.1 a) to d), this International Standard makes additional rules about what they shall or should say or may choose to do.

5.2.2.1 Direct conformance statements shall:

a) define which character set and encoding applies; the default is Unicode (see 6.7.5);

b) *if* an alternative mechanism for providing history and audit data is provided, define how it maps to the history and audit information on datatypes (see 7.1.3);

c) make clear how attribute and collection cardinality are specified (see 7.1.5);

d) define how the attributes nullFlavor, updateMode and flavorId on ANY are managed (see 7.3.3);

e) *if* quantities are used, make clear exactly how and when the QTY attributes expression, originalText, uncertainty and uncertaintyType are used;

f) make clear what methods may be used to provide alternative definitions for discrete set uniqueness (see 7.9.3);

g) *if* the structured documents types are used, document the scope of the document context and clearly define how references within this document context are resolved (see 7.12);

h) specify to what degree the XML format is adopted and define the namespace that is used (see A.1).

5.2.2.2 Direct conformance statements should:

a) define defaulting rules for language (see 7.4.2.3.7);

b) declare what languages are supported in the QTY.expression property (see 7.8.2.3.1);

c) describe which codes may be used in QSC.code (see 7.10.8.3);

d) *if* the structured documents types are used, define how version tracking works in the contexts where it is used (see 7.12.12.2.1).

5.2.2.3 Direct conformance statements may also:

a) define additional datatype flavors or additional authorities for the definition of flavors (see 6.7.6);

b) make additional arrangements for the use of derived data and the DER NullFlavor (see 7.1.4);

c) define how the controlInformationRoot and controlInformationExtension properties on HXIT are used (see 7.3.2.3.4);

d) clarify how telecommunication and postal addresses are selected for particular purposes (see 7.6.2.3.2);

e) define the code systems to which different name and address part types are bound (see 7.7.3.6 and 7.7.5.6).

5.3 Indirect conformance

5.3.1 Indirect conformance definition

An information processing entity which conforms indirectly to this International Standard shall:

a) provide mappings between its internal datatypes and the healthcare datatypes conforming to the specifications of Clause 7;

b) specify for which of the datatypes in Clause 7 an inward mapping is provided, for which an outward mapping is provided and for which no mapping is provided;

c) specify whether the XML representation described in this International Standard is used when the datatypes are represented in XML, or whether it is used optionally to provide an alternative namespace for the XML representation;

d) optionally, publish a formal conformance profile making these statements clear or reference one published by some other information processing entity.

Examples of entities which could conform indirectly are healthcare specifications, applications, software engineering tools and other interface specifications, and many other entities that have a concept of datatype and an existing notation for it.

Standards for existing healthcare specifications yet to be proposed as International Standards are expected to provide for indirect conformance rather than direct conformance.

Information processing entities claiming indirect conformance with this International Standard do not always need to use the datatypes defined in this International Standard to represent the concepts, i.e. simply because an address datatype is defined does not mean that the address datatypes must always be used for representing addresses. However the type defined within this International Standard shall be used where the context is interoperability using these datatypes.

Information processing entities claiming indirect conformance with this International Standard may further constrain the value domain of any of the datatypes within their context of use. The conformance statement must make clear how constraints are applied within the information processing entity and how values that do not conform to the imposed constraints are handled.

Information processing entities claiming indirect conformance are not required to call any or all of the types defined in this International Standard "types". Other terms, such as "data structures" may be used.

5.3.2 Conformance statements

When an information processing entity claims indirect conformance with this International Standard, it should make a conformance statement.

This International Standard makes no rules about either the form of the statement or how it is published, but it should be made available to all interested parties associated with the scope of the information processing entity.

In addition to specifying that conformance statements shall contain formal statements pertaining to 5.3.1 a) to d), this International Standard makes additional rules about what they shall or should say or may choose to do.

5.3.2.1 Indirect conformance statements shall:

a) define which character set and encoding applies; the default is Unicode (see 6.7.5);

b) make clear what equality definitions apply and how (see 7.1.2);

c) make clear how attribute and collection cardinality are specified, if relevant (see 7.1.5);

d) *if* the structured documents types are used, document the scope of the document context and clearly define how references within this document context are resolved (see 7.12).

5.3.2.2 Indirect conformance statements should:

a) define defaulting rules for language (see 7.4.2.3.7);

b) if any exist, declare the mapping between W3C digital signature and alternate implementations (see 7.4.5.1).

5.3.2.3 Indirect conformance statements may also:

a) define additional datatype flavors or additional authorities for the definition of flavors (see 6.7.6);

b) make additional arrangements for the use of derived data and the DER NullFlavor (see 7.1.4);

c) define how the controlInformationRoot and controlInformationExtension properties on HXIT are used (see 7.3.2.3.4);

d) clarify how telecommunication and postal addresses are selected for particular purposes (see 7.6.2.3.2);

e) define the code systems to which different name and address part types are bound (see 7.7.3.6 and 7.7.5.6);

f) declare what languages are supported in the QTY.expression property (see 7.8.2.3.1);

g) describe which codes may be used in QSC.code (see 7.10.8.3);

h) *if* the structured documents types are used, define how version tracking works in the contexts where it is used (see 7.12.12.2.1).

6 Datatypes overview

6.1 What is a datatype?

In ISO/IEC 11404, a "datatype" is defined as a set of distinct values, characterized by properties of those values, and by operations on those values (ISO/IEC 11404:2007, 3.12).

A datatype consists of three main features:

— a value space;

— a set of properties;

— a set of characterizing operations.

Generally, the definitions of the scope of datatypes revolve around one or other of the following notions.

— Immutability (the properties of the datatype cannot change, instead a new instance is created: datatypes have no lifecycle).

— The relationship between equality and identity (if two datatypes are equal they are the same instance).

— Coherency of a single concept (each datatype should represent a single concept space).

Since the application of these concepts to the healthcare information domain and the implications of these for the scope of datatypes are inherently a matter of perspective, the selection criterion for the datatypes defined in this International Standard is based on the set that has emerged from the debates held within the various stakeholder standardization bodies that define healthcare information standards. Since healthcare information standards and specifications are expected to provide mappings to this International Standard, the process has been deliberately inclusive. These other standards may choose to represent these datatypes with other more complex structures, but should explain how to interconvert these structures with the datatypes defined herein.

6.2 Definitions of datatypes

This International Standard defines a set of named datatypes. Each datatype defined in this International Standard is allocated both a short name and a long name. The formal name of the datatype is the short name. Each datatype is defined in two different ways:

— in terms of the datatype specification language and types defined in ISO/IEC 11404;

— in UML, using primitive types taken from the UML kernel package.

The ISO/IEC 11404 definition is provided to ensure continuity between this International Standard and the ISO/IEC 11404 GPDs, while the UML definition is provided to foster software-driven implementation of these datatypes. The ISO/IEC 11404 definitions are semantic and abstract in nature, while the UML definitions are concrete structural definitions. This International Standard is focused on providing structural concrete definitions, such that the UML definitions take precedence over the ISO/IEC 11404-based definitions, which are provided in the interests of continuity with ISO/IEC 11404.

The datatypes defined in this International Standard are an implementation of the HL7 V3 Abstract Data Types (R2). What this means is that it is possible to implement the exchange of information based on the HL7 V3 Abstract Data Type definitions using the datatypes defined in this International Standard. Annex B demonstrates how these datatypes are implementations of the HL7 V3 Abstract Data Types (R2).

The datatypes defined in this International Standard are not restricted to the features described by the HL7 V3 Abstract Data Types, nor is the HL7 V3 Data Types Abstract specification required in order to make use of these datatypes. The semantic definitions in the HL7 V3 Abstract Data Types may be consulted for further useful information to help implementors understand the use of these datatypes.