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Health informatics – Electronic health record communication

Part 3: Reference archetypes and term lists (ISO 13606-3:2019)

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 13606-3:2019. It supersedes BS EN 13606-3:2008, which is withdrawn.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 13606-3:2019) 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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13606-3:2008.

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Endorsement notice

The text of ISO 13606-3:2019 has been approved by CEN as EN ISO 13606-3:2019 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*.

This second edition cancels and replaces the first edition (ISO 13606-3:2009), which has been technically revised. The main changes compared to the previous edition are summarised in the Introduction.

A list of all parts in the ISO 13606 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

This document is part of a five-part series of standards, published jointly by CEN and ISO through the Vienna Agreement. In this document, dependency upon any of the other parts of this series of standards is explicitly stated where it applies.

0.2 Preface

ISO 13606-3 defines two kinds of specifications.

1) A normative set of (coded) term lists that each defines a controlled vocabulary for a Reference Model attribute that is defined in ISO 13606-1;

2) A set of Reference Archetypes that specify how the ISO 13606-1 Reference Model should be applied for communicating information for:

   — null_flavor;

   — access policies;

   — demographic entities;

   — example clinical reference archetypes, conforming to ISO 13940 (Contsys).

0.3 Term Lists

Each term list is referenced by its corresponding attribute as an invariant constraint in ISO 13606-1, by referring to its term list name. For each term list, every code value is accompanied by a phrase and description; however, in each case it is the code that is used as the Reference Model attribute value. Language translations of the phrase and description will therefore not affect the instances of RECORD_COMPONENT that are communicated using this document.

Should any revision prove necessary in the future to these term lists, a technical revision to this document will be required. Such a revised document should specify an updated Reference Model identifier that should then be used as the value of the rm_id of an EHR_EXTRACT, to inform the recipient of the version of this document that was used in its creation.

0.4 Reference archetypes

An archetype, sometimes known as a clinical model, specifies a pattern for representing an aspect of clinical documentation within an electronic health record. An archetype defines the structural and semantic relationships between fine-grained data items, including the domains of content each data item may contain in order to be a valid component of that archetype. The concept of archetypes is outlined in the introduction of ISO 13606-1, and the formal representation of archetypes is specified in ISO 13606-2. Archetypes are used in this document to shape parts of an EHR extract, in order to provide predictability of the way in which clinical information is represented within it.

Given the vast domain of health and healthcare, there might eventually be hundreds of archetypes covering its many different documentation and communication needs. Because archetypes might be created by different communities in different countries and settings, there is a risk that archetypes for similar areas of documentation will be made differently by different groups, and therefore hamper interoperability. *Reference archetypes* are archetypes that represent very fundamental areas of clinical documentation, which might be used as they are or may serve as a kind of *base pattern* for more specialised archetypes. By acting as the base pattern for a set of specialised archetypes, the members of the set are likely to be better structurally and semantically aligned with each other. Their use will facilitate semantic interoperability by making it easier for EHR extracts that have used different members of that set to be interpreted collectively.

A reference archetype is a starting point for archetype specialisation (using a sub-set of properties and/or constraints on the ELEMENT value domains), or localised by adding natural language or local terminology mappings, or may be extended with additional properties. In all such cases the reference archetype should be specified as the underlying "specialisation parent", in accordance with ISO 13606-2. Some reference archetypes may be implemented directly. A reference archetype is therefore a conventional archetype that has been designated as a recommended (informative) or mandated (normative) basis for developing commonly required archetypes.

This document defines several categories of reference archetypes, some of which have been designated as normative and others informative. The decision of which to make normative is based on the information source used to create each reference archetype: if the underlying source is itself part of this document or is required to implement it then it has been designated as normative. If it is an external source such as another standard, which might be revised at a different time point to this document, then the reference archetype has been made informative.

In this document, a normative null_flavor reference archetype is defined to be used for the corresponding property in ISO 13606-1. A normative access policy rule reference archetype is specified in accordance with the corresponding information model for an access policy rule specified in ISO 13606-4. Informative reference archetypes are defined for the most frequently needed demographic entities. An informative archetype is specified for medicinal product, which has been defined in accordance with the ISO IDMP standard series.

The examples of clinical reference archetypes presented in Clause 11 are based on the clinical reference information structures in Clause 12. The clinical reference information structures in Clause 12 are developed out from the clinical concepts as they are defined in ISO 13940:2015 (Contsys).

Each selected clinical concept in Contsys has been elaborated based on the definition, relations and explanations in notes given in ISO 13940. The attributes of the clinical reference information structures are thus mainly based on ISO 13940. Some further attributes are added to harmonize the structures with e.g. FHIR resources or openEHR.

The result is information structures representing basic clinical concepts including a gross list of attributes for each concept. The gross list is intended to be comprehensive and cover all needs for clinical information in different specializations and applications. This approach reflects the general idea to include all needed types of characteristics/attributes and constrain the number applied when specializing clinical archetypes for instantiation.

The level of granularity/abstraction of the classes/selected concepts in the clinical reference information structures in Clause 12 and in the examples of clinical reference archetypes in Clause 11 is explained by the purpose of being general at the conceptual level for all clinical situations where information about this type of concept is relevant (content as well as context) but still specific for that clinical concept.

One example of the chosen level of abstraction is healthcare activity element as the concretized specialization of healthcare activity with a specific purpose (e.g. investigation or treatment). Another example could be that the method of performing activity elements are specified at a general level common for surgical treatments, pharmacological treatments (including administration routes) and laboratory tests as investigations.

Clause 12 includes clinical reference information models, conformant to ISO 13940(Contsys), to be used as bases for specifying clinical reference archetypes. These are aimed for further specializations as clinical archetypes in an EHR. The clinical reference information models are also aimed for further use as a basis for harmonizing between coexisting standards for specifying clinical content. A future possibility could be to develop FHIR resources based on these reference models. Another possibility for future development is that CIMI archetypes could accept the same bases as a "middle layer" between their reference model and specific archetypes. Altogether such approaches could result in harmonization of the different information specification standards/approaches to the common conceptual basis of Contsys. These resources are offered in an informative Clause to indicate the direction of ongoing work to develop a portfolio of Reference Archetypes that align with Contsys and with corresponding FHIR resources, but which are not yet mature enough to include here as normative specifications.

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Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

1 Scope

This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository.

It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This document defines term lists that each specify the set of values for the particular attributes of the Reference Model defined in ISO 13606-1. It also defines normative and informative Reference Archetypes that enable frequently-occurring instances of EHR data to be represented within a consistent structure when communicated using this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 13606-1, *Health informatics — Electronic health record communication — Part 1: Reference model*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13606-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
healthcare activity
activity intended directly or indirectly to improve or maintain a health state

Note 1 to entry: Each specialization of this concept represents *healthcare activities* performed by a specialization of *healthcare actor*.

Note 2 to entry: Different types of *healthcare activity elements* (e.g. *healthcare investigation* or *healthcare treatment)* may be performed during a *healthcare activity*.

Note 3 to entry: See the *concepts healthcare provider activity*, *self-care activity*, *healthcare third party activity* and *automated healthcare* when it comes to the recording of *information* that are the result of *healthcare activities* (e.g. ratified observations).