BS EN ISO 13606-2:2019

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BSI Standards Publication

Health informatics - Electronic health record communication

Part 2: Archetype interchange specification

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National foreword

This British Standard is the UK implementation of EN ISO 13606-2:2019. It supersedes BS EN 13606-2:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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EN ISO 13606-2

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English Version

Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (ISO 13606-2:2019)

Informatique de santé - Communication du dossier de santé informatisé - Partie 2: Spécification d'échange d'archétype (ISO 13606-2:2019)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 2: Spezifikation für den Austausch von Archetypen (ISO 13606-2:2019)

This European Standard was approved by CEN on 2 July 2019.

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European foreword

This document (EN ISO 13606-2:2019) 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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.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 13606-2:2007.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13606-2:2019 has been approved by CEN as EN ISO 13606-2:2019 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).

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

For an explanation of 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 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 13606-2:2008), which has been technically revised. The main changes compared to the previous edition are as follows:

— Introduction of new internal coding scheme, consisting of id-codes, at-codes and ac-codes.

— Replace string archetype identifier with multi-part, namespace identifier.

— Addition of explicit value-sets replacing in-line value sets in the terms and definitions.

— Renaming archetype ontology section to terminology.

— Expression of all external term bindings as URIs following IHTSDO format.

— Introduction of ‘tuple’ constraints for co-varying attributes within Quantity, Ordinal structures.

— Re-engineering of all primitive constrainer types, i.e. C_STRING, C_DATE etc.

— Removal of the Archetype Profile specification.

— Full specialisation support: the addition of an attribute to the C_ATTRIBUTE class, allowing the inclusion of a path that enables specialised archetype redefinitions deep within a structure.

— Addition of node-level annotations.

— Structural simplification of archetype ontology section.

— The name of the invariant section has been changed to rules, to better reflect its purpose.

— A template is now just an archetype.

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

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Introduction

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

Comprehensive, multi-enterprise and longitudinal electronic health records will often in practice be achieved through the joining up of multiple clinical applications, databases (and increasingly devices) that are each tailored to the needs of individual conditions, specialties or enterprises.

This requires that Electronic Health Record (EHR) data from diverse systems be capable of being mapped to and from a single comprehensive representation, which is used to underpin interfaces and messages within a distributed network (federation) of EHR systems and services. This common representation has to be sufficiently generic and rich to represent any conceivable health record data, comprising part or all of an EHR (or a set of EHRs) being communicated.

The approach adopted in the ISO 13606 standards series, underpinned by international research on the EHR, has been to define a rigorous and generic Reference Model that is suitable for all kinds of data and data structures within an EHR, and in which all labelling and context information is an integral part of each construct. An EHR Extract (as defined in ISO 13606-1) will contain all of the names, structure and context required for it to be interpreted faithfully on receipt even if its organisation and the nature of the clinical content have not been “agreed” in advance.

However, the wide-scale sharing of health records, and their meaningful analysis across distributed sites, also requires that a consistent approach is used for the clinical (semantic) data structures that will be communicated via the Reference Model, so that equivalent clinical information is represented consistently. This is necessary in order for clinical applications and analysis tools safely to process EHR data that have come from heterogeneous sources.

0.1 Archetypes

The challenge for EHR interoperability is therefore to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates etc. required by different health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this standard series distinguishes a Reference Model, used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality or service.

The Reference Model is specified as an Open Distributed Processing (ODP) Information Viewpoint model, representing the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. In the 13606 standards series, the Reference Model is defined in Part 1. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this standard series).

Archetypes are effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure semantic interoperability, data consistency and data quality.

For an EHR_EXTRACT, as defined in ISO 13606-1, an archetype specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the datatypes and value ranges that ELEMENT data values can take, and might include other dependency constraints. Archetype instances themselves conform to a formal model, known as an Archetype Model

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(which is a constraint model, also specified as an ODP Information Viewpoint Model). Although the Archetype Model is stable, individual archetype instances can be revised or succeeded by others as clinical practice evolves. Version control ensures that new revisions do not invalidate data created with previous revisions.

Archetypes can be used within EHR systems to govern the EHR data committed to a repository. However, for the purposes of this interoperability standard series, no assumption is made about the use of archetypes within the EHR Provider system whenever this standard series is used for EHR communication. It is assumed that the original EHR data, if not already archetyped, can be mapped to a set of archetypes, if desired, when generating the EHR_EXTRACT.

The reference model defined in ISO 13606-1 has a property that can be used to specify the archetype to which any RECORD_COMPONENT within an EHR_EXTRACT conforms. The class RECORD_COMPONENT includes an attribute *archetype_id* to identify the archetype and node to which that RECORD_COMPONENT conforms.

Part 3 of this standard series includes a set of Reference Archetypes: which are base archetypes that are likely to be specialised further before they are used. Those archetypes are example instances of this Archetype Model.

The Archetype Model specified in this document was originally developed by the openEHR Foundation, which publishes its archetypes using Archetype Definition Language, conforming to this Archetype Model, referenced within Annex A. The Archetype Model has been the subject of collaborative updating to incorporate the requirements and modelling inputs from the Clinical Information Modeling Initiative (CIMI). CIMI is in the process of submitting a modelling language (Archetype Modeling Language, AML) to the Object Management Group. AML also aligns to this Archetype Model.

0.2 Archetype datatypes

It should be noted that ISO 13606-1 and ISO 13606-2 use datatypes for different purposes.

Part 1 defines datatypes to represent the properties of the Reference Model, as a profile of ISO 21090, in 5.3. It separately defines in Clause 7 the data types that can be the values of Element, also a subset of ISO 21090. All these datatypes are finally expressed in terms of the so-called “primitive” datatypes (Integer, Real, String, Boolean, Date/Time/Datetime).

Part 2 uses the same set of primitive datatypes to represent the properties of the Archetype Object Model. Additionally, Part 2 defines a set of classes that allow defining constraints over primitive datatypes of Part 1. These constraining classes are shown in Figure 9 of Part 2, as descendants of the C_PRIMITIVE_OBJECT class.

A single Part 1 complex datatype (e.g. PHYSICAL_QUANTITY) can be constrained by a combination of the constraining classes of the Archetype Object Model, defining constraints on both the complex and primitive datatypes it contains. Thus, Part 1 complex datatypes are treated as classes when defining constraints with Part 2, while Part 1 primitive data types are constrained by the C_PRIMITIVE_OBJECT hierarchy.

An example of a PHYSICAL_QUANTITY archetype can be seen in the example below. In this example, the value on a PHYSICAL_QUANTITY shall be between 0.0 and 1000.0 and their units shall be UCUM ‘mm[Hg]’ code.

```
PHYSICAL_QUANTITY matches {
        value matches {|0.0..<1000.0|}
        units matches {
            CODED_SIMPLE matches {
                        value matches {"mm[Hg]"}
```

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```
            }
        }
    }
```

This example archetype, expressed in terms of the Archetype Object Model, would have the structure shown in Table 1.

Table 1 — Example structure for representing physical quantity

Reference Model class, attribute or primitive value	**Archetype Model constraining class**
PHYSICAL_QUANTITY	C_COMPLEX_OBJECT
value	C_ATTRIBUTE
Real	C_REAL
units	C_ATTRIBUTE
CODED_SIMPLE	C_COMPLEX_OBJECT
value	C_ATTRIBUTE
String	C_STRING

Since the Archetype Object Model is also used to constrain other reference models, as for example the openEHR Reference Model, there will be a need to transform openEHR archetypes to ISO 13606 archetypes, and vice versa. The openEHR Reference Model also uses the same primitive datatypes, but includes a different set of complex datatypes, such as DV_ORDINAL, or DV_TEXT[1]. When transforming an openEHR archetype constraint to an ISO 13606 archetype, it might be necessary to introduce an additional CLUSTER structure to represent the equivalent openEHR sub-components as ELEMENTs.

For example, a representation of an openEHR DV_ORDINAL in ISO 13606 would have the structure shown in Table 2.

Table 2 — Example structure for representing an ordinal data value

openEHR	**ISO 13606**
DV_ORDINAL	CLUSTER matches { -- DV_ORDINAL
	parts matches {
symbol	ELEMENT matches { -- symbol
	value matches {
DV_CODED_TEXT	CODED_VALUE matches {*}
	}
	}
value	ELEMENT matches { -- value
	value matches {
Integer	INTEGER matches {*}
	}
	}
	}
	}

An example of how the LINK class defined in Part 1 of this standard series can be represented using the Archetype Object Model defined in this document is given in Annex B.

1) Please see http://www.openehr.org/releases/RM/latest/docs/data_types/data_types.html#_text_package for the specification of this datatype.

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0.3 Archetype repositories

The range of archetypes required within a shared EHR community will depend upon its range of clinical activities. The total set needed on a national basis is presently unknown, but there might eventually be several thousand archetypes globally. The ideal sources of knowledge for developing such archetype definitions will be clinical guidelines, care pathways, scientific publications and other embodiments of best practice. However, "de facto" sources of agreed clinical data structures might also include:

— the data schemata (models) of existing clinical systems;

— the lay-out of computer screen forms used by these systems for data entry and for the display of analyses performed;

— data-entry templates, pop-up lists and look-up tables used by these systems;

— shared-care data sets, messages and reports used locally and nationally;

— the structure of forms used for the documentation of clinical consultations or summaries within paper records;

— health information used in secondary data collections;

— the pre-coordinated terms in terminology systems.

Despite this list of *de facto* ways in which clinical data structures are currently represented, these formats are very rarely interoperable without substantial costs. The use of standardised archetypes provides an interoperable way of representing and sharing these specifications, in support of consistent (good quality) health care record-keeping and the semantic interoperability of shared EHRs.

The involvement of national health services, academic organisations and professional bodies in the development of archetypes will enable this approach to contribute to the pursuit of quality evidence-based clinical practice. A key next challenge is to foster communities to build up libraries of archetypes. It is beyond the scope of this document to assert how this work should be advanced, but in several countries so far it would appear that national eHealth programmes are beginning to organise clinical-informatics-vendor teams to develop and operationalise sets of archetypes to meet the needs of specific healthcare domains. In the future regional or national public domain libraries of archetype definitions might be accessed via the Internet, and downloaded for local use within EHR systems. Such usage will also require processes to verify and certify the quality of shared archetypes, which are also beyond the scope of this document but are being taken forward by not for profit organisations such as the open EHR Foundation (www.openehr.org), the Clinical Information Modeling Initiative (CIMI, http://www.opencimi.org) the EN13606 Association (http://www.en13606.org) and the European Institute for Innovation through Health Data (www.i-hd.eu).

0.4 Communicating archetypes

This document specifies, in Clause 6, the requirements for a comprehensive and interoperable archetype representation and defines, in Clause 7, the ODP Information Viewpoint representation for the Archetype Object Model.

This document does not require that any particular model be adopted as the internal architecture of archetype repositories, services or components used to author, store or deploy archetypes in collaboration with EHR services. It does require that these archetypes are capable of being mapped to the Archetype Object Model defined in this document in order to support EHR communication and interoperability within an EHR-sharing community.

A more detailed overview of archetypes can be found here:

http://www.openehr.org/releases/AM/latest/docs/Overview/Overview.html

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Health informatics — Electronic health record communication —

Part 2: Archetype interchange specification

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) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This document will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymization or aggregation of individual records, are not the focus of this standard series but such secondary uses might also find it useful.

This document defines an Archetype Model to be used to represent Archetypes when communicated between repositories, and between archetype services. It defines an optional serialised representation, which may be used as an exchange format for communicating individual archetypes. Such communication might, for example, be between archetype libraries or between an archetype service and an EHR persistence or validation service.

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 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

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

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/

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