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Health informatics — Electronic health record communication —

Part 2: Archetype interchange specification

Informatique de santé — Communication du dossier de santé informatisé —

Partie 2: Spécification d'échange d'archétype

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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 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.

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

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

(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]"}
```

```
            }
        }
    }
```

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.

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

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/

3.1
archetype repository
persistent repository of archetype definitions, accessed by a client authoring tool or by a run-time component within an electronic health record service

3.2
concept
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000]

Note 1 to entry: Concepts are not necessarily bound to particular languages. They are, however, influenced by the social or cultural background often leading to different categorizations.

3.3
operational template
template in which all references have been substituted by the corresponding structure

3.4
template
archetype defining a particular document or message intended for specific use cases

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

ADL	Archetype Definition Language
AOM	Archetype Object Model (synonym for Archetype Model)
CIMI	Clinical Information Modelling Initiative
EHR	Electronic Health Record
ODP	Open Distributed Processing (ISO/IEC 10746 series, used for describing distributed systems)
OWL	Ontology Web Language
RM	Reference Model e.g. the ISO 13606 Part 1 Reference Model
UML	Unified Modelling Language
XML	Extensible Mark-up Language

5 Conformance

The communication of an archetype that is used to constrain part of an EHR_EXTRACT shall conform to the information model defined in Clause 7. Conformance to the functions defined for each class in Clause 7, where specified, is optional. This document does not prescribe any particular representation of archetypes to be used internally within an archetype repository, server or EHR system. The representation of archetypes shall meet the requirements listed in Clause 6.

6 Archetype representation requirements

6.1 General

This clause lists a set of formal requirements for an archetype representation. This provides the basis on which the archetype model specified in 7.2 has been designed.

6.2 Archetype definition, description and publication information

6.2.1 The definition of an archetype shall include the following information.

6.2.1.1 The globally-unique identifier of this archetype definition.

6.2.1.2 The identifier of the repository in which this archetype originated or is now primarily held, or of the authority responsible for maintaining it. This repository shall be the one in which the definitive publication status of this archetype will be managed.

6.2.1.3 The concept that best defines the overall clinical scope of instances conforming to this archetype as a whole, expressed as a coded term or as free text in a given natural language.

6.2.1.4 The health informatics domain to which this archetype applies (e.g. EHR). This shall map to a set of reference models with which this archetype may be used.

6.2.1.5 The underlying reference model for which this archetype was ideally fashioned.

NOTE An archetype can be capable of use with more than one relevant reference model within a given health informatics domain, but it is expected that the archetype will be optimised for one.

6.2.1.6 The natural language in which this archetype was originally defined, represented by its ISO 639-code. In the event of imprecise translations, this is the definitive language for interpretation of the archetype.

6.2.2 The definition of an archetype may include the following information, if applicable.

6.2.2.1 The globally-unique identifier for the archetype of which this archetype is a specialisation and to which it shall also conform.

6.2.2.2 The globally-unique identifier of the former archetype that this definition replaces, if it not the first version of an archetype.

6.2.2.3 The reason for defining this new version of a pre-existing archetype.

6.2.2.4 The identifier of the replacement for this archetype, if it has been superseded.

NOTE It is possible that this information can only be added by reference within a version-controlled repository; how this is effected is not in scope for this document.

6.2.2.5 An archetype shall have one or more description sets, defining its usage and purpose. Multiple versions of this information may be included, represented in different natural languages or to inform different kinds of potential user.

6.2.3 An archetype description set shall include the following information.

6.2.3.1 The uniquely-identified person or organisation responsible for providing this description set. This may include contact information for that person or organisation.

6.2.3.2 The uniquely-identified person or organisation responsible for defining the archetype hierarchy itself. This may include contact information for that person or organisation.

6.2.3.3 The natural language in which this description set is provided, represented by its ISO 639-code.

6.2.3.4 A formal statement defining the scope and purpose of this archetype, expressed as a coded term or as free text in a given natural language.

NOTE These criteria can be expressed as coded terms to improve queries for relevant archetypes from the repository.

EXAMPLE The scope and purpose can specify:

1) the principal clinical specialty or kinds of user for which it is intended;

2) A list of clinical terms (keywords): diagnoses, acts, drugs, findings etc.;

3) the kind of patient in whom it is intended to be used (age, gender, etc.);

4) the kind of demographic entities it is intended to represent.

6.2.4 An archetype description set may include the following information, if applicable.

6.2.4.1 A formal statement of the intended use of this archetype.

NOTE Ideally this can be a coded expression, although a suitable terminology for this is not yet available.

6.2.4.2 A formal statement of situations in which users might erroneously believe this archetype should be used. This may also stipulate any kinds of Reference Model for which it is unsuitable.

6.2.4.3 A detailed explanation of the purpose of this archetype, including any features of particular interest or note. This may include an indication of the persons for which this definition is intended e.g. for students. This information might be included explicitly, and/or by reference (e.g. via a URL).

6.2.4.4 A description, reference or link to the published medical knowledge that has underpinned the definition of this archetype.

6.2.4.5 Information about evidence that has informed its development, e.g. an existing specification or standard, published knowledge or clinical experience.

6.2.4.6 How the archetype may be used in quality healthcare delivery.

6.2.4.7 The care processes it has been designed to support.

6.2.4.8 Information about which organisations, professional bodies or government bodies have endorsed the model, when this endorsement occurred, and under which criteria.

6.2.5 An archetype definition shall include a statement of its publication status.

6.2.5.1 An archetype definition may evolve through a series of publication states, for example an approval process, without otherwise being changed. These successive states shall be retained as part of

the archetype, for audit purposes. However, the modification of the publication status of an archetype shall not itself constitute a formal revision of the identifier by which the archetype is referenced within an EHR_EXTRACT, since the constraint specification will not have been changed.

6.2.6 The publication status of an archetype shall specify the following information.

6.2.6.1 The publication status of this archetype, taken from the following list:

— Test;

— In development;

— Release candidate;

— Rejected;

— Definitive;

— Deprecated.

6.2.6.2 The date when this particular publication status applied

NOTE The first instance of a publication status for this archetype will also be the date when it was first composed.

6.2.6.3 The unique identifier of the person committing this archetype to the repository and thereby asserting this publication status. This identification might optionally include the organisation which that person represents.

6.2.6.4 The unique identifier of the body authorising this change in publication status.

6.2.6.5 The date when it is anticipated that the present publication status, and the archetype content itself, ought to be reviewed to confirm it remains valid.

6.2.6.6 The unique identifier of the person or organisation that is nominated, authorised or has accepted responsibility for reviewing the validity of the archetype and optionally for updating it, when appropriate.

6.2.6.7 A clear statement of any copyright or licensing restrictions which apply to the use of the archetype.

6.2.6.8 The copyright holder and/or governing authority.

6.2.7 Version management.

6.2.7.1 An archetype definition shall indicate the version of the constraints it specifies.

6.2.7.2 An archetype definition may indicate the person or organization responsible for that version.

6.2.7.3 An archetype definition may indicate the date on which the current version was created.

6.2.7.4 The archetype version identifiers or other properties may indicate the nature of changes made from the previous version, and in particular if EHR instances communicated with the current and the previous version are compatible with each other.