BS EN ISO 13606-2:2019

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 It supersedes BS EN 13606-2:2007, which is withdrawn.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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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)

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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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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Endorsement notice

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Foreword

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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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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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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.

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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.

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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

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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.

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6.3 Archetype node constraints

6.3.1 General

An archetype definition shall include a specification of the hierarchical schema to which instances of data (e.g. EHR data) shall conform. This schema defines the hierarchical organisation of a set of nodes, the relationships between them, and constraints on the permitted values of attributes and data values. These shall also conform to the underlying reference model(s) for which this definition is applicable.

6.3.2 Archetype node references

6.3.2.1 Any node in the archetype hierarchy might be defined explicitly or, by reference, be specified to be part or whole of a pre-existing archetype.

6.3.2.2 A reference to a pre-existing archetype or archetype fragment may be explicit, by specifying the archetype identifier, and optionally the identifier of the node of the archetype fragment.

6.3.2.3 A reference to an archetype fragment may be internal to (i.e. part of) the current archetype.

6.3.2.4 An archetype node may be specified to be one of a set of possible archetypes, by defining an explicit list of candidates and/or by specifying a set of constraints on any of the attributes of an archetype definition.

6.3.2.5 In addition to specifying one or more archetype fragments by reference or constraint, it shall be possible to include an explanation of the rationale for incorporating that specification at the given point in the current archetype hierarchy.

6.3.3 The specification of an archetype node (if not by reference) shall include the following information.

6.3.3.1 A unique identifier of this archetype node. Either in itself or when combined with the globally-unique identifier of this archetype definition, it shall be a globally unique reference to the node itself.

6.3.3.2 The class in the EHR instance hierarchy, mapping to the underlying reference model that this archetype constrains, that shall be instantiated in order to conform to this archetype node.

6.3.3.3 The number of occurrences, expressed as a range that may be instantiated corresponding to this archetype node within an instance hierarchy.

6.3.3.4 Other constraints and rules may optionally be specified to govern the creation of instances corresponding to this archetype node.

6.3.3.5 Constraint rules may be expressed as logical conditions, and may include reference to environment parameters such as the current time or location or participants, or be related to the (pre-existing) values other nodes in the instance hierarchy. Constraint rules may be used to represent the relationship between EHR data and workflow or care pathway processes.

6.3.3.6 Constraint rules may be expressed as inclusion or exclusion criteria.

6.3.3.7 An archetype shall identify the formalism (including version) in which constraint rules are expressed (e.g. ADL, OWL).

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6.3.4 Binding archetype nodes to terms

6.3.4.1 Every node of an archetype schema hierarchy shall be associated with at least one term, which most accurately expresses the intended concept to be represented by that node on instantiation in the corresponding instance hierarchy. This term can usually be included or referenced within the instance.

6.3.4.2 Every node of an archetype schema hierarchy may additionally be associated with a description that elaborates on the meaning given by the term labelling that node.

6.3.4.3 Any node of an archetype may be mapped to any number of additional concepts, terms and synonyms from terminology systems, to support either the interrogation of the archetype repository or of the corresponding instances.

6.3.4.4 Any concept mapping term or text shall specify the purpose that this mapping serves, using one of the following list of values:

— Principal concept;

— Term binding;

— Synonym;

— Language translation.

6.3.4.5 Any reference to a coded term shall include the code, rubric, and identify the coding system (including version) from which the code and rubric have been taken. In addition, it shall be possible to specify the natural language in which this term was mapped, or in which a translation is expressed.

6.3.4.6 The meaning of every node in an archetype should be defined through a binding to the appropriate concept identifier from an appropriate concept model.

6.3.4.7 The meaning of any specified link between two or more nodes in an archetype may be defined through a binding to the appropriate concept identifier from an appropriate concept model.

6.3.5 Attribute and association constraints

6.3.5.1 An archetype node may specify constraints on any attributes or associations that correspond to the attributes and associations of that node in the underlying reference model.

NOTE These constraints can pre-determine or restrict some or all of the contextual information that is included within the corresponding instance, as represented within the reference model. Context information, such as the person to whom a particular observation or inference relates, is formally-represented in most generic EHR-like models to facilitate safe querying and retrieval, even if that information can be inferred from the archetype name or an axis within a terminology system used for the data value. Some archetypes or fragments will pre-determine the values of some of these, which shall be capable of specification within the archetype definition (for example, to constrain the subject of information to be a relative of the patient, and not the patient, in an archetype for family history).

6.3.6 For any given reference model property it shall be possible to specify the following information.

6.3.6.1 The name of the attribute or association, mapping to the underlying reference model for which this archetype was ideally fashioned, to which this constraint applies.

6.3.6.2 For a given reference model, if an attribute or association corresponding to this aspect of context is mandatory to be included within a valid EHR instance.

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6.3.6.3 The number of instances (expressed as a range) corresponding to this aspect of context that may be instantiated.

6.3.6.4 If multiple instances are permitted, it shall be possible to specify if these are to be represented as an ordered or unordered list.

6.3.6.5 If multiple instances are permitted, it shall be possible to specify if the corresponding data values (of leaf nodes or attributes) shall be unique.

6.3.6.6 Constraints may be specified for the data values of leaf nodes or leaf attributes.

6.3.6.7 It shall be possible to specify if instances conforming to an archetype shall include one or more optional or mandatory LINKs, where the value of the *role* attribute is to be one of a specified set of codes, and where the *target* attribute should refer to an instance of a RECORD_COMPONENT based on an archetype that is one of a specified set of archetypes.

6.3.6.8 It shall be possible to specify that the LINK shall have an external target where the *target information type* should be included in a specified set of such types.

6.3.6.9 Other constraints and rules may optionally be specified to govern the creation of instances corresponding to a reference model attribute or association.

6.4 Data value constraints

6.4.1 It shall be possible to specify constraints and rules for the data values of leaf nodes in the Reference Model hierarchy, or for any other attributes of any archetype node.

6.4.2 Constrains on a leaf node shall include specifying a single datatype for instance values, in conformance with the underlying reference model that this archetype constrains.

6.4.3 It shall be possible to specify the following data value constraint information.

6.4.3.1 If the data value is permitted to have a null value, and optionally to specify a reason (e.g. to specify a null flavour value).

6.4.3.2 If the constraint or rule is an inclusion or exclusion criterion.

6.4.3.3 The formalism (including version) in which this constraint specification is represented.

6.4.3.4 The intended fixed (prescribed) value for conforming instances.

6.4.3.5 The intended default value for conforming instances.

6.4.3.6 A list of permitted candidate values for conforming instances (i.e. to be a subset of those values legally permissible in the underlying reference model).

6.4.4 For quantity datatypes it shall be possible to specify:

— a value range within which values for conforming instances shall lie;

— a range within which values are considered exceptional or critical (e.g. cut off points, ranges, min, max values);

— the intended measurement units for conforming instances.

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6.4.5 For date and time datatypes it shall be possible to specify:

— a value range within which values for conforming instances shall lie;

— the intended measurement units for conforming instances.

6.4.6 For textual datatypes it shall be possible to specify:

— a string pattern defining a range of possible values;

— the intended coding scheme to be used for conforming instances;

— a valid value domain, by referencing a list of individual concepts from a given terminology (with appropriate identification of the terminology referenced);

— a valid value domain, by stating an intentional definition of the set of valid values from an identified terminology system;

— a valid value domain, by binding the coded data element to a predefined reference set from an identified terminology system;

— terminology value domains from different languages;

— optionally to specify different terminology value domains for different documentation purposes.

6.4.7 Constraint rules might be expressed as logical conditions, and may include reference to environment parameters such as the current time or location or participants, or be related to the (pre-existing) values other nodes in the instance hierarchy.

6.4.8 The reference to a pre-existing value shall specify that instance precisely and unambiguously. For example, it might be necessary to include a reference to:

— the archetype identifier;

— the archetype node identifier;

— the attribute or association name;

— the occurrence in the instance hierarchy, for example:

  — first;

  — most-recent;

  — any;

  — n ordered by y (the nth element of a set of instances ordered on y);

  — highest value;

  — lowest value;

  — one or more instances within a (definable) recent time interval.

— the intended relationship between this specified instance value and the data value being constrained, for example:

  — the same value as;

  — a subset or substring of;

  — greater than, greater than or equal to, less than, less than or equal to;

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— earlier than, later than, etc.;

— if … then…;

— shall not be the same as.

6.4.9 These relative constraints may be nested, and include logical or set operators in order to represent compound rules.

7 Archetype object model

7.1 Preface

7.1.1 Purpose

This clause contains the normative description of archetype and template semantics in the form of an object model. The model presented here can be used as a basis for building software that represents archetypes and templates, independent of their persistent representation. Equally, it can be used to develop the output side of parsers that process archetypes in a linguistic format.

7.1.2 Nomenclature

In this document, the term 'attribute' denotes any stored property of a type defined in an object model, including primitive attributes and any kind of relationship such as an association or aggregation. XML 'attributes' are always referred to explicitly as 'XML attributes'.

The word 'archetype' in a broad sense is also used to designate what are commonly understood to be 'archetypes' (specifications of clinical data groups / data constraints) and 'templates' (data sets based on archetypes). Statements about 'archetypes' in this specification can be always understood to also apply to templates, unless otherwise indicated.

7.2 Model overview

The model described here is a pure object-oriented model that can be used with archetype parsers and software that manipulates archetypes and templates in memory. It is typically the output of a parser of any serialised form of archetypes.

7.2.1 Package structure

The Archetype Object Model is defined as the package `am.archetype` , as illustrated in Figure 1.

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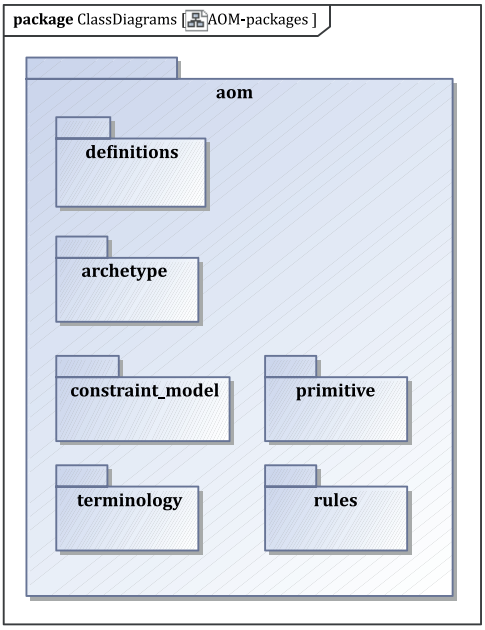

Figure 1 — Package Overview

7.2.2 Definition and utility classes

7.2.2.1 Overview

Various definitional classes are used in the AOM. Some are defined in the `aom.definitions` package, while others come from the `definitions` package. These are illustrated in Figure 2 below.

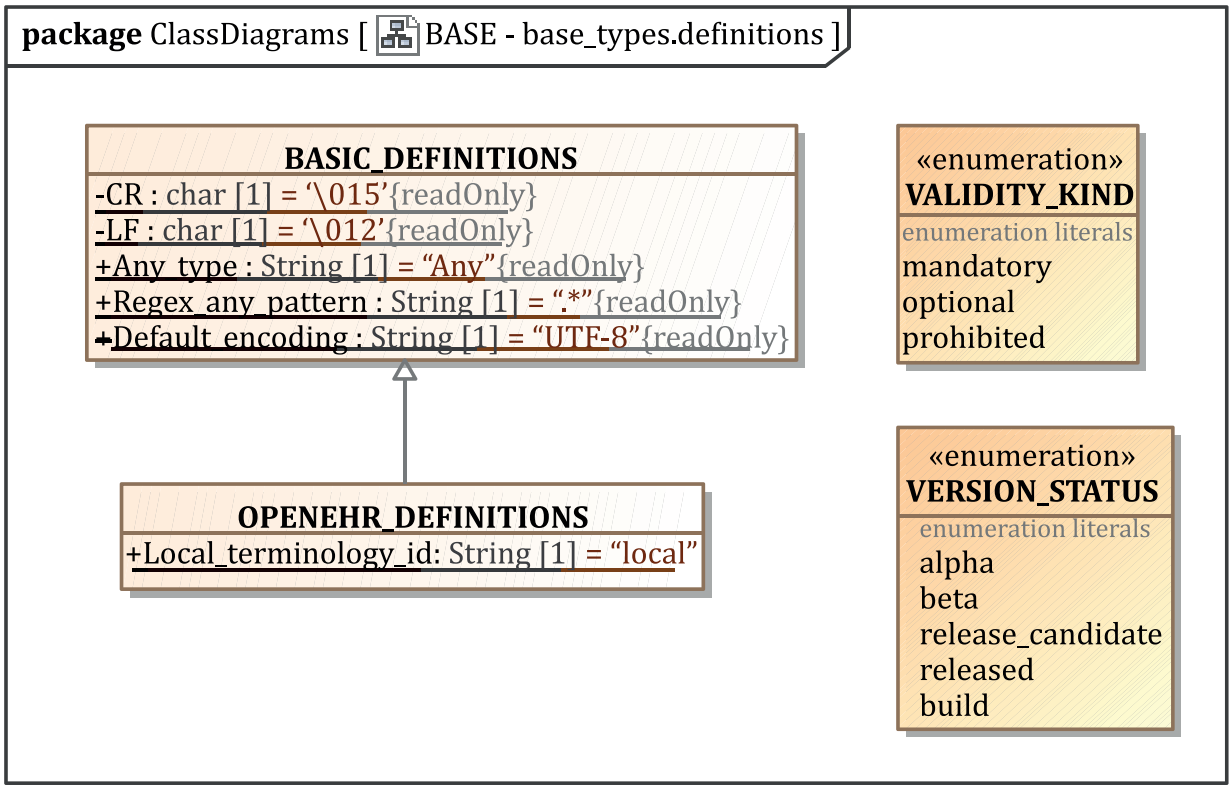

Figure 2 — Definition Package

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The enumeration type VALIDITY_KIND is provided in order to define standard values representing mandatory, optional, or disallowed in any model. It is used in this model in classes such as C_DATE , C_TIME and C_DATE_TIME. The VERSION_STATUS enumeration type serves a similar function within various AOM types.

Other classes used from the base package include AUTHORED_RESOURCE (resource package) and its subordinate classes. These are shown in full within the packages that use them.

7.2.2.2 Class definitions

7.2.2.2.1 VERSION_STATUS enumeration

Enumeration	VERSION_STATUS	
Description	Status of a versioned artefact, as one of a number of possible values: uncontrolled, prerelease, release, build.	
Attributes	Signature	Meaning
	alpha	Value representing a version which is 'unstable', i.e. contains an unknown size of change with respect to its base version. Rendered with the build number as a string in the form "N.M.P-alpha.B" e.g. "2.0.1-alpha.154".
	beta	Value representing a version which is 'beta', i.e. contains an unknown but reducing size of change with respect to its base version. Rendered with the build number as a string in the form "N.M.P-beta.B" e.g. "2.0.1-beta.154".
	release_candidate	Value representing a version which is 'release candidate', i.e. contains only patch-level changes on the base version. Rendered as a string as "N.M.P-rc.B" e.g. "2.0.1-rc.27".
	released	Value representing a version which is 'released', i.e. is the definitive base version. Rendered with the build number as a string in the form "N.M.P" e.g. "2.0.1".
	build	Value representing a version which is a build of the current base release. Rendered with the build number as a string in the form "N.M.P+B" e.g. "2.0.1+33".

7.2.2.2.2 VALIDITY_KIND enumeration

Enumeration	VALIDITY_KIND	
Description	An enumeration of three values that might commonly occur in constraint models. Use as the type of any attribute within this model, which expresses constraint on some attribute in a class in a reference model. For example to indicate validity of Date/Time fields.	
Attributes	Signature	Meaning
	mandatory	Constant to indicate mandatory presence of something.
	optional	Constant to indicate optional presence of something.
	prohibited	Constant to indicate disallowed presence of something.

7.2.2.2.3 ADL_CODE_DEFINITIONS class

Class	ADL_CODE_DEFINITIONS	
Description	Definitions relating to the internal code system of archetypes.	
Attributes	Signature	Meaning

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1..1	**Id_code_leader**: `String = "id"`	String leader of 'identifier' codes, i.e. codes used to identify archetype nodes.
1..1	**Value_code_leader**: `String = "at"`	String leader of 'value' codes, i.e. codes used to identify codes values, including value set members.
1..1	**Value_set_code_leader**: `String = "ac"`	String leader of 'value set' codes, i.e. codes used to identify value sets.
1..1	**Specialisation_separator**: `char = '.'`	Character used to separate numeric parts of codes belonging to different specialisation levels.
1..1	**Code_regex_pattern**: `String = "(0|[1-9][0-9]*)(\.(0|[1-9][0-9]*))*"`	Regex used to define the legal numeric part of any archetype code. Corresponds to the simple pattern of dotted numbers, as used in typical multi-level numbering schemes.
1..1	**Root_code_regex_pattern**: `String = "^id1(\.1)*$"`	Regex pattern of the root id code of any archetype. Corresponds to codes of the form id1, id1.1, id1.1.1 etc..
1..1	**Primitive_node_id**: `String = "id9999"`	Code id used for C_PRIMITIVE_OBJECT nodes on creation.

7.3 The archetype package

7.3.1 Overview

The top-level model of archetypes and templates (all variant forms) is illustrated in Figure 3: Archetype Package. The model defines a standard structural representation of an archetype. Archetypes authored as independent entities are instances of the class `AUTHORED_ARCHETYPE` which is a descendant of `AUTHORED_RESOURCE` and `ARCHETYPE`. The former provides a standardised model of descriptive meta-data, language information, annotations and revision history for any resource. The latter class defines the core structure of any kind of archetype, including definition, terminology, and optional rules part, along with a 'semantic identifier' (`ARCHETYPE.archetype_id`).

The `AUTHORED_ARCHETYPE` class adds identifying attributes, flags and descriptive meta-data, and is the ancestor type for two further specialisations - `TEMPLATE` and `OPERATIONAL_TEMPLATE`. The `TEMPLATE` class defines the notion of a 'templated' archetype, i.e. an archetype containing fillers/references (e.g. ADL's `use_archetype` statements), typically designed to represent a data set. To enable this, it may contain 'overlays', private archetypes that specialise one or more of the referenced / filler archetypes it uses. Overlays are instances of the `TEMPLATE_OVERLAY` class, have no meta-data of their own, but are otherwise computationally just like any other archetype.

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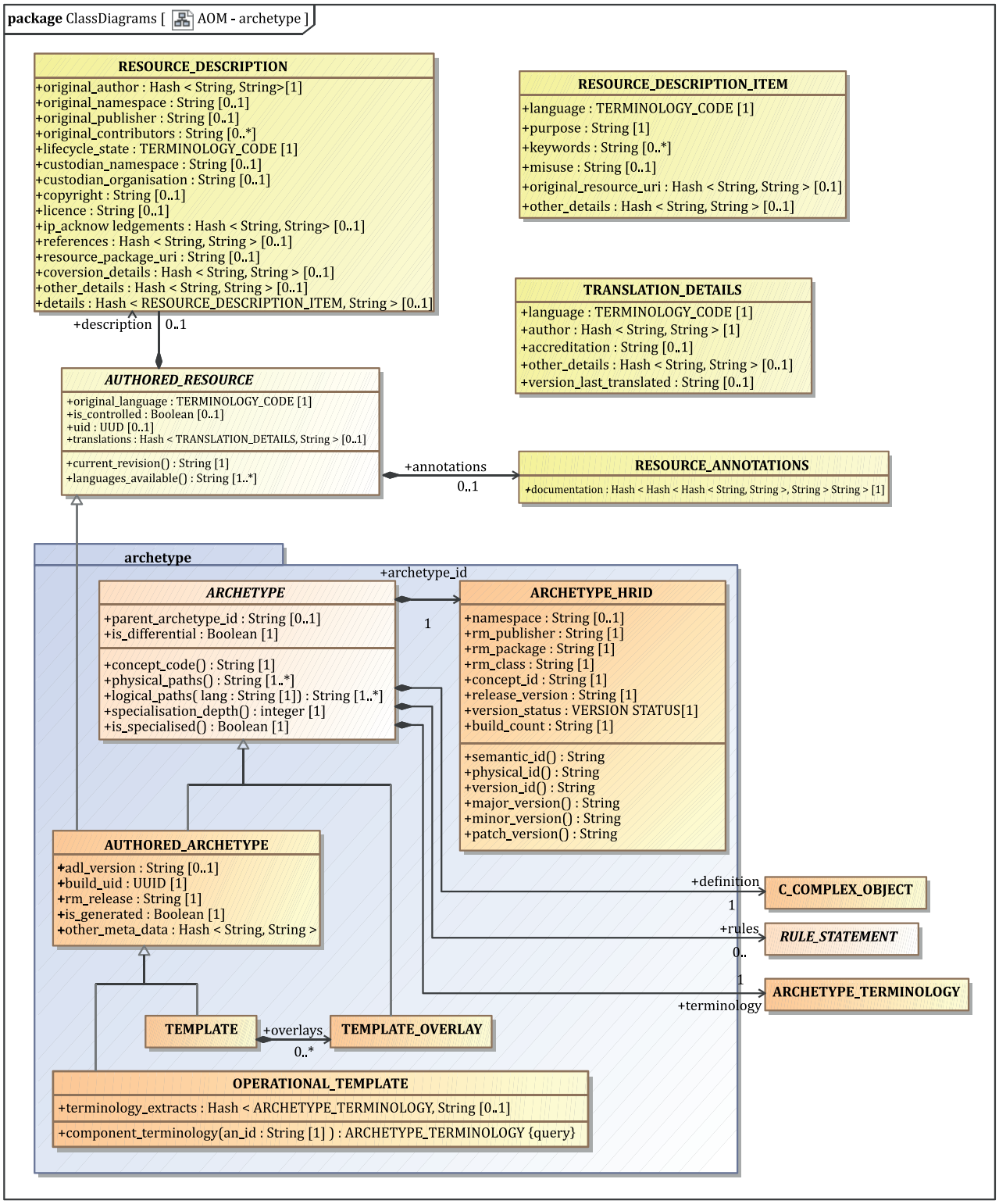

Figure 3 — Archetype Package

The `OPERATIONAL_TEMPLATE` class represents the fully flattened form of a template, i.e. with all fillers and references substituted and overlays processed, to form what is in practical terms, a single custom-made 'operational' artefact, ready for transformation to downstream artefacts. Because an operational template includes one or more other archetype structures inline, it also includes their terminologies, enabling it to be treated as a self-standing artefact.

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