BS EN ISO 13606-1:2019

BSI Standards Publication

Health informatics - Electronic health record communication

Part 1: Reference model

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National foreword

This British Standard is the UK implementation of EN ISO 13606-1:2019. It is identical to ISO 13606-1:2019. It supersedes BS EN ISO 13606-1:2012, which is withdrawn.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 1: Modèle de référence (ISO 13606-1:2019)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 1: Referenzmodell (ISO 13606-1:2019)

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European foreword

This document (EN ISO 13606-1:2019) 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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.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.

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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 13606-1:2008), which has been technically revised. The main changes compared to the previous edition are summarised in the Introduction.

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

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

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Introduction

0.1 Preface

The overall goal of this document is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient), or for a group of patients whose information might need to be communicated together (for example, a family). This is to support the interoperability of systems (see Annex C). and components that need to communicate (access, transfer, add or modify) EHR data:

— preserving the original clinical meaning intended by the author;

— incorporating the necessary provenance metadata to inform the recipient or receiving system about the context in which the EHR data were obtained and composed;

— observing and communicating the confidentiality of that data as intended by the author and subject of care.

This document considers the EHR to be the persistent longitudinal and potentially multi-organisation or multi-national record of health and care provision, most often relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform each subject's future healthcare and to provide a medico-legal record of care that has been provided. This corresponds to the definition provided in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture).

This document is not intended to specify the internal architecture or database design of EHR systems or components, nor is it intended to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. These might be used to communicate EHR data between two repositories, to update a centralised regional or national EHR repository, or within a distributed network of EHR components, systems and services. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc. this document has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

This document may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems. The components that might support an interface conforming to this document will be not only electronic health record systems but also other middleware services such as security components, guideline and workflow systems, alerting and decision support services, personal health systems and applications, sensors and wearable devices, and medical knowledge management services. This document might also prove useful for communicating data about individuals between electronic health record systems and population registries, and also for conducting (approved) research using electronic health records.

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.

0.2 Technical approach

This document is the second version of an original standard which was published in 2007 by CEN, and in 2008 by ISO. This revision has taken into account the experiences gained by EHR system developers and by large scale eHealth programmes from using the original standard. These were ascertained through an international survey, a wide range of 1:1 interviews, a review of the academic literature, and interactions with many experts active in R&D relating to the EHR. It also meets the relevant requirements in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture). The

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revision has taken into account, and aligns as far as possible, with other CEN and ISO Standards and Technical Specifications with which this document might also be used, with international terminology standards and with emerging standards from HL7: Fast Healthcare Interoperability Resources (FHIR). The specifications in this document have drawn from, and align as far as possible with, the reference model specifications published by the openEHR Foundation, and with the archetype models published by the openEHR Foundation and by the Clinical Information Modeling Initiative (CIMI).

The information model in this document is an Information Viewpoint of the ISO Reference Model for Open Distributed Processing (ISO/IEC 10746-1:1998**)**.

Given the diversity of deployed EHR systems, this document has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4 of this series, and through normative term lists (defined in Part 3 of this series).

0.3 The Dual Model approach

The challenge for EHR interoperability is 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 healthcare data sets, value sets, templates etc. required by different healthcare 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, defined in this document and used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model, defined in Part 2 of this series), which are meta-data used to define patterns for the specific characteristics of the healthcare data that represents the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. 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 series).

This generic information model needs to be complemented by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model. For an EHR_EXTRACT, as defined in this document, an archetype instance 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 data types and value ranges that ELEMENT data values may take, and other constraints.

This document recognises that archetypes (or equivalent clinical models) are not always directly incorporated within the present-day architectures of electronic health record systems. This document therefore does not mandate that archetypes are used within such systems. It does, however, require that the clinical information models or equivalents (data items, data item aggregations, data value constraints, terminology bindings, units of measure etc.) that have been used to generate an EHR_EXTRACT are themselves created and communicated, or referenced, within each EHR_EXTRACT. These communicated or referenced archetypes have to conform to Part 2 of this standard series, and maybe communicated through an interface conforming to part 5 of this Standard series.

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0.4 Overview of the EHR_EXTRACT record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organised under headings, and contained in "documents" such as consultation notes, letters and reports. These documents are usually filed in folders, and a subject of care may have more than one folder within a healthcare enterprise (e.g. medical, nursing, and obstetric).

The EHR Communications Reference Model needs to reflect this hierarchical structure and organisation, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organised within heterogeneous EHR systems.

These parts are summarised in Table 1 below.

Table 1 — Main hierarchy components of the EHR Extract Reference Model

EHR HIERARCHY COMPONENT	DESCRIPTION	EXAMPLES
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care or for a group of subjects of care (such as a family), for communication between an EHR Provider system and an EHR Recipient.	(Not applicable)
FOLDER	The high level organisation within an EHR, dividing it into compartments relating to care provided to a single subject of care, for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, Schizophrenia, Cholecystectomy, Paediatrics, St Mungo's Hospital, GP Folder, Episodes 2000-2001.
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, Laboratory test result form, Radiology report, Referral letter, Clinic visit, Clinic letter, Discharge summary, Functional health assessment, Diabetes review.
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, Past history, Family history, Allergy information, Subjective symptoms, Objective findings, Analysis, Plan, Treatment, Diet, Posture, Abdominal examination, Retinal examination.
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement.
CLUSTER	The means of organising nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses.
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight.

An EHR_EXTRACT contains EHR data as COMPOSITIONs, organised in a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

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Representing participation: The Reference Model in the previous version of this standard provided explicit classes at certain parts of the Record Component hierarchy through which it was possible to represent the identity and roles played by actors contributing to healthcare and to its documentation. In this version of the Reference Model the LINK class is intended to be used to reference demographic entities. The roles played by these entities can be labelled using extended term lists defined in Part 3 of this standard series. This updated mechanism offers greater flexibility than the previous version in where the references to such democratic entities may be represented within the Record Component hierarchy.

Representing context: Any EHR_EXTRACT references any other RECORD_COMPONENTS that are connected to the communicated content, for example via the RECORD_COMPONENT hierarchy and via LINK targets. If the EHR exchange service (e.g. as specified in Part 5) permits access to referenced components, any user would be able to access and review any additional areas of content that were not originally included. (Archetypes bring together the key elements of immediate documentation context.)

Representing authenticity: Every EHR_EXTRACT may contain attested views: these might be PDF or html or other renderings that are the authentic view of what was seen and persisted by the original author. The proof may also optionally be included, which is the evidence of a digital signature.

EHR_EXTRACTS are created for specific purposes, and will not automatically guarantee that these will be fit for other purposes.

0.5 Summary of changes made in this edition of the standard

The scope of all parts remains the same.

The objective of this revision was to:

— obtain implementer feedback on adoption experiences with the published version of the 13606 standard series;

— simplify the reference model by removing properties that have not proved useful to implementers;

— improve the demographics model to support the use of demographic archetypes;

— improve alignment with ISO 13940 System of concepts to support continuity of care (Contsys);

— align the data types with ISO 21090 Harmonized data types for information interchange (see Annex A);

— prepare the ground for alignment with HL7 FHIR;

— update the archetype model to align with the openEHR Archetype Object Model 2.0;

— include reference archetypes for commonly needed information (e.g. demographics);

— update the audit log model to align with ISO 27789 Audit trails for electronic health records, and the ISO 22600 series, Privilege management and access control.

Reference Model changes

Base Component

A class Base Component has been introduced higher in the inheritance hierarchy than Record Component, which has a unique identifier, version history information and attestation information.

This allows all of the structures within an EHR Extract to be version managed and attested, including LINK and demographic information, as well as the original family of Record Components.

Record Component

Several properties that had not proved useful have been removed from Record Component.

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Importantly, the model now semantically labels Record Components through archetype ID, avoiding duplicating and possibly conflicting semantic labels such as name and meaning.

Experience is that these different properties were not differentially well used, and resulted in inconsistent practices.

Consultation with vendors and providers who do not intend to use archetypes has confirmed that they could create a library of archetypes mapping their data structures, should they choose to adopt this standard series.

Properties relating to sensitivity and policy ID have been moved to Composition, to avoid the risk of a Composition containing data of mixed policies and therefore inconsistently complete access by different parties.

Structure Component

A generic parent class Structure Component is now the universal parent class of all Record Components and demographic classes.

All such classes inherit an archetype ID, which now also importantly allows demographic structures to be defined through archetypes, which was a popular change request.

EHR_Extract

Extract Criteria has been removed as implementers did not find it useful.

EHR_EXTRACT may now contain a set of extracted EHR components, and so may contain data on multiple subjects of care.

Folder

The Folder has the property subject of care, which allows an EHR extract potentially to contain information about more than one subject of care, such as a family, which was an important change request we received.

The EHR Extract is a kind of folder, with specific meta data about the extract generation.

Composition, Entry and Cluster

Some unused properties have been removed from Composition, Entry and Cluster.

This includes session_time, obs_time. Such dates and times are better included within relevant archetypes with more precisely specified names and roles.

Element

The Element class, and its counterpart Demographic Element, are more genuinely leaf nodes with fewer inherited properties and fewer inherited associations than in the past.

This is a response to a number of ICT vendors who indicated that the original Element was too property rich, inviting inconsistent adoption practice.

Null flavour is no longer an explicit Reference Model property. Instead a Reference Archetype has been defined in Part 3, to allow null to be asserted not only at Element level but higher up the hierarchy (e.g. that a Cluster or Entry is not present).

Data Value

The data values are now all represented as a constrained subset of the data types in ISO 21090, conforming to its mechanism for profiling (see Annex A).

Demographics

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Rather than being a separate package, demographic entities are represented using classes that inherit many of the same mechanics as Record Components, simplifying adoption.

This is now also means that demographic entries in a demographic extract can be uniquely identified, version managed and attested.

It is now much easier to refer specifically to actors within roles at care settings, in cases where actors play multiple roles and work within different care settings over time, which is relatively common.

Link

The Link class has been simplified, but enriched so that Links have a unique identifier, and can be versioned and attested.

Links can connect any identified components including demographic entities, which is now the way that most participations are represented. This was an important and well supported change request, to correct a less successfully modelled part of the previous standard.

The vocabulary for LINK has been greatly extended within part 3, and where appropriate aligned with Contsys.

LINKS can continue to be used to represent clinically relevant connections between parts of a record, point to point or as a linkage thread.

The former class FUNCTIONAL_ROLE and RELATED_PARTY have been removed, as the connection to demographic entities can now be made through archetyped DEMOGRAPHIC ENTITY instances connected to the relevant RECORD_COMPONENT via LINK.

A new class EXTERNAL_LINK enables references to be included to non-EHR data such as care protocols, safety reports or academic publications.

Audit information

The audit info class now aligns with ISO 27789, as does the corresponding audit model in Part 4 of this standard series.

0.6 Relationship of this standard to other relevant standards

— The data types used in this document are a profile of ISO 21090 Health informatics - Harmonized data types for information interchange.

— Alignment has especially been undertaken with ISO 13940 Health informatics - System of concepts to support continuity of care (Contsys). All of the terms and definitions within the standard series have been harmonised across the five parts, with most of the terms being in Part 1. All of them have been aligned with Contsys.

— An important 13606 FHIR profile project is in progress within HL7 (see Annex B). No challenges have been identified with being able to create such a profile. However there are a few areas of mapping alignment which need further work between ISO 13606 and HL7.

— Parts 1 and 4 align with ISO 27789 Health informatics - Audit trails for electronic health records. Alignment in Part 4 has been maintained with ISO 22600 Health informatics - Privilege management and access control.

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Health informatics — Electronic health record communication —

Part 1: Reference model

1 Scope

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

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

This document will predominantly be used to support the direct care given to identifiable individuals or self-care by individuals themselves, 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 document but such secondary uses might also find the document useful.

This Part 1 of the multipart series is an Information Viewpoint specification as defined by the Open Distributed Processing – Reference model: Overview (ISO/IEC 10746-1). This document is not intended to specify the internal architecture or database design of EHR systems.

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 21090:2011, *Health informatics — Harmonized data types for information interchange*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 Actors

3.1.1
attester
actor (person) who certifies and records legal responsibility for a particular unit of information

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3.1.2
committer
agent (party, device or software) whose direct actions have resulted in information being committed

3.1.3
composer
healthcare actor responsible for creating, synthesising or organising information that is committed to an electronic health record.

Note 1 to entry: This agent takes responsibility for its inclusion in that electronic health record, even if not the originator of it and even if not the committer of it.

3.1.4
electronic health record provider
healthcare actor in legitimate possession of electronic health record data and in a position to communicate it to another appropriate entity

3.1.5
healthcare provider
care provider
health provider
health service provider
healthcare service provider
healthcare actor that is able to be assigned one or more care period mandates

Note 1 to entry: The personnel of a *healthcare organization* that is a *healthcare provider* may include both *healthcare professionals* and others which participate in the provision of *healthcare*.

Note 2 to entry: This document includes only two specializations of *healthcare provider*. This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of *healthcare actors* are included in the concept of *healthcare provider*, the necessary specializations may be added.

Note 3 to entry: According to this definition, *organizations* solely responsible for the funding, payment, or reimbursement of *healthcare* provision are not *healthcare providers*; for the purpose of this document they are considered as *healthcare third parties*.

[SOURCE: ISO 13940:2015]

3.1.6
role
function or position

[SOURCE: ISO/HL7 21731:2014]

3.1.7
subject of care
subject of healthcare
patient, client
service user
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

Note 1 to entry: A fœtus may be considered as a *subject of care* when receiving *healthcare*.

EXAMPLE A treated patient, a client of a physiotherapist, each particular member of a target population for screening, each particular member of a group of diabetic people attending a session of medical education, a *person* seeking health advice.

[SOURCE: ISO 13940:2015]

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3.2 Concepts and terms

3.2.1
generic
applicable to requirements or information models across healthcare professions, domains and countries

3.3 Information management

3.3.1
abstract class
class that cannot be instantiated independently

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.24]

3.3.2
archetype
instance of an archetype model, specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an electronic health record extract

3.3.3
archetype model
information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record reference model

3.3.4
client application
healthcare application which is behaving at that moment as a requester of health record data from a shareable electronic health record

3.3.5
data
reinterpretable representation of *information* (3.3.9) in a formalized manner suitable for communication, interpretation or processing

Note 1 to entry: Data are defined without any context in such a way that by itself one cannot tell its correct meaning, where it has meaning this is information.

[SOURCE: ISO/IEC 2382 2015, 2121272]

3.3.6
data repository
an identifiable *data* (3.3.5) storage facility

Note 1 to entry: In ISO 10303 22:1998 this is the definition of repository.

[SOURCE: ISO 13940:2015]

3.3.7
healthcare data
data (3.3.5) produced during healthcare activities

[SOURCE: ISO 13940:2015]

3.3.8
healthcare information
information (3.3.9) about a person, relevant to his or her healthcare

[SOURCE: ISO 13940:2015]

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3.3.9
information
knowledge concerning objects that within a certain context has a particular meaning

Note 1 to entry: Facts, events, things, processes, and ideas, including concepts, are examples of objects.

Note 2 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

[SOURCE: ISO 13940:2015]

3.3.10
distributed processing
information (3.3.9) processing in which discrete components may be located in different places, and where communication between components may suffer delay or may fail

[SOURCE: ISO/IEC 10746-2:2009]

3.3.11
health record
data repository regarding the health and healthcare of a subject of care

Note 1 to entry: The term *electronic health record* may be used for a *health record* where all *information* is stored on electronic media. However, this concept is not formally defined in this document.

Note 2 to entry: A *health record* may include, for example, medical records, dental records, social care records.

[SOURCE: ISO 13940:2015]

3.3.12
health record component
part of a *health record* (3.3.11) that is identifiable for the purposes of referencing and revision

Note 1 to entry: This document defines one *health record component* specialization, the *electronic record component*. However, as the content of a *health record* is not limited to *information* in electronic format, the content of *health record components* may be in formats other than electronic.

Note 2 to entry: A *health record component* may itself result from an aggregation of multiple *health record components*.

[SOURCE: ISO 13940:2015]

3.3.13
electronic health record
health record (3.3.11) where all information is stored on electronic media

3.3.14
electronic health record system
system for recording, retrieving and manipulating information in *electronic health record* (3.3.13)

[SOURCE: ISO 18308:2011]

3.3.15
health record extract
part or all of a *health record* (3.3.11) extracted for the purpose of communication

[SOURCE: ISO 13940:2015]

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3.3.16
healthcare application
system for collecting, saving, processing, and presenting *healthcare information* (3.3.8) by means of a computer.

Note 1 to entry: This definition is based on the definition of application in ISO/IEC 19770-5:2015.

3.3.17
information architecture
structural design of an information space to facilitate task completion and intuitive access to content

3.3.18
metadata
data (3.3.5) that defines and describes other data

[SOURCE: ISO/IEC 11179-3:2013, 3.2.74]

3.3.19
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011]

3.3.20
view
alternate presentation of *data* (3.3.5) for a different purpose

3.4 Privacy and security

3.4.1
access control
means of ensuring that the resources of a *data* (3.3.5) processing system can be accessed only by authorised entities in authorised ways

[SOURCE: ISO 17090-1:2013]

3.4.2
audit trail
collection of audit records from one or more audit logs relating to a specific subject of care or a specific *electronic health record* (3.3.13)

[SOURCE: ISO 27789:2013]

3.4.3
authentication
provision of assurance of the claimed identity of an entity by securely associating an identifier and its authenticator

[SOURCE: ISO 22600-3:2014]

3.4.4
authorisation
granting of privileges

[SOURCE: ISO 22600-1:2014]

3.4.5
confidentiality
property that *information* (3.3.9) is not made available or disclosed to unauthorised individuals, entities, or processes

[SOURCE: ISO 7498-2:1989]

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3.4.6
digital signature
data (3.3.5) appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient

[SOURCE: ISO 7498-2:1989]

3.4.7
privacy
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of *data* (3.3.5) about that individual

[SOURCE: ISO/IEC 2382-8:2015, 2126263]

3.5 Process management

3.5.1
attest
activity of certifying and recording legal responsibility for a particular unit of *information* (3.3.9)

3.5.2
healthcare process
care process
set of interrelated or interacting healthcare activities which transforms inputs into outputs

Note 1 to entry: The main type of healthcare process is the clinical process that has a health state as input and output and includes all activities in relation to one or more specified health issues.

Note 2 to entry: A healthcare process is not by definition restricted to one healthcare provider or any other organizational unit borders.

[SOURCE: ISO 13940:2015]

4 Abbreviations

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

CEN	Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HL7	Health Level Seven
IANA	Internet Assigned Numbers Authority
IETF	Internet Engineering Task Force
ISO	International Organization for Standardization
OID	Object Identifier
R&D	Research and Development
RFC	Request For Comments

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UCUM	Unified Code for Units of Measure
UML	Unified Modelling Language
XML	Extensible Mark-up Language

5 Overview

5.1 Overview of the reference model

Figure 1 shows the reference model for EHR extracts and demographic extracts.

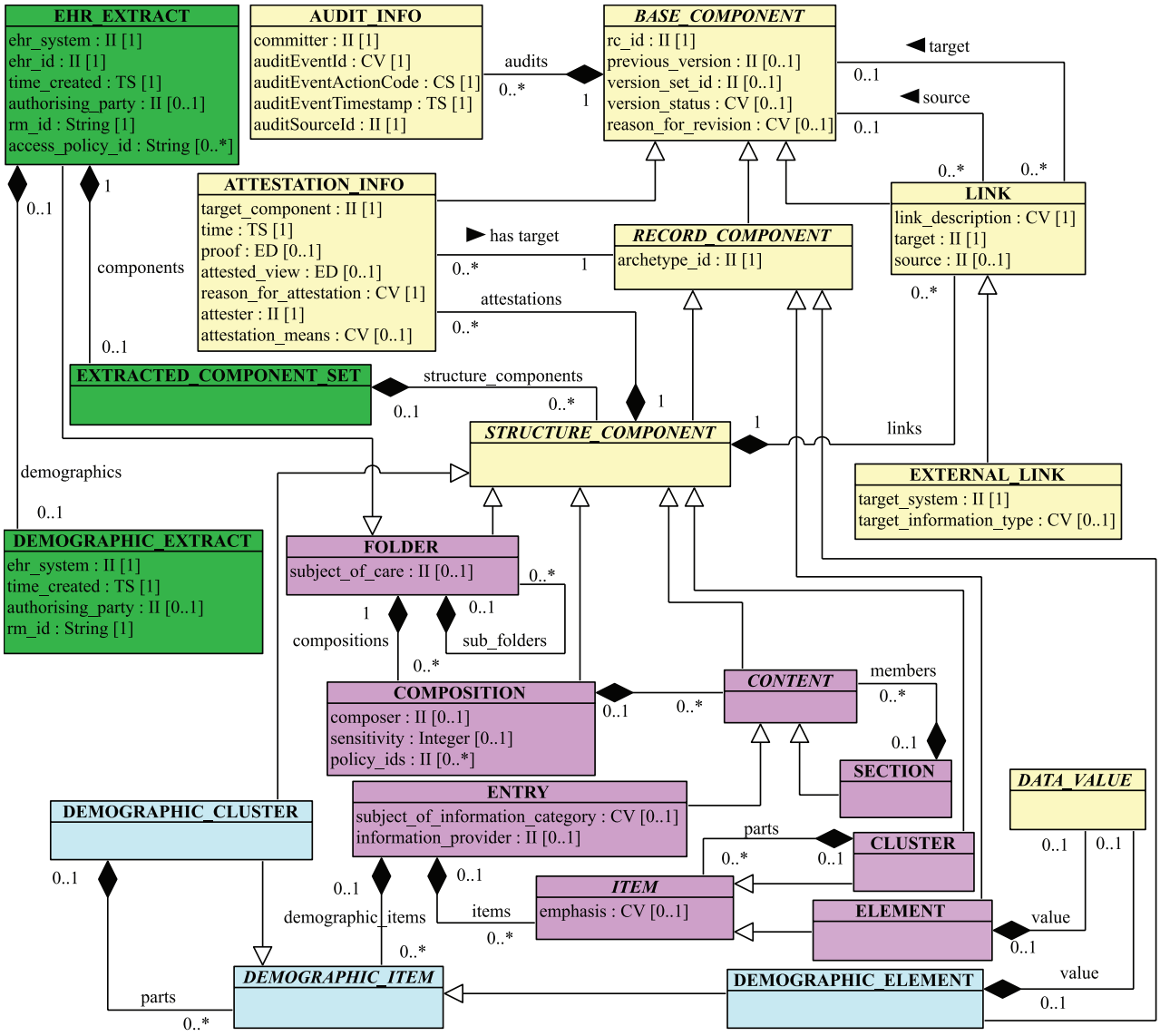

Figure 1 — Reference model for EHR extract and demographics

NOTE The colours in Figure 1, and subsequent diagrams, are offered only as an aid to the reader and have no normative significance. The green coloured classes are the high level containers of the EHR content being communicated. The purple classes represent the main specialisations of RECORD_COMPONENT that provide the main hierarchical organisation of the healthcare information being communicated. The blue classes provide a similar hierarchical organisation to the demographic information being communicated. The cream coloured classes provide additional context to the other classes of the diagram.

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5.2 Representing roles and responsibilities within the EHR _EXTRACT

5.2.1 General

One of the key areas of provenance that are communicated as part of a shared electronic health record is information about the actors involved in care provision and its documentation. Performing a care act in a modern health service can involve a large number of actors, with different roles and responsibilities, each of whom might need to be represented in a subject of care's EHR. The approach taken in most generic EHR architectures, including this document, is to differentiate these into three broad categories.

5.2.2 Actors playing a role in the actual healthcare process

This set will usually include a core actor who is the key person relating to the subject of care during that care activity, and a series of collaborating actors who may be providing or supporting parts of the care, are involved in making decisions, are observers, or are present to support or co-represent the subject of care. These actors might not all be present: for example, the policies of a consultant in charge of care may be followed because the subject of care is under his team, even if he is himself not with the subject of care on that occasion. Sometimes actors might be documenting a case review or a care planning negotiation involving one or more professionals but where the subject of care is not present. On the other hand, the subject of care might be the only actor involved in the care process, for illness self-management or prevention activities.

5.2.3 Actors contributing to the process of documenting care within the EHR

This will usually be a subset of those involved in care (and most commonly, the key actor), but might include people who were not part of delivering the care (e.g. a secretary or a transcriptionist) and may (more so in the future) include the subject of care themselves. It is important to recognise that the different actors will sometimes need to complete separate records of the same activity and may also attest them independently.

5.2.4 Actors confirming the validity of the EHR documentation

The paper analogy of attestation, the term used in this document, is the signing of a letter or report. Most commonly the act of signing a document combines two intentions: to confirm that the document is correct (e.g. is a complete record, is free of errors and omissions) and for the signer to confirm that he or she agrees to the content (e.g. to validate a prescription). In most of these situations the status or seniority of the signer is important. Some of the actors described in a care act will not themselves sign the entries describing their contribution to care: much of healthcare works through delegation. For example, the medical record documentation made by a junior doctor on a ward round is rarely reviewed by the consultant and almost never countersigned. Most observations on a paper monitoring chart are not individually signed. With electronic systems this practice might change, but some level of delegation and trust will probably always exist within care teams.

There is therefore a wide range of potential roles and responsibilities that might need to be represented in an EHR, and as patterns of health service evolve these might change in the future. The goal of the EHR_EXTRACT architecture is to permit any number of actors and roles to be defined within a COMPOSITION: either for the whole COMPOSITION or more narrowly for individual ENTRYs.

The approach taken in this document is:

— to specify a small number of roles that need to be unambiguously communicated to ensure safe interpretation of EHR_EXTRACTs by a receiving system, and which are likely to arise frequently;

— to permit other ad hoc participations to be defined by health services, systems or in individual EHR instances at the COMPOSITION or ENTRY level;

— to permit any number of attestations to be added to the EHR, to sign FOLDERs or COMPOSITIONs or only parts of COMPOSITIONs.

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The specific roles that have been defined in this Reference Model are discussed below.

5.2.5 Subject of care

In response to requirements received during the revision of this document, the EHR_EXTRACT may contain part or all of the electronic health record of one or more subjects of care. If the EHR of more than one subject of care is included, these shall be separated at the root FOLDER level within the EHR_EXTRACT. The document does not specify the precise rules governing when it is appropriate to combine extracts of more than one subject of care within a single EHR_EXTRACT, but examples of when this might be meaningful will include communicating records of multiple members of a single family or who live at the same address, multiple persons who have shared a common risk or incident, or are being transferred collectively to receive care in another setting.

However, there will be occasions when the FOLDER for a single subject of care still contains information about more than one person. Some commonly occurring examples are listed here.

— Pregnancy: it is common practice for the mother's record to contain the full pregnancy care record including that of her baby or babies until after birth, when any relevant information is copied into the new records of those babies.

— In utero interventions: in some situations, a new record is created well before a baby is born, perhaps if significant healthcare is required. In such situations the new record is created for the foetus as a convenience to permit a separation of data from the mother's record, and in anticipation of a new legal record for the baby. Depending upon the age of the foetus, and the laws pertaining to each country, either the baby or the mother will be the legal data subject, but in any case there is still a single identifiable subject of care for each record.

— Multiple pregnancy with each foetus having its own record: this is often cited as a situation in which health actions might really "belong" to two, conjoint twins or more subjects of care. In these situations it would seem logical that each baby's EHR_EXTRACT contains a copy of the relevant COMPOSITIONs, rather than attempting a complex join between two or more records to reference a single COMPOSITION held in one of these records. More complex cross-linkage arrangements might be made within local EHR systems, permitting users to enter the data once and have it logically added to both records.

— Donated organs: Some test results relating to the donor of an organ may be appropriate to store in the EHR of the person receiving the donated organ – such as the viral status or genetic record of the donor– as the person will from this time on be a genetic mosaic. For this reason, information in the EHR may be classified as pertaining to a "donor".

The subject of care identifier in the root FOLDER will reference a snapshot of demographic information as held by the EHR Provider, to enable the subject of care to be matched to the demographics repository of the EHR Recipient, and/or for the EHR_EXTRACT to be referenced to the individual subject of care even if external demographics services are not available.

5.2.6 Composer

This actor is the person who has actually composed the words, terms, figures and values etc. that are represented in the COMPOSITION. The composer will almost always have played a key role in the information gathering, thinking or enacting aspects of the healthcare being documented. Sometimes, though, he or she might be a junior team member creating a record on behalf of a team.

The Composer attribute therefore represents the party who composed the data in a COMPOSITION, irrespective of who committed it or who attested it. The COMPOSITION will be seen as being primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional, as it will depend upon the extent of the change made and if the revising party is willing and in a position to assume primary responsibility for the revised COMPOSITION as its composer. Applications may use the composer's name to label COMPOSITION data for display purposes. (The role of team members other than the composer can be added for individual ENTRYs as additional demographic_items.)

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5.2.7 Committer

In many situations the person who composes the words is not the one who types them in. A common example is dictated letters and reports, which may be typed up by a secretary or transcriptionist. A junior clinical team member might also describe himself as the committer if he is really only acting as the scribe for another (composing) senior team colleague. In some transcription scenarios the typed text is checked by the composer who then commits it to the subject of care's EHR himself. In some scenarios several clinical team members are working in collaboration to deliver a care service; each of these might be able to document (and attest) their own portions of this care in the subject of care's record.

Other situations might arise in which the committer is not responsible for data entry, for example when a measurement device is directly feeding a clinical application. In these situations the information_provider or demographic_items attributes of ENTRY can be used to supplement the set of defined actors.

5.2.8 Subject of information

This attribute is needed to identify the person about whom the information in an ENTRY relates if not the subject of care. The commonest example of this is family history, but information about the subject of care's friend, life partner, sexual partner, employer, child etc. might sometimes be recorded in an EHR. This needs to be unambiguously distinguished from the majority of the EHR information which is about the subject of care.

In some contexts, parties might only be specified precisely if they are registered within the local demographics service AND they have given their consent to be identified in this subject of care's EHR. This will increasingly arise in clinical fields like cancer genetics that manage subjects of care within their family context. The more common situation is where the subject of care is describing the health of others.

The subject_of_information category permits the relationship of that subject to the subject of care to be defined as a coded term, and optionally for more details of that subject to be provided through a LINK to DEMOGRAPHIC_ITEM. This approach will allow archetypes to be reused with different subjects of care, and the unambiguous processing of EHR ENTRYs to distinguish data about the subject of care from data about other parties. It is also possible to let an ENTRY contain a DEMOGRAPHIC_ITEM with information on the subject of information (but then the *subject of information DEMOGRAPHIC_ITEM* would have to be specified in the archetype, just as all other ITEMs).

5.2.9 Information provider

Most of the information documented in an EHR will originate from the subject of care or one of the other participants in the care act. However at times ENTRYs may be added whose data values have been provided by some other party, for example a relative or carer who might be with the subject of care or seeing the subject of care's doctor alone confidentially. Other clinical parties might provide information indirectly (e.g. by phone) to the composer. The information_provider property of ENTRY allows for the formal identification of such parties.

5.3 About the use of datatypes in this document

A constrained subset of ISO 21090:2011 Health informatics — Harmonized datatypes for information interchange is used both in the reference model and for defining the datatypes (DATA_VALUE specializations) to be used when creating archetypes.

Implementations that claim conformance to this document shall not use any of the following ISO 21090:2011 attributes from the classes ANY and HXIT:

— validTimeLow;

— validTimeHigh;

— controlInformationRoot;

— controlInformationExtension;

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— nullFlavor;

— flavorId;

— updateMode.

The following datatypes and UML support types specified in ISO 21090:2011, are used in this document.

— II - Implementations that claims conformance to this document shall not use the ISO 21090:2011 II attributes displayable, scope and reliability.

— TS

— CD.CV (In the diagrams shown as CV)

— ED - Implementations that claims conformance to this document shall not use any of the ISO 21090:2011 ED attributes value, xml, compression, charset, language and translation.

— CS

— TEL.URL (In the diagrams shown as URL) - Implementations that claims conformance to this document shall not use any of the ISO 21090:2011 TEL.URL attributes use, capabilities and usablePeriod.

— Boolean

— Binary

— String

— Integer

— Float

— Uid

The DATA_VALUE specialisations are defined in 7.2. These are the datatypes to be used when creating archetypes.

6 Common Properties of Record Components

6.1 Base, record and structure components

6.1.1 General

6.1.1.1 Base component

The main building block classes that are used to construct the EHR_EXTRACT are kinds of BASE_COMPONENT. This class provides a set of generic properties to all of its inheriting classes, including a unique identifier, information about when and by whom that unit of information was committed to the EHR, if the component has been revised, the reason why and providing references to other historic versions.

It is important that each component of an EHR be uniquely and consistently identified across multiple EHR_EXTRACTS, so that references to or between them remaining valid. Examples of such references are semantic links, revision and attestation. The BASE_COMPONENT unique identifier, the rc_id, is one that shall be issued to this EHR component by the EHR system in which it was first committed (its originating EHR system); other holders of this component need to retain this identifier value, and to reuse it whenever this component is subsequently communicated using this document, in order to ensure that identical components within multiple EHR_EXTRACTs are always consistently identified. This identifier

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is also to be used when referring to this component from other parts of the reference model, examples when referring to this as their component that has been revised, or if it is the target of a LINK.

The rc_id attribute is of data type Instance Identifier (II), which incorporates an ISO OID; II is considered internationally to be the most appropriate data type for persistent identifiers that are required to be globally unique. It is unlikely that contemporary EHR systems will have existing primary keys or internal identifiers that correspond directly to globally-unique II instances. However, an EHR Provider system that has been issued with an organisational OID might use its internal references to construct unique local extensions to that OID and thereby construct globally-unique rc_id values. Alternatively, it might create completely new rc_ids and retain a record of the mapping of these to each internal identifier, so that any future EHR_EXTRACTS it generates will use consistent rc_id values. It is also unlikely that an EHR Recipient system will be able to use received rc_id values as its internal primary keys for the data, since every database uses a slightly different approach to generating and using such keys. The EHR Recipient might therefore also need to keep a record of the mapping of imported rc_id values to its primary keys, so that future references to those RECORD_COMPONENTS can be appropriately matched, and it can create EHR_EXTRACTs that reapply those rc_id values to the exported data. An alternative approach is for EHR systems to explicitly store the rc_id values along with the EHR data, and treat this as part of the "payload" data and not attempt to use these also as primary keys. It should also be noted that the rc_id does not function as a primary key equivalent within an EHR_EXTRACT i.e. duplicate values of rc_id are permitted if each instance does indeed refer to the same piece of healthcare data within the EHR Provider system.

In some jurisdictions it is a medico-legal requirement to document and to communicate when and by whom EHR data were entered into an EHR system. This information is represented in BASE_COMPONENT as the class AUDIT_INFO which is a profile of ISO 27789:2013 (Audit trails for electronic health records). This information is optional, to allow for the possibility that some data will have been imported from simple legacy systems for which the original committal data are not known. It is deliberately positioned as part of BASE_COMPONENT to also enable LINK or ATTESTATION_INFO to be associated with a different date, time and committer to the STRUCTURE_COMPONENT containing it. Multiple instances of AUDIT_INFO may be included if there is a requirement to communicate information about successive committal of this information within different EHR repositories over time.

BASE_COMPONENT also represents the version status, an optional reason for revision, the identity of the immediately previous version that was the basis of this revision, and an identifier that is common to all versions – so that non-sequential versions made on different EHR systems can still be related to each other. An optional version status attribute indicates if the present version was, at the time of its committal, knowingly a draft (i.e. intended to be replaced in the near future), an update to a previous draft version, a correction of an erroneous former version, or an empty component that is the logical deletion of its predecessor (e.g. if the predecessor was saved in the wrong EHR). If no status is given, it is assumed that this is the definitive (first) version. The code set for this attribute is defined in Part 3 of this series.

BASE_COMPONENT has three inheriting classes: RECORD_COMPONENT, LINK, ATTESTATION_INFO. RECORD_COMPONENT is described below; the other two classes are described later in this subclause.

6.1.1.2 Record component

RECORD_COMPONENT is the abstract root class of all of the major hierarchical components making up the main structure of the healthcare data (FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT), and the structures representing demographic entities (DEMOGRAPHIC_FOLDER, DEMOGRAPHIC_ENTITY, DEMOGRAPHIC CLUSTER, DEMOGRAPHIC_ELEMENT). RECORD_COMPONENT contains an archetype_id property, and thereby relates aggregations of RECORD_COMPONENTs to the archetypes to which they correspond on a node by node basis.

6.1.1.3 Structure component

STRUCTURE_COMPONENT is the abstract class that functions as the common parent to all of the RECORD_COMPONENTs except for the leaf classes ELEMENT and DEMOGRAPHIC_ELEMENT. STRUCTURE_COMPONENTs may contain LINKs to any other BASE_COMPONENTs, and may be attested

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In the previous edition, the class ELEMENT had the ability to contain any number of instances of the LINK class and the ATTESTATION_INFO class. This added a complexity to ELEMENT that seldom was needed and that required functionality that existing EHR systems seldom has.

If a particular use-case requires an ELEMENT that has the ability to contain instances of the LINK class or the ATTESTATION_INFO class, then a cluster containing only that ELEMENT may be used.

6.1.2 Base component

Term: *base component*

Definition: abstract class that include the properties common for all revisable classes included in EHR extract

Class name: BASE_COMPONENT

Description: This is an abstract class that include the properties that are common for all revisable classes in the EHR extracts and in the demographic extract.

A model showing the associations of this class is shown in Figure 2.

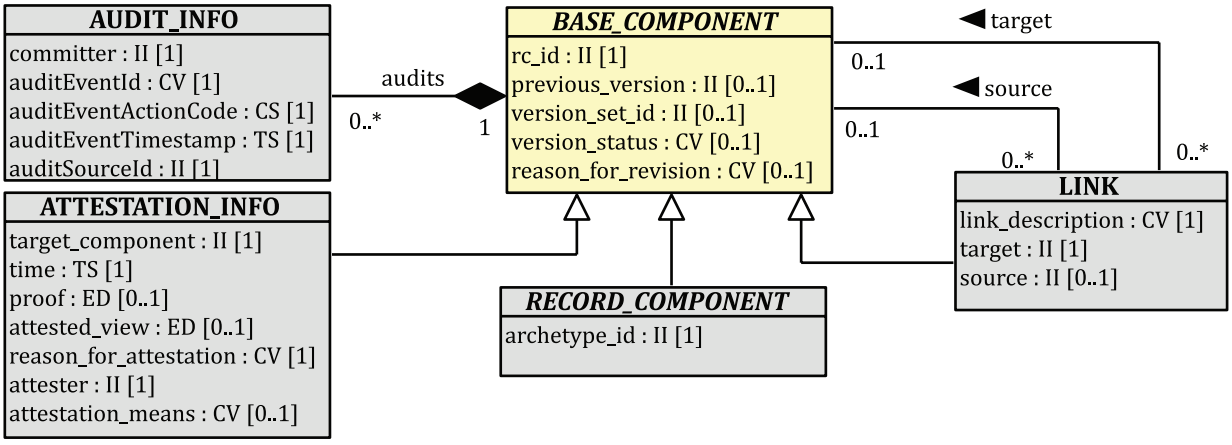

Figure 2 — UML diagram showing all direct relationships of the class BASE_COMPONENT

Attributes

#	Attribute name	Datatype	Description
1	rc_id	II[1]	The globally-unique identifier by which this instance of a BASE_COMPONENT is referenced in the EHR system to which the data were first committed. This identifier shall be retained by the EHR Recipient and re-used whenever this BASE_COMPONENT is subsequently included in another extract.
2	previous_version	II [0..1]	This attribute is the rc_id of the BASE_COMPONENT of which the current BASE_COMPONENT is a revision. If this attribute is null, there is no previous version (i.e. it is the very first version).
3	version_set_id	II [0..1]	This attribute value is the rc_id of the very first version of this BASE_COMPONENT. This attribute may be null if this BASE_COMPONENT is the very first version.

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