



NSAI
Standards

Irish Standard
I.S. EN ISO 13606-3:2019

Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists (ISO 13606-3:2019)

I.S. EN ISO 13606-3:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

EN ISO 13606-3:2019

Published:

2019-07-03

*This document was published
under the authority of the NSAI
and comes into effect on:*

2019-07-21

ICS number:

35.240.80

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 13606-3:2019 is the adopted Irish version of the European Document EN ISO 13606-3:2019, Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists (ISO 13606-3:2019)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This page is intentionally left blank

EUROPEAN STANDARD

EN ISO 13606-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2019

ICS 35.240.80

Supersedes EN 13606-3:2008

English Version

**Health informatics - Electronic health record
communication - Part 3: Reference archetypes and term
lists (ISO 13606-3:2019)**

Informatique de santé - Communication du dossier de
santé informatisé - Partie 3: Archétypes de référence et
listes de termes (ISO 13606-3:2019)

Medizinische Informatik - Kommunikation von
Patientendaten in elektronischer Form - Teil 3:
Referenzarchetypen und Begriffslisten (ISO 13606-
3:2019)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO 13606-3:2019 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 13606-3:2019) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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

This document supersedes EN 13606-3:2008.

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

Endorsement notice

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

This page is intentionally left blank

INTERNATIONAL STANDARD

**ISO
13606-3**

Second edition
2019-06

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

*Informatique de santé — Communication du dossier de santé
informatisé —*

Partie 3: Archétypes de référence et listes de termes



Reference number
ISO 13606-3:2019(E)

© ISO 2019

ISO 13606-3:2019(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviations	2
5 Conformance	2
6 Term lists	2
6.1 Introduction	2
6.2 Termlist SUBJECT_CATEGORY, Class ENTRY, attribute subject_of_information_category	3
6.3 Termlist VERSION_STATUS, Class BASE_COMPONENT, attribute version_status.....	3
6.4 Termlist MODE, Reference Archetype Healthcare activity participation	4
6.5 Class LINK, attribute link_description	4
6.5.1 Termlist RELATED_TO, Class LINK, attribute link_description.....	5
6.5.2 Termlist AUTHORISED_BY, Class LINK, attribute link_description	5
6.5.3 Termlist SAME_HEALTH_ISSUE, Class LINK, attribute link_description.....	6
6.5.4 Termlist SAME_PLAN, Class LINK, attribute link_description	8
6.5.5 Termlist RELATED_DOCUMENTATION, Class LINK, attribute link_description.....	8
6.6 Termlist, Class EXTERNAL_LINK, attribute target_information_type	9
6.7 Termlist, Classes ELEMENT and DEMOGRAPHIC_ELEMENT, attribute null_flavour	10
6.8 Termlist, Class ATTACHMENT, attribute IntegrityCheckAlgorithm.....	10
7 Reference archetype for null flavor	10
7.1 Archetype name: Null_flavor.....	10
8 Reference archetype for the access policy COMPOSITION	11
8.1 Archetype name: Access_policy_rule	11
9 Reference archetypes for demographic entities	12
9.1 Archetype name: EntityIdentifier	12
9.2 Archetype name: useablePeriod	13
9.3 Archetype name: LocationAddress	13
9.4 Archetype name: TelecommunicationAddress	14
9.5 Archetype name: Address.....	16
9.6 Archetype name: Namepart.....	17
9.7 Archetype name: PersonName.....	18
9.8 Archetype name: Person.....	19
9.9 Archetype name: HealthcareOrganization.....	20
9.10 Archetype name: ServiceDepartment.....	21
9.11 Archetype name: HealthcarePersonnel.....	22
9.12 Archetype name: MedicalDevice	23
9.13 Archetype name: SubjectOfInformation	25
9.14 Archetype name: Contact.....	25
9.15 Archetype name: HealthcareActivityParticipation	26
9.16 Archetype name: HealthcareActivityFacility.....	26
9.17 Archetype name: HealthcareActivityFramework.....	27
9.18 Summary of demographic-related data types in ISO 21090	27
9.18.1 Identification and Location Datatypes.....	27
9.18.2 Name and Address Datatypes.....	29
10 Reference archetypes for medicinal product	31
10.1 Archetype name: MedicinalProduct	31
11 Reference archetypes for clinical information specifications	37
11.1 General.....	37

ISO 13606-3:2019(E)

11.2	Archetype name: Health condition.....	38
11.3	Archetype name: Healthcare activity element.....	42
11.4	Archetype name: ClinicalContext.....	47
11.5	Archetype name: Activity management.....	49
11.6	Archetype name: Association.....	50
11.7	Archetype name: Consideration.....	51
11.8	Archetype name: Dosage.....	52
11.9	Archetype name: Method.....	52
12	Contsys-based clinical reference information structures as the basis for development of clinical archetypes.....	54
12.1	Introduction.....	54
12.1.1	Criteria/characteristics.....	56
12.1.2	Basic concepts as bases for the Contsys-based information structure.....	56
12.1.3	Method for development of Contsys-based clinical reference information structures.....	56
12.1.4	Steps in defining the information structures.....	57
12.2	Content of information structures.....	58
12.2.1	Structures for single concepts.....	58
12.2.2	Structures for reuse in clinical situations — Clusters complementing structures for basic clinical concepts.....	58
12.2.3	Structures for compound documents in an EHR.....	59
12.2.4	Other comments.....	59
12.2.5	Format.....	60
12.3	Specializations of types of Health condition.....	60
12.4	Information structures for single concepts.....	61
12.4.1	Health condition.....	61
12.5	Healthcare activity element.....	67
12.5.1	Performer.....	72
12.6	Pharmacological treatment.....	73
12.6.1	Pharmacological treatment.....	73
12.6.2	Dosage.....	74
12.7	Indirect healthcare activity elements.....	74
12.7.1	Healthcare assessment.....	75
12.7.2	Assessments to conclude or exclude health conditions.....	75
12.7.3	Healthcare needs Assessment.....	76
12.7.4	Clinical risk assessment.....	78
12.7.5	Healthcare evaluation.....	78
12.8	Care plan.....	80
12.9	Clusters complementing the information structures for single clinical concepts.....	83
12.9.1	Activity Management including healthcare planning.....	83
12.9.2	Assessment scale representation.....	84
12.9.3	Association.....	84
12.9.4	Clinical Context.....	85
12.9.5	Clinical process concern.....	87
12.9.6	Clinical risk.....	87
12.9.7	Consideration.....	88
12.9.8	Knowledge base.....	89
12.9.9	Method specification.....	90
12.9.10	Priority Level.....	91
12.9.11	Version information.....	92
12.10	Compound structures as combinations of the Contsys based clinical reference information structures for clinical content and clinical context.....	93
12.10.1	Personal health record overview.....	93
12.10.2	Professional health record overview.....	93
12.10.3	Knowledge based healthcare activity planning of healthcare investigations.....	93
12.10.4	Knowledge based healthcare activity planning of healthcare treatments.....	94
	Bibliography.....	95

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

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

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

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

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

ISO 13606-3:2019(E)

Introduction

0.1 General

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

0.2 Preface

ISO 13606-3 defines two kinds of specifications.

- 1) A normative set of (coded) term lists that each defines a controlled vocabulary for a Reference Model attribute that is defined in ISO 13606-1;
- 2) A set of Reference Archetypes that specify how the ISO 13606-1 Reference Model should be applied for communicating information for:
 - null_flavor;
 - access policies;
 - demographic entities;
 - example clinical reference archetypes, conforming to ISO 13940 (Contsys).

0.3 Term Lists

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

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

0.4 Reference archetypes

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

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

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

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

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

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

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

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

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

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

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

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

1 Scope

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

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

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13606-1, *Health informatics — Electronic health record communication — Part 1: Reference model*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

healthcare activity

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

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

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

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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-