SLOVENSKI STANDARD
oSIST prEN ISO 12967-2:2019

01-december-2019

Zdravstvena informatika - Arhitektura storitve - 2. del: Informacijski vidik (ISO/DIS 12967-2:2019)

Health informatics - Service Architecture (HISA) - Part 2: Information viewpoint (ISO/DIS 12967-2: 2019)

Medizinische Informatik - Servicearchitektur - Teil 2: Informationssicht (ISO/DIS 12967-2:2019)

Informatique de santé - Architecture de service - Partie 2: Point de vue d'information (ISO/DIS 12967-2: 2019)

Ta slovenski standard je istoveten z: **prEN ISO 12967-2**

ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN ISO 12967-2:2019 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 12967-2

ISO/TC **215**

Secretariat: **ANSI**

Voting begins on:
2019-11-01

Voting terminates on:
2020-01-24

Health informatics — Service Architecture (HISA) —

Part 2:
Information viewpoint

Informatique de santé — Architecture de service —

Partie 2: Point de vue d'information

ICS: 35.240.80

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 12967-2:2019(E)

COPYRIGHT PROTECTED DOCUMENT

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

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 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.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

This second edition is a revision of, cancels and replaces the first edition (ISO 12967-2:2009), which was based on the European Standard EN 12967-2:2007.

ISO 12967 consists of the following parts, under the general title Health informatics — Service architecture:

— Part 1: Enterprise viewpoint

— Part 2: Information viewpoint

— Part 3: Computational viewpoint

The main changes compared to the previous edition of this part (part 2, information viewpoint) are as follows:

— Use of terms, definitions and concepts from part 1 of ISO 12967, in turn aligned with ISO 13490:2016 (Contsys)

— Reference to further standards, such as HL7

— Updating regarding text and figures related to the UML diagrams based on the revision of part 1 of this 3-part standard, aligned in turn with ISO 13940:2016 Contsys

— Updates to the Bibliography

Introduction

ISO 12967 is a multi-part standard that provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organizations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the service architecture), distinct from individual applications and accessible throughout the whole information system through information services, as shown in Figure 1.

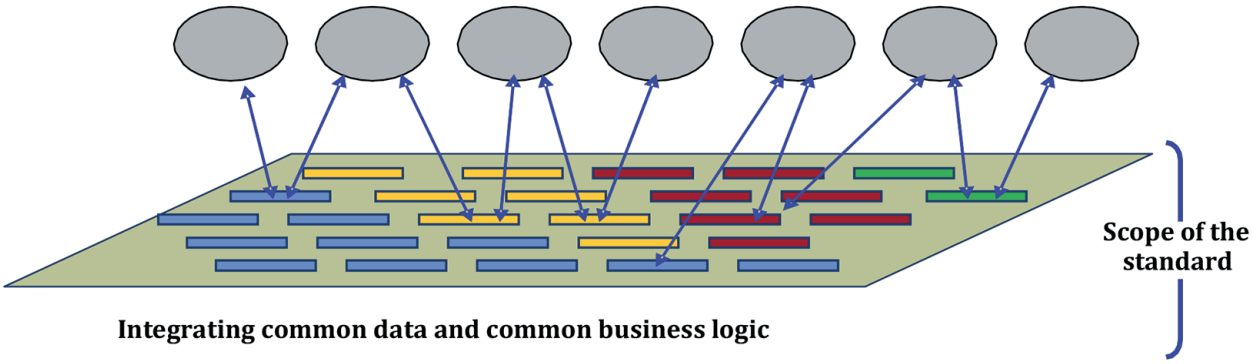

Figure 1 — Scope of this International Standard

The overall architecture is formalized according to ISO/IEC 10746 (all parts)[10][11][12][13] and is therefore structured through the following three viewpoints.

a) Enterprise viewpoint: specifies a set of fundamental common requirements at enterprise level with respect to the organizational purposes, scopes and policies that must be supported by the information and functionality of the service architecture. It also provides guidance on how one individual enterprise (e.g. a regional healthcare authority, a large hospital or any other organization where this model is applicable) can specify and document additional specific business requirements, with a view to achieving a complete specification, adequate for the characteristics of that enterprise.

   Enterprise viewpoint is specified in ISO 12967-1.

b) Information viewpoint: specifies the fundamental semantics of the information model to be implemented by the service architecture to integrate the enterprise's common data and to support the enterprise requirements formalized in ISO 12967-1. It also provides guidance on how one individual enterprise can extend the standard model with additional concepts needed to support local requirements in terms of information to be put in common.

   Information viewpoint is specified in ISO 12967-2.

c) Computational viewpoint: specifies the scope and characteristics of the information services that must be provided by the service architecture for allowing access to the common data as well as for the execution of the business logic supporting the enterprise processes identified in the information viewpoint and in ISO 12967-1. It also provides guidance on how one individual enterprise can specify additional information services needed to support local specific requirements in terms of common business logic to be implemented.

   Computational viewpoint is specified in this part of ISO 12967-3.

Health informatics — Service Architecture (HISA) —

Part 2: Information viewpoint

1 Scope

This part of ISO 12967 specifies the fundamental characteristics of the information model to be implemented by a specific architectural layer (i.e. the service architecture) of the information system to provide a comprehensive and integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organization, as defined in ISO 12967-1.

The information model is specified without any explicit or implicit assumption on the physical technologies, tools or solutions to be adopted for its physical implementation in the various target scenarios. The specification is nevertheless formal, complete and non-ambiguous enough to allow implementers to derive an efficient design of the system in the specific technological environment that will be selected for the physical implementation.

This specification does not aim at representing a fixed, complete, specification of all possible data that can be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics, in terms of overall organization and individual information objects, identified as fundamental and common to all healthcare organizations, and that is satisfied by the information model implemented by the service architecture.

Preserving consistency with the provisions of this part of ISO 12967, physical implementations allow extensions to the standard information model in order to support additional and local requirements. Extensions include both the definition of additional attributes in the objects of the standard model, and the implementation of entirely new objects.

Also, this standard specification is extensible over time according to the evolution of the applicable standardization initiatives.

The specification of extensions is carried out according to the methodology defined in ISO 12967-1:2019, Clause 7, “Methodology for extensions”.

2 Normative references

The following referenced documents are indispensable for the application 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 12967-1:2019, *Health informatics — Service architecture — Part 1: Enterprise viewpoint*

ISO 12967-3:2019, *Health informatics — Service architecture — Part 3: Computational viewpoint*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 information object

information held by the system about entities of the real world, including the ODP system itself, is represented in an information specification in terms of information objects, their relationships and behaviour

3.2 package

cluster of information objects

3.3 middleware

enabling technology of enterprise application integration (EAI) describing a piece of software that connects two or more software applications so that they can exchange data

3.4 enterprise application integration EAI

use of software and computer systems architectural principles to integrate a set of enterprise computer applications

4 Abbreviations

ODP	Open Distributed Processing
HISA	Health Informatics Service Architecture
UML	Unified Modelling Language
GPIC	General Purpose Information Component

5 Methodological principles

5.1 Language and notation adopted for the specification of the model (informative)

The objective of the information viewpoint specification is to describe the information relevant for the enterprise to be handled by the service architecture. It consists of a formal information model detailing the semantic and syntactic aspects of all data to be managed.

The specification is based on an object model, derived from the enterprise viewpoint by properly structuring and aggregating the information that has been identified as relevant in the specification of the business processes, tasks and activities.

While the general approach of the ODP standard is also used for ISO 12967-1, the modelling language to be used is UML, which was not available at the time of the first edition of the ODP standard.

The information viewpoint is concerned with information modelling (i.e. the kinds of information handled by the system). It focuses on the semantics of information and information processing in the system. The individual components of a distributed system must share a common understanding of the information they communicate when they interact, or the system will not behave as expected. Some of these items of information are handled, in one way or another, by many of the objects in the system. To ensure that the interpretation of these items is consistent, the information language defines concepts

for the specification of the meaning of information stored within, and manipulated by, an ODP system, independently of the way the information processing functions themselves are to be implemented.

Thus, information held by the ODP system about entities in the real world, including the ODP system itself, is represented in an information specification in terms of information objects, and their associations and behaviour. Atomic information objects represent basic information elements. More

complex information is represented as composite information objects, each expressing associations over a set of constituent information objects.

Some elements visible from the enterprise viewpoint will be visible from the information viewpoint and vice versa. For example, an activity seen from the enterprise viewpoint may appear in the information viewpoint as the specification of some processing which causes a state transition of an information entity.

Different notations for information specifications model the properties of information in different ways. Emphasis may be placed on classification and reclassification of information types, or on the states and behaviour of information objects. In some specification languages, atomic information objects are represented as values. The approach to be taken will depend on the modelling technique and notation being used.

Assessment of conformance to the information specification of a system involves relating the requirements expressed in the specification to sets of observations of the behaviour of the system at conformance points identified in the engineering and technology specification, and assessing the degree of consistency between the requirements and the observations.

5.2 UML Class Diagram notation guidelines and profile (informative)

For each cluster of objects identified in the enterprise viewpoint, the information objects will be illustrated according to the following rationale.

— Information objects (i.e. classes) grouped in the packages will be not be coloured.

— Classes not expressly grouped in the package will also be represented if there are associations from classes belonging to the package to these classes. These classes, however, will be coloured in yellow.

— The names of classes will be meaningful and start with a capital letter (e.g. Person). If the name is composed of more than one word the blank spaces between the words present in the diagrams will be instead omitted in the section of the tables containing the class identifiers (e.g. “Subject of care will have as class identifier “SubjectOfCare”). Blank spaces are left in the class names and diagrams also with the scope of supporting readability.

— Associations will be labelled when the label adds value to the diagram.

— Associations may be labelled through a property, or through a verb phrase; in the latter case, an arrow will be added to the association label to avoid ambiguity.

— Labels are always in lower case and, if a label is a verb phrase (with arrow), it will have one blank space in between words.

— Navigability is not relevant when using UML for an information specification and will not be represented.

— In general, in order to support readability, the classes should only contain the name of the class. Properties should be described in the tables; however, if properties are displayed in the diagrams, the following two points hold.

  — Notation for visibility of properties is not used, as it is not pertinent for the conceptual models used in the information viewpoint. Although visibility symbols could be used to indicate access control, this is not done as all healthcare-related information should be accessed through careful authorization.

  — Data types of the properties should be displayed in the class in the diagram.

— For some classes, associations to other classes could be modelled (in the UML diagrams) as attributes to the class. This reflects that the association has value rather than reference semantics, in addition to the resulting simplification of the model. In other cases, the same method might be used in the UML diagrams even though the association has reference semantics. This is done just to simplify the

models. In the related class descriptions, these instances of simplified modelling are described as associations rather than attributes.

— Properties (attributes) of classes start with a lower-case letter (e.g. name). If the property is composed of more than one word, the blank spaces in between words are omitted (e.g. familyName, birthDate).

— Current ISO and low-level data types will preferably be used. These will allow mapping to CEN or ISO (in the future) when possible.

— Many-to-many binary associations named "related to" may be implemented as a set of specific associations or association classes of specific multiplicities.

— Cardinalities of properties are used in case of associations, especially to distinguish between optional and mandatory properties.

— Cardinality '*' is never used, as the reader might be confused as to whether a 0..* or 1..* was intended.

— When the composition symbol is used, the non-displayed cardinality will always be '1'.

5.3 Clusters of objects in the information model

The information specification is built by considering the elements of the enterprise viewpoint specification. ODP does not impose any methodology for the definition and use of the viewpoints. Thus, the enterprise specification has been used here for building the UML specification. This approach greatly facilitates the definition of the correspondences between the related entities that appear in the different viewpoints, also allowing the treatment of the consistency among the viewpoints.

In particular, this information specification incorporates the information handled by the system as described in clauses 6.2 to 6.4 of ISO 12967-1:2009.

According to the methodology identified in the enterprise viewpoint, seven clusters of objects have been identified, each of which is responsible for organizing and storing the information necessary for supporting the users' activities identified in the related areas of the enterprise viewpoint.

1) Classification objects

   These objects shall organize and store the information necessary for supporting the users' activities related to the management of classifications, coding criteria and dictionaries, as identified in ISO 12967-1.

2) Subject of care objects

   These objects shall organize and store the information necessary for supporting the users' activities identified in the "Subject of Care workflow" of ISO 12967-1.

3) Activity management objects

   These objects shall organize and store the information necessary for supporting the users' activities identified in the "Activity Management workflow" of ISO 12967-1.

4) Healthcare Information objects

   These objects shall organize and store the information necessary for supporting the users' activities identified in the "Healthcare Information workflow" of ISO 12967-1.

5) Resources objects

   These objects shall organize and store the information necessary for supporting the users' activities related to the management of resources, as identified in ISO 12967-1.

6) Users and authorization objects

These objects shall organize and store the information necessary for supporting the users' activities related to the management of users and authorizations, as identified in ISO 12967-1.

7) Messaging objects

These objects shall organize and store the information necessary for supporting the structuring of data and the communications with other systems through messaging mechanisms, as identified in ISO 12967-1

These clusters of objects are specified in Clause 7 by means of UML models.

As also stated in 12967-1, the HISA information models in ISO 12967-2 are not a one-to-one unfolding of the concepts described in part 1, but addressing key elements hereof such as Healthcare Information, with a viewpoint of the information constructs needed from a system perspective.

HISA is mainly about the IT domain. HISA defines models with classes and services related hereto, in the sense of what should be supported in the enterprise domain at an overall level, not at all detailed concepts and relations in the business domain.

HISA focuses on the information services, through which information is created, read, updated and deleted in connection with and as a result of many healthcare activities. The management of information through the services are key, but not as much the information itself. The high-level information models of HISA refer, for example, to only a fraction of the concepts and terms in Contsys (for a complete coverage of all the concepts and terms of the business domain ISO 13940 -Contsys is highly recommended).

Further general information on mapping between different domains and models with different purpose, levels and scopes is provided in Annex C of 12967-1.

NOTE In the following representative UML models, several terms and descriptions of the HISA classes have been updated to reflect current state of art regarding terminology. However, the original HISA class identifiers have not changed. These are unique to HISA and maintain the previous class identifier supporting also backward compatibility.

5.4 Operational and descriptive information: classifications, knowledge and its instantiation

From the textual descriptions in the enterprise viewpoint, the service architecture shall be able to manage not only the daily operational information directly related to the various business processes, but also a knowledge base, allowing managing the descriptive concepts, vocabulary items, and rules required to instantiate particular properties of the operational information. Such "concept descriptive information" is the basic knowledge base required for the actual instantiation of the operational information in the healthcare enterprise.

HISA Information Objects in each package shall thus be classified as:

— **"Operational"**, usually representing the actual (clinical, organizational, etc.) objects that are continuously generated during (and for) the daily activities. These include the personal and healthcare treatment information on patients, the individual resources used for carrying out the actual activities, etc.

  — The operational information objects model the entities involved in the daily activities of the healthcare enterprise in the treatment of subjects of care and in the functioning of the enterprise itself.

— **"Descriptive"**, usually enterprise or organization-related, specifying the criteria according to which the organization works and is structured. It includes general classifications of clinical concepts, rules

according to which the activities are performed, and more (e.g. the types of activities which are carried out in the radiology department, the diagnostic classification in use in the clinical setting, etc.).

— The descriptive information objects model the entities required for the overall knowledge base that is required by the healthcare enterprises to carry out daily activities related to the treatment of subjects of care and in the functioning of the enterprise itself.

For each "operational" information object, therefore, the model foresees one "descriptive" information object, containing the main classification data, the properties, the rules and the default values that are necessary for the management of the live data instantiated in the "operational" object, as exemplified in Figure 2.

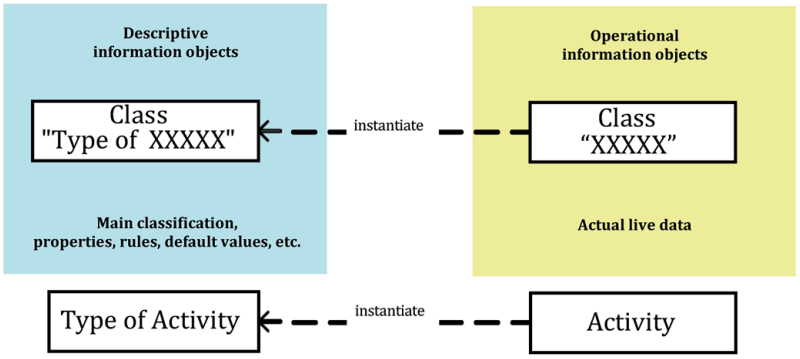

Figure 2 — Knowledge base implemented through the Descriptive Information Objects

In addition to the properties and to the classification provided by the related "descriptive" class, each class and each attribute of each class may need to be classified according to different, multiple, multi-language classifications for different (clinical, epidemiological, statistic, etc.) purposes. To support this requirement, the HISA model provides the package of "Concept Information Objects", capable of organizing multiple classifications, terminologies and other concepts. See Figure 4.

Each individual information element (entire instance of one class or individual attribute of one class) can be related to the concept class to allow specifying as many classifications as necessary. In this case also, the principle of implementing a knowledge base is implemented by the HISA model that provides the following.

— **"Descriptive"** information objects, allowing the specification of the concepts according to which each class and each attribute of the class may be classified.

— **"Operational"** information objects (natively present in each HISA class, as described in the "Generic HISA class"), allowing the classification of each individual instance and each individual attribute according to multiple concepts.

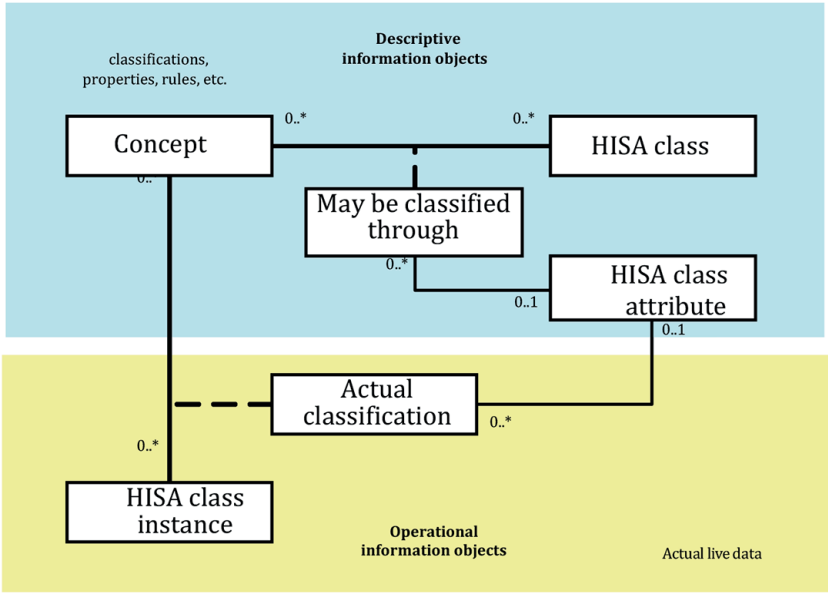

Figure 3 — Further classification criteria for each HISA class

5.5 Data types

The primitive data types given in Table 1 are used in this specification.

Table 1

Data type	Semantics
String	Series of characters, as defined in ISO/IEC 11404:2007
Boolean	Boolean value, as defined in ISO/IEC 11404:2007
Integer	Integer, 32 bit two's complement
Double	Double precision floating point (64-bit IEEE 754)
Octet	8-bit code, as defined in ISO/IEC 11404:2007

Table 2 —

HISA data type	Primitive data type	Semantics
Byte	Octet	Synonym of octet
ObjectIdentifier	String	Unchangeable string allowing the permanent and non-ambiguous identification of one instance of one information object. The syntax and the structure of the string shall be defined locally by the individual implementations, according to criteria capable of ensuring the uniqueness of the value also across different models and distributed, multiple physical environments.
Identifier	String	Short, human-readable string allowing the non-ambiguous identification of one instance of one information object.
InternalTimestamp	Array of bytes	Internal system representation of date and time at least up to the level of the millisecond. DateTime representations are specified in ISO 8601, Date and time — Representations for information interchange, Prats 1 and 2.