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Health informatics — Service architecture —

Part 2: Information viewpoint

Informatique de santé — Architecture de service —

Partie 2: Point de vue d'information

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 12967-2 was prepared by Technical Committee ISO/TC 215, *Health informatics*, based on the European Standard EN 12967-2:2007 with minor editorial amendments.

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*

Introduction

This is the second part of ISO 12967, 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 middleware), distinct from individual applications and accessible throughout the whole information system through services, as shown in Figure 1.

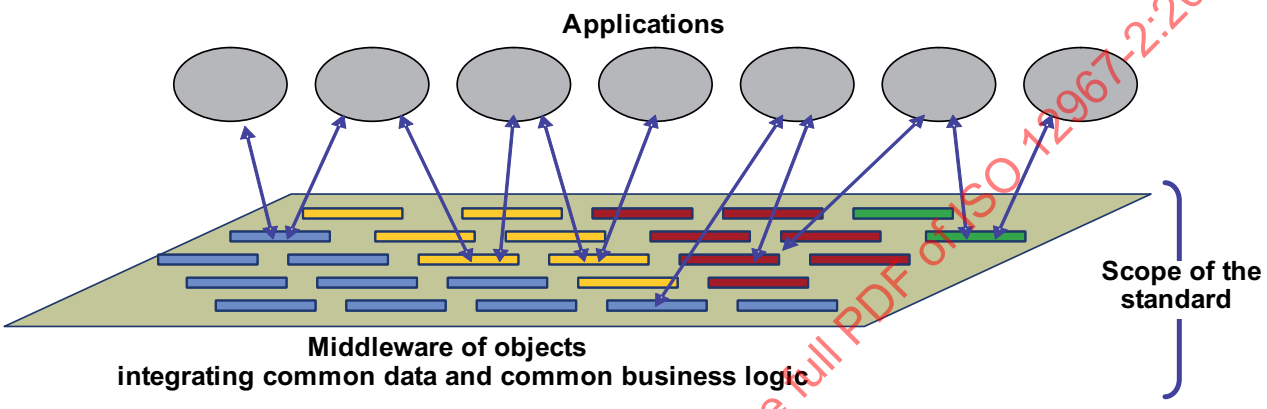

Figure 1 — Scope

The overall architecture is formalized according to ISO/IEC 10746 (all parts) 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 middleware. 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 middleware to integrate the common enterprise 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 this part of ISO 12967.

c) Computational viewpoint: specifies the scope and characteristics of the services that must be provided by the middleware for allowing access to the common data as well as 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 services needed to support local specific requirements in terms of common business logic to be implemented.

   Computational viewpoint is specified in ISO 12967-3.

Health informatics — Service architecture —

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 middleware) 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 middleware.

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 12967-1:2009, 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/IEC 11404:2007, *Information technology — General-Purpose Datatypes (GPD)*

ISO 12967-1:2009, *Health informatics — Service architecture — Part 1: Enterprise viewpoint*

ISO 12967-3:2009, *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 Symbols and 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 middleware. 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 tables describing the classes (e.g. “Period of care” in the diagram will become “PeriodOfCare” in the tables, “Subject of care” in the diagram will become “SubjectOfCare”). Blank spaces are left in the diagrams for readability reasons.

— 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, for readability reasons, 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 holds.

  — 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 6.2 to 6.4 of ISO 12967-1:2009.

Figure 2 shows, at a first level of abstraction, the main objects of the model and their relations according to the concepts identified in the enterprise viewpoint, with respect to the fundamental workflows and groups of users’ activities to be supported by the middleware.

By proceeding according to the same methodology adopted for the specification of the enterprise viewpoint, this high-level model can be refined by identifying seven clusters of objects, each of them 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) Clinical and health objects
These objects shall organize and store the information necessary for supporting the users’ activities identified in the “Clinical 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.

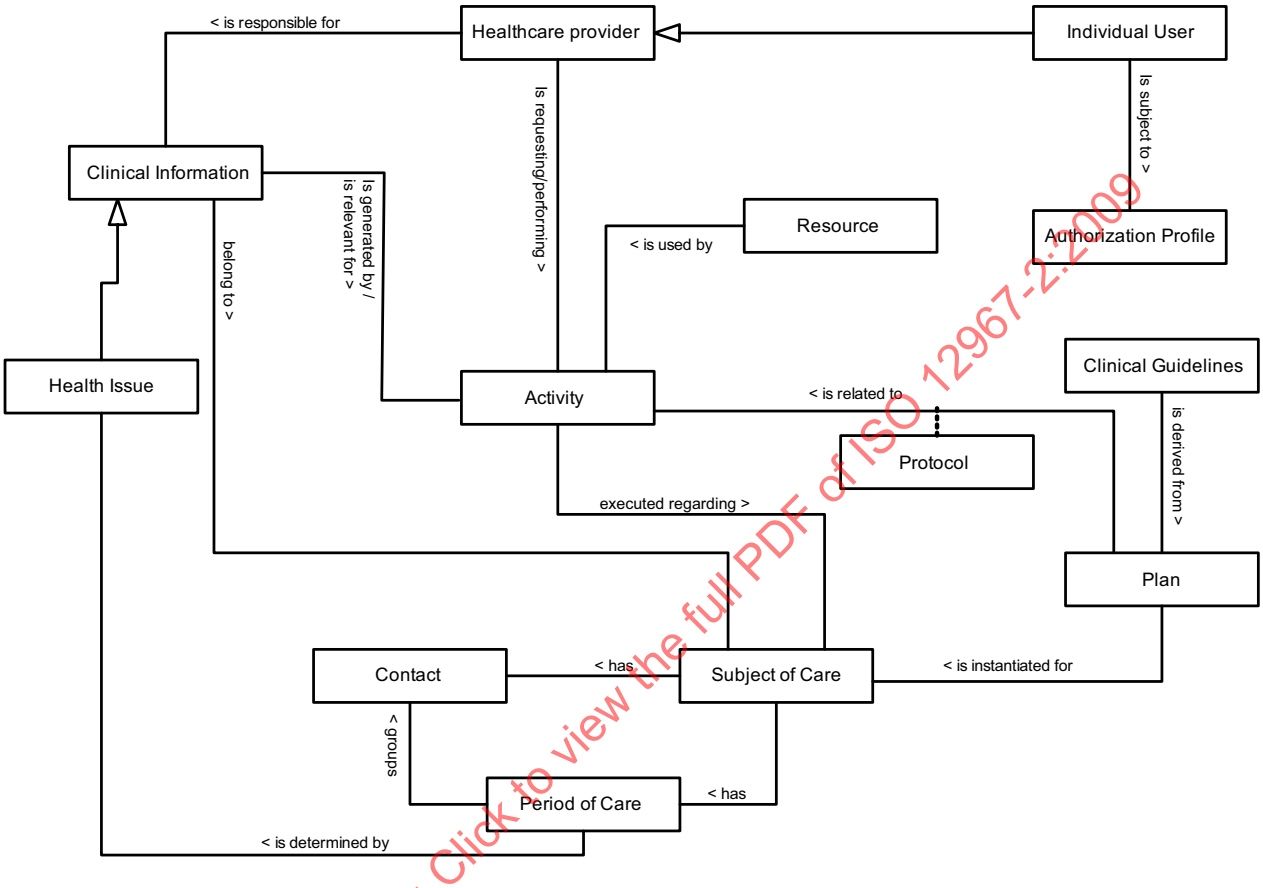

Figure 2 — High-level model of the information objects

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

From the textual descriptions in the enterprise viewpoint, the middleware 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 organization-related, specifying the criteria according to which the organization works and is organized. 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 3.

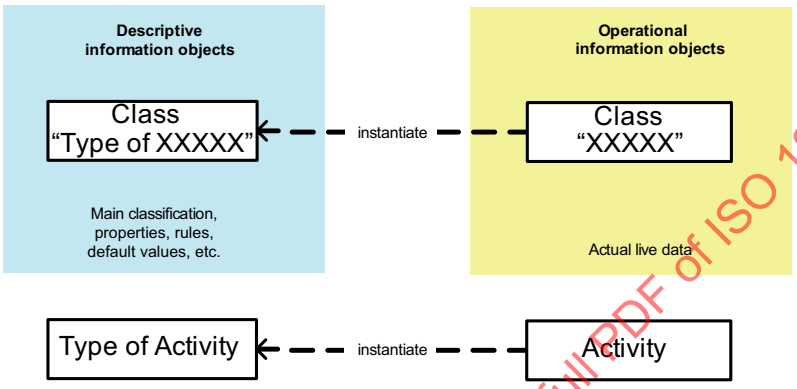

Figure 3 — Knowledge base implemented through the Descriptive Information Objects

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. Also in this case, 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.

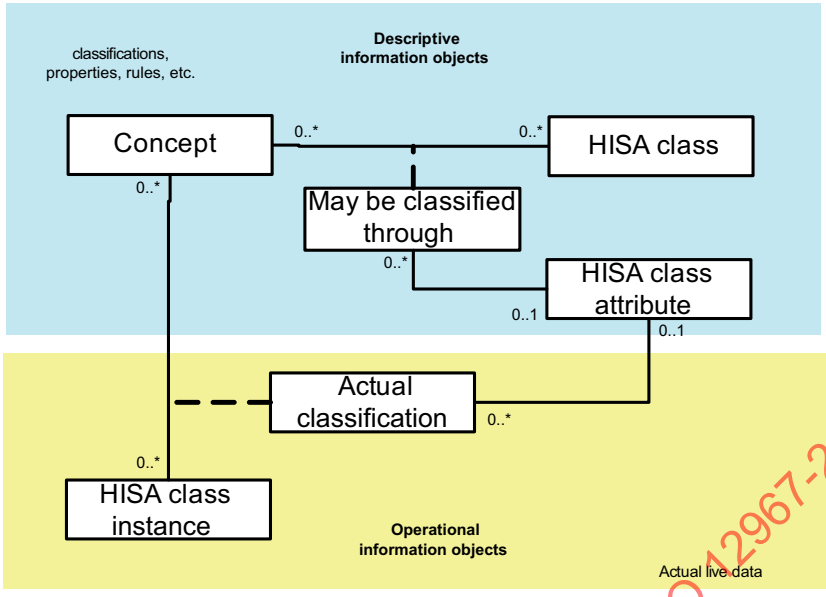

Figure 4 — Further classification criteria for each HISA class

5.5 DataTypes

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

On the basis of the primitive data types, the following HISA data types are also used in this specification to further define the meaning of data values that can be assigned to a data element.

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	Representation of date and time at least up to the level of the millisecond.
DateTime	String	Representation of date and time at least up to the level of the second.
Ordinal	Integer	A number which defines a position in an ordered series (CEN/TS 14796:2004).
Unit	String	Unit of measure, expressed according to codes defined in the "*Unified Code for Units of Measures*" (http://aurora.rg.iupui.edu/UCUM).
URI	String	Telecommunication address as specified by Internet standard RFC 1738 (http://www.isi.edu/in-notes/rfc1738.txt) as relates to one of the following schema codes: "http" (RFC 2068), "ftp" (RFC 1738), "file" (RFC 1738).
SET<DataType>		Value that contains multiple values of the data type specified as its elements.

5.6 Organization of the document

The specification of the overall information model is structured through the following sections:

— Formalization of the general criteria and of the properties common to all classes identified in the model.

— One schema for each business process identified in the enterprise view, showing the sole classes relevant for that business process.

NOTE Due to the integration of the whole model, in each schema there are some classes that are related to objects relevant for other business processes and therefore described in the relevant sections; these classes are highlighted with a brown colour.

— Specification of the identified objects, with the definition of the related properties and of the relations among them.

— Informative Annex A summarizes essential guidelines on the UML notation adopted for the specification of the schemas.

6 General characteristics of the model

6.1 Common structure of each information object: the GenericHisaClass

Each object of the information model shall conform to a common structure (i.e. the “GenericHISAClass”) comprising the following:

— set of attributes (named “specific attributes”), describing the semantic aspects specific to the class itself (e.g. Person’s name, gender, etc.);

NOTE 1 These attributes are the ones that are illustrated in the property list of the classes in the diagrams in Clause 7.

— set of attributes (named “system attributes”), common to all objects, supporting general requirements in terms of accountability, auditing, legal/clinical requirements, etc. (e.g. the date time of registration/updating of the instance);

— indefinite number of multi-media properties (named “extended attributes”), which may be added dynamically at run-time and that allow to record further information on the objects; these properties shall comprise, among others, the following attributes:

  — actual datum (i.e. the value, for example a Person’s photo, the colour of his/her eyes, etc.);

  — characteristics describing the properties of the actual datum (e.g. type [=IMAGE], size, etc.; these shall be described, where possible, through the CEN data types);

  — "system attributes”, common to all instances of the object;

— indefinite number of textual properties (named “business rules”), which may be added dynamically at run-time and that allow to record specific (e.g. legal, clinical, organizational, operational) rules and criteria that may by applicable when operating with the instance in certain contexts; these properties shall comprise, among other, the following attributes:

  — actual text of the rule;

  — scope of applicability of the rule;

  — "system attributes”, common to all instances of the object;

NOTE 2 The formalization of the semantics and of the syntax of such rules is under the responsibility of the specific implementation scenario and is outside the scope of this part of ISO 12967, which only prescribes the capability of each object to allow the recording and management of such type of information.

— indefinite number of properties (named “state changes”), which shall be added dynamically at run-time automatically by the class itself, and that shall record the changes that occurred in the “specific attributes” of the class, in order to keep track of the life cycle of the instance during the time; these properties shall comprise, among others, the following attributes:

  — value of the “system attributes” prior to the change;

  — identification of the system attributes that have been changed;

  — new values assigned to the system attributes that have been changed;

  — date, time of the change;

  — identification of the agent (i.e. individual or system process) that has effected the change;

— set of attributes (named “versioning attributes”), common to all objects, supporting the definition and management of multiple versions of the instance of the object, each of them characterized by an identification label and the time frame (i.e. starting date and ending date) of validity;

At a certain moment, either one or no instance shall be valid, therefore time frames of validity shall not overlap.

— relationship linking one version of the object with the instance representing the previous version;

— indefinite number of relationships (named “classification criteria”), which may be added dynamically at run-time and that allow to classify the entire class and/or individual attributes according to multiple classification criteria, defined in the “Concept” class of the model.

6.2 UML diagram

All the classes in Figure 5 are specified in 6.3, except the HISA Concept class, which is specified in 7.1.3.2.

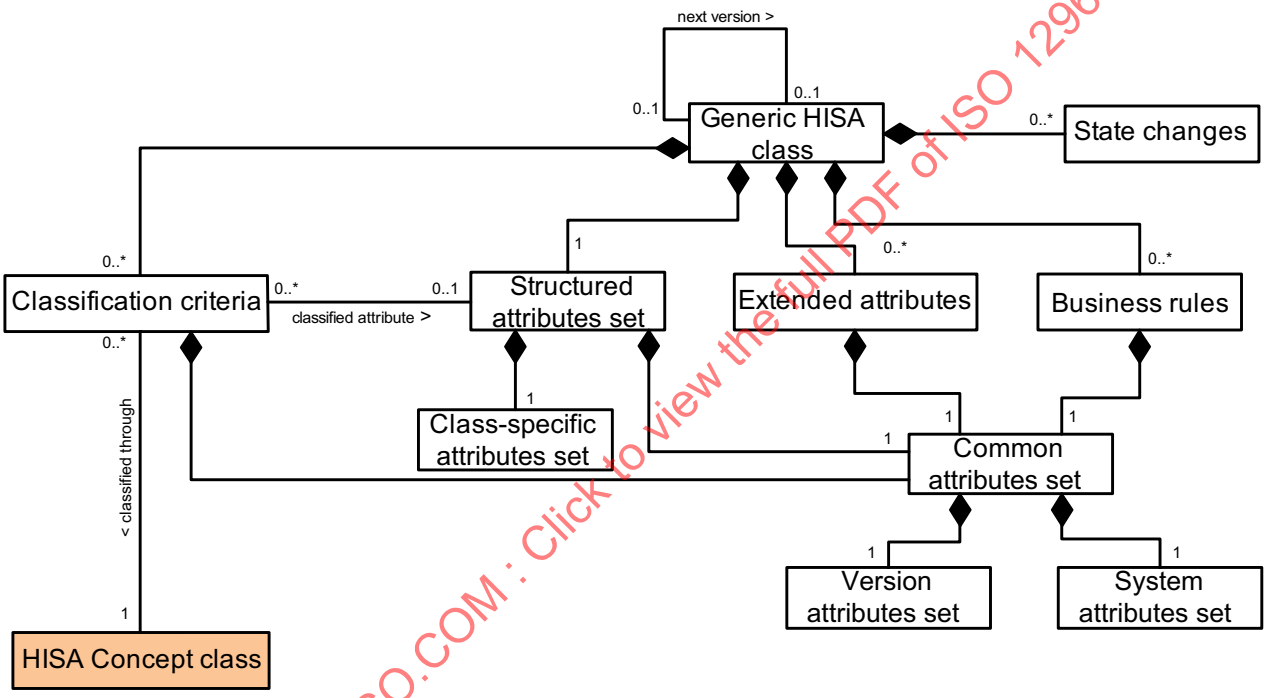

Figure 5 — The generic HISA class

6.3 Specification of Generic HISA Class

6.3.1 General

Class identifier: GenericHISAClass			
Description	This meta-class represents the HISA information objects belonging to the information model		
Associated classes		**Type of association**	**Multiplicity**
StructuredAttributes		Composition	1
ExtendedAttributes		Composition	0..*
BusinessRules		Composition	0..*
StateChanges		Composition	0..*
ClassificationCriteria Relating the instance with multiple classifications		Composition	0..*
Versioning Relating the instance with its previous version, if it exists		Association	0..1
Attributes	**Type**	**Description**	
none			

6.3.2 Class: Set of structured attributes

Class identifier: StructuredAttributes			
Description	Set of all structured attributes of the HISA information object consisting of the composition of a) the specific attributes peculiar to the HISA information object and b) the set of common attributes that shall be present in all classes		
Associated classes		**Type of association**	**Multiplicity**
CommonAttributes		Composition	1
ClassSpecificAttributes		Composition	1
Attributes	**Type**	**Description**	
none			

6.3.3 Class: Set of class specific attributes

Class identifier: ClassSpecificAttributes			
Description	Set of attributes specific to the individual HISA information object		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
Dependent on the specific object		Detailed for each class in the relevant specifications	

6.3.4 Class: Set of common attributes

Class identifier: CommonAttributes			
Description	Set of all attributes common to all HISA information objects		
Associated classes		**Type of association**	**Multiplicity**
SystemAttributes		Composition	1
VersionAttributes		Composition	1
Attributes	**Type**	**Description**	
none			

6.3.5 Class: Set of system attributes

Class identifier: SystemAttributes			
Description	attributes, common to all objects, supporting general requirements in terms of accountability, auditing, etc. of the instance		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
instanceID	ObjectIdentifier	Permanent, unchangeable, unique identifier of the instance of the class.	
displayName	String	Short, human-readable description of the object, that may be abbreviated for display purposes.	
userCode	Identifier	Short, human-readable code of the object, allowing to uniquely identify the instance of the class.	
timestamp	InternalTimestamp	Internal Timestamp of the last update of the instance,	
creationTime	DateTime	Identifies time and date of the original creation of the instance	
creationAgent	ObjectIdentifier	Identifier (i.e. instanceID) of the individual that has initially created the instance.	
creationUnit	ObjectIdentifier	Identifier (i.e. instanceID) of the unit of the organization that has initially created the instance	
updateTime	DateTime	Identifies time and date of the last update of the instance.	
updateAgent	ObjectIdentifier	Identifier (i.e. instanceID) of the individual that has executed the last modification in the instance.	
updateUnit	ObjectIdentifier	Identifier (i.e. instanceID) of the unit of the organization that has executed the last modification in the instance.	
authorization	String	Specific constraints with respect to the authorization rights on reading, updating or deleting the specific instance.	
isDeleted	Boolean	If True, specifies that the instance has been logically deleted.	
isFrozen	Boolean	If True, specifies that the instance cannot be modified.	

6.3.6 Class: Set of version attributes

Class identifier: VersionAttributes			
Description	attributes, common to all objects, supporting the definition and management of multiple versions of the instance of the object		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence number of the version	
startValidityDate	DateTime	Starting date of validity of the version of the instance	
endValidityDate	DateTime	Ending date of validity of the version of the instance	

6.3.7 Class: Extended attributes

Class identifier: ExtendedAttributes			
Description	Formatted or unformatted texts, multimedia data or structured information as defined by a different standard, which may be attached/removed dynamically at run-time to the instance to record further information in addition to those already specified by the StructuredAttributes		
Related terms	See also “Encapsulated data”, as defined in CEN/TS 14796:2004.		
Notes	Attributes extend those defined in CEN/TS 14796:2004.		
Associated classes		**Type of association**	**Multiplicity**
CommonAttributes		Composition	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence number of the property	
type	String	Specification of the semantics of the property NOTE The classification criteria to be adopted shall be defined and published locally in the individual implementations.	
mediaType	String	Identifies, according to the MIME datatypes and notations, the encoding of the data and a method to interpret or render the data	
charset	String	Where applicable, specifies, according to the IANA character set, the character set and character encoding used.	
language	String	Name of language used, if data is formatted text (according to ISO 639))	
compression	String	Id data are compressed, indicates the compression algorithm that was used	
reference	URI	URI reference to a location external to the system if the data are not natively stored in the middleware	
integrityCheck	Array of Byte	A short binary value representing a cryptographically strong checksum over the binary data	
integrityCheckAlgorithm	String	Specifies the algorithm used to compute the integrity check value	
data	Array of Byte	Actual value of the datum	
alternateString	String	Textual title of the multi-media property, to be displayed in lieu of multimedia display	

6.3.8 Class: State changes

Class identifier: StateChanges			
Description	Properties that may be added dynamically at run-time to document the updates made to the “SpecificAttributes” of the class		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence position of the property	
dateOfChange	DateTime	Identifies the time in which the change was made	
authorOfChange	identifier	Identifier (i.e. instanceID) of the individual that has performed the change	
oldInstance	Set<String>	Identifiers and values of all attributes of the instance, prior to the change	
newValues	Set<String>	Identifiers of the attributes that have been changed and new values assigned to each of them	

6.3.9 Class: Business rules

Class identifier: BusinessRule			
Description	Properties that may be added dynamically at run-time to the record to specify rules and criteria (e.g. legal, clinical, organizational, operational) that may be applicable when operating with the instance in certain contexts		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence position of the property	
title	String	Title of the rule property	
context	String	Specification of the context (if any) where the rule is applicable The notation and criteria to be adopted for the specification of such datum shall be defined locally by the individual implementations.	
value	String	Text of the rule	

6.3.10 Class: Classification criteria

Classification Criteria			
Description	Properties that may be added dynamically at run-time to the record to classify the instance and/or individual attributes according to different terminologies and other classification concepts (e.g. legal, clinical, organizational, operational) rules and criteria that may by applicable when operating with the instance in certain contexts		
Associated classes		**Type of association**	**Multiplicity**
StructuredAttributesSet Identifies the specific attribute of the instance being classified with the external classification item		Binary association	0..1 If no attribute is specified, the classification applies to the entire instance of the class
HISAConcept Specifies the classification item to be related to the instance and to the attribute (if referred with the relation “classified attribute”)		Binary association	0..*
Attributes	**Type**	**Description**	
context	String	Identification of the context of applicability of the classification	

7 The reference information models

7.1 Classification objects

7.1.1 Scope

The classification package groups the information services that support the rest of the healthcare information system in the management of the concept “descriptors” (classifications, code sets, etc.) used in the information system. The information handled by the classification package includes:

— terms defined in a concept vocabulary;

— semantic types which are applied to classify the terms in the concept vocabulary;

— types of rules which may be used to define relationships or dependencies between different entities, as well as between different individual items, on the basis of particular values of their attributes;

— actually defined semantic relationships;

— rules which may be associated with particular entities or individual items, describing knowledge about how to manage them in actual applications.

— package identifier (for any coded reference to this group of objects): cm.

7.1.2 UML information model

See Figure 6.

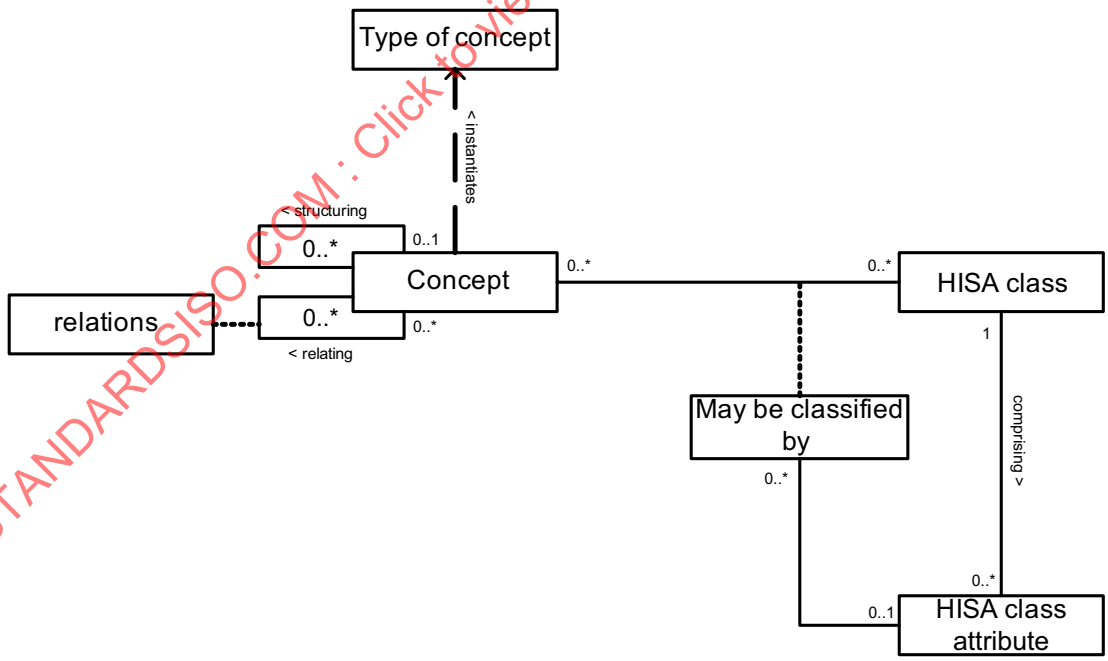

Figure 6 — UML model for classification objects

7.1.3 Specification of the individual classes

7.1.3.1 Class: Type of concept

Class identifier: TypeOfConcept			
Description	Types of concepts being adopted in the system for describing the HISA objects		
Associated classes		**Type of association**	**Multiplicity**
Concept		Parent of dependency	
Attributes	**Type**	**Description**	
Id	Identifier	One identifier that may be used to uniquely identify the type of concept	
description	String	A phrase by which the concept is described in a manner that is intended to be unambiguous in the given language	

7.1.3.2 Class: Concept

Class identifier: Concept			
Description	Concept used to describe a HISA object, i.e. an element of a classification, a code in a code set, etc.		
Notes	The attributes defined for this class conform to the “Coded Value” data type defined in CEN/TS 14796:2004, 8.5		
Examples	The concept class will be handling different sorts of concept systems used when HISA classes are instantiated that are required for different applications: epidemiological, territorial, statistical, clinical, economical, etc. Hierarchical classifications, as well as other forms of terminologies, can be applied through the structuring relations.		
Associated classes		**Type of association**	**Multiplicity**
TypeOfConcept		Dependency	0..*
HISAClass Information objects that may be classified by means of the concept		Binary association Through association class “May be classified by”	0..*
Concept (structuring) Concepts being aggregated and structured in a hierarchy by means of the concept		Binary association	0..*
Concept (relating) Concepts being related for different reasons with the concept		Binary association Through association class “relations”	0..*
Attributes	**Type**	**Description**	
Id	Identifier	One identifier that may be used to uniquely identify the concept	
description	String	A phrase by which the concept is described in a manner that is intended to be unambiguous in the given language	
codeValue	String	The conventional value of the concept in the given language	
language	String	Identification of the language used for the name and preferred term of the concept.	
codingSchemeName	String	Name of the coding schema	
codingSchemeVersion	String	Version of the coding schema	

7.1.3.3 Class: HISA class

Class identifier: HISAClass			
Description	Information objects instantiated in the middleware		
Associated classes		**Type of association**	**Multiplicity**
TypeOfConcept		Dependency	0..*
HISAClass Information objects that may be classified by means of the concept		Binary association Through association class “May be classified by”	0..*
Concept Concepts according to which instances of the class may be classified		Binary association Through association class “May be classified by”	0..*
HISA class attribute Attributes of the HISA class		Binary association	1..*
Attributes	**Type**	**Description**	
id	Identifier	One identifier that may be used to uniquely identify the class NOTE For those classes specified in this part of ISO 12967, this value will be structured according to the notation. <packageID>.<classID>, individually representing the identifiers of the package and of the class as defined in this part of ISO 12967	
description	String	A phrase by which the concept is described in a manner that is intended to be unambiguous in the given language	

7.1.3.4 Class: HISA class attribute

Class identifier: HISAClassAttribute			
Description	Attributes of the information objects instantiated by the middleware		
Associated classes		**Type of association**	**Multiplicity**
HISAClassInformation objects that comprise the attribute		Binary association Through association class “May be classified by”	1
Attributes	**Type**	**Description**	
id	Identifier	One identifier that may be used to uniquely identify the attribute NOTE For those classes specified in this part of ISO 12967, this value will be structured according to the notation. <packageID>.<classID>.<attribute> individually representing the identifiers of the package , of the class and of the attribute as defined in this part of ISO 12967	
description	String	A phrase by which the attribute is described in a manner that is intended to be unambiguous in the given language	
dataType	String	Specification of the data type of the allowed values	

7.1.3.5 Association class: Relations among concepts

Class identifier: Relations			
Description	Association class allowing to relate different concepts to each other for different purposes (e.g. synonyms, clinical and organizational reasons, etc.)		
Associated classes		**Type of association**	**Multiplicity**
Concept First concept being related		Binary association	1
Concept Second concept being related		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second concept in the list	
context	String	Context of applicability of the relation	
reason	String	Reason of applicability of the relation	
startDate	DateTime	Starting time of validity of the relation	
endDate	DateTime	Ending time of validity of the relation	
properties	String	Properties and other information depending on the relation between the two concepts	

7.1.3.6 Association class: May be classified by

Class identifier: MayBeClassifiedBy			
Description	Association class identifying the concepts that may be used to classify the instances of the various information objects of the HISA model, as well as the specific attributes of each class		
Associated classes		**Type of association**	**Multiplicity**
Concept Concept that can be used for the classification		Association class	1
HISAClass HISA class that may be classified through the concept		Association class	1
HISAClassAttribute Specific attribute of the HISA class that may be classified through the concept		Binary association	0..1 NOTE If no attribute is specified, than the classification relates to the class instance meant as a whole.
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second concept in the list	
context	String	Reason and context of applicability of the classification	
IsOptional	Boolean	Specifies whether the classification of the related instance/attribute is optional or mandatory	

7.2 Subject of care objects

7.2.1 Scope

The subject of care package groups the information services which support the rest of the healthcare information system in the identification of the subject of care, including person identification and demographic data, and basic administrative "placeholders" for managing a variety of clinical and administrative issues related to the treatment, care and administration of subjects of care.

Package identifier (for any coded reference to this group of objects): pm.

7.2.2 UML information model

All non-coloured classes belonging to the subject of care cluster of objects in Figure 7 are specified in 7.2.3. The clinical information and health issue classes are specified in 7.4.3.1 and 7.4.3.3. The activity class is specified in 7.3.3.2. The agent, individual agent, and the organization element are specified in 7.6.3.2, 7.6.3.4 and 7.6.3.3, respectively. The staff member is specified in 7.5.3.10.

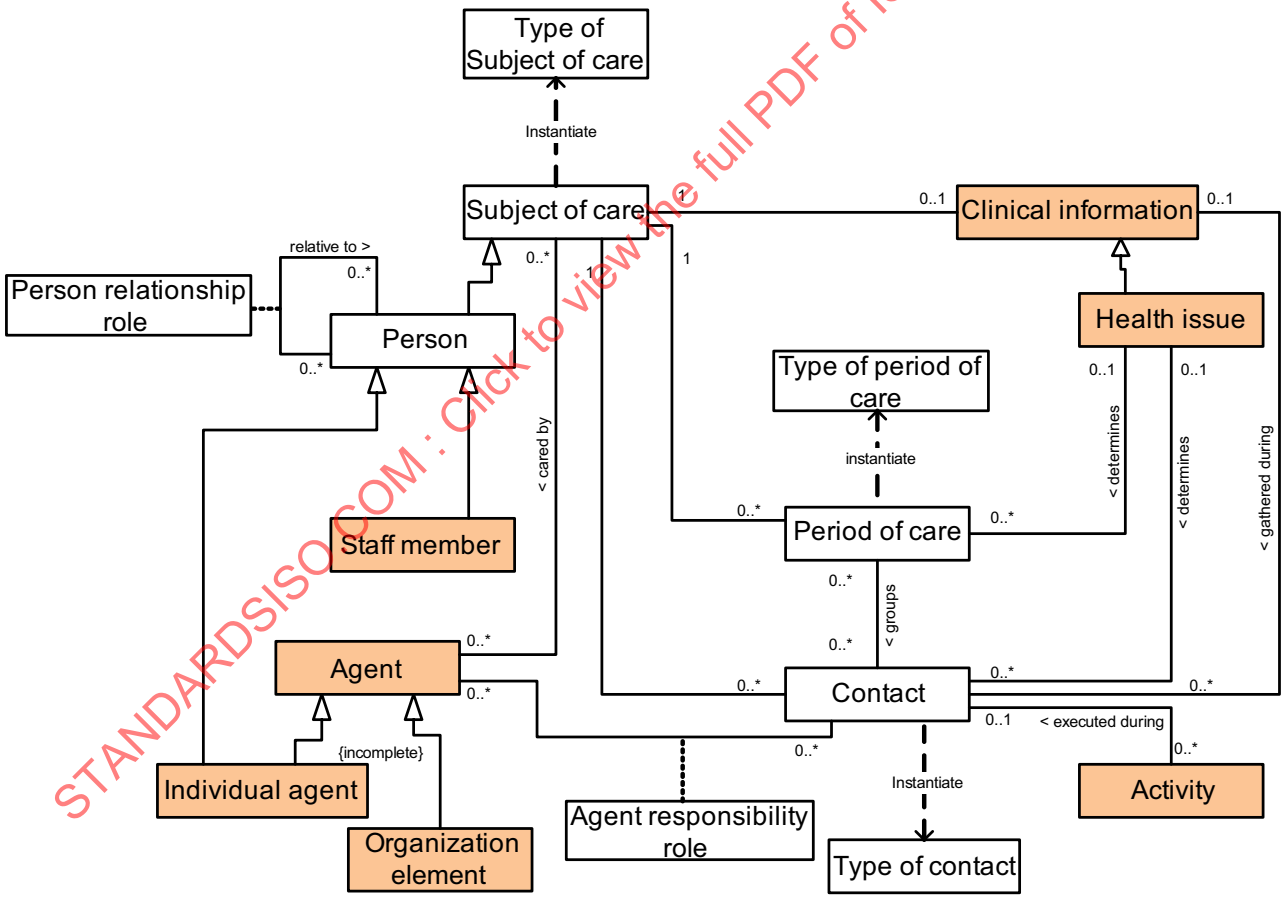

Figure 7 — UML model for subject of care objects

7.2.3 Specification of the individual classes

7.2.3.1 Class: Type of subject of care

Class identifier: TypeOfSubjectOfCare			
Description	Type of entity scheduled to receive, receiving or having received health care services (CONTSYS)		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare		Dependency	
Attributes	**Type**	**Description**	
id	SET<String>	Identifier(s) that may be used to uniquely identify the type of subject of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.2 Class: Subject of care

Class identifier: SubjectOfCare			
Description	Entity scheduled to receive, receiving or having received health care services (CONTSYS)		
Related terms	Subject of Care: Acts as a generalization of the GPICs used to provide information about human and non-human subjects of care (GPIC) Subject of Care Person: A set of information about a person that is, has, or shall be, receiving healthcare related services (GPIC) Patient Standard Information: A set of general information about a human subject of care (GPIC) Patient Extended Information: An extended set of demographic and social information about a human subject of care (GPIC)		
Notes	In this part of ISO 12967, Subject of Care is mainly intended as an individual person.		
Examples	None		
Associated classes		**Type of association**	**Multiplicity**
TypeOfSubjectOfCare		Dependency	
Person (subtype) Those Subjects of Care being human beings		Generalization	
Contact Contacts had by the Subject of Care		Binary association	0..*
PeriodOfCare Period(s) of care related to the Subject of Care		Binary association	0..*
ClinicalInformation Clinical information related to the Subject of Care		Binary association	0..*
Agent Agent(s) (individuals and organizations) that take care of the Subject of Care		Binary association	0..*
Attributes	**Type**	**Description**	
id	String	Unique identifier of the subject of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.3 Class: Person

Class identifier: Person			
Description	Individual human being, scheduled to receive, receiving or having received health care services.		
Related terms	Person: general demographic information about a person (GPIC)		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare (*supertype*)		Generalization	
StaffMember (*subtype*) Those persons also working as staff members in the organization		Generalization	
IndividualAgent (*subtype*) Those persons also acting as agents of the system in the organization		Generalization	
Person (Relative) Relative(s) of the person		Binary association Through association class role	0..*

Attributes	**Type**	**Description**
id	SET<String>	Identifier(s) that may be used to uniquely identify the person
name	SET<String>	A name or names by which the person is, or has been, known
birthTime	DateTime	Date and possibly time of birth
deceasedTime	DateTime	Date and time of death
gender	String	(Administrative) gender of the person
address	SET<String>	Postal address(es) associated with the person
telcom	SET<URI>	Communication data associated with the person

7.2.3.4 Class: Type of contact

Class identifier: TypeOfContact			
Description	Class handling all types of contact, describing the actual contacts		
Associated classes		**Type of association**	**Multiplicity**
Contact		Dependency	

Attributes	**Type**	**Description**
id	String	Identifier(s) that may be used to uniquely identify the type of contact
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language

7.2.3.5 Class: Contact

Class identifier: Contact	
Description	Situation on the uninterrupted course of which one health care provider performs health care services for a subject of care (CONTSYS – modified)
Related terms	Contact: Situation in the uninterrupted course of which one health care provider performs health care services for a subject of care, and/ or accesses his or her health care record (CONTSYS) Encounter: Situation on the uninterrupted course of which one health care professional delivers health care services to a subject of care, accesses his or her health care record, and updates it (CONTSYS) Contact element: Part of a contact that specifically addresses one and only one health issue (CONTSYS) Care encounter: A specialization of ClinicalInformationComplex containing a set of information about a patient care encounter that has happened or is planned, cancelled, postponed, etc. *(GPIC)* Related care encounter: Set of information concerning a care encounter that is related to some other activity (GPIC)
Notes	The Contact is an administrative placeholder for managing the set of health issues recorded, activities performed, resources used, subject of care and health care providers involved, etc. during the period of time the Contact lasts. Healthcare information systems may be implemented without using the Contact as an administrative container. Thus, all associations from this class to other classes are modelled with multiplicities 0..1 or * at the Contact class end. However, if the Contact class is implemented, the associations should have multiplicities 1 or 1..* at this end.
Examples	An ambulatory visit, an in-patient stay, a day-hospital stay, telemedical supervision, telephone advisory, etc.

Associated classes	**Type of association**	**Multiplicity**
SubjectOfCare Subject of care to whom the contact relates	Binary association	1
PeriodOfCare Period of care in which the contact is clustered	Binary association	0..*
Activity Activity(ies) performed in the interest of the patient during the contact	Binary association	0..*
ClinicalInformation Clinical information on the Subject of Care that are gathered during the contact	Binary association	0..*
HealthIssue Health issue of the Subject of Care that is determining the contact	Binary association	0..*
Agent Agent(s) responsible, at various levels, for the Contact during its various phases	Binary association Through association class “Responsible for”	1..*

Attributes	**Type**	**Description**
id	Identifier	Unique identifier for the Contact
startTime	DateTime	Date and time when the contact is started (or is planned to start, depending on the life-cycle status)
endTime	DateTime	Date and time when the contact is ended (or is planned to end, depending on the life-cycle status)
startReason	String	Reason for the initiation of the contact
endReason	String	Reason for terminating the contact
status	String	Status of the contact; described, at least, through values: “Planned”, “Active”, “Terminated”, “Annulled”

7.2.3.6 Association class: Agent responsibility role

Class identifier: AgentResponsibilityRole			
Description	Agents responsible for the contact during its evolution. The responsibility is different for an Agent if it is a individual agent or an organizational unit		
Associated classes		**Type of association**	**Multiplicity**
Agent Agent responsible for the contact		Binary association	1
Contact		Binary association	1
Attributes	**Type**	**Description**	
role	String	Specification of the type of involvement of the Agent, described, at least, through values: “Referring”, “Caring”	
startTime	DateTime	Date and time when the Agent starts to be involved in the contact according to the specified “Role”	
endTime	DateTime	Date and time when the Agent terminates being involved in the contact according to the specified “Role”	
startReason	String	Reason for the starting of involvement in the contact	
endReason	String	Reason for the termination of involvement in the contact	

7.2.3.7 Class: Type of period of care

Class identifier: TypeOfPeriodOfCare			
Description	Class handling all types of period of care, describing the actual period of care through which contacts are grouped		
Associated classes		**Type of association**	**Multiplicity**
PeriodOfCare		Dependency	
Attributes	**Type**	**Description**	
id	String	Identifier(s) that may be used to uniquely identify the type of period of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.8 Class: Period of care

Class identifier: PeriodOfCare	
Description	Construct that groups health issues and/or contacts and associated elements that are recorded in the health information system regarding a subject of care under the clinical framework of one particular health Issue
Related terms	Period of Service: Time interval during which one or more contacts occur between a subject of care and a health care provider in the framework of a care mandate (CONTSYS) Episode of Care: Situation encompassing all contact elements related to the same health issue (CONTSYS) Cumulative Episode of Care: Situation encompassing the occurrence of all health care services related to only one health issue thread (CONTSYS)
Notes	The period of care thus corresponds to a folder of a problem-oriented patient record, for a specific problem (health issue).

Associated classes	**Type of association**	**Multiplicity**
TypeOfPeriodOfCare	Dependency	
SubjectOfCare Subject of care to whom the Period of Care relates	Binary association	1
Contact Contacts being grouped in the Period of Care	Binary association	0..*
HealthIssue Health issue of the Subject of Care that has determined the starting of the Period of Care	Binary association	1

Attributes	**Type**	**Description**
Id	Identifier	Unique identifier for the Period of Care
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language
startTime	DateTime	Date and time when the period of care is started (or is planned to start, depending on the life-cycle status)
endTime	DateTime	Date and time when the period of care is ended (or is planned to end, depending on the life-cycle status)

7.2.3.9 Association class: Person relationship role

Class identifier: PersonRelationshipRole	
Description	Persons can have different relationships with each other, e.g. mother of, married to, etc.

Associated classes	**Type of association**	**Multiplicity**
Person First person in relationship (i.e. the Relative)	Binary association	0..*
Person Other person in relationship (i.e. the “Mother”, “Tutor”, etc.)	Binary association	0..*

Attributes	**Type**	**Description**
role	String	Specification of the type of relationship between the persons, described, for example, through values: “Parent”, “Tutor”, “Married to”.
startTime	DateTime	Date and time when the relationship starts according to the specified “Role”
endTime	DateTime	Date and time when the relationship terminates according to the specified “Role”
reason	String	Reason for the relationship

7.3 Activity management objects

7.3.1 Scope

The activity package groups the information services which support the rest of the healthcare information system in the management of the healthcare activities, and the life cycles of these activities as they are planned to be, are being or have been carried out in the various parts of the healthcare enterprise.

It also groups the information services which support the rest of the healthcare information system in the management of the elements of clinical guidelines and clinical planning as relates to particular health issues (i.e. standard plans) or particular subjects of care (i.e. patient plans).

Package identifier (for any coded reference to this group of objects): am

7.3.2 UML information model

All non-coloured classes belonging to the Activity Management cluster of objects in Figure 8 are specified in the 7.3.3. The clinical information, the demand for care class, the association class Activity C.I., and the association class role of agent in C.I. life cycle are specified in 7.4.3.1, 7.4.3.2, 7.4.3.10 and 7.4.3.8, respectively. The contact class is specified in 7.2.3.5. The type of resource and resource classes are specified in 7.5.3.1 and 7.5.3.8. The Agent class is specified in 7.6.3.2. The staff member is specified in 7.5.3.10.

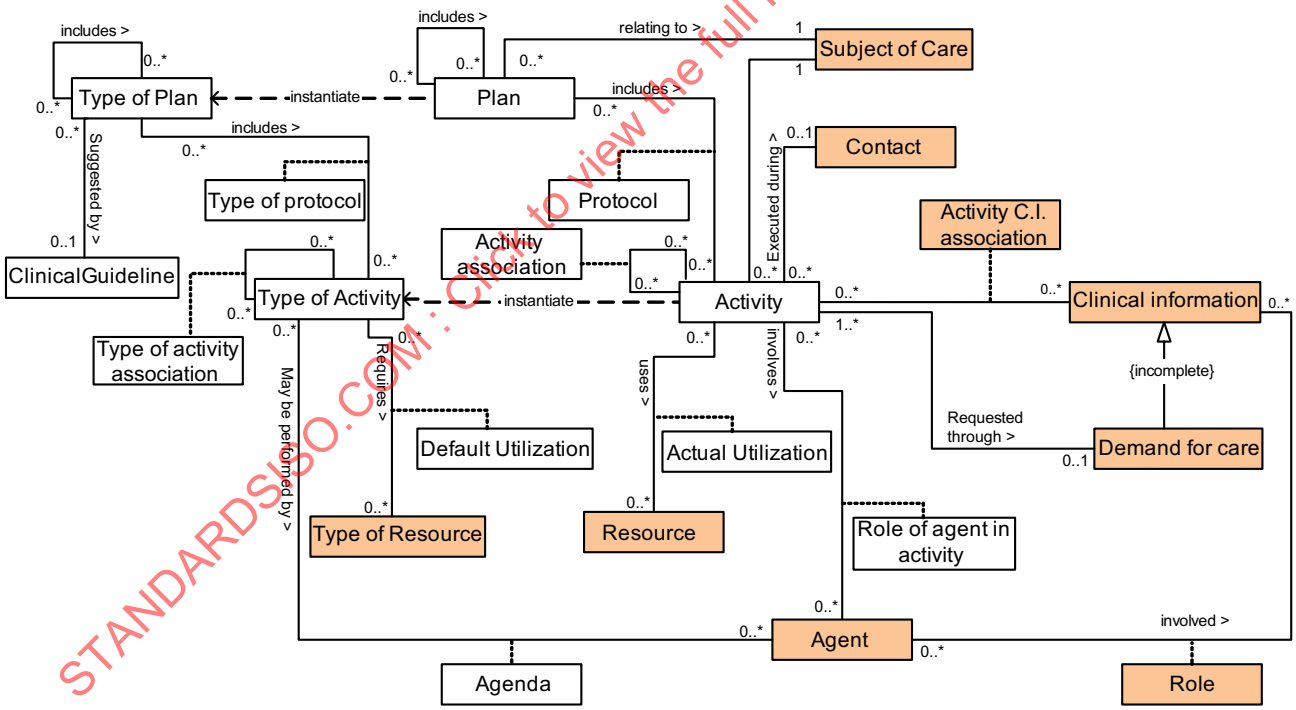

Figure 8 — UML model for activities objects

7.3.3 Specification of the individual classes

7.3.3.1 Class: Type of activity

Class identifier: TypeOfActivity			
Description	Class handling all types of activities, describing the actual activities and interventions carried out within the healthcare organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity Hierarchy of types of activities		Binary Association	0..*
TypeOfPlan		Binary Association through Association Class TypeOfProtocol	0..*
TypeOfResource		Binary Association through Association Class Default Utilization	0..*
Agent Agent(s) may perform the type of activity		Binary Association through Association Class Agenda	0..*
Activity		Dependency	
Attributes	Type	Description	
id	Identifier	Unique identifier for the type of activity	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
duration	Double	Average duration of the type of activity	
durationMeasure	Unit	Unit of measure of the average duration of the type of activity	
cost	Double	Average cost of the type of activity	

7.3.3.2 Class: Activity

Class identifier: Activity	
Description	Activity performed for a subject of care by a healthcare provider with the intention of directly or indirectly improving or maintaining the health of that subject of care (CONTSYS modified)
Related terms	Activity performed for a subject of care by a health care agent with the intention of directly or indirectly improving or maintaining the health of that subject of care (CONTSYS) Act: Act represents intentional activities within the healthcare domain such as observations, investigations, transportation, patient encounters, referrals, etc. (GPIC)
Examples	Observation, intervention, procedure, medication, drug dispensation, drug administration, transportation, etc.

Associated classes	**Type of association**	**Multiplicity**
SubjectOfCare Subject of care for whom the activity is performed	Binary association	0..1
Agent Agent(s) involved with different roles during the life cycle of the activity	Binary association through Association Class Role	0..*
ClinicalInformation Clinical information related to an activity (e.g. relevant for the execution of the activity, generated as outcomes of the activity)	Binary association through Association Class ActivityClinicalInformationAssociation	0..*
Plan Plan in which the activity is organized	Binary association through Association Class Protocol	0..1
Resource Resource(s) used for the execution of the activity	Binary association through Association Class Actual Utilization	0..*
Contact Contact during which the activity is performed	Binary association	0..1
TypeOfActivity	Dependency	

Attributes	**Type**	**Description**
id	Identifier	Unique identifier for the Activity
status	String	Status of the activity in its life cycle from the initial request to the completion
requestTime	DateTime	Date and time of request
execRequest	DateTime	Date and time requested for the execution of the activity
execStartTime	DateTime	Date and time when the execution of the activity has been started
execEndTime	DateTime	Date and time when the execution of the activity has been completed
urgency	String	Level of urgency of the activity
cost	Double	Actual cost for the execution of the activity
duration	Double	Actual duration of the execution of the activity

7.3.3.3 Class: Type of plan

Class identifier: TypeOfPlan	
Description	Class handling all types of plans, describing the plans through which interventions and activities are carried out for actually treating patients within the healthcare organization

Associated classes	**Type of association**	**Multiplicity**
Plan	Dependency	
TypeOfPlan (includes) Implements a hierarchy in the types of plan, allowing to structure a type of plan by combining other types	Binary association	0..*
TypeOfActivity Type of Activities (to be) included in the type of plan	Binary association through Association Class TypeOfProtocol	0..*
ClinicalGuideline Clinical Guidelines that suggest the implementation of the Type of Plan	Binary association	0..1

Attributes	**Type**	**Description**
id	String	Identifier(s) that may be used to uniquely identify the type of plan
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language

7.3.3.4 Class: Plan

Class identifier: Plan	
Description	Bundle of activities addressing the treatment and care of one particular health issue of one particular subject of care, as defined by a healthcare provider as a standard planning element encompassing all activities to be performed to achieve the specified clinical objective for the given health issue
Related terms	Programme of Care: Description of planned and duly personalized services bundles adopted by one healthcare organization, typically informed by one or more protocols, addressing one or more health issues, accounting for one or more health issue threads, and encompassing all health care activities to be performed for a subject of care by one or more health care parties (CONTSYS)

Associated classes	**Type of association**	**Multiplicity**
SubjectOfCare Subject of care to whom the plan refers	Binary association	0..1
Activity Activities (to be) executed through the plan	Binary association through Association Class Protocol	0..*
Plan (includes) Implements a hierarchy in the plans, allowing to structure a plan by combining other plans	Binary association	0..*
TypeOfPlan	Dependency	

Attributes	**Type**	**Description**
Id	String	Unique identifier of the plan
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language
definitionTime	DateTime	Date and time of definition of the plan
reason	String	Motivation of the plan

7.3.3.5 Association Class: Type of activity association

Class identifier: TypeOfActivityAssociation			
Description	Class handling all types of associations between types of activities, describing the sequences and dependencies of the types of activities included in the structure for actually treating patients within the healthcare organization A set of systematically developed statements specifying the roles and dependencies between types of activities as part of an aggregation		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity Type of activity (to be) referred in the aggregation		Binary association	1
TypeOfActivity Type of Activities (to be) included in the aggregation		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the Type of Activity in the specification of the aggregation	
rules	String	Dependencies, preparations, and other rules applicable for the execution of the Type of Activity within the aggregation	
reason	String	Reason for aggregating the types of activities	

7.3.3.6 Association Class: Activity association

Class identifier: ActivityAssociation			
Description	Class handling all associations between activities, describing the sequences and dependencies of the activities included in the structure A set of systematically developed statements specifying the roles and dependencies between activities as part of an aggregation		
Associated classes		**Type of association**	**Multiplicity**
Activity Activity (to be) referred in the aggregation		Binary association	1
Activity Activities (to be) included in the aggregation		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the activity in the specification of the aggregation	
rules	String	Dependencies, preparations and other rules applicable for the execution of the activity within the aggregation	
reason	String	Reason for aggregating the activities	

7.3.3.7 Association Class: Type of protocol

Class identifier: TypeOfProtocol			
Description	Class handling all types of protocols, describing the sequences and dependencies of the types of activities included in plans for actually treating patients within the healthcare organization. A set of systematically developed statements specifying the roles and dependencies between planned activities as part of a clinical plan.		
Examples	“Type of Activity B starts two days after Type of activity A”, “If the result of Type of Activity A is <result> then start Type f Activity B as soon as possible, or else start Type of Activity C within one day”		
Associated classes		**Type of association**	**Multiplicity**
TypeOfPlan Type of Plan (to be) referred in the type of protocol		Binary association	1
TypeOfActivity Type of Activities (to be) included in the type of protocol		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the Type of Activity in the specification of the Type Of Plan	
rules	String	Dependencies, preparations, and other rules applicable for the execution of the Type of Activity within the Type of Plan	

7.3.3.8 Association Class: Protocol

Class identifier: Protocol			
Description	A set of systematically developed statements specifying the roles and dependencies between planned activities as part of a plan		
Examples	“Activity B starts two days after activity A”, “If the result of Activity A is <result> then start Activity B as soon as possible, or else start Activity C within one day”		
Associated classes		**Type of association**	**Multiplicity**
Activity Activity involved in the protocol		Binary association	1
Plan Plan in which the activity is organized		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the activity in the plan	
rule	String	Rule to be applied for the execution of the activity, inherited from the corresponding item in “Type of Protocol” and customized according to the specific needs of the actual Plan	

7.3.3.9 Association Class: Actual utilization

Class identifier: ActualUtilization			
Description	Detail of resources used for the execution of one activity		
Associated classes		**Type of association**	**Multiplicity**
Activity Activity using the resource		Binary association	1
Resource Resource used by the activity		Binary association	1
Attributes	Type	Description	
sequence	Ordinal	Sequence order of the resource in the list	
planStartTime	DateTime	Planned starting date and time of utilization of the resource	
planEndTime	DateTime	Planned ending date and time of utilization of the resource	
planQuantity	Double	Planned quantity of resource used	
actualStartTime	DateTime	Actual starting date and time of utilization of the resource	
actualEndTime	DateTime	Actual ending date and time of utilization of the resource	
actualQuantity	Double	Actual quantity of resource used	
unitOfMeasure	Unit	Unit of measure of the used quantity	
reason	String	Reason of utilization of the resource	
modality	String	Modality of utilization (e.g. administration for drugs)	
cost	Double	Actual unit cost related to the utilization of the resource	

7.3.3.10 Association Class: Default utilization

Class identifier: DefaultUtilization			
Description	Baseline of resources generally used for the execution of one type of activity		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity Type of activity using the type of resource		Binary association	1
Type of resource Type of resource being used by the type of activity		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the resource in the list	
quantity	Double	Quantity of resource used	
unitOfMeasure	Unit	Unit of measure of the used quantity	
reason	String	Reason of utilization of the resource	
modality	String	Modality of utilization (e.g. administration for drugs)	
cost	Double	Unit cost of utilization of the Type of Resources	

7.3.3.11 Association Class: Role of agent in activity

Class identifier: RoleOfAgentInActivity			
Description	Role of one agent in the life cycle of one activity		
Associated classes		**Type of association**	**Multiplicity**
Activity		Binary association	1
Agent		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the agent in the list	
startTime	DateTime	Starting time of involvement of the agent	
endTime	DateTime	Ending time of involvement of the agent	
role	String	Role of the agent (e.g. requestor, planner, executor, etc.)	

7.3.3.12 Association Class: Agenda

Class identifier: Agenda			
Description	Agenda and rules according to which one type of activity can be planned and performed by one agent		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity		Binary association	1
Agent		Binary association	1
Attributes	**Type**	**Description**	
startTime	DateTime	Starting date and time of the agenda period	
endTime	DateTime	Ending date and time of the agenda period	
rules	String	Rules according to which the activity may be planned and performed by that agent	

7.3.3.13 Class: Clinical guideline

Class identifier: ClinicalGuideline			
Description	A set of systematically developed statements to assist the decision of health care providers about activities to be provided with regard to a specific health issue (CONTSYS – modified)		
Related terms	Clinical guideline: Set of systematically developed statements to assist the decision of health care parties about health care services to be provided with regard to a health issue in specified clinical circumstances (CONTSYS) Clinical Procedure: A specialization of ClinicalInformationItem which provides a general description of a clinical procedure (GPIC)		
Associated classes		**Type of association**	**Multiplicity**
TypeOfPlan TypeOfPlan(s) (to be) referred to the Clinical Guideline		Binary association	0..*
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier for the clinical guideline	
endDate	DateTime	Date and time until which the clinical guideline is valid	
approvedTime	DateTime	Date and time of approval of the clinical guideline	

7.4 Clinical and health information objects

7.4.1 Scope

The clinical information package groups the information objects which support the rest of the healthcare information system in the management of the clinical and health information recorded in the healthcare information system in relation to the treatment and care of each subject of care.

Package identifier (for any coded reference to this group of objects): **hm**

7.4.2 UML information model

All non-coloured classes belonging to the Clinical Information cluster of objects in Figure 9 are specified in 7.4.3. The contact class is specified in 7.2.3.5, while the subject of care class is specified in 7.2.3.2. The agent class is specified in 7.6.3.2. The activity class is specified in 7.3.3.2.

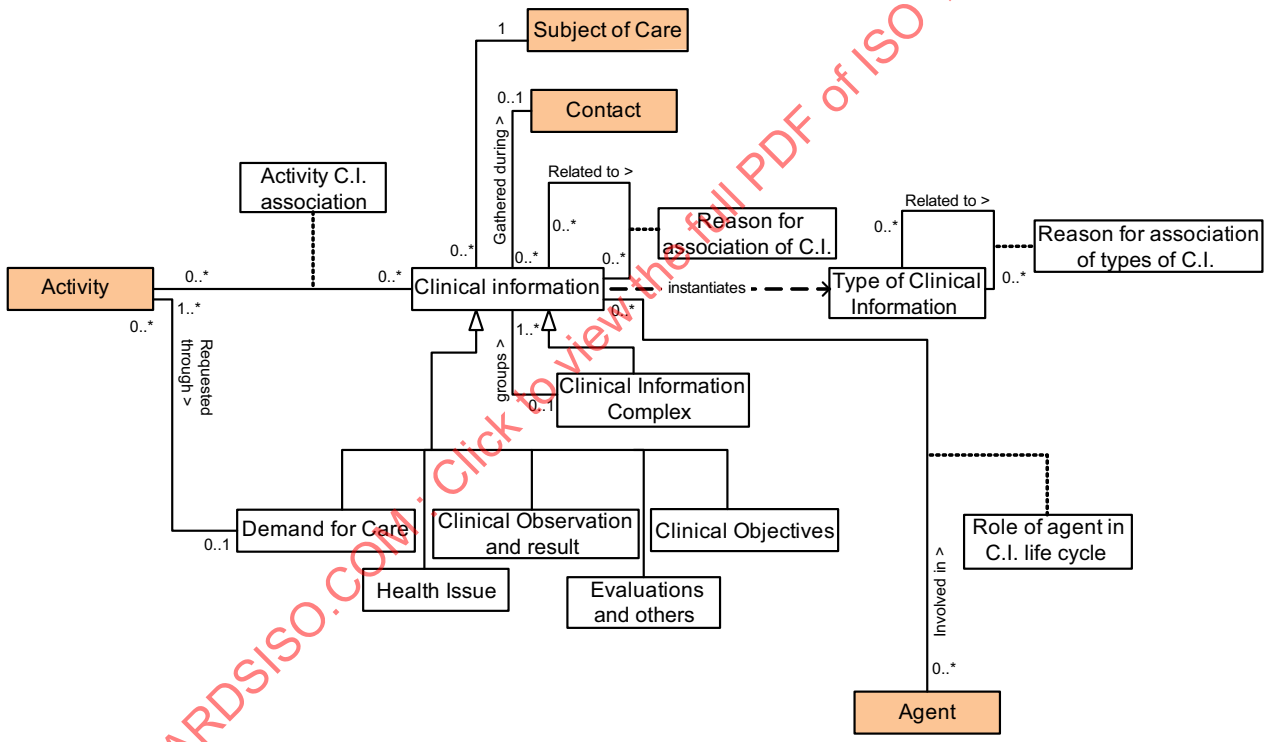

Figure 9 — UML model for clinical and health information objects

7.4.3 Specification of the individual classes

7.4.3.1 Class: Clinical information

Class identifier: ClinicalInformation	
Description	Information about the health or treatment and care of a subject of care, as recorded in the healthcare information system by on behalf of a healthcare provider
Related terms	Clinical information: Information about a patient, relevant to the health or treatment of that patient, that is recorded by, or on behalf of, a healthcare professional (GPIC)
Notes	In relation to the CONTSYS (seemingly more restricted) definition of an health Issue, health issues may, in the context of this part of ISO 12967, comprise any clinically relevant information related to a Subject of Care that may be recorded by a Healthcare Provider in the health information system
Examples	Recorded diagnoses, advice given to the subject of care, objectives of activities, results of activities, clinical values and measurements (temperature), anamnesis, etc.

Associated classes	**Type of association**	**Multiplicity**
HealthIssue	Generalization	
ClinicalObservationAndResult	Generalization	
EvaluationAndOthers	Generalization	
Clinical Objective:	Generalization	
Demand for care:	Generalization	
ClinicalInformationComplex Clinical information obtained as aggregation of other clinical information	Generalization	
SubjectOfCare Subject of care to whom the Clinical Information pertains	Binary association	1
Contact Contact through which the Clinical information has been gathered	Binary association	0..*
Agent Agents involved in the collection, validation of the clinical information	Binary association through Association Class Role	0..*
Activity Activities to which the clinical information is related (e.g. relevant for the execution or generated as outcome)	Binary association through association class ActivityClinicalInformationAssociation	0..*
ClinicalInformation Other clinical information related, for various reasons with the clinical information	Binary association	0..*
ClinicalInformation Clinical information grouped in the Clinical information Complex	Binary association	1..*
TypeOfClinicalInformation	Dependency	

Attributes	**Type**	**Description**
id	Identifier	Unique identifier for the Clinical information
value	Any	Recorded value of the Clinical information
unitMeasure	Unit	Unit of measure applicable
status	String	Status of the Clinical Information during its life cycle, including, at least, “To be validated”, “Validated”, “Annulled” as possible values

7.4.3.2 Class: Demand for care

Class identifier: DemandForCare			
Description	Demand expressed by a health care provider and/or subject of care that healthcare services be provided to a subject of care		
Related terms	Demand for Care: Demand expressed by a health care party that health care services be provided to a subject of care. (CONTSYS) Care Service Request: *A specialization of ClinicalInformationComplex containing a set of information that relates to a request for one or more care services* (GPIC)		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Activity Activities requested in the Demand for Care		Binary association	0..*
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.3 Class: Health issue

Class identifier: HealthIssue			
Description	Issue related to the health of a subject of care, as defined by a specific health care party		
Related terms	Issue related to the health of a subject of care, as defined by a specific health care party (CONTSYS)		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.4 Class: Clinical observation and result

Class identifier: ClinicalObservationAndResult			
Description	Information about the clinical observations and result as clinical measurements (temperature), result of activities, etc. of a subject of care		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.5 Class: Evaluation and other

Class identifier: EvaluationAndOther			
Description	Information about the evaluations of a subject of care		
Related terms			
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.6 Class: Clinical objective

Class identifier: ClinicalObjective			
Description	Desired or intended purpose and results of an activity		
Related terms	Health Care Objective: Desired ultimate achievement of a programme of care. (CONTSYS) Health Care Goal: desired achievement of a care plan, considered as an intermediate operational step to reach the ultimate objective of a programme of care. (CONTSYS)		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.7 Class: Clinical information Complex

Class identifier: ClinicalInformationComplex			
Description	Clinical information obtained as aggregation of other clinical information		
Related terms	A specialization of ClinicalInformation containing a grouping or collection of clinical information (GPIC)		
Examples	Any complex aggregation of clinical information		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
ClinicalInformation		Binary association	0..1
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.8 Association Class: Role of agent in C.I. life cycle

Class identifier: RoleOfAgentInClinicalInformationLifeCycle			
Description	Reasons why the agent is involved in the life cycle of one Clinical Information		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation		Binary association	1
Agent		Binary association	1
Attributes	**Type**	**Description**	
startTime	DateTime	Starting date and time of involvement of the agent	
endTime	DateTime	Ending date and time of involvement of the agent	
role	String	Role of the agent in the life cycle of the Clinical Information, including values “Collector” and “Validating Agent”.	

7.4.3.9 Association Class: Reason for association of clinical information

Class identifier: ReasonForAssociationOfClinicalInformation			
Description	Relations among individual clinical information for various purposes (e.g. structuring, dependency, substitution, etc.)		
Related terms			
Notes			
Examples			
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation First clinical Information being related		Binary association	1
ClinicalInformation Second clinical information being related		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second clinical information in the list	
reason	String	Reason why the two items of clinical information are related, including values: “Aggregation” (when the first clinical information is an aggregation, containing the second one for certain purposes) and “Substitution” (when the first clinical information is annulled and substituted with the second one)	
context	String	Context and rules according to which the second clinical information is related to the first one	

7.4.3.10 Association Class: Activity C.I. association

Class identifier: ActivityClinicalInformationAssociation			
Description	Reasons why the Activity is related to one Clinical Information		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation		Binary association	1
Activity		Binary association	1
Attributes	**Type**	**Description**	
startTime	DateTime	Starting date and time of relationship	
endTime	DateTime	Ending date and time of relationship	
role	String	Role of the relationship amongst the Activity and the Clinical Information, including values “Generated by” (i.e. clinical information generated as a result of the activity) and “Relevant for” (i.e. clinical information that is relevant for the execution of an activity).	

7.4.3.11 Class: Type of clinical information

Class identifier: TypeOfClinicalInformation			
Description	Class handling all types of clinical information, describing the contents of actual health-related classes measured and observed within the healthcare organization		
Related terms	*None*		
Notes	None		
Examples	None		
Associated classes	**Type of association**		**Multiplicity**
Clinical Information	Dependency		
TypeOfClinicalInformation Type of Clinical Information being related	Binary association Through association class "Reason"		0..*
Attributes	**Type**	**Description**	
id	String	Identifier(s) that may be used to uniquely identify the type of Clinical Information	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
domainValues	String	Domain of the possible values that can be obtained by the Type of Clinical Information	

7.4.3.12 Association Class: Reason for association of type of clinical information

Class identifier: ReasonForAssociationOfTypesOfClinicalInformation			
Description	Relations among type of clinical information for various purposes		
Related terms			
Notes			
Examples			
Associated classes		**Type of association**	**Multiplicity**
TypeOfClinicalInformation First type of clinical Information being related		Binary association	1
TypeOfClinicalInformation Second Type of Clinical Information being related		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second type of clinical information in the list	
reason	String	Reason why the two type of clinical information are related.	
context	String	Context and rules according to the second type of clinical information is related to the first one (e.g. for structuring the second clinical information into a more complex document/dossier represented by the first clinical information)	

7.5 Resource management objects

7.5.1 Scope

The resource management cluster groups the information services which support the rest of the healthcare information system in the management of the resources used in relation to healthcare activities.

Package identifier (for any coded reference to this group of objects): rm

7.5.2 UML information model

All non-coloured classes belonging to the Resource management cluster of objects in Figure 10 are specified in 7.5.3. The person class is specified in 7.2.3.3. The agent class is specified in 7.6.3.2 and the organization and the individual agent are specified in 7.6.3.3 and 7.6.3.4. The classes type of activity, activity, actual utilization, and default utilization are specified in 7.3.3.1, 7.3.3.2, 7.3.3.9 and 7.3.3.10 respectively.

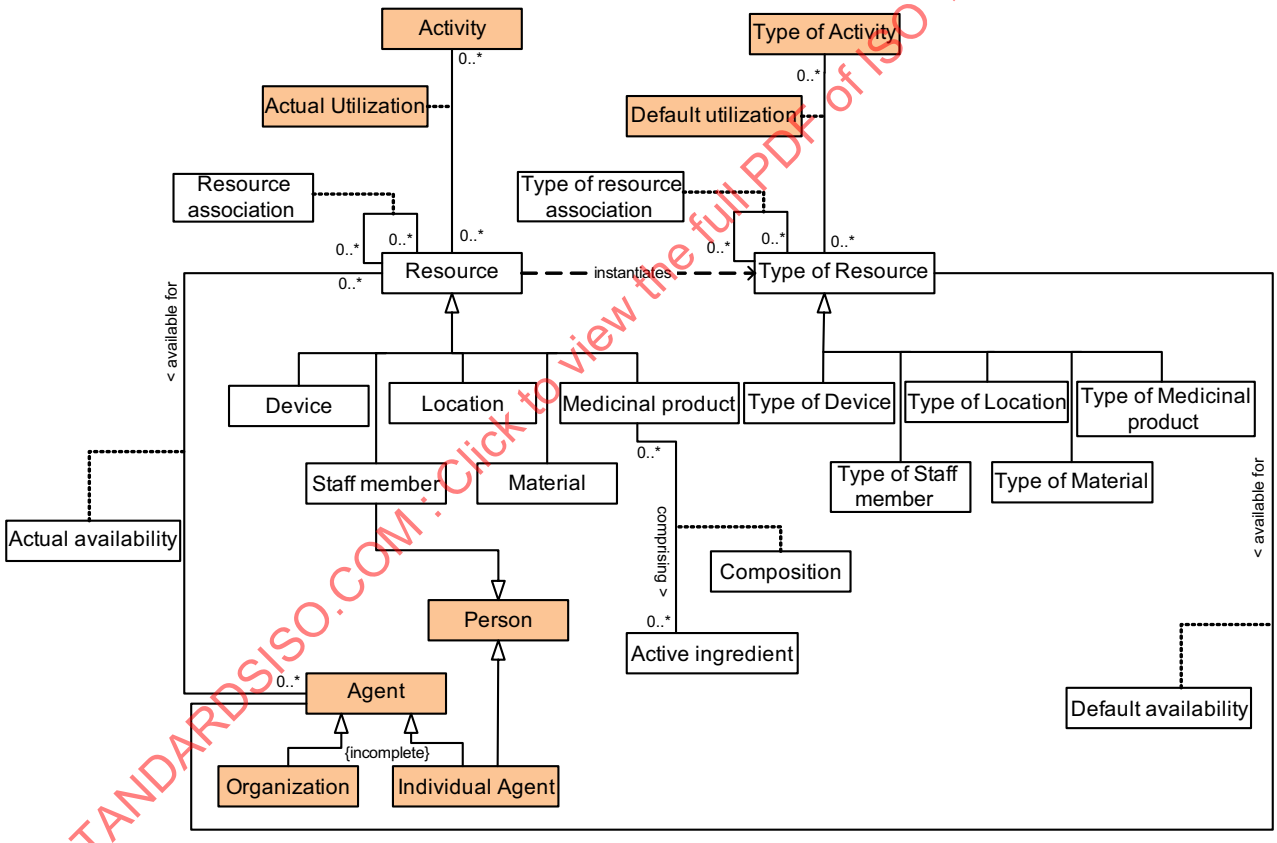

Figure 10 — UML model for resource management Objects

7.5.3 Specification of the individual classes

7.5.3.1 Class: Type of resource

Class identifier: TypeOfResource			
Description	Class describing all types of resources used within the organization		
Associated classes	**Type of association**		**Multiplicity**
Resource	Dependency		
TypeOfDevice (subtype)	Generalization		
TypeofStaffMember (subtype)	Generalization		
TypeOfLocation (subtype)	Generalization		
TypeOfMaterial (subtype)	Generalization		
TypeOfMedicinalProduct (subtype)	Generalization		
TypeOfActivity Types of activities generally using the Type of Resource	Binary association through Association Class DefaultUtilization		0..*
Agent General criteria for the assignment and availability of the Type of Resources to one Agent	Binary association through Association Class DefaultAvailability		0..*
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier of the type of resource	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
unitMeasure	Unit	Default Unit of Measure for the utilization of the type of resource	
administration	String	Default administration modality for the type of resource	
unitCost	String	Average unit cost of the type of resource	

7.5.3.2 Class: Type of device

Class identifier: TypeOfDevice			
Description	Class describing the types of devices and equipment used within the organization		
Associated classes	**Type of association**		**Multiplicity**
TypeOfResource	Generalization		
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.3 Class: Type of staff member

Class identifier: TypeOfStaffMember			
Description	Class describing the types of staff members employed in the organization		
Examples	e.g. “Physician”, “Nurse”, “Administrative personnel”, etc.		
Associated classes	**Type of association**		**Multiplicity**
TypeOfResource	Generalization		
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.4 Class: Type Of Location

Class identifier: TypeOfLocation			
Description	Class describing the types of locations available within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.5 Class: Type of material

Class identifier: TypeOfMaterial			
Description	Class handling the types of materials used within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.6 Class: Type of medicinal product

Class identifier: TypeOfMedicinalProduct			
Description	Class handling the types of medicinal products used within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.7 Association Class: Type of resource association

Class identifier: TypeOfResourceAssociation			
Description	Types of Resources can be grouped to describe possible aggregations of types of locations, types of materials, etc.		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource First type of resource in relationship		Binary association	0..*
TypeOfResource Other type of resource in relationship		Binary association	0..*
Attributes	**Type**	**Description**	
role	String	Specification of the type of relationship between the types of resources.	
startTime	DateTime	Date and time when the relationship starts according to the specified “Role”	
endTime	DateTime	Date and time when the relationship terminates according to the specified “Role”	
reason	String	Reason for the starting of the relationship	

7.5.3.8 Class: Resource

Class identifier: Resource			
Description	Actual resources available and used in the organization		
Related terms	Health Care Device: Device or equipment used in the provision of health care services (CONTSYS) Resource: Inherits the Role attributes plus an extra attribute concerned with the size of the time slot allocated to the use of the resource (GPIC)		
Examples	Individual staff, drugs, physical premises, actual materials, available equipment, devices, etc.		
Associated classes		**Type of association**	**Multiplicity**
StaffMember (*subtype*)		Generalization	
Drug (*subtype*)		Generalization	
Location (*subtype*)		Generalization	
Material (*subtype*)		Generalization	
Device (*subtype*)		Generalization	
MedicinalProduct (*subtype*)		Generalization	
TypeOfResource		Dependency	
Activity Activity(ies) that have used the resource		Binary Association through Association Class ActualUtilization	0..*
Agent Agent(s) for whom the Resource is available		Binary Association through Association Class ActualAvailability	0..*

Attributes	**Type**	**Description**
id	Identifier	One identifiers that may be used to uniquely identify the resource
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language
unitMeasure	Unit	Unit of Measure for the utilization of the resource
unitCost	Double	Unit cost of the resource

7.5.3.9 Association Class: Resource association

Class identifier: ResourceAssociation			
Description	Resources can be grouped to describe possible aggregations of types of drugs, locations, types of materials, etc.		
Associated classes		**Type of association**	**Multiplicity**
Resource First resource in relationship		Binary association	0..*
Resource Other resource in relationship		Binary association	0..*

Attributes	**Type**	**Description**
role	String	Specification of the type of relationship between the resources.
startTime	DateTime	Date and time when the relationship starts according to the specified “Role”
endTime	DateTime	Date and time when the relationship terminates according to the specified “Role”
reason	String	Reason for the starting of the relationship

7.5.3.10 Class: Staff member

Class identifier: StaffMember			
Description	Individual employed or working for the healthcare organization		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Person (supertype)		Generalization	
Attributes	**Type**	**Description**	
qualification	String	Qualification of the staff member	
name	SET<String>	A name or names by which the individual is, or has been, known	

7.5.3.11 Class: Medicinal product

Class identifier: MedicinalProduct			
Description	Individual medicinal product (GPIC)		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.12 Class: Location

Class identifier: Location			
Description	Information about actual locations available in the organization		
Related terms	Location: Information about a location where a services are provided (GPIC)		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.13 Class: Device

Class identifier: Device			
Description	*Information about a piece of equipment or a device*		
Related terms	*None*		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.14 Class: Material

Class identifier: Material			
Description	Information about other materials and services used (e.g. consumables, assets, etc.)		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.15 Association Class: Actual availability of resources

Class identifier: ActualAvailability			
Description	*Association Class describing the availability of each individual Resource with respect to each Agent of the organization*		
Associated classes		**Type of association**	**Multiplicity**
Agent		Binary association	1
Resource		Binary association	1
Attributes	**Type**	**Description**	
startDate	DateTime	Starting date and time of availability of the resource	
endDate	DateTime	Ending date and time of availability of the resource	
quantity	Double	Actual quantity of availability	
unitMeasure	Unit	Unit of measure of the available quantity	

7.5.3.16 Association Class: Standard availability of types of resources

Class identifier: StandardAvailability			
Description	Association Class relating Agents and Types Of Resources, to define the standard availability of the latter for each agent of the organization		
Associated classes		**Type of association**	**Multiplicity**
Agent		Binary association	1
TypeOfResource		Binary association	1
Attributes	**Type**	**Description**	
minQuantity	Double	Minimum quantity of that type of resource to be available to the agent	
maxQuantity	Double	Maximum quantity of that type of resource to be available to the agent	
unitMeasure	Unit	Unit of measure for the specified quantities	
rule	String	Constraints and other rules according to which the resource has to be available to the agent	

7.5.3.17 Class: Active ingredient

Class identifier: ActiveIngredient			
Description	The pharmacologically active parts of medicinal products		
Associated classes		**Type of association**	**Multiplicity**
Medicinal Product Medicinal Product(s) containing the Active Ingredient		Binary association Through association class "Composition"	0..*
Attributes	**Type**	**Description**	
id	Identifier	One or more identifiers that may be used to uniquely identify the Active ingredient	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.5.3.18 Association Class: Composition

Class identifier: Composition			
Description	Active Ingredients contained in one Medicinal Product		
Associated classes		**Type of association**	**Multiplicity**
Medicinal Product		Binary association	1
Active Ingredient		Binary association	1
Attributes	**Type**	**Description**	
quantity	Double	Quantity of active ingredient present in the medicinal product	
unitMeasure	Unit	Unit of measure of the specified quantity	

7.6 User and authorization objects

7.6.1 Scope

This package groups the information services that support the rest of the healthcare information system in the management of the following:

— authorization rules that govern the access control within the healthcare information system;

— organizational structure of the enterprise;

— user management;

— package identifier (for any coded reference to this group of objects): um

7.6.2 UML information model

All non-coloured classes belonging to the user and authorization cluster of objects in Figure 11 are specified in 7.6.3. The person class is specified in 7.2.3.3, while the contact and the agent's role in the contact are specified in 7.2.3.5 and 7.2.3.6. The classes type of activity, activity, agenda, and role of agent in activity are specified in 7.3.3.1, 7.3.3.2, 7.3.3.12 and 7.3.3.11, respectively. The clinical information class and the role of the agent in the life cycle of the clinical information class are specified in 7.4.3.1 and 7.4.3.8. The HISA class and HISA class attribute are specified in 6.3.

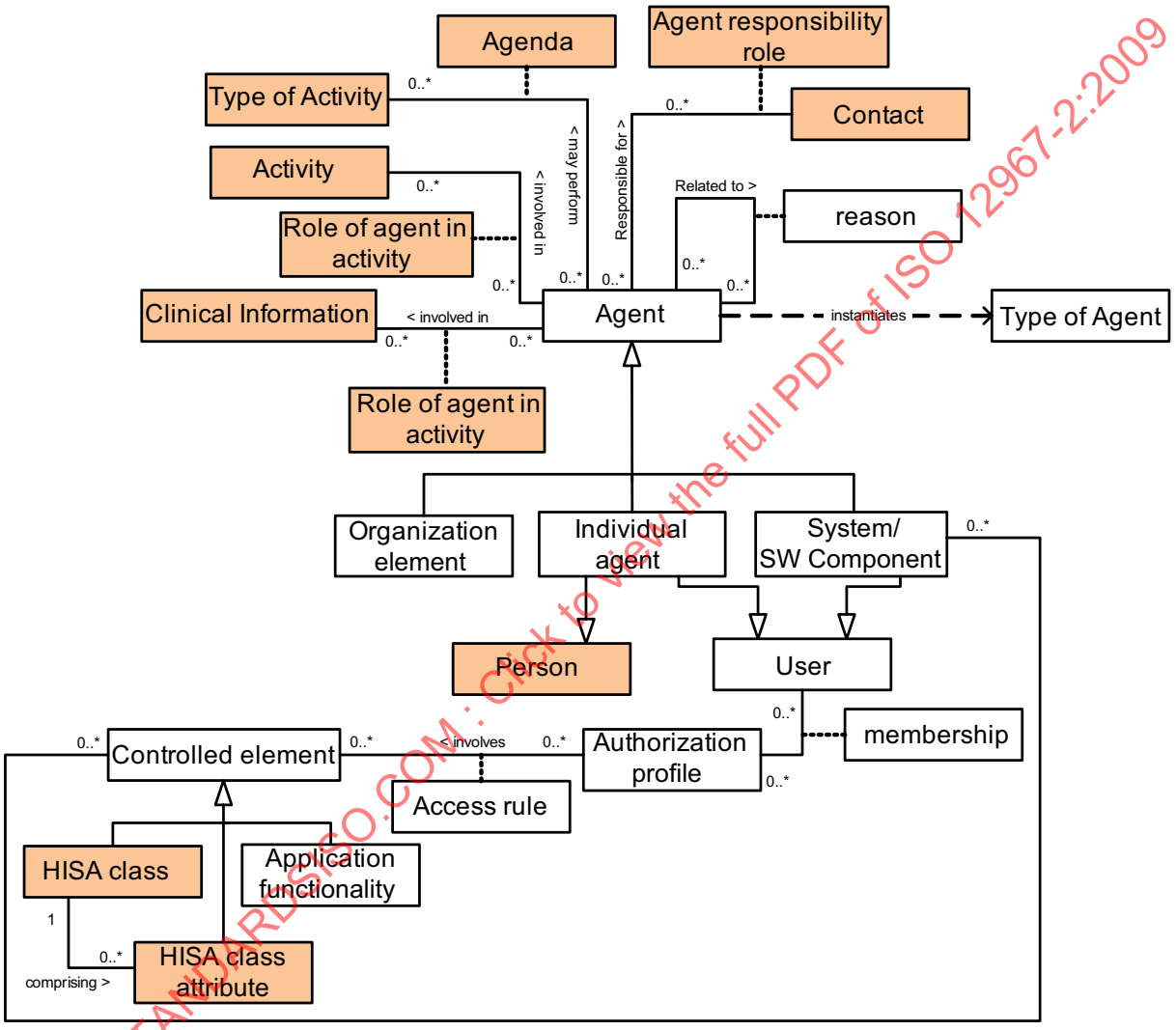

Figure 11 — UML model for Users and Authorization Objects