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Health informatics — Service architecture (HISA) —

Part 2: Information viewpoint

Informatique de santé — Architecture de service —

Partie 2: Point de vue de l'information

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Foreword

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

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

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12967-2:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

— use of terms, definitions and concepts from ISO 13940:2015 (Contsys), with textual alignment throughout the document including figures, to the extent possible and beneficial;

— reference to further standards, such HL7®;

— updates to the Bibliography.

A list of all parts in the ISO 12967 series can be found on the ISO website.

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

Introduction

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

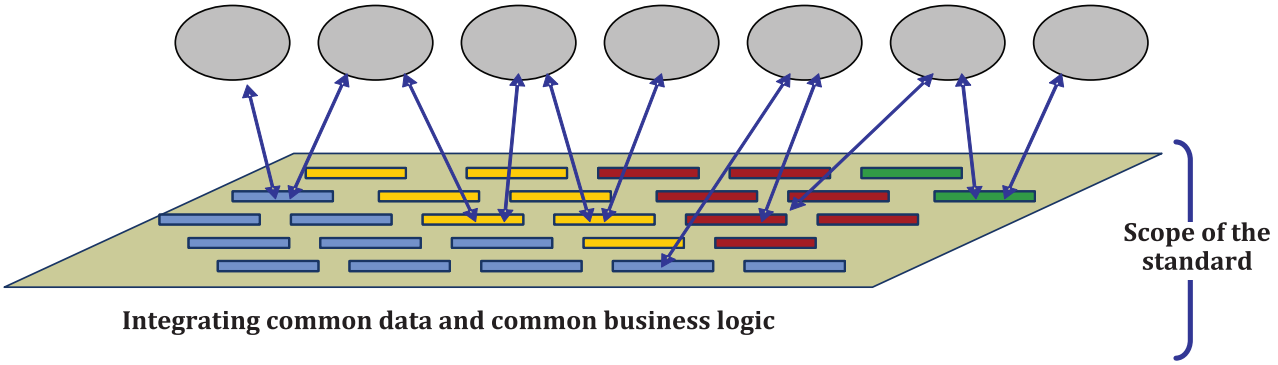

Figure 1 — Scope of the ISO 12967 series

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 should be supported by the information and functionality of the service architecture. It also provides guidance on how one individual enterprise (e.g. a regional healthcare authority, a large hospital or any other organization where this model is applicable) can specify and document additional specific business requirements, with a view to achieving a complete specification, adequate for the characteristics of that enterprise.

   Enterprise viewpoint is specified in ISO 12967-1.

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

   Information viewpoint is specified in this document.

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

   Computational viewpoint is specified in ISO 12967-3.

ISO 12967-1:2020, Annex C includes an explanation of ISO 23903:—[1)] and its relevance in regard to the ISO 12967 series, for integration with other International Standards such as ISO 13940.

1) Under preparation. Stage at the time of publication: ISO/DIS 23903:2020.

Health informatics — Service architecture (HISA) —

Part 2: Information viewpoint

1 Scope

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

The information model is specified in this document without any explicit or implicit assumption on the physical technologies, tools or solutions to adopt 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 document does not aim at representing a fixed, complete, specification of all possible data that can be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics, in terms of overall organization and individual information objects, identified as fundamental and common to all healthcare organizations, and that is satisfied by the information model implemented by the service architecture.

Preserving consistency with the provisions of this document, physical implementations are allowed 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 document 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 12967-1:2020, Clause 7.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
information object
information held by the system about entities of the real world

Note 1 to entry: Entities including the ODP system itself can be represented in an information specification in terms of information objects, their relationships and behaviour.

3.2
package
cluster of *information objects* (3.1)

3.3
middleware
enabling technology of *enterprise application integration* (3.4) 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

3.5
subject of care
patient
subject of healthcare
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

[SOURCE: ISO 13940:2015, 5.2.1, modified — Note and Examples omitted.]

4 Abbreviated terms

ODP Open Distributed Processing

HISA Health Informatics Service Architecture

UML Unified Modeling Language

5 Methodological principles

5.1 Language and notation adopted for the specification of the model

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

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

The general approach of the ODP standard [i.e. ISO/IEC 10746 (all parts)] is also used in ISO 12967-1, the modeling language used in this document is UML.

The information viewpoint is concerned with information modeling (i.e. the kinds of information handled by the system). It focuses on the semantics of information and information processing in the system. It is fundamental that the individual components of a distributed system 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 will be 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. It is possible to place emphasis 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 modeling 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

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

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

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

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

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

— Association labels indicate a property, or a verb phrase; in the latter case, an arrow is added to the association label to avoid ambiguity.

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

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

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

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

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

- For some classes, associations to other classes could be modelled (in the UML diagrams) as attributes to the class. This reflects that the association has value rather than reference semantics, in addition to the resulting simplification of the model. In other cases, the same method might be used in the UML diagrams even though the association has reference semantics. This is done just to simplify the models. In the related class descriptions, these instances of simplified modeling 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 ISO 12967-1:2020, 6.2 to 6.4.

According to the methodology identified in the enterprise viewpoint, seven clusters of objects have been identified, each of which is responsible for organizing and storing the information necessary for supporting the users' activities identified in the related areas of ISO 12967-1, as follows.

a) Classification objects

   These objects handle the information necessary for supporting the users' activities related to the management of classifications, coding criteria and dictionaries.

b) Subject of care objects

   These objects handle the information necessary for supporting the users' activities that are identified in the "subject of care workflow".

c) Activity management objects

   These objects handle the information necessary for supporting the users' activities identified in the "activity management workflow".

d) Healthcare information objects

   These objects handle the information necessary for supporting the users' activities identified in the "healthcare information workflow".

e) Resources objects

These objects handle the information necessary for supporting the users' activities related to the management of resources.

f) Users and authorization objects

These objects handle the information necessary for supporting the users' activities related to the management of users and authorizations.

g) Messaging objects

These objects handle the information necessary for supporting the structuring of data and the communications with other systems through messaging mechanisms.

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

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

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

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

Further general information on mapping between different domains and models with different purpose, levels and scopes is provided in ISO 12967-1:2020, Annex C.

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

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

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

NOTE The topic is also explained in in ISO 12967-1:2020, 11.9.

HISA information objects in each package shall thus be classified as:

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

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

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

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

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

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

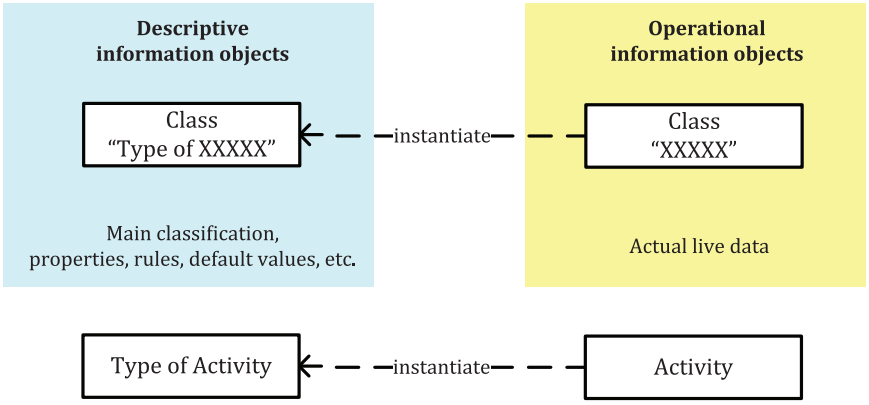

Figure 2 — Knowledge base implemented through the descriptive information objects

In addition to the properties and to the classification provided by the related "descriptive" class, each class and each attribute of each class can 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 3.

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

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

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

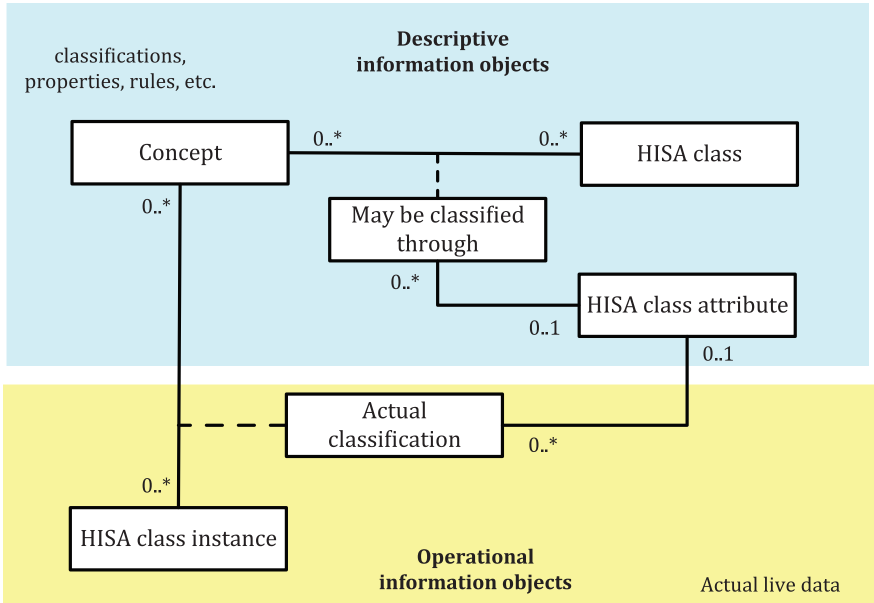

Figure 3 — Further classification criteria for each HISA class

5.5 Data types

The primitive data types given in Table 1 are used in this specification, as illustrated in Table 2.

Table 1 — Primitive data types

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 Biblio entry)
Octet	8-bit code, as defined in ISO/IEC 11404:2007

Table 2 — Usage of primitive data types

HISA data type	Primitive data type	Semantics
Byte	Octet	Synonym of octet
ObjectIdentifier	String	Unchangeable string allowing the permanent and non-ambiguous identification of one instance of one information object. The syntax and the structure of the string shall be defined locally by the individual implementations, according to criteria capable of ensuring the uniqueness of the value also across different models and distributed, multiple physical environments.
Identifier	String	Short, human-readable string allowing the non-ambiguous identification of one instance of one information object.
InternalTimestamp	Array of bytes	Internal system representation of date and time at least up to the level of the millisecond. DateTime representations are specified in ISO 8601-1:2019 and ISO 8601-2:2019.

Table 2 *(continued)*

HISA data type	Primitive data type	Semantics
DateTime	String	DateTime representation are specified in ISO 8601-1:2019 and ISO 8601-2:2019. Representation of date and time shall be at least up to the level of the second.
Ordinal	Integer	A number which defines a position in an ordered series.
Unit	String	Unit of measure, expressed according to codes defined in the "Unified Code for Units of Measures" (https://unitsofmeasure.org).
URI	String	Uniform Resource Identifier NOTE First defined in Request for Comments (RFC) 2396 and finalized in RFC 3986.
SET<DataType>		Value that contains multiple values of the data type specified as its elements.

5.6 General characteristics of the model

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 other sections; for readability reasons 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.

— Clause 5.2 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 all classes 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 are 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 business rule 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 document, which 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 the following Figure 4 are specified in 6.3, except the HISA Concept class, which is specified in 7.1.3.2.