NORMA
EUROPEA

Informatica sanitaria
Componenti delle informazioni per utilizzo generale
Parte 1: Visione d'insieme

UNI EN 14822-1

SETTEMBRE 2006

Health informatics
General purpose information components
Part 1: Overview

La norma specifica i componenti delle informazioni per l'utilizzo generale da impiegare nelle norme per lo scambio delle informazioni e in quelle dei modelli di informazioni che sono di supporto ai vari requisiti specifici per la sanità.

TESTO INGLESE

La presente norma è la versione ufficiale in lingua inglese della norma europea EN 14822-1 (edizione ottobre 2005).

ICS 35.240.80

UNI
Ente Nazionale Italiano di Unificazione
Via Sannio, 2
20135 Milano, Italia

www.uni.com

PREMESSA NAZIONALE

La presente norma costituisce il recepimento, in lingua inglese, della norma europea EN 14822-1 (edizione ottobre 2005), che assume così lo status di norma nazionale italiana.

La presente norma è stata elaborata sotto la competenza della Commissione Tecnica UNI

Informatica medica

La presente norma è stata ratificata dal Presidente dell'UNI ed è entrata a far parte del corpo normativo nazionale il 14 settembre 2006.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14822-1

October 2005

ICS 35.240.80

English Version

Health informatics - General purpose information components - Part 1: Overview

Informatique de santé - Unité d'information dans les messages - Partie 1: Vue d'ensemble

Medizinische Informatik - Allgemein verwendbare Informationskompomenten - Teil 1: Überblick

This European Standard was approved by CEN on 16 August 2005.

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

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

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 14822-1:2005: E

Contents

Page

Foreword

This European Standard (EN 14822-1:2005) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2006, and conflicting national standards shall be withdrawn at the latest by April 2006.

This is part one of a multipart standard under the heading:

Health informatics - General purpose information components

with the following parts:

— Part 1: Overview

— Part 2: Non-clinical

— Part 3: Clinical

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

Introduction

Many previous messaging and information structure standards for health have overlapping parts with a number of objects being defined in separate documents, sometimes with small variations making implementation of conformant applications more difficult. It therefore makes sense to define a set of general purpose components that can be used for definition of communication structures for different purposes. This approach was suggested and approved as a strategy for CEN/TC 251 in the Short Strategic Study on message standards alignment in 1999 examining a set of five European prestandards for messages. This standard is aiming to provide such a set of components and has been developed jointly with a new European Standard for Service Request and Report messages that is using the components defined herein.

Another important background to the development of this European Standard has been the wish for a harmonisation of information models for health developed in Europe and the USA expressed in the collaboration agreement entered March 2000 between CEN/TC 251 and HL7 (Health Level Seven, Ann Arbor. Michigan). The goal was set for a maximum degree of alignment while maintaining their independence and need to serve the business requirements of the respective markets but also to make the results available to ISO for possible international standardization.

HL7 have adapted a general strategy similar to CEN/TC 251 using information modelling expressed in UML (Unified Modelling Language) for their new standards and a lot of interaction and information sharing has occurred between CEN experts and HL7 in an open spirit of collaboration.

This European Standard includes a large number of objects which are technically similar to descriptions in draft documents of HL7, although partly described differently due to the fact that CEN is following the ISO rules for drafting and presentation of standards which HL7 is not. CEN wishes to express its gratitude towards HL7 experts for generously sharing their models with the European expert team.

1 Scope

This European Standard specifies General Purpose Information Components to be used in standards for information exchange and information models supporting various health specific business requirements. The components defined in this standard are the most commonly needed basic building blocks for such standardization but these components may require further specialisation and be complemented by other objects required for specific purposes not met by these generally useful components. Such standardization using these general purpose information components could be performed both on a European (CEN) level or be done nationally or for specific user communities regionally as well as internationally.

This European Standard provides an informative overview of this series of standards and includes rules for using the components defined in the other parts and on conformance claims.

2 Normative references

Not applicable.

3 Terms and definitions

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

3.1
General Purpose Information Component
GPIC
commonly useful information component that is a specialisation of classes in an international reference information model which is intended to be used in the specification of an information service for health or of a communication between health information systems

3.2
Health Related Service
service provided to one or more persons or other living subjects aiming at improving the health status or diminishing the probability of disease service provided to one or more persons or other living subjects aiming at improving the health status or diminishing the probability of disease

4 Symbols and abbreviations

HL7	Health Level Seven Inc.
GPIC	General Purpose Information Component
RIM	Reference Information Model
UML	Unified Modelling Language

5 General Purpose Information Components – their design

5.1 Basic design objectives

The healthcare information components which are presented in EN 14822-1 and EN 14822-2 and have been selected to meet major requirements from existing European message standards and some projected requirements for other types of information exchange.

It is noteworthy that this document may be useful in the design of interacting components in a local application as well as for remote communication across organisational boundaries. The information components defined in this series can support database design, interacting objects using SOAP (Simple Object Access Protocol), COM (Common Object Model) or CORBA (Common Object Request Broker Architecture) as well as traditional store and forward messaging systems.

5.2 General Purpose Information Components and the Health Level Seven RIM

A General Purpose Information Component (GPIC) is a specification of a component of an information system or of a communication between such systems and we may use a number of these components in order to build a larger systems or communications.

In particular, the GPICs which are the subject of this multipart standard are generated so as to provide a set of generic templates for commonly encountered concepts that are found in healthcare information systems and in the communication between such systems.

Given that GPICs are a set of components that may be used in combination to describe a larger whole, there is a need to have consistency in the internal design principles of the GPICs and also in the external interfaces which allow components to be combined in a consistent manner. If such principles are rigorously adhered to it becomes easier to provide tools to support the development of messaging and other communication systems.

Achieving the necessary degree of consistency in the internal design and external interfacing of the GPICs has been facilitated by the use of the Health Level Seven (HL7) Reference Information Model (RIM). It shall be understood that this RIM is NOT a model of healthcare nor of healthcare records; rather it is a high level model of healthcare information elements and the relationships between these elements. The RIM therefore provides us with an abstract model from which those elements that we need in order to design the relevant GPICs can be selected. In effect the RIM provides the basic building blocks from which we construct larger building blocks: the GPICs (see Figure 1).

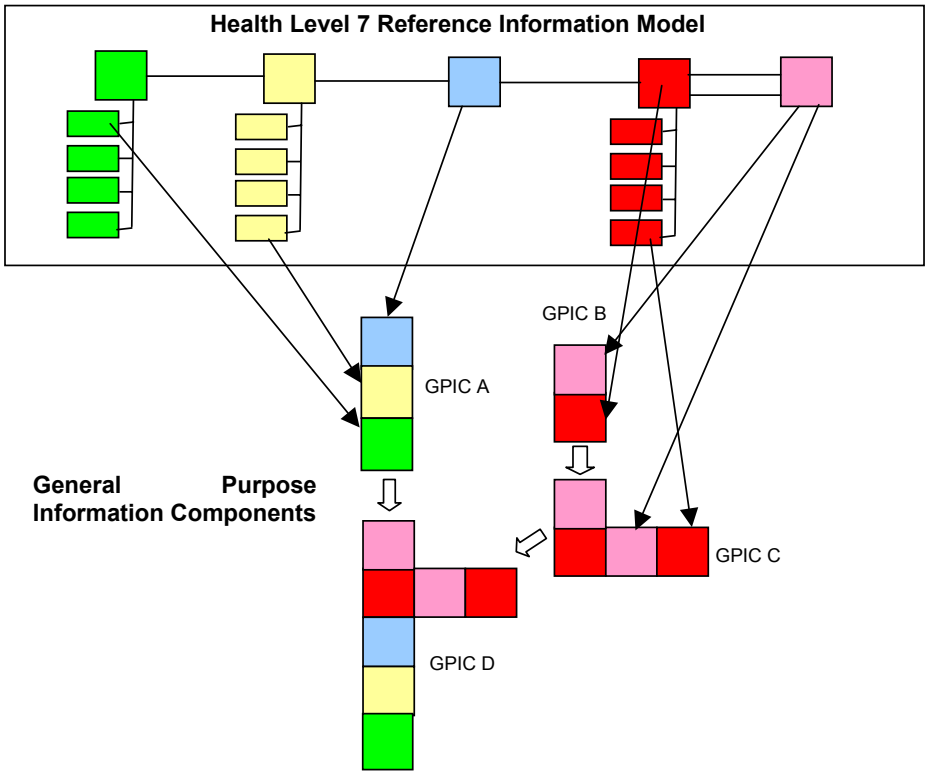


Figure 1 — HL7 reference information model and GPIC design

Figure 1 illustrates that RIM classes are being used to construct a number of different GPICs which may be further combined, either with additional RIM classes or other GPICs to make larger, more complex GPICs.

An example may be used to illustrate the basics of the process. The RIM contains a concept of person which could be used in GPICs which describe patients, doctors, nurses, next of kin, animal owners etc. A GPIC design will use those attributes of the Person class which are appropriate to the function of the particular GPIC and then combine this with another RIM concept of Role to produce a tailored description of the person/role that describes the person playing the role of patient, nurse etc.

The RIM provides the generic classes such as Act, Entity and Person (see next subclause) together with a set of generic attributes with their data types and rules concerning the number and type of relationships with other RIM classes. The GPIC takes from the RIM those classes, attributes and class associations that are required and imposes constraints by defining:

— the precise purpose of the combination of RIM classes, i.e. what is the scope of the GPIC;

— the sub-set of attributes which are being used in each class. For example, the use of the Person attribute 'deceased_time' may be appropriate to the concept of Patient but not to the concept of Healthcare Professional;

— the exact purpose of each attribute. For example in different GPICs, the use of the attribute 'code' derived from the Entity class may be used to provide a coded description of a very wide range of 'things' such as the type of medicinal product pack or the kind of care setting or the type of device etc.;

— limitations upon data types associated with each attribute. For example, although most of the RIM attributes are associated with precise data types there are many attributes where a wide range of data types are allowed. This is especially prevalent in describing time where there may be requirements for a date/time, a date/time range, a period of time, and so on. In designing a GPIC the use of each attribute is more focussed. This permits the imposition of constraints upon the data types and also of the underlying vocabulary sets associated with coded attributes.

5.3 Health Level 7 (HL7) Reference Information Model

5.3.1 Introduction

The General Purpose Information Components described within this multi-part standard conform to HL7's Reference Information Model Version 3 Version 2.01 (successfully balloted July 2003). This subclause describes those aspects of the Reference Information Model that is relevant to the design of the General Purpose Information Components.

The HL7 RIM consists of a large number of classes and relationships. Four of these classes are, however, of prime importance and form the 'backbone' of the RIM. These classes are Entity, Role, Participation and Act. These four classes (plus the 'relationship classes) are shown in Figure 2 below.

The backbone may be read left to right as: an Entity (e.g. person) plays a Role (e.g. patient) and participates in some Act (e.g. consultation). The backbone can be read from right to left as: an Act (e.g. appendectomy) has the participation, of Entity (person) who is in the Role of nurse.

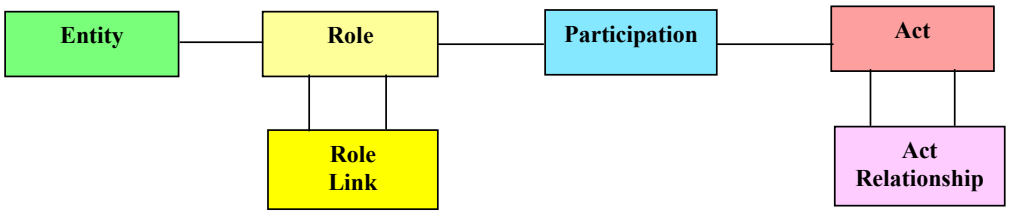


Figure 2 — HL7 Reference information backbone

5.3.2 Entities

General description

Entities represent physical things such as persons, animals, organisations, medicinal products, devices, places, samples etc. A simplified model of Entity and its more important specialisations are shown in Figure 3 below.

Within these standards Entities are indicated by the colour green.

Entities may only be associated with classes of type Role, i.e. Entities cannot be directly associated with each other[1], only through Role classes.

An entity may be associated with any number of instances of Role classes.

NOTE A fuller representation of the HL7 Entity Classes is provided in Annex B. Further note that this material is owned by HL7 Inc. and subject to their terms and conditions.

[1] Although Entity may me associated with Language Communication which is also coloured green in these standards.

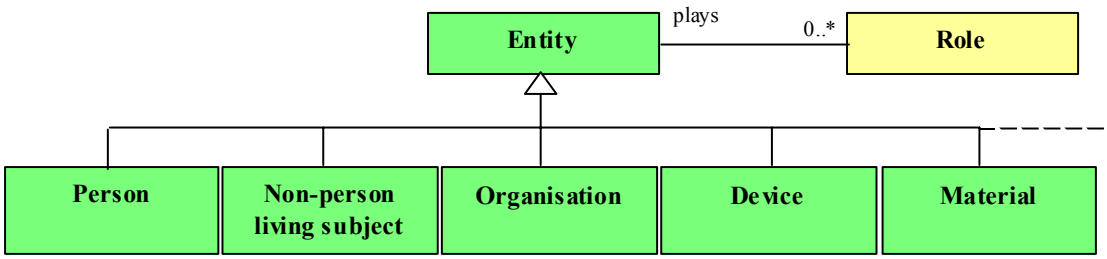


Figure 3 — Entity specialisations

Description of specialisations

Here some information about some of the more important attributes is included, especially those where their function is less obvious.

Entity: this core class includes:

— *classCode*: a means of defining which specialisation of Entity is being used. In this, Entity itself may be the specialisation (i.e. no specialisation). The classCode shall always be present. The values which classCode may adopt are presented in 10.1.1 of EN 14822-2:2005.

— *determinerCode*: provides a means of specifying whether the instance of Entity (or its specialisation) is describing an actual instance of something, e.g. an actual pack of medicine that has been issued to a patient, a 'kind' of thing, e.g. the type of pack of medicine that is being ordered for a patient, or a quantified_kind, for example a three packs of medicine. Allowed values are:

  — INST = Instance of;

  — KIND = Kind of;

  — QUANTIFIED_KIND.

— *code*: is the main classifying attribute of the Entity class and all of its specialisations. This code indicates what kind of Entity is being referred to by using a code from one of several coding systems depending on the class of entities, such as living subjects (typed by animal and plant taxonomies), chemical substance (e.g. IUPAC(International Union of Pure and Applied Chemistry) code), organizations, place, device etc.

— *desc*: provides a description of an entity or is specialisations using free text or multimedia data.

— *id*: provides a unique identifier for an entity. Ideally each entity will have only one identifier assigned to it, however, since different systems will maintain different data bases, there may be different instance identifiers assigned by different systems.

— *name*: provides a name of the entity, for example, person name, animal name, organisation name, device name etc.

— *quantity*: specifies the quantity of the given entity. In this context the quantity is an extensive "amount" type of quantity (e.g., number, length, volume, mass, surface area, energy etc.).

— *handlingCode*: a code or set of codes to describe how the entity needs to be handled to avoid damage to it or other entities. Examples include: keep at room temperature; keep frozen below 0 °C; keep in a dry environment; keep upright, do not turn upside down.

— *riskCode*: a code or set of codes indicating the existence of a risk or hazard associated with the Entity.

Person: inherits the Entity attributes plus 'Person' type attributes which include the usual person demographics such as date of birth/death, gender, address(es), religious affiliation, marital status, ethnic group etc. Note that the fact that the person is a patient or a doctor, or an employee etc. is reflected in the Role that they are playing and their patient number, doctor id, or employee number, and other such details are to be found in the particular Role specialisation.

Non-person living subject: is limited in this standard to animals. Inherits the Entity attributes plus 'Animal' type attributes which include taxonomic classification, breed, date of birth/death, gender and gender status.

Organisation: inherits the Entity attributes plus 'Organisation' type attributes which are organisation type and address(es).

Place: describes a physical place or site with its contained structures, if any. Place may be natural or man-made. The geographic position of a place may or may not be constant. Examples include a field, lake, city, county, state, country, building, pipeline, power line, playground, ship, truck. Places may be work facilities (where relevant acts occur), homes (where people live) or offices (where people work). Places may contain sub-places (floor, room, booth, bed). Places may also be sites that are investigated in the context of health care, social work, public health administration (e.g., buildings, picnic grounds, day care centres, and prisons). Place inherits the Entity attributes plus 'Location' type attributes which include textual, coded and identifier links to the location being described.

Device: a device is anything used in an activity without being substantially changed through that activity. This includes durable (reusable) medical equipment as well as disposable equipment.

Device inherits the Entity attributes plus 'Device' specific attributes which describe, for example, the last calibration date, the software incorporated and the manufacture's name for the model.

Material: examples of Material are pharmaceutical substances (including active vaccines containing retarded virus), disposable supplies, durable equipment, implantable devices, food items (including meat or plant products), waste, traded goods etc.

Material inherits the Entity attributes plus 'Material' specific attributes which describe, for example, the form of the material (e.g. tablet), its expiration date, lot number and stability time.

5.3.3 Roles

General description

Role defines the competency of an Entity in a particular Role to participate in any particular Act.

Thus, a person in the role of practitioner can participate in a patient emergency encounter as the attending physician or as one who assesses the patient's lung function. The Role defines the competency of the Entity irrespective of any Act, as opposed to Participation which is limited to the scope of an Act.

A simplified model of Role and its more important specialisations are shown in Figure 5 below.

Within these standards, Roles are indicated by the colour yellow.

A Role shall be associated with at least one Entity:

An Entity may play a role that is 'scoped' by another Entity. For example, a person may have a position of 'Trainee Nurse' with respect to a particular hospital. This is shown below in Figure 4.

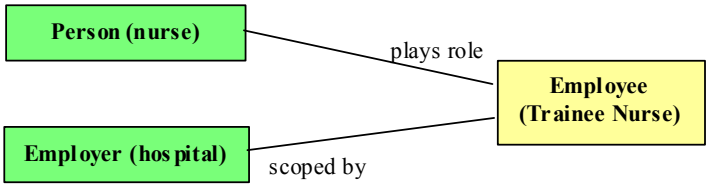


Figure 4 — A scoped role

Two Roles may be associated using an instance of Role Link. A Role may be linked to several other Roles in this way. For example, one may wish to denote that Dr. X who has the role of junior doctor, is supervised by Dr. Y who as the role of hospital consultant.

An Entity in a Role may be associated with zero, one or many Acts through associated Participations.

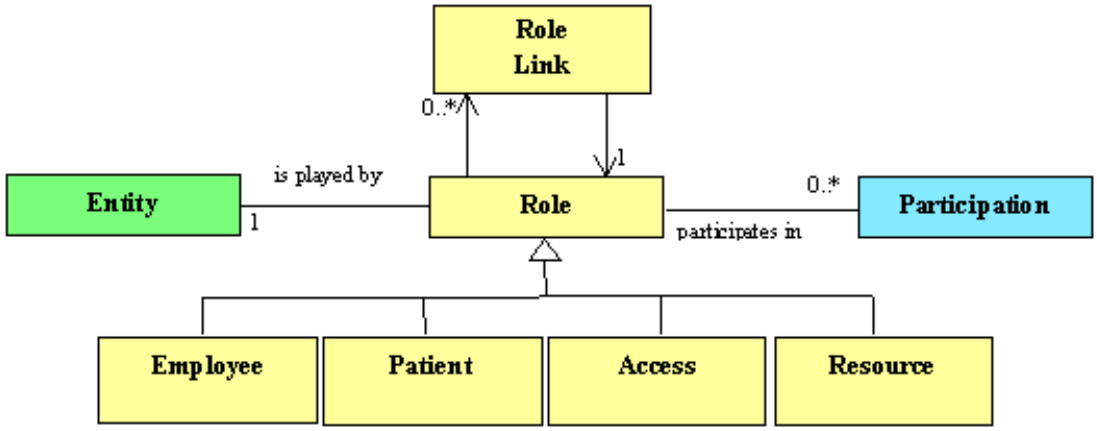


Figure 5 — Role specialisations

NOTE A fuller representation of the HL7 RoleClasses is provided in Annex B. Further note that this material is owned by HL7 Inc. and subject to their terms and conditions.

Description of specialisations

Here some information about some of the more important attributes of Role and some of its specialisations are included.

Role: this core class includes:

— *classCode*: provides a means of defining the broad category of Role the entity is playing. EN 14822-2 contains a list of codes.

— code: describes the role being played by the entity using a code value.

— *effectiveTime*: describes the time or time interval during which the Entity played this Role.

— *quantity*: used with composition-relationships (e.g. has-parts, has-ingredient, has-content) and specifies that a numerator amount of the target entity is comprised by a denominator amount of the source entity

of such composition-relationship. For example an Estracombi combination pack contains *4* Estraderm patches and *4* Estragest patches.

— *id*: provides an identifier for the entity when playing that particular role. For example: patient hospital number, doctor id.

— *addr*: address that is appropriate to the entity in this Role. For example: address for consulting physician.

— *telecom*: telecommunication numbers and addresses associated with the entity in this Role. For example, Physician's office number.

Employee: inherits the Role attributes to which are added 'Employee' type attributes. In particular, this specialisation is used to describe persons who are employed as healthcare professionals. This specialisation includes attributes that can describe the healthcare professional's position and their healthcare specialty.

Patient: inherits the Role attributes plus 'patient' type attributes which include any particular confidentiality constraints placed upon their healthcare information, e.g. member of staff.

Access: inherits the Role attributes plus attributes associated with the routing of treatment, (especially medication) to a particular anatomical site. These attribute are limited to:

— *guageQuantity*: the gauge of an access as a measure of the inner diameter of an access tube;

— *approachSiteCode*: a code representing the anatomic site where the line or drain first enters the body. For example in an arteria pulmonalis catheter targets a pulmonary artery but the access approach site is typically the vena carotis interna at the neck, or the vena subclavia at the fossa subclavia;

— *targetSiteCode*: a code representing the target site of the access, i.e., the compartment into which material is administered or from which it is collected. For example, a pulmonary artery catheter will have the target site arteria pulmonalis with or without a known laterality. For environmental testing this could be the incubation chamber or the cooling tower or the overflow reservoir etc.

Resource: Inherits the Role attributes plus an extra attribute concerned with the size of the time slot allocated to the use of the resource. For example: Thursday's well men clinic.

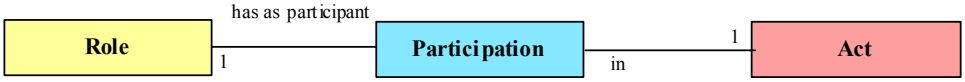
5.3.4 Participations

General description

Participations represent the part played be the entity in some activity. For example, the person in the role of nurse may administer medication to the patient, and may be responsible during recovery from anaesthesia.

Within these standards, Participations are indicated by the colour blue.

Participations are always associated with a single Act class but this could be external to the GPIC.



Participations are always associated with a single Role class but this could be external to the GPIC.

Figure 6 — Participation associations

Description of Participation

Here some information about some of the more important attributes is included.

— *typeCode*: identifies the particular kind of Participation that an Entity performs in the Act. In practice, there are very many different participation types whose names and responsibilities vary. A list of such participation types is provided in EN 14822-2.

— *functionCode*: provides a means of specifying the participation type with greater granularity using an external coding scheme.

— *time*: provides the effective time range of the participation.

— *modeCode*: is a code specifying how the participant is involved in the act, e.g., as physically present, over the telephone, or in written communication.

— *sequenceNumber*: permits sequencing between multiple participations for an act. The sequencing might be undertaken for functional reasons or to establish a priority between participations.

— *awarenessCode*: indicates whether the associated patient or family member is aware of the service, and especially of the observation made. For example, a patient (or his next family members) may not be aware of a malignancy diagnosis, the patient and family may be aware at different times, and some patients may go through a phase of denial.

— *signatureCode*: specifies whether the participant has performed some sort of signature relating to his/her participation in the act or whether such a signature is required.

— *signatureText*: the signature by which the associated Entity endorses that its participation in the Act is as stated in the Participation.typeCode and that it assumes accountability for the Act accordingly.

5.3.5 Act

General description

Act represents intentional activities within the healthcare domain such as observations, investigations, transportation, patient encounters, referrals etc.

A simplified model of Act, including its more important specialisations and associations are shown in Figure 6 above.

Within these standards, Acts are indicated by the colour red.

Acts may be associated with any number of Participations

Acts may be associated with any number of other Acts by use of instances of Act Relationship.

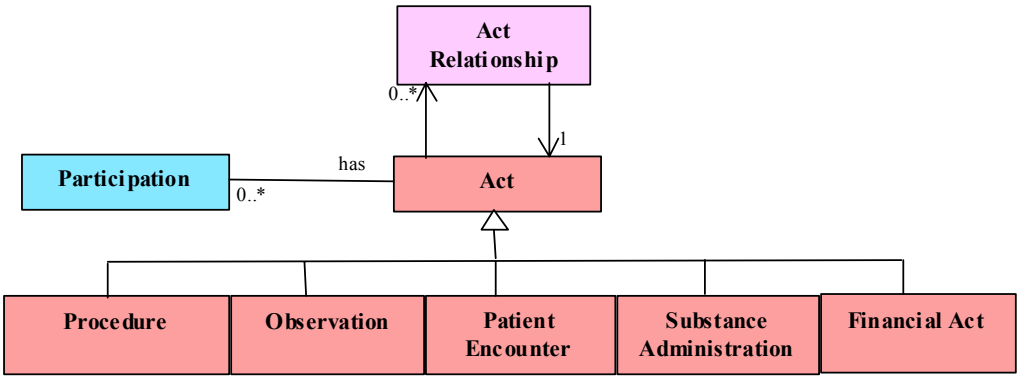


Figure 7 — Act associations and specialisations

NOTE A fuller representation of the HL7 ActClasses is provided in Annex B. Further note that this material is owned by HL7 Inc. and subject to their terms and conditions.

Description of Act and its specialisations

Here some information about some of the more important attributes is included, and especially those where their function is less obvious.

Act: This core class includes:

— *classCode*: provides a means of defining which specialisation of Act is being used. In this, Act itself may be the specialisation (i.e. no specialisation). EN 14822-3 provides the current set of such codes and their meanings.

— *moodCode*: all instances of Act classes shall define whether the action is to be conceived as fact or in some other manner (as command, possibility, or wish). In particular, the 'mood' of the Act may be recording (not a complete listing):

  — an event that happened (fact);

  — an ordered service (command);

  — an intention to carry out a service;

  — an appointment to carry out a service;

  — a request for an appointment for a service;

  — an intention to order;

  — a proposal to another party that an action should be carried out;

  — a recommended action;

  — a possible service (master);

  — a goal (wish) of health care;

— a criteria for starting/stopping of an activity.

EN 14822-3 provides the current set of moodCode values:

— *statusCode*: the state of the action. For example, suspended, active, completed, cancelled, aborted. EN 14822-3 provides the current set of statusCode values.

— *code*: a code specifying a kind of action (e.g. physical examination), serum potassium, patient encounter, financial transaction etc.). The Act.code specifies the act conceptually using a code from one of several, typically external, coding systems.

— *id*: instance identifier of a particular Act.

— *activityTime*: the time when the action happened, is ordered or scheduled to happen, or when it can possibly happen (depending on the mood). When used with procedures and other events, this is the total time of activity including preparation and clean-up actions. Thus it may be longer than the effective time of the same act, which is the period during which the procedure actually takes place.

— *effectiveTime*: is the time at which the action focuses. This attribute is distinguished from activity time:

  — for observations, the time of the observation action may be much later than the time of the observed feature. For instance, in a Blood Gas Analysis (BGA), a result will always come up several minutes after the specimen was taken, meanwhile the patient's physiological state may have changed significantly. Even more so in history taking, when the doctor records an episode of Hepatitis A under which the patient suffered last year for several weeks. So, the effective time is the time at which the observation is applicable.

  — for surgical procedures, the time between first cut and last suture is taken as the effective time of the procedure. For transport and supply services the critical time is the time en route or time of delivery respectively (discounting the travel time to the pick-up location and from the drop-off location.) So the effective time does not count in the overhead that is not relevant for the objective of the act. This overhead, however, is relevant for scheduling and potentially billing.

  — for administrative acts, such as patient encounters, this is the "administrative" time, i.e., the encounter start and end date required to be chosen by business rules, as opposed to the actual time the healthcare encounter related work is performed (which would be the activityTime).

— *repeatNumber*: is the range of integer numbers stating the minimal and maximal number of repetitions of an act.

— *priorityCode*: encodes the urgency under which the act is to be scheduled and performed, or was performed.

— *text*: the description of an act is a piece of free text or multimedia data that describes the act in all necessary detail.

Procedure: inherits Act attributes plus 'Procedure' type attributes which include approach site, target site and methods used.

Observation: inherits Act attributes plus the values associated with the observation which may be represented using a very wide range of data types including numerical results, numerical ranges, code values, time values, string, multimedia etc. In addition, this specialisation of Act permits the recording of methods, anatomical site and a normal/abnormal range indicator.

Patient encounter: inherits Act attributes plus a wide range of attributes associated with mainly in-patient care. For example, accident code, admission source, discharge disposition, length of stay, acuity level, referral source etc.

Substance administration: inherits Act attributes plus information about medicinal substance administration such as dose, rate of administration, route of administration etc.

Financial Act: inherits Act attributes plus financial information such as costs.

5.3.6 Act Relationships

May be used to link together two instances of Act and may provide details of the nature of the relationship.

Within this European Standard, Act Relationships are indicated by the colour purple.

Acts Relationships are always associated with two instances of Act (the source and the target), although the GPICs generally only show one of these. A code is used to denote the nature of the relationship between the two Acts. EN 14822-3 provides a set of codes for this purpose.

5.3.7 Cardinality rules between HL7 RIM classes

HL7 have defined rules which govern the cardinalities between class types. These cardinalities are summarised in Table 1 and shall govern the uses of all GPICs.

Table 1 — RIM Class Relationship Cardinalities

From \ To	Entity	Role	Role Link	Participation	Act	Act Relationship
Entity		*zero to many* An entity may play or scope many roles				
Role	*exactly one* A role is played as either a role player or role scoper		*zero to many* An entity playing or scoping a role may be associated with zero to many instances of Role Link.	*zero to many* An entity playing a role may be associated with zero to many instances of Participation		
Role Link		*exactly two* An instance of role link links together two instances of Role, the source and the target.				
Participation		*exactly one* An instance of participation is always associated with an entity playing a role			*exactly one* An instance of participation is always associated with a particular act	
Act				*zero to many* An act may have zero to many participants		*zero to many* An instance of act may be related to zero to many other acts, each through an instance of act relationship
Act Relationship					*exactly two* An instance of act relationship links together two instances of act.	

6 Common features of the general purpose information components

The GPICs are generally described at two levels: the *GPIC core* and the *GPIC extensions.*

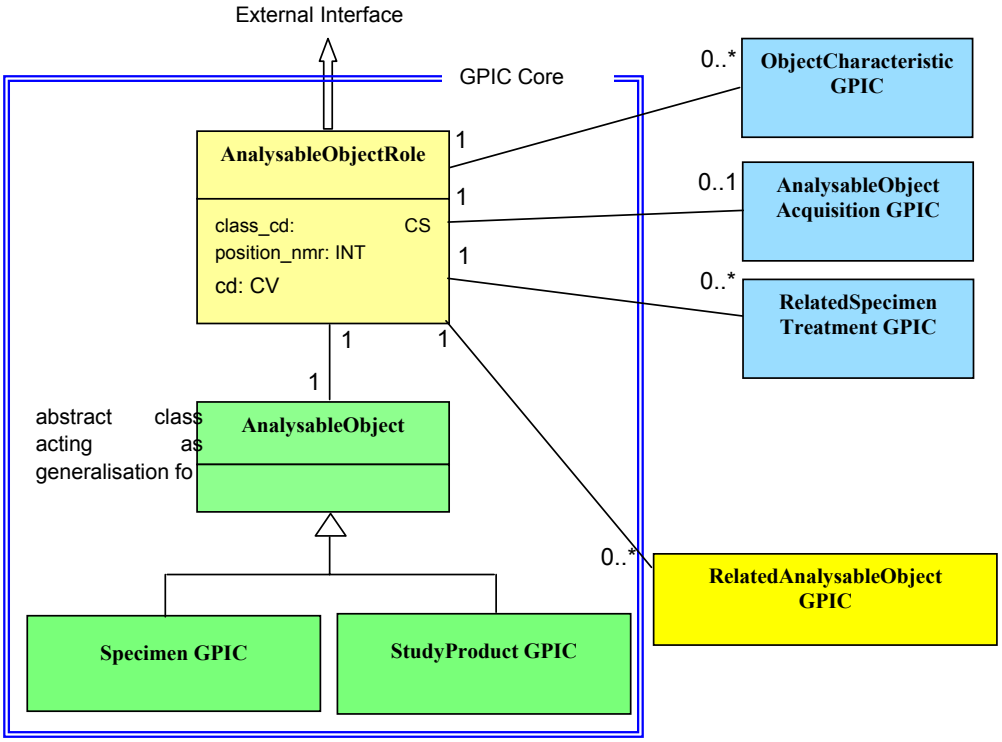


Figure 8 — An example GPIC

Overall description:

Each GPIC shall have a name. This name should be unique within the communicating community.

Each GPIC shall have a unique identifier. This shall be unique throughout all communicating communities. Where a user community creates a new GPIC, they shall create a new unique identifier. What constitutes a 'new' GPIC is described later in this overview. In this standard an ISO compliant Object Identifier (OID) will be assigned to each GPIC.

Each GPIC has a boundary, inside of which is the GPIC core, and outside of which are example GPIC extensions.

For each GPIC there are described restrictions upon the types of classes to which the GPIC may be attached to a parent model. In the above example (Figure 8), the GPIC text will indicate that the GPIC may only be associated to a parent model through a class of type Participation (which will link it to some activity) or Role Link (which will link it to some other entity).

GPICs may be used as 'templates' for use in the description of:

— commonly encountered 'things' or 'activities'.

EXAMPLES

- ‘things’: person, healthcare professional, patient, organisation, place, medicinal product, device, sample etc.;
- ‘activities’: observation, procedure, medication treatment, patient encounter, treatment plan/scheduling etc.;

— groupings of ‘things’ or activities.

EXAMPLES

- analysable objects – encompassing samples, x-rays, digitally encoded data etc.;
- healthcare agents – encompassing professionals, devices, organisations.

— groupings of ‘activities’.

EXAMPLES

- healthcare information – encompassing observations, procedures, medication treatment, investigations & results, care planning, counselling etc.;
- care service – encompassing planning, procedures, medication treatment, investigations etc.

— related ‘things’ and ‘activities’
In many situations it is necessary to associate a ‘thing’ (healthcare professional, device, sample etc.) or an activity (observation, investigation etc.), with some other ‘thing’ or ‘activity’. In conformance to the underlying semantics of the Health Level 7 (HL7) Reference Information Model (RIM) upon which this standard is built, there is a requirement to make the relationships explicit. This gives rise to a number of GPICs of the general type RelatedTHING, ParticipatingTHING, RelatedACTIVITY etc.

The GPIC core descriptions:

Each GPIC defines a ‘core’ which represents the normative description and properties of the GPIC. This core is represented by the double blue line.

Each GPIC shall have as its interface to external models a RIM class. In the example this is the class AnalysableObjectRole. This class is the only point at which the GPIC can be attached to a parent model.

The GPIC may contain ‘abstract’ classes which have no attributes of their own but which inherit attributes from its specialisations. An abstract class is shown as a ‘double box’ with no attributes shown (as with the AnalysableObject class in the example).

The GPIC model may show the specialisation of an abstract class as other GPICs (e.g. Specimen and StudyProduct).

Within a GPIC, core associations between classes are always mandatory.

The GPIC extensions:

Most of the GPICs descriptions in this European Standard indicate extensions which shall be treated as informative.

It is not a requirement of the methodology employed by this standard to include extension descriptions.

In this European Standard, GPIC extensions are always shown as associations which cross the GPIC core boundary between a RIM class within the GPIC core and another GPIC which is external to the core. For

example, a clinical observation may be associated with a healthcare professional that made the observation, a care encounter where the observation was made, an investigation result that prompted the observation etc.

The external GPIC may be the GPIC being defined, i.e. the description may be used to define a recursion, e.g. an organisation within an organisation.

Within the GPIC there may be only one point (class) which will act as a link to extension GPICs. This is known as an 'EXIT POINT', i.e. any cardinality between the GPIC and the external GPIC should be understood to be the cardinality between the exit point class and the external GPIC.

The RIM class within the core of the GPIC that is the source of the external association may be an abstract class such that all specialisations described within the GPIC may inherit these optional associations.

The precise nature of such extensions cannot be defined because of the diversity and complexity of healthcare information. Moreover, it is important to reserve decisions about which extensions are required to the local situation. Not that the extensions described are only indicative and user-defined extensions are permitted.

7 Use of general purpose information components in communication

The basic rules underpinning the use of the GPICs are:

— information sources (senders) shall always populate mandatory attributes.

— information receivers shall always be able to receive and deal appropriately with both mandatory and optional attributes within the GPIC core.

NOTE All associations described within the core or all GPICs are mandatory.

8 Localisation of the general purpose information components

Healthcare information is diverse and the situations where this information is created and used is more so. It is therefore not feasible to be too prescriptive about which information elements may be required. The basic GPICs described in this European Standard contain classes with few mandatory attributes but often many optional attributes. For example, a 'participating patient' may contain information about the nature of the participation, the need for authorisation to proceed, and so on. However, it is not appropriate to always require that this information is needed.

Localisation of a GPIC may be required due to national, regional or local requirements/legislation or may be due to the nature of the healthcare situation where the information is used. Where localisation of a GPIC is required it is necessary to produce a new GPIC which may be based upon the original but with a different unique GPIC identifier.

Localisation may not only add/remove attributes but may also place restrictions upon the values, for example:

— limiting the set of codes available to certain attributes to those present in a particular vocabulary

— limiting numeric values to be within a certain range

Again it is necessary that the precise nature of the localisation to be agreed and documented by the communicating community.

9 Overview of the content of EN 14822-2 and EN 14822-3

9.1 EN 14822-2 GPICs: Non-Clinical

Person Related GPICs: including the generic concept of person, a short version of person for use where an identifier and possibly a name suffices, and person language which includes language ability, signing etc.

Organisation Related GPICs: Including organisations within organisations and contact persons.

Subject of Care Identification GPICs: including the criteria for the identification of persons and animals.

Subject of Care GPICs: including general 'patient' type information about persons, animals and groups of animals that are in the subject of care role.

Subject of Care Related GPICs: including information about other subjects of care that have a relationship (e.g. mother/baby) and patient related parties (e.g. next of kin, employer). This group of GPICs also includes descriptions of how to describe the participation of the patient or other persons in healthcare activities.

Healthcare Agent GPICs: including information about professionals and organisations (plus devices) and their roles and participations in the delivery of healthcare services.

Device GPICs: including their description, use, calibration and location of use.

Locations GPICs: including care locations such as ward, bed, home. Also includes non-healthcare locations such as the site of origin of a food sample.

Transport GPICs: including the transport or arrangements for the transport of persons, animals or inanimate objects.

Financial GPICs: including care costs, authorisation and service agreements.

9.2 EN 14822-3 GPICs: Clinical

Analysable Object GPICs: including specimen and how they are preserved/treated; study products such as x-rays; manufactured materials such as vaccines; characteristics of the specimen or study product; the procedures used to acquire the analysable objects and how the patient was prepared; the location and description of study products held digitally.

Clinical Information GPICs: especially, GPICs which may be used to describe ENV 13606 type complexes and data items.

Clinical Observation GPICs: including details of the patient's condition.

Clinical Procedure GPICs: including details of routing, devices and patient preparation.

Counselling GPICs: including who received the counselling.

Laboratory and Diagnostic Investigation GPICs: including information about the requests and the results, reference limits, body systems and measurement procedures.

Medication GPICs: including medication treatment, dose administration, treatment regimen, medication supply, medicinal products, medicinal product packs, appliances, ingredients and conditions when treatment should start/stop.

Treatment Routing GPICs: including the routing and any devices used.

Care Encounter GPICs: including service requests, service reports and care planning, plus details of the services which being requested, reported or planned.

Annex A
(informative)

How to read the models

A.1 Introduction

The modelling technique and the definition of terms in the models follow the conventions described within the Unified Modelling Language (UML).

This annex contains a brief overview of the modelling conventions used in this document. However, modelling is used in this European Standard only to demonstrate consistency and to illustrate the domain. It is not the intention of this European Standard, or this annex to present this modelling method, or its implementation, as a general method for modelling healthcare information for other purposes.

A.2 Classes

A class is the descriptor for a set of objects with similar structure, behaviour, and relationships. This document provides a graphical notation for the relationships between instances of the classes where this adds to the clarity of the description of the domain. All classes are described textually.

NOTE An instance of a class may be called 'an object'.

Within UML, a Class is shown as a solid-outline rectangle with 3 compartments separated by horizontal lines. The upper name compartment holds the class name; the middle compartment holds a list of attributes; the bottom list compartment holds a list of operations. In this European Standard the representation of a class includes only two compartments, the name compartment and the attribute compartment.

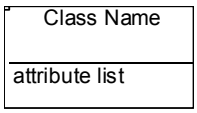


Figure A.1 — 1 Representation of classes

A.3 Associations between classes

An association is any relationship between classes. A solid line between two class symbols illustrates an association between those classes. The ends of the line are labelled with the multiplicities of the association (that is the numbers of instances of one class that may be associated with a single instance of the associated class). In the figure below, each instance of Class A is associated with exactly one instance of Class B. Each instance of Class B may be associated with zero, one or many instances of A.

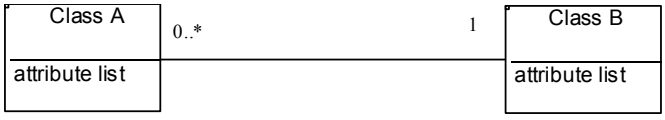


Figure A.2 — Illustration of associations between classes

A.4 Generalisation/specialisation

A generalisation/specialisation relationship between classes implies that the specialisation is a kind or subtype of the generalised class. For example a dog is a specialisation of animal.

A solid line between classes with a hollow triangle at the generalisation end indicates as generalisation/specification relationship. The lines from several classes may converge on and connect to the generalisation through a single hollow triangle. This indicates that a single instance can only be one of the specialisations shown.

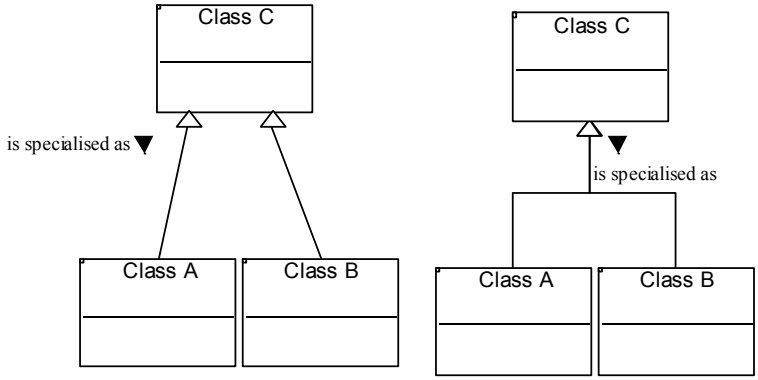


Figure A.3 — Illustrations of classes A and B as specialisations of Class C

Specialisation classes inherit all attributes and relationships from their generalisation class(es). A generalisation may be an *abstract* class. In this case, no instances of the generalised class exist except as instances of one of the specialisations.

Annex B
(informative)

HL7 RIM Class specialisations

B.1 Introduction

The GPICs utilise a subset of the Health Level Seven (HL7) Reference Information Model. This annex provides a more complete representation of the RIM as specified in HL7's version 2.01.

This graphical representation includes a definition of the classes, their attributes and the data types associated with these attributes. It should be noted that not all of the data types specified for use in the RIM are utilised in the GPICs defined in this multi-part standard. However, all of the data types used by GPICs are specialisations of HL7 data types as specified by HL7 in their Abstract Data Types definitions.

B.2 Entity class and its specialisations

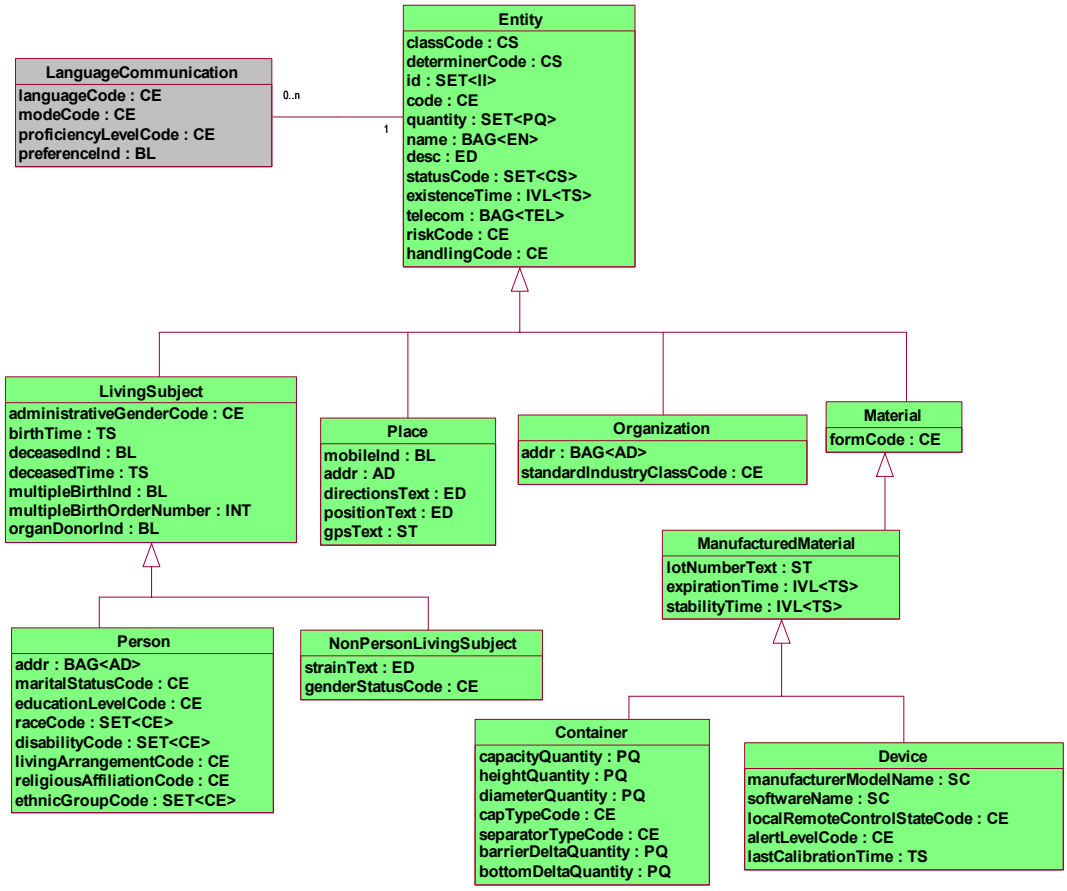


Figure B.1 — Entity class and its specialisations

B.3 Role class and its specialisations

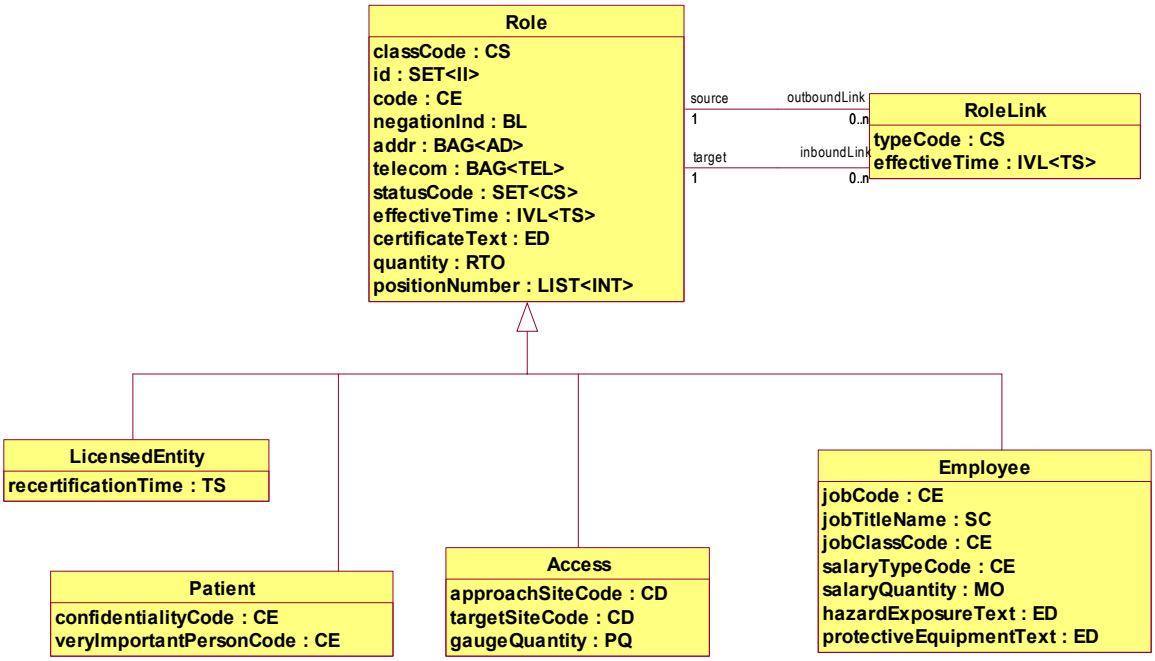


Figure B.2 — Role class and its specialisations

B.4 Act class and its specialisations

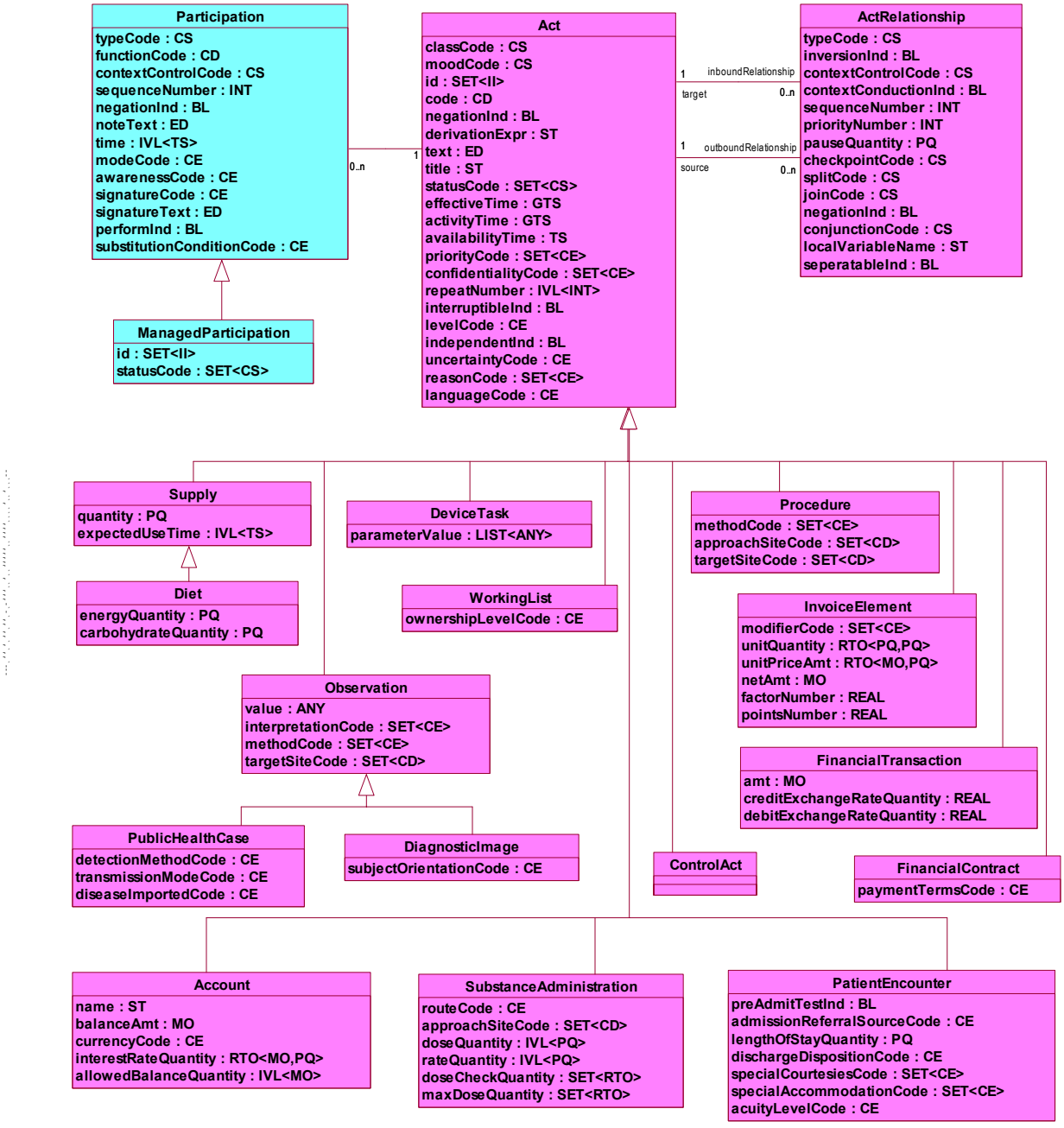


Figure B.3 — Act class and its specialisations

Bibliography

The following documents will be used as appropriate guides to the method and presentation used within the proposed European Standard.

[1] ENV 12537-1:1997, *Medical informatics – Registration of information objects used for EDI in healthcare – Part 1: The Register*

[2] ENV 12537-2:1997, *Medical informatics – Registration of information objects used for EDI in healthcare – Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare*

[3] ENV 13606-1:2000, *Health informatics – Electronic healthcare record communication – Part 1: Extended architecture*

[4] ENV 13606-4:2000, *Health informatics – Electronic healthcare record communication – Part 4: Messages for the exchange of information*

[5] ENV 13940:2001, *Health informatics – System of concepts to support continuity of care*

[6] CR 12587:1996, *Medical informatics – Methodology for the development of healthcare messages*[2].

[7] CEN/TC 251/N99 093, *Short Strategic Study: Strategic review of message standards alignment*.

The following existing International Standards and ongoing work are also relevant to the form and content of the proposed European Standard.

[8] EN 14822-2, *Health informatics – General purpose information components – Part 2: Non-clinical*

[9] EN 14822-3, *Health informatics – General purpose information components – Part 3: Clinical*

[10] ISO/IEC 11179-1, *Information technology – Metadata registries (MDR) – Part 1: Framework*

[11] CEN/TS 14796:2004, *Health Informatics – Data Types*

[12] HL7 v3.0 Version 2.01, *Data Types Specification – HL7 data types*

[13] ISO 17113, *Method for Development of Messages*

[2] This is partly superseded by the instructions of the following document approved by TC 251, December 1999.

UNI
Ente Nazionale Italiano di Unificazione
Via Sannio, 2
20135 Milano, Italia