

**Implementation of
ENV 1613 : 1995**

**Medical informatics —
Messages for exchange of
laboratory information**

Product code 00621111
ICS 11.100; 35.240.60

Committees responsible for this Draft for Development

This Draft for Development was entrusted to Technical Committee IST/35, Medical informatics, upon which the following bodies were represented:

- BCS Nursing Specialist Group
- British Computer Society
- British Computer Society (Health Informatics Specialist Groups)
- College of Radiologists (Clinical Oncology)
- Computing Services and Software Association
- Conference of Royal Colleges Information Group
- Department of Health
- Electro Medical Trade Association Limited
- Faculty of Public Health Medicine of the Royal College of Physicians in the UK
- Institute of Medical Laboratory Sciences
- Management Consultancies Association
- National Health Services
- NHS (Information Management Centre)
- Nine Tiles Computer Systems Ltd.
- Royal College of Surgeons of England
- Simpler Trade Procedures Board (SITPRO)
- Society for Computing & Technology in Anaesthesia
- Co-opted members

This Draft for Development having been prepared under the direction of the Information Systems Technology Assembly, was published under the authority of the Standards Board and comes into effect on 15 January 1996

© BSI 1996

The following BSI references relate to the work on this standard:
Committee reference IST/35
Draft for comment 94/647884 DC

ISBN 0 580 24884 4

Amendments issued since publication

Amd. No.	Date	Text affected

National foreword

This Draft for Development is the English language version of ENV 1613 : 1995 *Medical informatics — Messages for exchange of laboratory information*, prepared by the European Committee for Standardization (CEN) whose members have committed themselves to making it available in an appropriate form. In the UK the Draft for Development is the form now chosen for ENVs in the information technology area.

This Draft for Development is published under the direction of the Information Systems Technology Assembly whose Technical Committee IST/35 has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European Committee any enquiries on interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

NOTE. International and European Standards, as well as overseas standards, are available from Customer Services, BSI, 389 Chiswick High Road, London W4 4AL.

After two years this ENV will be reviewed by CEN members with a view to its:

- conversion into a European Standard (which would be implemented in the UK as a British Standard);
- extension once for a further two years;
- replacement by a revised ENV (which would be published in the UK as a revised Draft for Development);
- withdrawal.

The future of this Draft for Development is therefore bound to that of the ENV and the Draft for Development will not be reviewed or developed separately.

This publication is not to be regarded as a British Standard.

ICS 11.100; 35.240.60

Descriptors: Medicine, data processing, information interchange, messages, laboratories, specifications

English version

Medical informatics — Messages for exchange of laboratory information

This European Prestandard (ENV) was approved by CEN on 1995-03-10 as a prospective standard for provisional application. The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into an European Standard (EN).

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

© 1995 All rights of reproduction and communication in any form and by any means reserved in all countries to CEN and its members.

Foreword

This European Prestandard has been prepared by the Technical Committee CEN/TC 251, Medical informatics, of which the secretariat is held by IBN.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to announce this European Prestandard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

	Page
Foreword	2
Introduction	3
1 Scope	5
2 Normative references	7
3 Definitions	8
4 Requirements	11
5 Communication roles and supported services	12
6 Domain Information Model	16
6.1 Approach	16
6.2 Domain Information Model diagrams	16
6.3 Textual description of the objects, their relationships and attributes	20
6.4 Textual description of common attribute groups	44
7 General Message Descriptions	46
7.1 Introduction	46
7.2 New laboratory service order General Message Description	46
7.3 Laboratory service order modification General Message Description	50
7.4 Laboratory service order cancellation General Message Description	52
7.5 New laboratory service report General Message Description	53
7.6 Laboratory service report modification General Message Description	56
7.7 Laboratory service report cancellation General Message Description	58
7.8 Attribute layer	59
Annexes	
A How to read the models (normative)	77
B Questions and answers (informative)	80
C Example scenarios of message use (informative)	86
D EDIFACT messages (informative)	89
Index	106

INTRODUCTION

The increased use of data processing and telecommunications capabilities has made possible the interchange of information in machine readable and machine processable formats. As automated interchange of information in healthcare increases, it is essential to provide appropriate information interchange standards.

Computer systems are in use for the storage and processing of information in many clinical laboratories. Similarly many of the requesters of investigations or recipients of reports use computer systems to store and process information. This information includes details of investigations requested and results received. Clinical laboratories carry out investigations requested by healthcare parties and send the results of these investigations to the requester and sometimes to other healthcare parties.

Electronic transfer of requests and results reduces the need for manual data entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision. Standards are required to facilitate electronic transfer of requests for and results of investigations between the many systems currently used.

Implementation of this European Prestandard will therefore :

- a) facilitate the electronic transfer of orders for laboratory investigations from requesting healthcare parties, to clinical laboratories;
- b) facilitate the electronic transfer of reports from clinical laboratories to requesters and other healthcare parties;
- c) reduce the need for human intervention in information interchange between applications used by clinical laboratories and those used by other healthcare parties;
- d) minimise the time and effort required for the introduction of information interchange agreements;
- e) reduce the development effort required by suppliers to allow communication between a wide range of applications in this field;
- f) reduce (in consequence of the foregoing) the cost of information interchange between clinical laboratories and parties requesting clinical laboratory services.

When implementing information exchange based upon this European Prestandard data protection and secrecy principles must be guaranteed according to the laws actually in force in the different CEN member countries.

The method by which this European Prestandard has been developed is based on the recommendations of the CEN Technical Report "Investigation of Syntaxes for Existing Interchange Formats to be used in Healthcare" (CR 1350:1993).

This standard is intended for use by message developers. Its provisions are directly relevant to suppliers of computer systems for use in clinical laboratories, hospitals, general practices, clinical departments and specialist clinics. Its provisions are also relevant to those planning, specifying, procuring or implementing information systems for use in clinical laboratories, hospitals, general practices, clinical departments and specialist clinics.

The main normative provisions in this European Prestandard are expressed in clauses 4 and 5 and apply to the General Message Descriptions (GMDs), clause 7.

The symbols used in this Prestandard have the meaning as defined in normative annex A for the purposes of this Prestandard only. Informative annex B provides additional explanation to the Domain Information Model. Informative annex C gives a number of example scenarios of message use.

Annex D (informative) provides message definitions using the EDIFACT (Electronic data interchange for administration, commerce and transport) standard ISO 9735 and is in line with the procedures for submission of EDIFACT-based standards of the UNECE. These message definitions are Implementable Message Specifications conforming with this European Prestandard.

Annex D has been submitted to the UNECE and in due course is expected to achieve the status of a United Nations Standard Message (UNSM).

Arrangements between CEN and the Western European EDIFACT Board ensure that UNSMs can become ENVs. Annex D will therefore become an ENV in its own right through separate standardisation procedures.

A supplementary document to this ENV, called "Generic EDIFACT message implementation guide", provides in its first chapters the method and conformance information on how the EDIFACT messages meet the requirements of the General Message Descriptions of the ENV.

This supporting document contains message implementation guidelines for the Implementable Message Specifications (IMSs). They should be considered an essential component of the IMS providing a generic EDIFACT implementation specification for use in Europe.

Specifically these chapters cover :

- A general description of how the mapping from GMDs to EDIFACT is carried out.
- A structure table indicating how the defined IMSs meet the relationships defined in the GMDs.
- Data tables indicating how the defined IMSs support the objects and attributes of the GMDs

The supporting document is not a constituent part of this ENV.

Medical Informatics - Messages for exchange of laboratory information

1. SCOPE

1.1 This European Prestandard specifies general messages for electronic information exchange between clinical laboratories' computer systems and computer systems used by healthcare parties requesting the services of, or receiving results from, clinical laboratories (abbreviated as laboratories in this Prestandard).

1.2 This European Prestandard is applicable to messages requesting or reporting on the results of the services of the following specialties :

- Clinical Chemistry;
- Clinical Biochemistry;
- Toxicology;
- Clinical Immunology;
- Immunohaematology;
- Haematology;
- Clinical Microbiology (including Bacteriology, Mycology, Parasitology and Virology).

1.3 This European Prestandard is not applicable to messages requesting or reporting on the results of the services of the following specialties (see 1.11) :

- Anatomic Pathology;
- Histopathology;
- Cytology; and
- Autopsies.

1.4 This European Prestandard does not specify the manner in which clinical laboratory services are divided between specialties as this varies in accordance with different national and local practices.

1.5 The scope of the messages specified by this European Prestandard comprises requests and results related to investigations carried out by clinical laboratories on subjects of investigation. This European Prestandard is applicable whether the healthcare party communicating with the clinical laboratory is a person (such as a doctor or other healthcare professional) or an organisation (such as a hospital, clinic or department). A clinical laboratory may itself act as the healthcare party submitting requests to, or receiving results from other clinical laboratories. However, this European Prestandard has not been developed to meet the needs of messages that are specific to communications between one clinical laboratory and another.

1.6 This European Prestandard is applicable to requests for investigation and modifications and cancellations of previously issued requests. It is applicable both to samples that are obtained from subjects of investigation at the point of care or at any other location and submitted to the clinical laboratory, and to requests for investigation for which the laboratory is requested to obtain samples. The messages it specifies support standing orders for laboratory services.

1.7 This European Prestandard is applicable to reports of the results of investigation and modifications and cancellations of previously issued reports. The messages it specifies support the communication of partial, supplementary, final supplementary, complete and cumulative reports. Reporting modes which can be implemented using this European Prestandard include: sending a laboratory service report only when all laboratory investigation results are available; sending individual results as they become available; sending new results as part of a cumulative report; and sending partial results.

1.8 This European Prestandard is not applicable to the communication of graphical or image information that forms part of a request for or result of a laboratory investigation.

1.9 This European Prestandard has not been developed to meet the needs of messages supporting administration, financing, management, interpersonal mail or external quality control nor of messages communicating sample collection lists, work lists or queries.

1.10 This European Prestandard does not support negative acknowledgment or error indication at the application level, nor positive acknowledgment at the application level.

1.11 The provisions of this European Prestandard have been validated in the domains and for the purposes described above (see 1.2 and 1.3). However messages conforming to this European Prestandard may be considered by some user communities to meet their needs for purposes outside this scope. Use of the messages in such circumstances is not precluded by the scope.

1.12 While the messages specified in this European Prestandard may convey clinical and administrative information concerning patients, the way in which this information is treated in this European Prestandard does not constrain the development of future standards for the electronic healthcare record or for other clinical and administrative messages.

1.13 The method for the specification of the messages in this European Prestandard only applies to this European Prestandard. This Prestandard does not constrain the development of other methods for the specification of standardised edi messages. The symbols used in this Prestandard have the meaning as defined in normative annex A for the purposes of this Prestandard only.

2. NORMATIVE REFERENCES

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited in the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments and revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment and revision. For undated references the latest edition of the publication referred to applies.

CR 1350:1993	Investigation of syntaxes for existing interchange formats to be used in Healthcare
ENV 1068:1993	Medical Informatics - Healthcare information interchange -Registration of coding schemes
ENV 1614: 1995	Health care informatics. Structure for nomenclature, classification and coding of observable properties in clinical laboratory sciences.
EN 23166: 1993	Codes for representation of names of countries
EN 28601: 1992	Data elements and interchange formats - Information interchange -Representation of dates and times
EN 29735: 1990	Electronic data interchange for administration, commerce and transport (EDIFACT) - Application level syntax rules
ISO 639: 1988	Symbols for languages, geographical areas and authorities
ISO 646: 1991	Information technology - ISO 7-bit coded character set for information interchange
ISO 2382: 1987	Information processing - Vocabulary Part 4 : Organisation of data
ISO 4217: 1990	Codes for the representation of currencies and funds
ISO 5218: 1977	Information interchange - Representation of human sexes
ISO 6523: 1984	Data interchange - Structure for the identification of organisations
ISO 8824-1: 1993	Information technology - Open Systems Interconnection - Abstract Syntax Notation One (ASN.1) Part 1 : Specification of basic notation
ISO 8825-1: 1993	Information technology - Open Systems Interconnection - Specification of ASN.1 encoding rules Part 1 : Basic Encoding Rules (BER)
ISO 8859: 1987	Information Processing - Registration of graphics character subrepertoires - Eight-bit single byte coded graphic character sets

3. DEFINITIONS

For the purposes of this standard, the following definitions (listed in alphabetical order) apply :

3.1 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.

NOTE : Clinical information about a patient may include information about the patient's environment or about related people or animals where this is relevant.

3.2 clinical investigation : Laboratory, physiological, radiological or other healthcare examination that leads to the production of one or more results.

3.3 clinical observation : Clinical information excluding information about treatment and intervention.

NOTE : Clinical information that does not record an intervention is by nature a clinical observation. The observer may be the patient or related person (information about symptoms, family history, occupation or life style), or a healthcare professional (information about physical signs, measurements, properties observed or diagnoses). While information about the nature of a planned or performed treatment is excluded by the definition, clinical observations may be recorded as the results of a treatment or during the course of a treatment or as its result.

3.4 code meaning : Element within a coded set.

EXAMPLE : "Paris Charles-De-Gaulle" which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

[ENV 1068]

3.5 code value : Result of applying a coding scheme to a code meaning.

EXAMPLE : "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

[ENV 1068]

[ISO 2382-1987], modified

3.6 coding scheme : Collection of rules that maps the elements of one set on to the elements of a second set.

[ENV 1068]

[ISO 2382-1987], modified

3.7 domain information model : Conceptual model describing common concepts and their relationships for communication parties required to facilitate exchange of information between these parties within a specific domain of healthcare.

NOTE : In this Prestandard the abbreviation DIM is used.

3.8 general message description : Subset of a domain information model prescribing the information content and semantic structure of a message used to meet one or more identified information interchange requirements.

NOTE 1 : General message descriptions are independent of the syntax used for constructing an actual message. They provide statement of the information interchange requirements in a form that can be implemented using different syntaxes.

NOTE 2 : In this Prestandard the abbreviation GMD is used.

3.9 healthcare administrative information : Information about a subject that is requested or required by a healthcare party to enable, finance or manage the provision of healthcare services to that subject.

3.10 healthcare coding scheme designator : Unique permanent identifier of a healthcare coding scheme registered for use in information interchange under the terms of the European Prestandard ENV 1068.

3.11 healthcare organisation : Organisation responsible for the direct or indirect provision of healthcare services to a subject, or involved in the provision of healthcare related services such as environmental measurement results.

NOTE : A healthcare organisation may be used stand-alone or as a superstructure containing departments and sub-departments.

3.12 healthcare party : Organisation or person responsible for the direct or indirect provision of healthcare to an individual, or involved in the provision of healthcare-related services such as environmental measurement results.

3.13 healthcare professional : Person who is entrusted with the direct or indirect provision of defined healthcare services to a subject or population of subjects.

EXAMPLE : Primary care physician, dentist, nurse, social worker, veterinary surgeon.

3.14 healthcare service : Service provided with the intention of directly or indirectly improving the health of the people, populations or animals to whom it is provided.

3.15 implementable message specification : Specification of a general message description in a particular message syntax.

NOTE : In this Prestandard the abbreviation IMS is used.

3.16 interchange format : Specification of a message type according to a given message syntax, covering the identification of the message type components, their arrangement, representation and interrelationships.

3.17 intervention information : Information about medical or surgical actions performed on or planned to be performed on a subject of investigation.

NOTE : Intervention information refers to clinical information related to planned or actual interventions as distinct from information obtained by observation. It includes but is not limited to prescription or administration of drugs, therapeutic and diagnostic procedures.

3.18 laboratory investigation : clinical laboratory examination that leads to the production of one or more results.

EXAMPLE : As a laboratory investigation is the synthesis of its component parts and may be variously constituted, the following are all examples of laboratory investigations : liver function tests, bilirubin, albumin, blood-albumin-substance concentration, globulin, alkaline phosphatase, aspartate aminotransferase, full blood count, glucose tolerance test, creatinine clearance, C-reactive protein, rubella antibodies, microscopy & or culture & or sensitivity, viral antigen isolation, detection of antinuclear antibodies (ANA), antibodies to Streptococci, VDRL test, antibiotic sensitivity tests, MIC/MBC determination, microscopy for detection of parasites.

NOTE : In this context, a clinical laboratory investigation; indicated by the term the requester uses to describe his/her wishes, or by the term(s) used for investigations conducted in the laboratory in pursuit of those wishes.

3.19 laboratory investigation result item : Set of information including all essential or useful data relevant to the result of a single laboratory investigation.

NOTE : A laboratory investigation result item is an object which encompasses all useful information in connection with an investigation result (e.g. all of : numerical value, uncertainty interval, reference limits, status, date and time and all generic quantity attributes); this object corresponds to what is normally called a 'line' on a paper report.

3.20 (laboratory) service order : Set of one or more requested laboratory investigations submitted to a (laboratory) service provider, pertaining to one or more specified systems, usually in one individual, and including pertinent specific and general information.

3.21 (laboratory) service provider : Authorised healthcare party qualified to perform laboratory services and to validate the resulting (laboratory) service report.

NOTE : In this context, a (laboratory) service provider usually is a laboratory and/or a member of its staff.

3.22 (laboratory) service report : Report of results of (laboratory) investigations of one or more properties pertaining to one or more specified systems, usually in one individual, and including pertinent information extracted from the (laboratory) service order as well as additional comments, suggestions and advice given by the (laboratory) service provider.

3.23 (laboratory) service requester : Authorised healthcare party issuing a (laboratory) service order for one or more (laboratory) investigations pertaining to one or more systems usually in one individual.

3.24 message profile : Specification derived from an implementable message specification by selecting its optional elements, appropriate to the specific business requirements of the communicating parties.

3.25 message syntax : System of rules and definitions specifying the basic component types of messages, their interrelationships and their arrangement.

3.26 message type : An identified, named and structured set of functionally related information which fulfills a specific business purpose.

3.27 organisation : Unique framework of authority within which a person or persons act, or are designated to act towards some purpose.

NOTE : Groupings or subdivisions of an organisation may also be considered as organisations where there is need to identify them for information interchange.

[ISO 6523-1984]

3.28 problem domain : Field under consideration in the modelling process.

EXAMPLE : Information interchange in clinical chemistry.

3.29 requested laboratory investigation : Request for a single laboratory service to be carried out in respect of a specified subject of investigation.

NOTE : A requested laboratory investigation is an object which includes all information associated with a single investigation as requested in a laboratory service order; it is usually a request for a single measurement but can be used for a battery/panel/profile and/or for a function test (on one or several different samples or on a patient as such).

3.30 sample : One or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these.

NOTE : The system from which a sample is taken may be a subject of investigation or may itself be a sample. The sample is assumed to be representative of the system. The term specimen is sometimes used with the same meaning.

3.31 subject of investigation : Person, animal or material subject to investigation.

NOTE : In the present context, the subject of investigation usually is a patient subject to clinical laboratory investigation.

3.32 transmitted message : Message instance created in a message syntax in alignment with a particular message profile and therefore in full conformance with the relevant general message description and implementable message specification.

4. REQUIREMENTS

4.1. Messages for transmission of laboratory service orders from laboratory service requesters to those laboratory service providers covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions in clause 7.

4.2. Messages for transmission of laboratory service reports from those laboratory service providers covered by the scope of this European Prestandard to laboratory service requesters and other parties to receive copies, shall enable electronic interchange of the semantic content defined in the General Message Descriptions in clause 7.

4.3. Implementable message specifications (IMS) shall conform to the General Message Descriptions defined in this ENV. They shall support both mandatory and optional objects, attribute groups and attributes as defined in the General Message Descriptions of this ENV. They shall also support the relationships between objects as defined by the General Message Descriptions.

4.4. Implementable message specifications should be expressed in terms of a syntax which is an international standard except where the healthcare user requirements cannot be met.

5. COMMUNICATION ROLES AND SUPPORTED SERVICES

5.1 General

This clause defines the communication roles which shall comply with the specifications of this European Prestandard when exchanging clinical laboratory information. It establishes the relationships between the communication roles and the General Message Descriptions, as well as the relationships amongst the General Message Descriptions (GMDs). Annex C (informative) specifies scenarios based upon which the communication roles, the General Message Descriptions and the supported services are derived.

5.2 Communication roles

Four types of communication roles can use the messages based upon the General Message Descriptions defined within the scope of this European Prestandard :

- laboratory service order originating roles,
- laboratory service order receiving roles,
- laboratory service report originating roles,
- laboratory service report receiving roles.

A single healthcare party may have one, two or more of the above mentioned roles.

EXAMPLE : a general practitioner may have a laboratory service order originating role and a laboratory service report receiving role.

5.3 Communication roles and General Message Descriptions

5.3.1 The relationships between the communication roles and the message types for which this European Prestandard provides General Message Descriptions are expressed by figure 1.

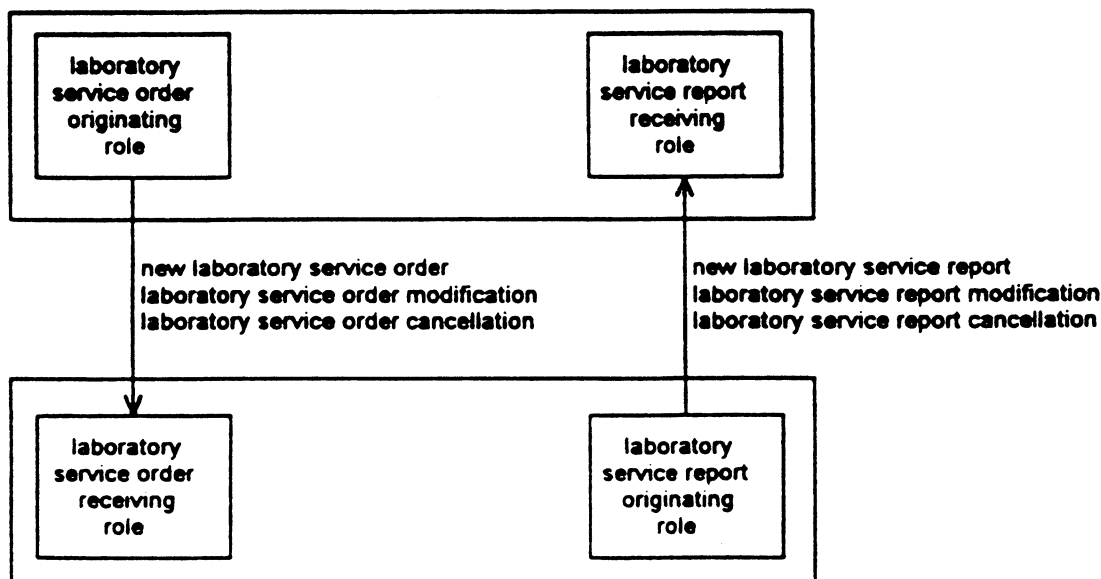


Figure 1: Relationship between communication roles and GMDs.

5.3.2 Communication parties with a laboratory service order originating role can send message instances based upon:

- the new laboratory service order General Message Description,
- the laboratory service order modification General Message Description,
- the laboratory service order cancellation General Message Description.

5.3.3 Communication parties with a laboratory service order receiving role can receive message instances based upon:

- the new laboratory service order General Message Description,
- the laboratory service order modification General Message Description,
- the laboratory service order cancellation General Message Description.

5.3.4 Communication parties with a laboratory service report originating role can send message instances based upon:

- the new laboratory service report General Message Description,
- the laboratory service report modification General Message Description,
- the laboratory service report cancellation General Message Description.

5.3.5 Communication parties with a laboratory service report receiving role can receive message instances based upon:

- the new laboratory service report General Message Description,
- the laboratory service report modification General Message Description,
- the laboratory service report cancellation General Message Description.

5.4 Communication roles and supported services

5.4.1 The services that shall be supported by a communication party with a laboratory service order originating role are:

- issue new laboratory service order message instances which comply with the new laboratory service order General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue laboratory service order modification message instances which comply with the laboratory service order modification General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue laboratory service order cancellation message instances which comply with the laboratory service order cancellation General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue these message instances in accordance with the state transition rules for laboratory service order message originating roles (see figure 2).

5.4.2 The services that shall be supported by a communication party with a laboratory service order receiving role are:

- receive new laboratory service order message instances which comply with the new laboratory service order General Message Description and which allow the complete and exact understanding of the information as intended by the requester,
- receive laboratory service order modification message instances which comply with the laboratory service order modification General Message Description and which allow the complete and exact understanding of the information as intended by the requester,
- receive laboratory service order cancellation message instances which comply with the laboratory service order cancellation General Message Description and which allow the complete and exact understanding of the information as intended by the requester,
- inform the healthcare party with this role about message instances which are not in accordance with the state transition rules for laboratory service order message originating roles (see figure 2 and see also B.2).

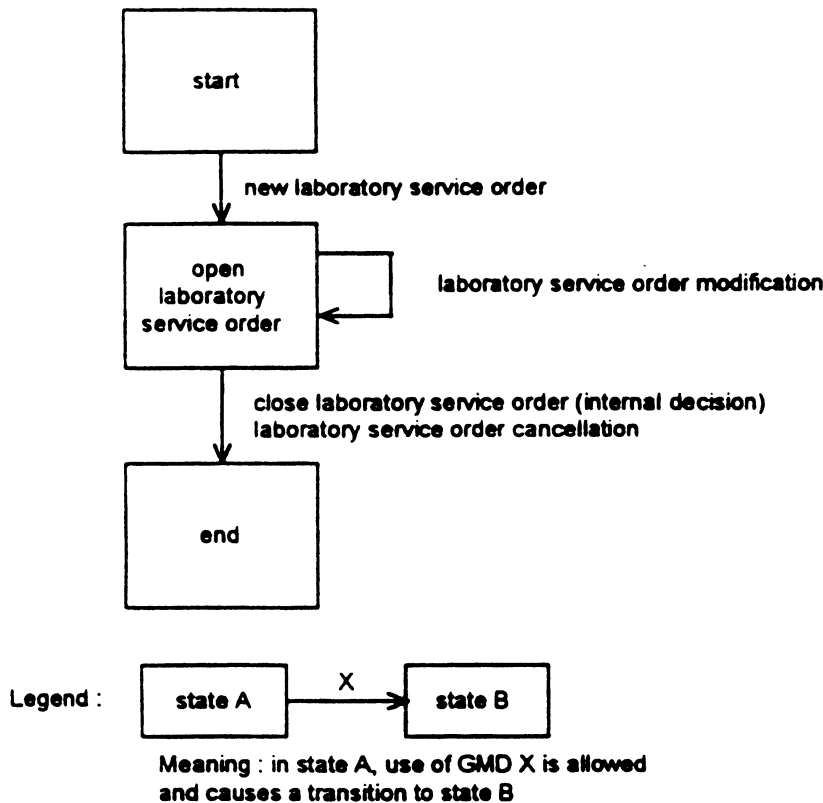


Figure 2: State transition rules for laboratory service order message originating roles.

5.4.3 The services that shall be supported by a communication party with a laboratory service report originating role are:

- issue new laboratory service report message instances which comply with the new laboratory service report General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue laboratory service report modification message instances which comply with the laboratory service report modification General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue laboratory service report cancellation message instances which comply with the laboratory service report cancellation General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver,
- issue these message instances in accordance with the state transition rules for laboratory service report message originating roles (see figure 3).

5.4.4 The services that shall be supported by a communication party with a laboratory service report receiving role are:

- receive new laboratory service report message instances which comply with the new laboratory service report General Message Description and which allow the complete and exact understanding of the information as intended by the laboratory service provider,
- receive laboratory service report modification message instances which comply with the laboratory service report modification General Message Description and which allow the complete and exact understanding of the information as intended by the laboratory service provider,
- receive laboratory service report cancellation message instances which comply with the laboratory service report cancellation General Message Description and which allow the complete and exact understanding of the information as intended by the laboratory service provider,
- inform the healthcare party with this role about message instances which are not in accordance with the state transition rules for laboratory service report message originating roles (see figure 3 and see also B.2).

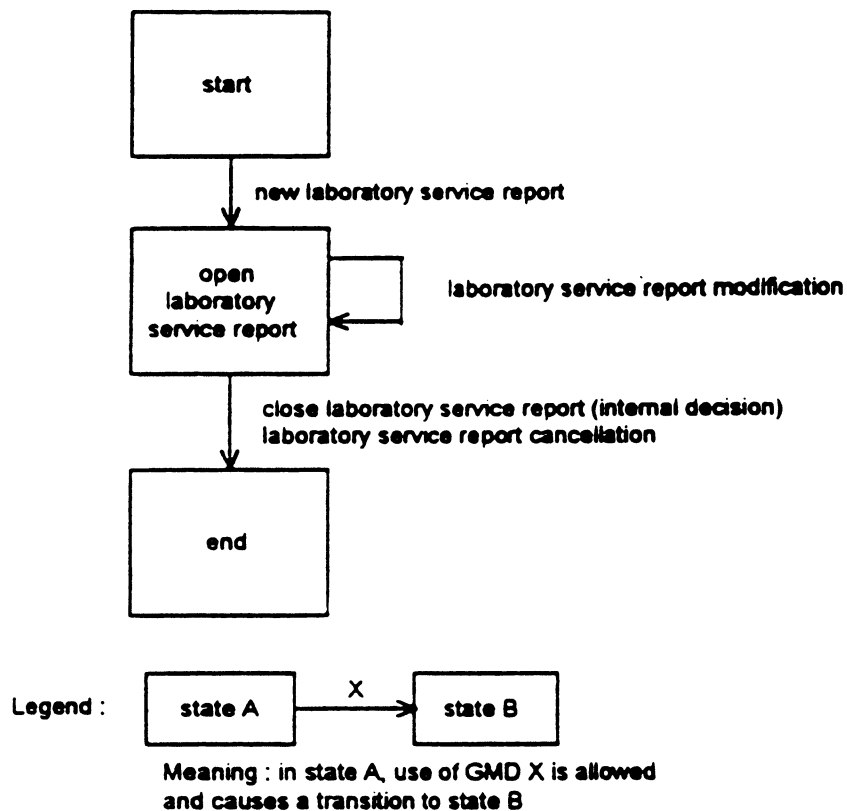


Figure 3: State transition rules for laboratory service report message originating roles.

6. DOMAIN INFORMATION MODEL

6.1. Approach

The Domain Information Model (DIM) and the General Message Descriptions (GMDs) were built based on the approach defined by CR 1350 "Investigation of syntaxes for existing interchange formats to be used in Healthcare" and the technique described by P. Coad and E. Yourdon¹. To enhance readability other symbols have been used within the presentation. The models specify subjects, classes and class-&-objects, and relationships between these components. The attribute layer specification is given in clause 7. See normative annex A for more information on how to read the models and on the symbols used.

6.2 Domain Information Model diagrams

6.2.1 Introduction

The Domain Information Model, as defined for the specification of the General Message Descriptions, is represented by four diagrams :

- a) the laboratory service order and report model (which is the top-level model);
- b) the subject models for :
 - healthcare party;
 - subject of investigation;
 - sample.

¹ 1. Peter Coad, Edward Yourdon, Object Oriented Analysis, 2nd edition, 1991, Yourdon Press, Prentice Hall Building, Englewood Cliffs, NJ 07632.

6.2.2 Laboratory service order and report model

This model (see figure 4) is the top-level model of the DIM. Its components are :

- copy destination : see 6.3.8;
- intended recipient of report copy : see 6.3.15;
- laboratory investigation : see 6.3.17;
- laboratory investigation result item : see 6.3.18;
- laboratory service order : see 6.3.19;
- laboratory service provider : see 6.3.20;
- laboratory service requester : see 6.3.22;
- payment party : see 6.3.26;
- related laboratory service provider : see 6.3.29;
- requested laboratory investigation : see 6.3.30;
- sample subject : see 6.2.5;
- subject of investigation subject : see 6.2.4.

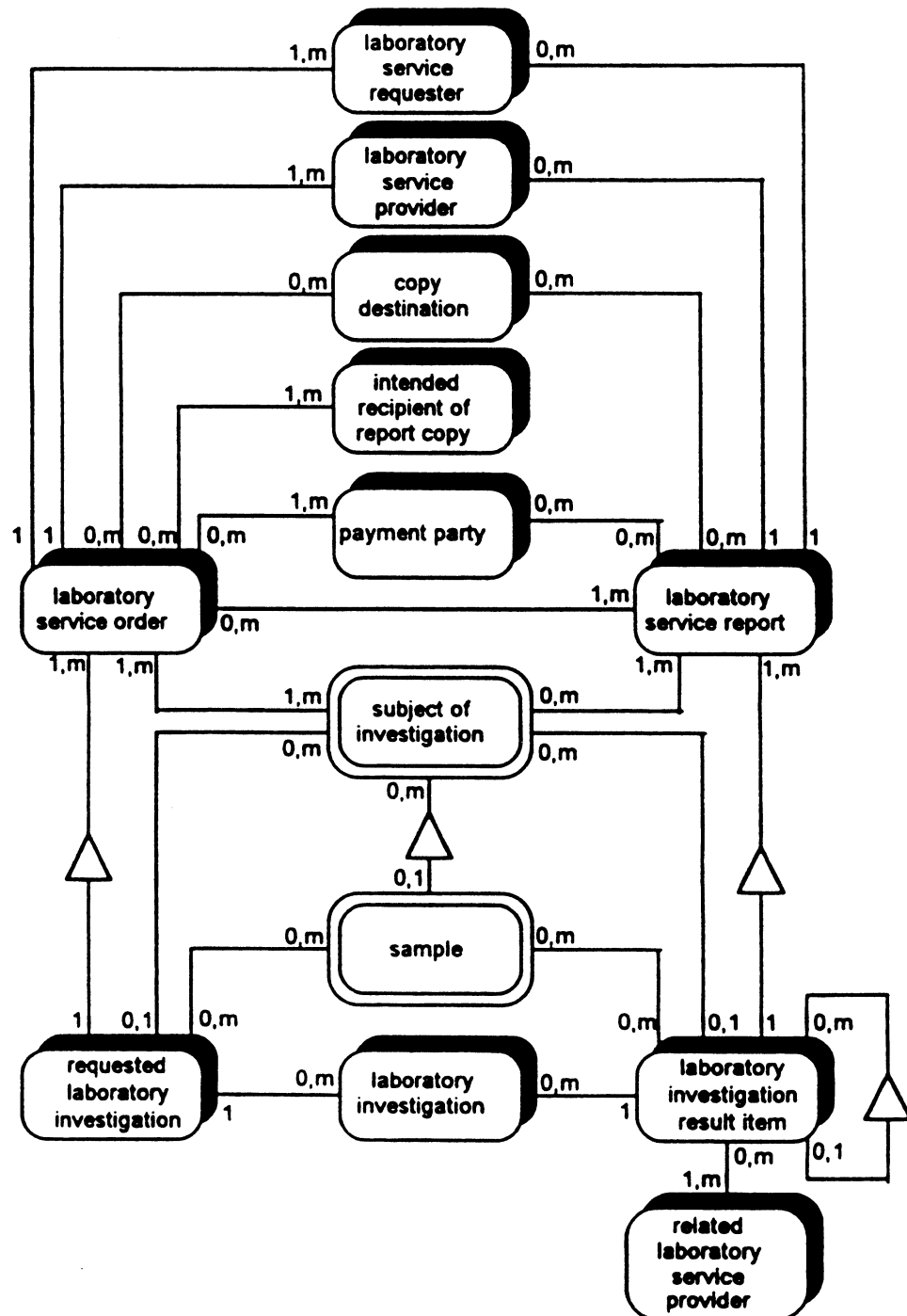


Figure 4 : Laboratory service order and report model

6.2.3 Subject model for healthcare party

This model (see figure 5) has the following components :

- healthcare organisation : see 6.3.11;
- healthcare party : see 6.3.12;
- healthcare party role : see 6.3.13;
- healthcare professional : see 6.3.14;

The following components are included to express the relationship with the other models :

- copy destination : see 6.3.8;
- healthcare administrative information : see 6.3.10;
- intended recipient of report copy : see 6.3.15;
- laboratory service provider : see 6.3.20;
- laboratory service requester : see 6.3.22;
- origin of clinical information : see 6.3.24;
- payment party : see 6.3.26;
- related healthcare service provider : see 6.3.28;
- related laboratory service provider : see 6.3.29;
- sample collection location : see 6.3.32;
- sample collector : see 6.3.33;
- supervising healthcare party : see 6.3.36.

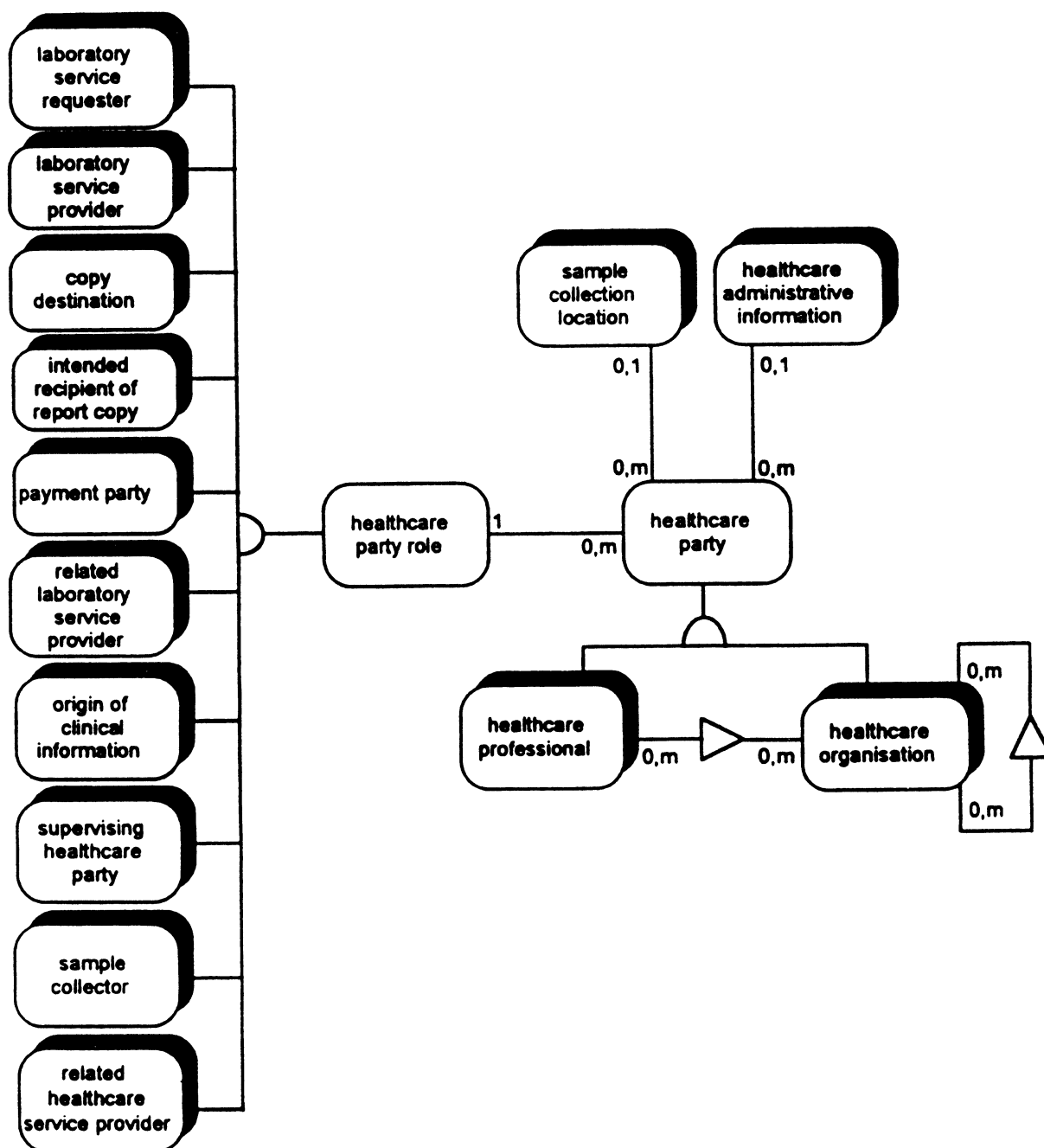


Figure 5 : Subject model for healthcare party

6.2.4 Subject model for subject of investigation

This model (see figure 6) has the following components :

- animal : see 6.3.2;
- clinical information : see 6.3.3;
- clinical investigation : see 6.3.4;
- clinical investigation result item : see 6.3.5;
- clinical observation : see 6.3.6;
- drug : see 6.3.9;
- healthcare administrative information : see 6.3.10;
- intervention information : see 6.3.16;
- material : see 6.3.23;
- origin of clinical information : see 6.3.24;
- patient : see 6.3.25;
- related healthcare service provider : see 6.3.28;
- subject of investigation : see 6.3.35;
- supervising healthcare party : see 6.3.36.

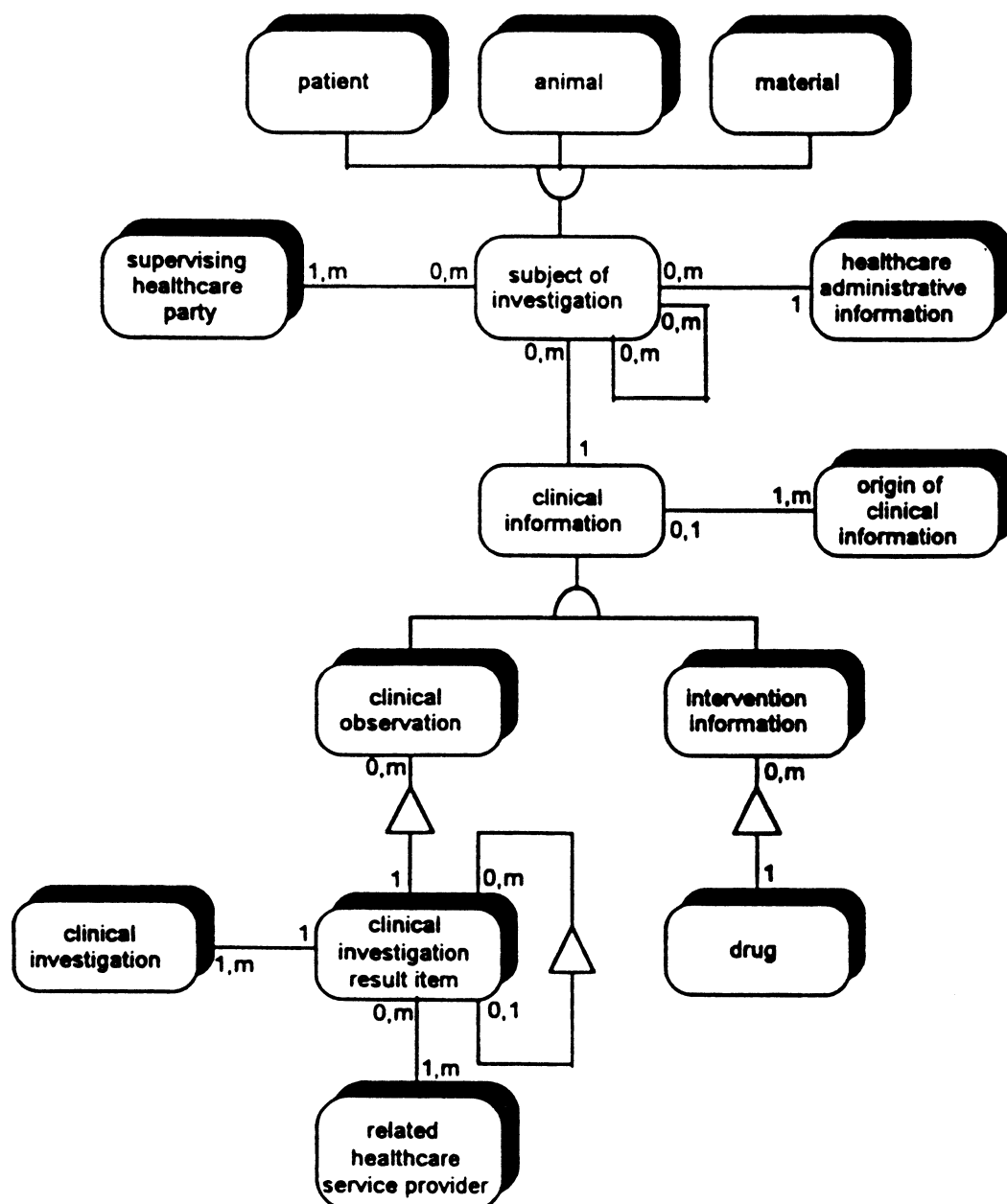


Figure 6 : Subject model for subject of investigation

Note : although the objects clinical observation, clinical investigation, clinical investigation result item and related healthcare service provider may be considered as generalisations of laboratory service report, laboratory investigation, laboratory investigation result item and related laboratory service provider respectively, they are not modelled as such in view of the scope of this European Prestandard and in order not to constrain future work in this area.

6.2.5 Subject model for sample

The subject model for the sample subject (see figure 7) has the following components:

- collected sample : see 6.3.7;
- sample : see 6.3.31;
- sample collector : see 6.3.33;
- pre-treatment : see 6.3.27;
- sample collection location : see 6.3.32;
- sample to be collected : see 6.3.34.

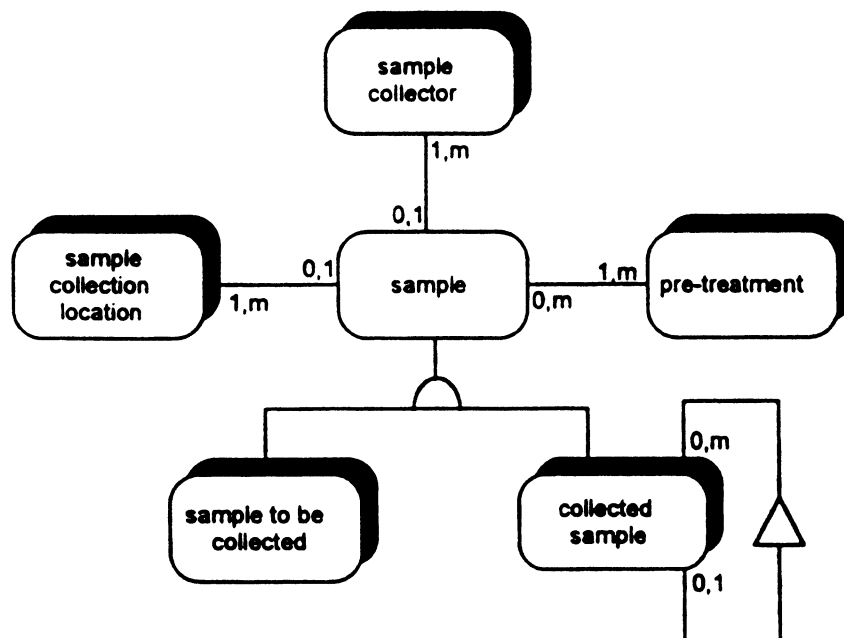


Figure 7 : Subject model for sample

6.3. Textual description of the objects, their relationships and attributes

6.3.1 General

This description is a complement to the Domain Information Model drawings. The objects are listed in alphabetical order, numbered and underlined. Attributes are grouped under the object to which they belong and are underlined. Attribute groups are printed in *italics* and underlined. Indentation is used to indicate the components of an attribute group. Attributes groups common to several objects are detailed in clause 6.4.

6.3.2 Animal

Purpose :

To allow the specification of the characteristics required when the subject of investigation is an animal.

Note :

Veterinary investigative services are included within the scope, so animals (dead or alive) as well as patients may be subjects of investigation.

Relationships :

- with subject of investigation : an animal is a specialisation of a subject of investigation.

Attributes :

species of animal :

- Example(s) : dog, mouse, rabbit, rat.

breed of animal :

- Description : subspecies or special breed of animal.
- Note : this may influence e.g. reference intervals.

name of animal :

- Self-explanatory.

animal sex :

- Self-explanatory.

date and time of birth :

- Note : in case the exact date and time is unknown, year only or year + month or year + month + day are sufficient.

animal owner person name details :

- Note : this attribute group has the same components as the common attribute group person name details which is detailed in clause 6.4.2.

date and time of death :

- Note : in case the exact date and time is unknown, year only or year + month or year + month + day are sufficient.

6.3.3 Clinical information

Description :

Information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional.

Example(s) :

Family history (e.g. father diabetic), symptoms (e.g. headache), signs (e.g. hepatomegaly), problems (e.g. weight loss or loss of body mass), diagnoses (e.g. thyrotoxicosis, both known and tentative), quantities (e.g. mass, length, body surface area), drugs (e.g. warfarin), diet (e.g. fat free), operative procedures (e.g. pancreatectomy).

Purpose :

The object is the generalisation of any kind of clinical information relating to a subject of investigation. As such, its purpose is to carry all common information related to the different specialisations of the object.

Note 1:

Clinical information about a patient may include information about the patient's environment or about related people or animals where this is relevant.

Note 2:

The modelling of this object has been kept generic since other future standards will address more specific requirements (cf. the electronic healthcare record Prestandard).

Relationships :

- with subject of investigation : clinical information is related to exactly one subject of investigation.
- with origin of clinical information : clinical information may optionally be associated with a single origin of clinical information.
- specialisation : clinical information is always specialised into either clinical observation or intervention information.

Attributes :

date and time of clinical information :

- Description : date and (if appropriate) time of the occurrence of a clinically relevant event.
- Example(s) : date and time of : Grand Mal fit, hypoglycaemic coma, total colectomy, blast (explosion) injury, exposure to tuberculosis.
- Note 1 : for use when it is not important to indicate a period of applicability for the clinical information. This may be because the clinical information indicates a brief event (see examples) or because it indicates a prolonged event whose start and end dates are unknown, uncertain, ill-defined or considered unimportant. Consequently a single date may legitimately be associated with 'diabetes mellitus type II' even though this leaves unspecified whether it is the date when the disease process began, when symptoms appeared, when the diagnosis was considered or confirmed, or when medical intervention was considered necessary.
- Note 2 : sometimes this date and time is called physiologic date and time.

period of clinical information :

- Note : this attribute group consists of the attributes start date and time of clinical information and end date and time of clinical information.

start date and time of clinical information :

- Description : beginning of a period of applicability of clinical information
- Example(s) : (compare with examples for date and time of clinical information) start date and time of : epilepsy, diabetes mellitus type I, myoglobinuria, productive cough, thyrotoxicosis, heart failure, warfarin treatment.
- Note : for use when it is important to convey the continuation of the clinical information's applicability over a period of time. If used with a date value in the past and without an end date/time, it indicates continuation to the present time.

end date and time of clinical information :

- Description : end of a period of applicability of clinical information.
- Example : end date and time of antibiotic treatment.
- Note : may be used without a start date/time if it is the moment when the clinical information ceased to be applicable that is of greatest relevance.

6.3.4 Clinical investigation

Description :

Laboratory, physiological, radiological or other examination that leads to the production of one or more results.

Relationships :

- with clinical investigation result item : a clinical investigation may be reported upon through one or many clinical investigation result items.

Attributes :

identification of clinical investigation :

- Description : unique and unambiguous identification of a clinical investigation.

specifications to clinical investigation :

- Description : coded or plain text description of a complementary information to clinical investigation.

comment to clinical investigation :

- Self-explanatory.

6.3.5 Clinical investigation result item

Description :

Set of information including all essential or useful data relevant to the result of a single clinical investigation.

Note :

A clinical investigation result item is an object which includes all useful information in connection with an investigation result (e.g. numerical value, uncertainty interval, reference limits, status, date and time of result status change, date and time of investigation performed); this object corresponds to what is normally called a 'line' on a paper report.

Relationships :

- with clinical observation : a clinical investigation result item is part of exactly one clinical observation.
- with clinical investigation : a clinical investigation result item is the result for exactly one clinical investigation.
- with related healthcare service provider : a clinical investigation result item is associated with zero, one or many related healthcare service providers.
- with clinical investigation result item : a clinical investigation result item may consist of zero, one or many other clinical investigation result items. A clinical investigation result item may be part of zero or one higher level clinical investigation result items.

Attributes :

service type of clinical investigation result item :

- Example(s) : new, cancel, modify (e.g. when a corrected result value is sent).
- Note : to specify unambiguously the action to be performed with the information sent, e.g. when the status of the result has changed.

identification of clinical investigation result item :

- Description : identifier assigned to a clinical investigation result item.
- Note : users of clinical or laboratory investigation systems may wish to identify an instance of a clinical investigation result item uniquely and unambiguously.

numerical measurement result :

- Note : this attribute group consists of the attributes arithmetic comparator, numerical value of a measurement result, unit of measurement.

arithmetic comparator :

- Example(s) : >, >=, =, <=, <

numerical value of a measurement result :

- Example : 140 when a result is 140 mmol/L.

unit of measurement result :

- Self-explanatory.

uncertainty interval of a measurement result :

- Description : value range, not statistically based, defining a lower and upper limit between which a measurement result falls.
- Example : 0 - 10 mg.
- Note 1 : is related to precision and detection limits, not to accuracy.
- Note 2 : this attribute group consists of the attributes lower limit of uncertainty interval of a measurement value, upper limit of uncertainty interval of a measurement value and unit of uncertainty interval values.

lower limit of uncertainty interval of a measurement value :

- Self-explanatory.

upper limit of uncertainty interval of a measurement value :

- Self-explanatory.

unit of uncertainty interval values :

- Description : chosen reference quantity that may be used in comparing magnitudes of quantities of the same kind.
- Example : mole (symbol : mol).

date value of a clinical investigation result item :

- Self-explanatory.

text value of a clinical investigation result item:

- Description : text-result expressed using text or codes.
- Note : in early implementations and according to specific interchange agreements this attribute may be used to carry in free style the entire clinical investigation result item value.

deviating result indicator :

- Description : indicator of degree of deviation from reference values of a measurement result.

date and time of clinical investigation :

- Note : to indicate the date and time at which the clinical investigation was finished.

status of clinical investigation (result item) :

- Example(s) : unverified, pending, new, intermediate, modified.

date and time of clinical investigation (result item) status change :

- Note : to indicate the date and time at which the status of a clinical investigation result changed to its communicated status.

comment to clinical investigation result item :

- Note : to cover any kind of free-style comment related to a clinical investigation result item

reference limit :

- Note : this attribute group consists of the attribute group numerical reference limit of quantity and of the attributes textual reference limit of quantity, reference population definition and type of reference interval.

numerical reference limit of quantity :

- Note : this attribute group consists of the attributes numerical value of lower reference limit of quantity, numerical value of upper reference limit of quantity and unit of numerical reference limit values.

numerical value of lower reference limit of quantity :

- Description : value characterising the lower end of a cumulative number fraction distribution of values obtained from a well-defined population by stated statistical means.
- Note : it is often assumed that the lower reference limit is the 0.025-fractile for the distribution of a healthy population having other relevant properties matching those of the patient (sex, age, race).

numerical value of upper reference limit of quantity :

- Description : value characterising the upper end of a cumulative number fraction distribution of values obtained from a well-defined population by stated statistical means.

unit of numerical reference limit values :

- Self-explanatory.

textual reference limit of clinical investigation result item :

- Example : "> 60% of B-Glucose" can be a reference limit for a "Sp-Glucose" value.

reference population definition :

- Example(s) : sex, age, race, smoker/non-smoker, clinical status, breed (in the case of animals).
- Note : to indicate the meaning of the reference limit.

type of reference interval :

- Example : therapeutic (in the case of drug-monitoring).

6.3.6 Clinical observation

Description :

clinical information excluding information about treatment and intervention.

Note :

clinical information that does not record an intervention is by nature a clinical observation. The observer may be the patient or related person (information about symptoms, family history, occupation or life style), or a healthcare professional (information about physical signs, property results or diagnoses). While information about the nature of a planned or performed treatment is excluded by the definition, clinical observations may be recorded as the results of a treatment or during the course of a treatment or as its result.

Relationships :

- with clinical information : a clinical observation is a specialisation of clinical information.
- with clinical investigation result item : a clinical observation consists of zero, one or many clinical investigation result items.

Attributes :

type of clinical observation :

- Example(s) : diagnosis, symptom, physical sign, occupation, problem.

clinical observation description :

- Example(s) : gastric carcinoma, abdominal pain, axillary lymphadenopathy, airline pilot, failure to thrive.

degree of certainty of clinical observation :

- Description : degree of certainty that the observation is correct.
- Example(s) : high, medium, low, proved by anatomopathology.
- Note : the requester may wish to mention a serious diagnosis even when it is unlikely that the patient is suffering from it. The laboratory can then take this possibility into account when investigating/reporting/commenting.

language of clinical observation :

- Self-explanatory.

6.3.7 Collected sample

Description :

One or more parts taken from a system and intended to provide information on that system or on a subsystem or to provide a basis for a decision on either of these.

Note :

This usually means that the sample has already been collected when the service order is communicated to the laboratory (see sample to be collected and sampling performed indicator), as opposed to "sample to be collected". Collected sample is to be interpreted as sample available. Collected sample refers to the case where the requester, the requester's agent or the patient are responsible for the collection. System is a term that may be applied to any arbitrarily chosen, but stated part of the universe, irrespective of form and size.

Relationships :

- with collected sample : a collected sample may be part of zero or one other collected sample; a collected sample may contain (be the basis for) zero, one or many other collected samples (see B.3.1).
- with sample : a collected sample is a specialisation of a sample.

Attributes :

date and time of sample collection :

- Note : for use when the sample is not collected over a prolonged period.

period of sample collection :

- Note : this attribute group consists of the attributes start date and time of sample collection and end date and time of sample collection.

start date and time of sample collection :

- Example : 13 January 1995, 8.00 a.m.

end date and time of sample collection :

- Example : 14 January 1995, 8.00 a.m.

amount of collected sample :

- Note : this attribute group consists of the attributes numerical value of amount of collected sample and unit of amount of collected sample.

numerical value of amount of collected sample :

- Self-explanatory.

unit of amount of collected sample :

- Self-explanatory.

duration of sample collection

- Note 1 : for use when the time period during which the sample is collected is of significance (cf. 24 hours urine collection).
- Note 2 : this attribute group consists of the attributes numerical value of duration of sample collection and unit of duration of sample collection.

numerical value of duration of sample collection :

- Self-explanatory.

unit of duration of sample collection :

- Self-explanatory.

transport logistics of collected sample :

- Description : means by which a sample reaches the laboratory.
- Example(s) : routine transport van, public postal service.
- Note : this information is to aid the lab in scheduling or interpretation of results.

date and time of receipt of collected sample :

- Description : date and time of receipt by the laboratory of a collected sample.

sample handling warning :

- Description : warning of dangers that the sample presents to those who may come into contact with it.
- Example(s) : radioactive, hepatitis risk.
- Note : this has significance for the sample collector, for the laboratory staff and for those involved in its transportation. Many possible values will be the same as those of "collection warning" (see subject of investigation) but the overlap will not be complete.

sample collector's comments :

- Example : difficult clotting after venepuncture and echymosis.

sampling performed indicator

- Description : indicator showing whether the sample has been collected at the time the service order is communicated to the laboratory.
- Example(s) : yes or unknown.
- Note : usually 'yes' but may be 'unknown' when the patient is subsequently to obtain (collect) the sample at home.

6.3.8 Copy destination

Description :

Party, other than the (laboratory) service provider or (laboratory) service requester, to which a copy of the (laboratory) service order or report is sent.

Relationships :

- with laboratory service order : a copy destination may be the copy destination for zero, one or many laboratory service orders (see B.3.2).
- with laboratory service report : a copy destination may be the copy destination for zero, one or many laboratory service reports.
- with healthcare party role : a copy destination is a specialisation of a healthcare party role.

6.3.9 Drug

Description :

Substance or chemical compound, other than food, used in the prevention, alleviation or treatment of a disease.

Example(s) :

Salbutamol inhaler, paracetamol, warfarin tablets, salbutamol syrup, soluble insulin.

Note :

As opposed to pre-treatment where the specific intention is to administer the drug for diagnostic purposes and which is a part of the measurement procedure. Drug treatment may influence the results and/or interpretations of laboratory investigations; this includes those drugs whose administration is being monitored by measurement of drug levels; may include 'presentation' (e.g. tablets, capsules, injection, inhaler, syrup) as well as the drug itself.

Relationships :

- with intervention information : a drug (treatment) is a part of exactly one intervention information.

Attributes :

identification of drug :

- Note : the brand identification or the generic identification of the drug.

dosage and administration specification of drug :

- Description : information which, together with the drug identification, provides a full specification of the subject's treatment with the drug.
- Example(s) : 100 µg daily (of drug thyroxine), 3 mg in the evening (of drug warfarin tablets), 2 puffs before exercise (of drug salbutamol inhaler) 1 mg patch twice weekly (of drug oestrogen), 80 mg intravenously every 8 h (of drug gentamicin injection).
- Note : may include one or more of : presentation (e.g. tablets, inhaler); route of administration (e.g. oral, sublingual, topical, intravenous injection); unit dose (e.g. 3 tablets, 250 mg, 2 puffs); dosage regime (e.g. one unit dose three times daily, one twice daily and two at night, one before administration trigger, one after administration trigger, one at 10:00 am); maximum permitted daily dose (e.g. 8 unit doses); trigger for administration (e.g. chest pain, meals, exercise).

6.3.10 Healthcare administrative information

Description :

Information about a subject that is requested or required by a healthcare party to enable, finance or manage the provision of healthcare services to that subject.

Relationships :

- with subject of investigation : healthcare administrative information may specify one or many subjects of investigation.
- with healthcare party : healthcare administrative information may optionally be associated with a single healthcare party.

Attributes :

admission date and time :

- Description 1 : date and time that responsibility for the subject's care passed to/is to pass to a secondary healthcare organisation (wide definition).
- Description 2 : date and time the subject is admitted to a hospital as an inpatient (narrow definition).
- Note : usually this means the date/time a patient is admitted to a hospital as an inpatient, ie with the expectation of at least one overnight stay.

discharge date and time :

- Description 1 : date and time the subject is discharged from inpatient care at a secondary care institution and responsibility for care passes to a primary healthcare provider (wide definition).
- Description 2 : date and time the subject is discharged from inpatient care at a hospital (narrow definition).

ward stay :

- Description : the attribute group for an individual's stay in a ward. One or many ward stays may occur within a single hospital admission (between the admission date and time and discharge date and time). Alternatively, a subject of investigation (usually a patient) may attend a ward without being admitted to the hospital.
- Note : this attribute group contains the attributes ward, room, bed, start date and time and end date and time of ward stay and the attribute administrative status of a subject of investigation.

ward :

- Description : separate division in a hospital.

room :

- Self-explanatory.

bed :

- Self-explanatory.

start date and time of ward stay :

- Note : this date and time corresponds to the admission date and time only when the ward is the first one during the stay. Not of any use if there is only one ward stay during hospitalisation.

end date and time of ward stay :

- Note : this date and time corresponds to the discharge date and time only when the ward is the last during the stay. Not of any use if there is only one ward stay during hospitalisation.

administrative status of a subject of investigation :

- Description : status of a subject of investigation in relation to specific administrative procedures.
- Example(s) : inpatient, outpatient, day-care patient.

6.3.11 Healthcare organisation

Description :

Organisation responsible for the direct or indirect provision of healthcare services to a subject, or involved in the provision of healthcare related services such as environmental measurement results.

Note :

A healthcare organisation may be used stand-alone or as a superstructure containing departments and sub-departments.

Relationships :

- with healthcare party : a healthcare organisation is a specialisation of a healthcare party.
- with healthcare professional : a healthcare organisation may consist of zero, one or many healthcare professionals.
- with healthcare organisation : 1 a healthcare organisation may consist of zero, one or many other healthcare organisations, 2 a healthcare organisation may be part of zero, one or many other healthcare organisations.

Attributes :

name of healthcare organisation :

- Self-explanatory.

type of healthcare organisation :

- Example(s) : university hospital, private laboratory.

6.3.12 Healthcare party

Description :

Organisation or person responsible for the direct or indirect provision of healthcare to an individual, or involved in the provision of healthcare related services such as environmental measurement results.

Note :

May be a person or an organisation.

Relationships :

- with healthcare party role : a healthcare party may be the healthcare party associated with zero, one or many health care party roles.
- specialisation : a healthcare party is always either a healthcare professional or a healthcare organisation.
- with sample collection location : a healthcare party may be associated with zero, one or many sample collection locations.
- with healthcare administrative information : a healthcare party may be associated with zero, one or many instances of healthcare administrative information.

Attributes :

partner-agreed identification of healthcare party :

- Description : identification of a healthcare party agreed upon between communication partners.

healthcare registration identification :

- Description : unique and official identification of a healthcare party, in general issued by an authorised organisation such as a governmental or international body.

identification of healthcare party by (laboratory) service requester :

- Description : identification of a healthcare party given by a (laboratory) service requester.

identification of healthcare party by (laboratory) service provider :

- Description : identification of a healthcare party given by a (laboratory) service provider.

address :

- Note : this common attribute group is detailed in clause 6.4.1.

telecommunication :

- Note : this common attribute group is detailed in clause 6.4.3.

language :

- Self-explanatory.

6.3.13 Healthcare party role

Purpose :

the purpose of this object is to associate a healthcare party with a specific role in the context of the information exchange.

Relationships :

- with healthcare party : a healthcare party role is associated with exactly one healthcare party.
- specialisation : a healthcare party may specialise into a laboratory service requester, a laboratory service provider, a copy destination, an intended recipient of report copy, a payment party, a related laboratory service provider, an origin of clinical information, a supervising healthcare party, a sample collector, a related healthcare service provider.

6.3.14 Healthcare professional

Description :

Person who is entrusted with the direct or indirect provision of defined healthcare services to a subject or population of subjects.

Example(s) :

Primary care physician, dentist, nurse, social worker, veterinary surgeon.

Relationships :

- with healthcare party : a healthcare professional is a specialisation of a healthcare party.
- with healthcare organisation : a healthcare professional may optionally be a member of zero, one or many healthcare organisations.

Attributes :

person name details :

- Note : this common attribute group is detailed in clause 6.4.2.

type of healthcare professional :

- Example(s) : medical doctor, nurse, pharmacist, laboratory worker.

medical specialty of healthcare professional :

- Description : particular subject area or branch of medical science, as practised by a healthcare professional.

position of healthcare professional :

- Example(s) : head of department, trainee GP, hospital consultant.

qualification of healthcare professional :

- Example(s) : M.D., M.Sc.

military rank of healthcare professional :

- Example(s) : captain, major.

6.3.15 Intended recipient of report copy

Description :

Healthcare party, other than the laboratory service requester, to which a copy of a laboratory report is requested to be sent for information (see B.3.3).

Relationships :

- with laboratory service order : an intended recipient of a report copy may be mentioned in one or more laboratory service orders (see B.3.3).
- with healthcare party role : an intended recipient of report copy is a specialisation of a healthcare party role.

6.3.16 Intervention information

Description :

Information about medical or surgical actions performed on or planned to be performed on a subject of investigation.

Note :

Intervention information refers to items of clinical information related to planned or actual interventions as distinct from information obtained by observation. It includes but is not limited to prescription or administration of drugs, therapeutic and diagnostic procedures.

Relationships :

- with clinical information : intervention information is a specialisation of clinical information.
- with drug : intervention information may consist of zero, one or many drug informations.

Attributes :

intervention type :

- Example(s) : diagnostic, therapeutic, surgical.

intervention description :

- Description : coded or plain text description of medical or surgical actions performed or planned to be performed on a subject of investigation.

6.3.17 Laboratory investigation

Description :

Clinical laboratory service that leads to the production of one or more results.

Example(s) :

As a laboratory investigation is the synthesis of its component parts and may be variously constituted, the following are all examples of laboratory investigations : liver function tests, bilirubin, albumin, blood-albumin-substance concentration, globulin, alkaline phosphatase, aspartate aminotransferase, full blood count, glucose tolerance test, creatinine clearance, C-reactive protein, rubella antibodies, microscopy & or culture & or sensitivity, viral antigen isolation, detection of antinuclear antibodies (ANA), antibodies to Streptococci, VDRL test, antibiotic sensitivity tests, MIC/MBC determination, microscopy for detection of parasites.

Purpose :

To carry the laboratory investigation related information that must be shared between a laboratory service provider and a laboratory service requester. It is to be considered as one component of the central specification or catalogue of laboratory investigations that can be ordered or reported upon.

Note :

In this context, a clinical laboratory investigation; indicated by the term the requester uses to describe his/her wishes, or by the term(s) used for laboratory investigations conducted in the laboratory in pursuit of those wishes.

Relationships :

- with requested laboratory investigation : a laboratory investigation may be associated with zero, one or many requested laboratory investigations (see B.3.4).
- with laboratory investigation result item : a laboratory investigation may be reported upon with zero, one or many laboratory investigation result items (see B.3.4).

Attributes :

observable property :

- See ENV 1614: 1995.
- Description : attribute of a phenomenon, body or substance that may be distinguished qualitatively and subjected to observation.
- Example : the colour of a patient's urine; in systematic notation : Patient-Urine; colour.
- Note 1 : observable property is the superordinate concept to measurable quantity. The above definition is a modification of the VIM definition of measurable quantity.
- Note 2 : this attribute exists both as an attribute group and as a single attribute. As an attribute group, it consists of the attributes system, component and property.

system :

- See ENV 1614: 1995.
- Description : demarcated arrangement of a set of components and a set of relationships between these components.
- Example(s) : examples of systems relevant to clinical laboratories are: a man; a portion of urine; the thrombocytes in the blood of a person
- Note 1 : the component parts of a system and therefore the system itself may have observable properties.
- Note 2 : a system which contains other systems (subsystems) may be referred to as a "supersystem" of those systems.
- Note 3 : the above definition is essentially that of Gottschalk (reference H.5. Annex H (informative) of ENV 1614: 1995, Bibliography) but with substitution of 'components' for 'elements'.

component :

- See ENV 1614: 1995.
- Description : definable part of a system.
- Example(s) : blood plasma of a person; glucose in a portion of urine; the process of coagulation in a sample of blood (The process of coagulation is conventionally regarded as a component of blood in the Quantities and Units work of IUPAC/IFCC. This has been accepted by the International Society of Thrombosis and Haemostasis).
- Note : is called "analyte" or even "test" by others.

property :

- See ENV 1614: 1995
- Description : nature of a set of observable properties necessary for arranging their values on a scale.
- Example(s) : length, colour, amount of substance concentration, mass, transparency.
- Note 1: property is the superordinate concept to quantity as defined in the ENV 1614: 1995 Prestandard. It is an extension of the concept 'quantity in a general sense' (used but not defined in VIM) to include observable properties which are not measurable.
- Note 2: Authoritative lists of properties are issued by ISO (in ISO 31), IFCC, and IUPAC.

measurable quantity :

- See ENV 1614: 1995.
- Description : attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively (VIM)
- Example(s) : length of a human body; amount-of-substance concentration of glucose in urine; volume fraction of erythrocytes in blood.
- Note 1 : measurable quantity is a subordinate concept to observable property.
- Note 2 : VIM indicates that the term 'quantity' may be used as a synonym for 'measurable quantity'. This usage is deprecated for the purpose of this Prestandard.
- Note 3 : this attribute exists both as an attribute group and as a single attribute. As an attribute group, it consists of the attributes system, component and quantity.

system :

- See ENV 1614: 1995.
- Description : demarcated arrangement of a set of components and a set of relationships between these components.
- Example(s) : examples of systems relevant to clinical laboratories are: a man; a portion of urine; the thrombocytes in the blood of a person
- Note 1 : the component parts of a system and therefore the system itself may have observable properties.
- Note 2 : a system which contains other systems (subsystems) may be referred to as a "supersystem" of those systems.
- Note 3 : the above definition is essentially that of Gottschalk (reference H.5. Annex H (informative) of ENV 1614: 1995, Bibliography) but with substitution of 'components' for 'elements'.

component :

- See ENV 1614: 1995.

- Description : definable part of a system.
- Example(s) : blood plasma of a person; glucose in a portion of urine; the process of coagulation in a sample of blood (The process of coagulation is conventionally regarded as a component of blood in the Quantities and Units work of IUPAC/IFCC. This has been accepted by the International Society of Thrombosis and Haemostasis).
- Note : is called "analyte" or even "test" by others.

quantity :

- See ENV 1614: 1995.
- Description : nature of a set of measurable quantities necessary for arranging their values on a scale according to magnitude.
- Example(s) : length, amount-of-substance concentration; mass; volume fraction.
- Note 1 : quantity is a subordinate concept to property as defined in this Prestandard.
- Note 2 : VIM calls this concept 'quantity in a general sense', but does not define it.
- Note 3 : authoritative lists of quantities are issued by ISO (in ISO 31), International Federation of Clinical Chemistry (IFCC) and International Union of Pure and Applied Chemistry (IUPAC).
- Note 4 : This concept was formerly called 'kind-of-quantity' by IFCC/IUPAC. This term was invented in 1966 to distinguish between the two possible interpretations of the term 'quantity' (reference H.3, Annex H (informative) of ENV 1614: 1995, Bibliography).

specifications to observable property / measurable quantity :

- See ENV 1614: 1995.
- Description : type of characteristic related to one of the essential types of characteristic.
- Example(s) : specification that the system plasma is from human blood, specification of the component calcium as only the free ion, specification to quantity that the measurement is using an international procedure and/or an international standard as reference.
- Note : concept of additional specification(s) to system, component, property, quantity.

compound :

- Description : homogeneous, pure substance composed of two or more essentially different chemical elements that are present in definite proportions [The Van Nostrand Chemist's Dictionary 1953].
- Example : to express the antibiotic sensitivity to Cefuroxime, and depending on the coding schemes used, the name of the laboratory investigation may be : generic component equal to "micro-organisms", kind-of-quantity equal to "arbitrary chemosensitivity", and its specified compound equal to "Cefuroxime".
- Note : to be used in the case of e.g. antibiotic sensitivity to express instances of antibiotics.

laboratory investigation cost :

- Note 1 : the laboratory investigation cost is related to the cost of having performed the laboratory investigation. It may be used to convey the "attributable cost".
- Note 2 : this attribute group consists of the attributes laboratory investigation cost type, laboratory investigation cost amount value and laboratory investigation cost currency unit.

laboratory investigation cost type :

- Examples : re-imbursable cost, full cost, patient cost.

laboratory investigation cost amount value :

- Self-explanatory.

laboratory investigation cost currency unit :

- Self-explanatory.

principle of measurement :

- Description : scientific basis of a measurement.
- Example : thermoelectric effect applied to the measurement of temperature.

method of measurement :

- Description : logical sequence of operations, described generically, used in the performance of measurements.

measurement procedure :

- Description : set of operations, described specifically, used in the performance of particular measurements according to a given method of measurement.
- Note : a measurement procedure is usually sufficiently detailed to enable an operator (or team of operators) to carry out a measurement without significant additional information; terms such as method of measurement, assay and test are not synonyms of measurement procedure.

measuring equipment :

- Description : complete set of measuring instruments and other equipment including any reagents assembled to carry out specified measurements.

comment to laboratory investigation :

- Self-explanatory.

6.3.18 Laboratory investigation result item

Description :

Set of information including all essential or useful data relevant to the result of a single laboratory investigation.

Note :

A laboratory investigation result item is an object which includes all useful information in connection with an investigation result (e.g. numerical value, uncertainty interval, reference limits, status, date and time and all generic quantity-attributes); this object corresponds to what is normally called a 'line' on a paper report.

Relationships :

- with laboratory service report : a laboratory investigation result item is part of exactly one laboratory service report.
- with subject of investigation : a laboratory investigation result item is associated with zero or one subject of investigation.
- with sample : a laboratory investigation result item is a result associated with zero or more samples.
- with laboratory investigation : a laboratory investigation result item is the result for exactly one laboratory investigation.
- with related laboratory service provider : a laboratory investigation result item is associated with zero, one or many related laboratory service providers.
- with laboratory investigation result item : a laboratory investigation result item may consist of zero, one or many other laboratory investigation result items. A laboratory investigation result item may be part of zero or one higher level laboratory investigation result items (see B.3.5).

Attributes :

service type of laboratory investigation result item :

- Example(s) : new, cancel, modify (eg when a corrected result value is sent).
- Note : to specify unambiguously the action to be performed with the information sent, eg when the status of the result has changed. In case of a new laboratory service report, the only value allowed is new. In case of a laboratory service report cancellation the laboratory investigation result item object is not applicable.

identification of laboratory investigation result item :

- Description : identifier assigned to a laboratory investigation result item.
- Note 1 : users of clinical or laboratory investigation systems may wish to identify an instance of a laboratory investigation result item uniquely and unambiguously.
- Note 2 : a unique reference must be given to a result item when it is first produced if a subsequent correction is to be undertaken successfully at the receiver's application.

numerical measurement result :

- Note : this attribute group consists of the attributes arithmetic comparator, numerical value of a measurement result, unit of measurement.

arithmetic comparator :

- Example(s) : >, >=, =, <=, <

numerical value of a measurement result :

- Example : 140 when a result is 140 mmol/L.

unit of measurement result :

- Self-explanatory.

uncertainty interval of a measurement result :

- Description : value range, not statistically based, defining a lower and upper limit between which a measurement result falls.
- Example : 0 - 10 mg.
- Note 1 : is related to precision and detection limits, not to accuracy.
- Note 2 : this attribute group consists of the attributes lower limit of uncertainty interval of a measurement value, upper limit of uncertainty interval of a measurement value and unit of uncertainty interval values.

lower limit of uncertainty interval of a measurement value :

- Self-explanatory.

upper limit of uncertainty interval of a measurement value :

- Self-explanatory.

unit of uncertainty interval values :

- Description : chosen reference quantity that may be used in comparing magnitudes of quantities of the same kind.
- Example : mole (symbol : mol).

date value of a laboratory investigation result item :

- Self-explanatory.

text value of a laboratory investigation result item :

- Description : text-result expressed using text or codes.