SLOVENSKI STANDARD
SIST ENV 1613:2003

01-oktober-2003

Medicinska informatika ï Sporoļ ila za izmenjevanje laboratorijskih informacij

Medical informatics - Messages for exchange of laboratory information

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: **ENV 1613:1995**

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

ICS:

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

SIST ENV 1613:2003 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

SIST ENV 1613:2003

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

SIST ENV 1613:2003

EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM

ENV 1613

July 1995

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

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 existance 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.

SIST ENV 1613:2003

Contents

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-

SIST ENV 1613:2003

Foreword

This European Prestandard has been prepared by the Technical Committee CEN/TC 251 "Electrically propelled road vehicles" of which the secretariat is held by AFNOR.

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

SIST ENV 1613:2003

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;

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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;

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

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 UN/ECE. These message definitions are Implementable Message Specifications conforming with this European Prestandard.

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

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

SIST ENV 1613:2003

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.

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

SIST ENV 1613:2003

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d7e50b1b725/sist-env-1613-2003

SIST ENV 1613:2003

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]

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

[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.

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW

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

(standards.iteh.ai)

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.

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

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.

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-7d47cbbff723/sist-env-1613-2003

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.

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f07e69dd-1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

SIST ENV 1613:2003

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1613:2003
https://standards.iteh.ai/catalog/standards/sist/f[illegible]1ee8-48ee-af3a-2d47cbbf0723/sist-env-1613-2003

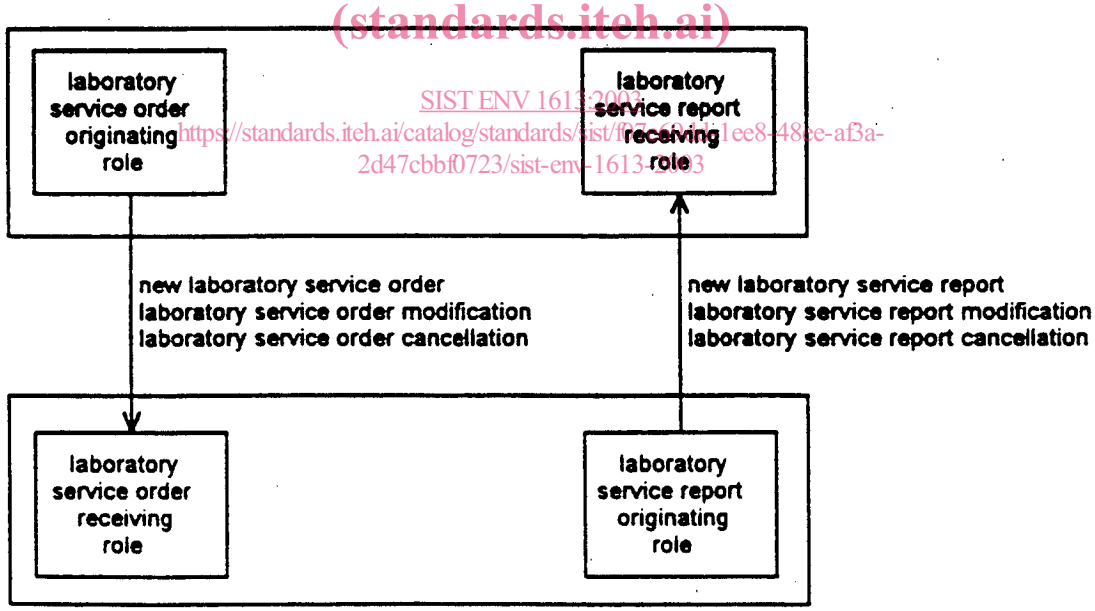

Figure 1: Relationship between communication roles and GMDs.

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: