SLOVENSKI STANDARD
SIST ENV 12539:2003

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Medicinska informatika - Sporoḍ ila z zahtevami in poroḍ ili za oddelke diagnostiḍ nih storitev

Medical informatics - Request and report messages for diagnostic service departments

Medizinische Informatik - Anforderungs- und Ergebnismitteilungen für diagnostische Dienstleistungsstellen

Informatique de santé - Messages de demandes et de comptes rendus de service de diagnostic

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

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Medical informatics - Request and report messages for diagnostic service departments

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Medizinische Informatik - Anforderungs- und Ergebnismitteilungen für diagnostische Dienstleistungsstellen

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CEN

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

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FOREWORD

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of 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.

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 standards.

Computer systems are used for the storage and processing of information in many diagnostic service departments. Many of those asking for and receiving results of investigations also use computer systems to store and process patient related information. This information includes details of investigations requested and results received. Diagnostic service departments carry out investigations requested by healthcare parties and send the results of these investigations to requesters 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 diagnostic services from requesting healthcare parties, to diagnostic service departments;

b) facilitate the electronic transfer of reports from diagnostic service departments to requesters and other healthcare parties;

c) reduce the need for human intervention in information interchange between applications used by diagnostic service departments 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 the cost of information interchange between diagnostic service departments and parties requesting diagnostic service department services.

When implementing information exchange based on this European Prestandard, data security services including confidentiality provisions must be ensured 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 Report "Investigation of Syntaxes for Existing Interchange Formats to be used in Healthcare" (CR 1350:1993). Extensions to the method, proposed by CEN TC251 PT3-025 while this document was being drafted, have also been applied where possible and relevant.

This standard is intended for use by message developers. Its provisions are directly relevant to suppliers of computer systems for use in diagnostic service departments, 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 diagnostic service departments, 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 explains how the Domain Information Model relates to actual requests and reports. Informative annex C gives a number scenarios as examples of message use.

A supporting document to this ENV entitled "Generic EDIFACT message implementation guide for diagnostic service request and report messages" is being prepared. This will contain message definitions using the EDIFACT (Electronic data interchange for administration, commerce and transport) standard ISO 9735, in line with the procedures for submission of EDIFACT-based standards of the UN/ECE. These message definitions will be Implementable Message Specifications (IMSs) conforming with this European Prestandard. The supporting document will also contain message implementation guidelines for these messages. They should be considered an essential component of the IMS providing a generic EDIFACT implementation specification for use in Europe.

The supporting document will be submitted to CEN for ballot as a CEN Report. The EDIFACT message definitions that it contains will also be submitted to the UN/ECE as a proposal for a United Nations Standard Message (UNSM). Arrangements between CEN and the Western European EDIFACT Board ensure that UNSMs can become ENVs. The supporting document will therefore become an ENV in its own right through separate standardisation procedures.

1. SCOPE

1.1 This European Prestandard specifies general messages to enable electronic exchange of requests for, and reports of, diagnostic services. The information exchanges covered are those between computer systems used by diagnostic service departments and computer systems used by healthcare parties requesting, or receiving results of, diagnostic services.

1.2 Within limits identified by subsequent clauses of this scope statement, this European Prestandard is applicable to messages requesting, or reporting on the results, of the following diagnostic services:

- Radiology;
- Nuclear medicine;
- Ultrasound;
- Other imaging techniques (e.g. magnetic resonance tomography);
- Electrophysiology;
- Physiological function tests;
- Diagnostic audiology;
- Cytology;
- Anatomic pathology;
- Histopathology; and
- Post-mortem studies (autopsies).

The messages specified also allow the inclusion of clinical observations about the patient where these are required to perform or interpret the results of these studies.

1.3 This European Prestandard is not applicable to messages requesting or reporting on the results of diagnostic laboratory specialties already covered by ENV1613:

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

1.4 This European Prestandard is not applicable to messages requesting or reporting on blood transfusion services.

1.5 This European Prestandard does not specify the manner in which diagnostic service department services are divided between specialties as this varies in accordance with different national and local practices.

1.6 The messages specified by this European Prestandard, supplement those specified in other related standards, such as ENV1613. In some borderline situations more than one member of this family of standards may meet the requirements. In these circumstances, the decision as to which messages are applicable to particular departments or studies in particular healthcare environments should be agreed by communicating parties.

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

1.8 This European Prestandard is applicable to requests for diagnostic services to be performed on:

- patients;
- samples, obtained from a patient, submitted to the diagnostic service department by the requester;
- samples that are to be obtained, from a patient, by the diagnostic department in response to a request for an investigation;
- materials or information resulting from a previous diagnostic service (e.g. a second opinion on films from a previous diagnostic service procedure).

It is also applicable to modifications or cancellations of previously issued requests.

1.9 This European Prestandard is applicable to reports of the results of diagnostic services. The report message it specifies supports the communication of partial, supplementary, complete and cumulative reports.

It is also applicable to modifications and cancellations of previously issued reports.

1.10 This European Prestandard permits diagnostic service report messages to be sent whether or not a diagnostic service request message has been received.

1.11 This European Prestandard also specifies diagnostic service plan report messages. These may be sent before a diagnostic service has been undertaken to communicate information about the acceptance of a diagnostic service request and the planning and progress of the requested diagnostic services. These messages also allow the diagnostic service provider to send the service requester instruction for preparation of the patient prior to the investigation.

1.12 The messages specified in this European Prestandard do not support standing orders for diagnostic services.

1.13 The messages specified in this European Prestandard do not support the communication of graphical, image or dynamic signal information that forms part of a request for or result of a diagnostic service. However, provision is made within the messages for external references to files which may contain these types of information.

1.14 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.

1.15 The provisions of this European Prestandard have been validated in the domains and for the purposes described above. 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.

1.16 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.

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 1064:1993	Medical Informatics - Computerised Electrocardiography Interchange Format
ENV 1068:1993	Medical Informatics - Healthcare Information Interchange -Registration of Coding Schemes
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 3166: 1988	Codes for representation of names of countries
ISO 4217: 1990	Codes for the representation of currencies and funds
ISO 5281: 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 8601: 1988	Data elements and interchange formats - Information interchange - Representation of dates and times
ISO 8859: 1987	Information Processing - Registration of graphics character subrepertoires - Eight-bit single byte coded graphic character sets Part 1 : Latin No 1
ISO 9735: 1992	Electronic data interchange for administration, commerce and transport (EDIFACT) - Application level syntax rules
ENV 1613	Medical Informatics - Messages for exchange of laboratory information.
ENV 1614	Medical Informatics - Structure for nomenclature, classification and coding of observable properties in clinical laboratory sciences.

3. DEFINITIONS AND ABBREVIATIONS

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

3.1 **analysed object** : Something derived from or to be derived from a patient as part of a diagnostic investigation.

NOTES

1. Analysed object is a generalisation that includes samples taken from a patient and physical or digital records of information derived from a patient as part of a diagnostic service. An analysed object that is not a sample is referred to as a study product.
2. An analysed object need not exist in a tangible form but may represent something observed briefly by a diagnostic service provider.

EXAMPLES

1. An X-ray image, a series of X-ray images, part of an X-ray image. The image may exist in a digitised form or as a film.
2. An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.
3. An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy.
4. A view observed through an endoscope, an observation during an echocardiographic examination.

3.2 **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.

[ENV1613]

3.3 **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]

3.4 **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

3.5 **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

3.6 **diagnostic investigation** : A clinical investigation that is, or may be, requested or reported using a message specified in accordance with this European Prestandard.

NOTES

1. A diagnostic investigation may be indicated by the terms the requester uses when making a request, or by the terms used by the diagnostic service provider to refer to an investigation or to actions undertaken while performing an investigation.
2. A diagnostic investigation may be subdivided into several separate constituent investigations. Each constituent investigation is also considered as diagnostic investigation (e.g. examination of a biopsy may include macroscopic and microscopic examinations. Furthermore, the microscopic examination may apply to several separate sections of the sample and different staining techniques may have been applied to some sections).

EXAMPLES : Chest X-ray, erect abdominal X-ray, intravenous pyelogram, obstetric ultrasound, CT scan, electrocardiography, lung function tests, cervical cytology, endoscopy, post-mortem examination of a body, post-mortem examination of a particular organ, examination of a biopsy, microscopic examination of a particular section taken from a biopsy and stained in a particular way, interpretation of the results of a histological examination, interpretation of the change in the appearance of an opacity on a series of X-ray films.

3.7 **diagnostic service plan report** : A message from a diagnostic service provider containing information about their plans for undertaking one or more diagnostic investigations.

3.8 **diagnostic service provider** : Authorised healthcare party qualified to perform diagnostic investigations and to validate the resulting diagnostic service report.

NOTE : A diagnostic service provider is usually a diagnostic service department and/or a member of its staff.

3.9 **diagnostic service report** : A message from a diagnostic service provider containing information about the results of one or more diagnostic investigations.

3.10 **diagnostic service request** : A message from a diagnostic service requester containing requests for one or more diagnostic investigations and related information that may be required by the intended diagnostic service provider.

3.11 **diagnostic service requester** : Authorised healthcare party issuing a diagnostic service request.

3.12 **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.

[ENV1613]

3.13 **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.

NOTES

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

In this Prestandard the abbreviation GMD is used.

[ENV1613]

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

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

NOTE : In this Prestandard the abbreviation HCD is used.

[ENV1068]

3.16 **healthcare organisation** : Organisation responsible for the direct or indirect provision of healthcare services.

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

[ENV1613]

3.17 **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.

[ENV1613]

3.18 **healthcare professional** : Person who is entrusted with the direct or indirect provision of defined healthcare services to a patient or population of patients.

EXAMPLE : Primary care physician, dentist, nurse, social worker, veterinary surgeon, technologist, radiographer, medical secretary or clerk.

[ENV1613]

3.19 **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.

[ENV1613]

3.20 **hierarchical general message description** : A general message description presented as a nested hierarchy of related objects rather than as a network of inter-related objects.

NOTE : In this Prestandard the abbreviation H-GMD is used.

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

NOTE : In this Prestandard the abbreviation IMS is used.

[ENV1613]

3.22 **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.

[ENV1613]

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

[ENV1613]

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

3.25 **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]

3.26 **procedure step** : Individually distinct activity performed as part of a diagnostic service and directly relevant to interpretation of an analysed object.

NOTES

1. A procedure step may occur or may be carried out prior to, or during, an investigation.

EXAMPLES

1. Fasting before an investigation.
2. Exercise during an electrocardiograph.
3. Administration of contrast medium during a radiographic examination.

3.27 **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 patient 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.

[ENV1613]

3.28 **study product** : An identifiable record of information derived from a patient as part of a diagnostic service. It may take the form of a physical object or may consist of digital information in an electronic information system.

NOTES

1. A study product differs from a sample in that a sample is something taken from a patient whereas a study product is a recording of information derived from a patient. A consequence of this distinction is that a study product can be copied. Furthermore, if the study product is represented in a digital form it can be held within or transferred between computer systems.

EXAMPLES

1. An X-ray image, a series of X-ray images, part of an X-ray image. The image(s) may exist in a digitised form or as a film.
2. An electrocardiograph (ECG) monitor tracing or a twelve lead ECG. The tracing may exist on paper or as a digitised signal.

3.29 **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.

[ENV1613]

3.30 ABBREVIATIONS

The following abbreviations are used for the terms defined in this European Prestandard.

DIM Domain Information Model
ECG Electrocardiograph
GMD General Message Description
HCD Healthcare Coding scheme Designator
H-GMD Hierarchical General Message Description
IMS Implementable Message Specification

4. REQUIREMENTS

4.1 Messages for transmission of orders or requests for diagnostic investigations, covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Diagnostic Service Request Messages in clause 7.

4.2 Messages for transmission of reports of diagnostic services covered by the scope of this European Prestandard shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Diagnostic Service Report Messages in clause 7.

4.3 Messages for transmission of information about the acceptance or rejection of diagnostic service requests, and the scheduling and preparation for diagnostic investigations covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Diagnostic Service Plan Report Messages in clause 7.

4.4 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.

4.5 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 by using such a Standard syntax.

4.6 Unless the syntax in which an IMS is expressed specifically supports the types of relationships shown in the General Message Descriptions, the IMS shall follow the structure of the appropriate Hierarchical General Message Descriptions (H-GMD) in clause 7. The precise order of the objects, attribute groups and attributes shown in the H-GMD need not be followed where an alternative ordering simplifies implementation. However, to conform with this European Prestandard the relationships between objects and the overall nesting structure shall be as shown in the H-GMD.