SLOVENSKI STANDARD
SIST ENV 12537-2:2003

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Medicinska informatika – Registracija informacijskih objektov pri elektronski izmenjavi podatkov (EDI) v zdravstvenem varstvu – 2. del: Postopki za registracijo informacijskih objektov pri elektronski izmenjavi podatkov (EDI) v zdravstvenem varstvu

Medical informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare

Medizinische Informatik - Registrierung von Informationsobjekten für den elektronischen Datenaustausch (EDI) im Gesundheitswesen - Teil 2: Prozeduren für die Registrierung von Informationsobjekten für den elektronischen Datenaustausch (EDI) im Gesundheitswesen

Informatique de santé - Enregistrement d'objets d'information utilisés pour l'échange de données informatisé dans le domaine de la santé - Partie 2: Procédures

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This European Prestandard (ENV) was approved by CEN on 1997-02-09 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).

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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.

The standard is published in two parts. This part specifies the procedures for the operation of registration authorities. Part 1 of this European Prestandard specifies the information to be registered for information objects used in EDI in healthcare.

Introduction

The following Introduction wording is also used in Part 1.

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 data interchange standards.

All the methods of electronic data interchange (EDI) currently in use require the division of the information to be interchanged into suitable components, which are then identified in some way, so that the receiving system can recognize them and process them appropriately. The components are assembled into messages, each message representing a transaction or being equivalent to a form in paper based working methods.

In the context of this European Prestandard a component may range from a data element, which is a unit of data normally considered to be indivisible, through logically associated groups of data elements, to complete messages. All are information objects.

The rapid growth in EDI is resulting in the almost simultaneous development of systems each designed to satisfy the requirements of a particular application area. Unfortunately these uncoordinated developments also result in unnecessary variations in the manner in which information is represented, identified, named and described. The use of identical identifiers and names for different data concepts introduces a serious risk of misunderstanding and confusion when data is exchanged between application areas which have developed independently. In English the term "date of delivery", for example, may represent entirely different concepts for gynaecologists and couriers.

This European Prestandard describes a procedure by which the components and messages required to facilitate the use of EDI in support of healthcare may be registered and allocated an internationally unique identifier. This European Prestandard also specifies how components when registered may be included in a widely available International Register which is so indexed and constructed that those designing EDI messages can ascertain easily whether a component or message which is suitable for their purposes already exists.

If it is established that new components or messages are essential the procedures for registration specified in this European Prestandard are designed to encourage their derivation from existing entries thus avoiding unnecessary variations in the way similar data concepts are represented. Registration will also enable synonyms, i.e. two or more information objects serving an identical function, to be identified. Perhaps most importantly it will highlight the situations where similar or identical names are in use for EDI information objects which are significantly different in one or more respects.

The procedures specified in this European Prestandard recognise that the development of EDI messages is a dynamic and fast moving process and may involve the use of more than one syntax. They are therefore designed to be syntax independent and also to minimize administrative delay.

This European Prestandard is based on work within CEN TC 251 which uses a domain information model (DIM) as a basis for the design of EDI messages. It also draws on work within ISO.

1 Scope

This European Prestandard specifies a procedure for the registration of information objects used in electronic data interchange messages (EDI) for the purpose of information interchange related to healthcare.

The naming and definition of the information objects is covered in Part 1 of this European Prestandard. This European Prestandard does not specify the file organisation techniques, storage media, programming languages, etc., to be used in its implementation.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this European Prestandard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO/IEC 8824:1990, *Information technology- Open Systems Interconnection- Specification of Abstract Syntax Notation One (ASN.1)*

3 Definitions

For the purposes of this European Prestandard the following definitions apply.

3.1 requesting organization: An Organization recognized by a sponsoring authority as having a requirement to register EDI information objects for use in inter-organizational electronic data interchange for the purposes of healthcare

3.2 the Register: The register of information objects maintained in accordance with this European Prestandard

3.3 Registration Authority (RA): The body responsible for maintaining the register of information objects and for the issue of Numeric EDI Information Object Identifiers (NOIs).

3.4 sponsoring authority: A body recognized in accordance with the requirements of this European Prestandard to receive proposals for the registration of information objects and to submit applications to the RA.

4 The Registration Authority

4.1 Designation of the Registration Authority

A Registration Authority shall be designated to undertake the functions required by this European Prestandard.

The RA for this European Prestandard shall be:

The European Committee for Standardization

The RA may, if it wishes, subcontract the work of maintaining the Register to another party but the RA shall not divest itself of its responsibilities under this European Prestandard.

5 Responsibilities of the Registration Authority

5.1 Identification of the Register

The Register operated in accordance with this European Prestandard shall be identified by the RA in accordance with clause B5 of ISO/IEC 8824. The RA shall also allocate a name to the Register for use as a user friendly informal identifier.

5.2 Maintaining the Register

The RA shall receive and process applications for the registration of EDI information objects, assign Numeric Identifiers for EDI information Objects (NOI) values, and maintain a Register of EDI information objects in accordance with the following provisions.

5.3 Providing software

The R A shall make available to sponsoring authorities and, if it wishes to others, software for the interrogation of a computerised copy of the Register and for the creation of new entries, amendments and deletions in a format acceptable to the RA.

5.4 Licensing the use of software and recording authorised users.

If the software distributed by the RA incorporates proprietary software which is subject to a licensing agreement or the payment of a fee for its use the RA shall distribute the software on terms that will ensure that the intellectual property rights of the owners or authors are properly protected and that any licensing fees are collected and properly accounted for.

The distribution arrangements shall also ensure that an adequate, but not necessarily centralized, record of the names and addresses of all authorised users together with any appropriate information is maintained so that they can be informed of updates and defects.

5.5 Providing copies of the register

The RA shall make available to sponsoring authorities and, if it wishes to others, copies of the Register in machine readable form The RA shall determine when new versions shall be made available basing the decision on the number and significance of the alterations to the Register but updated versions shall not be issued less frequently than every six months if any changes to the Register have occurred during the period.

5.6 Verification of formal notation

If ASN.1 or any other formal notation is used in the Register it shall as far as practicable, be checked by submitting it to a syntax checking program after updating has occurred before the updated version is made available and the Register shall only be made available when any errors have been corrected.

5.7 Conduct of business

The RA shall also conduct all business relating to the Register in English or such other languages as the RA and the corresponding party may find mutually convenient.

The RA shall determine the form in which applications shall be submitted. The RA shall also provide Sponsoring Authorities with guidance on the submission of applications.

The RA shall handle all aspects of the registration process in accordance with good business practice and in particular it shall take all reasonable precautions to safeguard the Register.

6 Assignment of NOI values

6.1 The format of a NOI

The NOI shall be a numeric code of six characters as specified in clause 5 of Part 1 of this European Prestandard.

6.2 Ensuring the NOI is unique

The NOI shall be assigned by the RA in such a manner that it is a unique identifier but NOIs are not required to be assigned sequentially.

Ranges of NOI values shall be determined in consultation with any other registration authorities recognised by ISO for the purpose of allocating identifiers to EDI information objects. Ranges shall be selected in an effort to ensure that every NOI issued by the RA is globally unique when used on its own. When used in conjunction with the Register identifier specified in 5.1 it shall certainly be globally unique.

6.3 Reserving a range of NOI values for private use

A range of 500 NOI values shall be designated by the RA for private use. The series is reserved for use by interchange parties for the purpose of identifying EDI information objects that have not been registered in the Register or any other directory of EDI information objects. The significance of values in this series shall be determined by prior agreement between the parties using them and it shall be their responsibility to ensure that in the environment in which they are operating duplications resulting in ambiguities do not occur.

7 Registration Authority procedures for new applications

7.1 Period for decision

As soon as practicable and normally within 30 days of receipt of an application from a sponsoring authority the RA shall decide whether an application is acceptable.

7.2 Processing acceptable new applications

If the application is acceptable the RA shall allocate an NOI value determined in accordance with clause 6 and add the NOI and the information provided in the application to the Register. The sponsoring authority shall be sent a copy of the entry and requested to check the entry and advise the RA immediately if any errors are detected.