SLOVENSKI STANDARD
SIST ENV 13730-2:2003

01-oktober-2003

Healthcare Informatics - Blood transfusion related messages - Part 2: Production related messages (BTR-PROD)

Healthcare Informatics - Blood transfusion related messages - Part 2: Production related messages (BTR-PROD)

Ta slovenski standard je istoveten z: ENV 13730-2:2002

ICS:

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

SIST ENV 13730-2:2003 **en**

EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM

ENV 13730-2

September 2002

ICS 35.240.80

English version

Healthcare Informatics - Blood transfusion related messages - Part 2: Production related messages (BTR-PROD)

This European Prestandard (ENV) was approved by CEN on 18 October 2001 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 a European Standard.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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

Ref. No. ENV 13730-2:2002 E

CONTENTS

Foreword

This document (ENV 13730-2:2002) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by SIS.

It was developed by Project Team 32 under mandate M/255 given by the European Commission and the European Free Trade Association, order voucher BC/CEN/97/23.

This is Part 2 of a multipart standard (ENV 13730) under the general heading *Health informatics – Blood transfusion related messages* with the following parts:

Part 1: Subject of care related messages

Part 2: Production related messages

Annex C of this European Prestandard is normative, all other annexes are informative.

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

Introduction

Part 2 of this European Prestandard (ENV) provides a set of messages that enables the electronic transfer of messages in the blood transfusion domain.

The motivation for this ENV derives from a combination of the following factors:

Electronic messages developed in the Healthcare Informatics domain contain sensitive healthcare information about specified individuals that requires a high level of confidence both in the parties sending and receiving messages and that the information being made available is unchanged. Standards are required to facilitate electronic transfer of blood transfusion related messages and reports between the many systems currently used. Information transferred in the blood transfusion related messages and any reports passing between healthcare parties form part of the information system of each of the communicating parties. Electronic transfer of these blood transfusion related messages and reports reduces the need for manual entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision.

This ENV has been developed following the methods recommended in the CEN Report on "Medical Informatics - Methodology for the development of healthcare messages" (CR 12587:1996). However, in accord with the decisions of CEN TC251 WGI, a different modelling technique has been used. This is a subset of the Unified Modelling Language (UML) as documented in Annex A.

This ENV specifies messages in a syntax independent form. Its requirements for conformance define the minimum acceptable content and structure for these messages. Compliant messages can be developed in a variety of implementation syntaxes and these syntax specific implementations may be the subject of future Standards.

This ENV is directly relevant to suppliers of computer systems for use in development. Its provisions are also relevant to those planning, specifying, procuring or implementing information systems for use in the blood transfusion domain.

Particular note for implementers: Some attributes may have the same title but modified in meaning for use in Part two than in Part one.

1 Scope

Transfusion of blood [**3.7**] and blood components [**3.9**] (blood products) to subjects of care [**3.48**] is a medical activity that is subject to many legal regulations and constraints. Many problems may be encountered during treatment due to immunological conditions, transmitted diseases, sustainability and other difficulties. Mistakes and failures may have serious or even fatal consequences. Minimising human activity through the increased use of data processing and automated messaging will introduce an additional safety mechanism.

This ENV specifies general messages [**3.41**] for electronic information interchange between computer systems used by healthcare [**3.29**] parties [**3.33**] in the blood transfusion [**3.16**] domain. The content and structure of the messages specified in this ENV have been developed with the aim of optimising the safety of blood transfusion activity and to facilitate compliance monitoring and secure audit trails [**3.2**].

This ENV is applicable to blood transfusion related messages including those for:

- the collection of blood/blood components [**3.22**] from blood donor
- manufacturing [**3.40**] and processing [**3.44**] of blood components
- classification [**3.19**] of blood donations
- issue of blood components to the blood components dispenser

Within the blood transfusion process there are a number of actors:

(1) The blood components *dispenser* [**3.10**] obtains blood components and blood products from one or more providers, then stores and dispenses them to the user, in some countries this function is known as the Hospital Blood Bank. This actor may appear as a separate entity, or as subdivision, within either the class producer or user. In certain circumstances communication may be required with a different blood components dispenser or with all dispensers within another region or a country.

(2) The blood components *manufacturer* [**3.11**] prepares blood components for transfusion from donor blood and issues blood components to the blood components dispenser [**3.10**] a blood components processor or to another blood components manufacturer. In many countries the production process utilises a special blood transfusion data system providing internal communications between the subdivisions (blood collection, collected blood classification [**3.17**], manufacturing of blood components [**3.40**], processing of blood components [**3.52**]), and issues blood components to a blood components *dispenser*.

(3) The blood components *processor* [**3.12**] receives blood components from a blood components manufacturer [**3.11**] for processing into blood products.

(4) The *Laboratory service provider* [**3.39**] provides a laboratory service (serological, biochemical, bacteriological and virological analyses), to classify a sample of donor blood received from the blood/blood components collector. The laboratory can be an integral part of the healthcare organisation.

(5) The *blood /blood components collector* [**3.8**] provides the service of collecting blood from a blood donor, to be delivered to the manufacturer, and to forward a sample of the blood to the *Laboratory service provider* [**3.46**] for the classification of blood donation [**3.17**].

The messages identified within scope are :

The messages used in :

- collection,
- classification
- production activities

They communicate messages between separately organised units within blood collection and production.

Communication between the following parties should be exchanged according to ENV 1613 :

- the blood/blood components collector and the laboratory service provider
- the laboratory service provider and the blood/blood components manufacturer

Production related messages:
The use of the messages are dependent on the administrative procedures of the transfusion service provider and are concerned with:

Blood/blood component collection request
Blood/blood component classification request
Blood/blood component classification report
Blood/blood component collected delivery note
Blood component request
Blood component manufactured delivery note
Blood component processing request
Blood component processed delivery note

Messages for the transmission of Requests for blood components, covered by the scope of this ENV, shall enable electronic interchange of the semantic content defined in the General Message Descriptions (GMDs) for Request for blood components in clause 6.

Messages for transmission of blood collection requests, covered by the scope of this ENV, shall enable electronic interchange of the semantic content defined in the GMDs for blood collection requests in clause 6.

Messages for transmission of blood component classification requests/reports, covered by the scope of this ENV, shall enable electronic interchange of the semantic content defined in the GMDs for blood component classification request/reports in clause 6.

Messages for transmission of blood component processing requests, covered by the scope of this ENV, shall enable electronic interchange of the semantic content defined in the GMDs for blood component processing requests in clause 6.

Messages for transmission of blood component manufacturing delivery note and blood component processing delivery note, covered by the scope of this ENV, shall enable electronic interchange of the semantic content defined in the GMDs for blood component manufactured delivery notes in clause 6.

Messages for transmission of blood component processed delivery notes, covered by the scope of this ENV, shall enable electronic interchange of the semantic content defined in the GMDs for blood component processed delivery notes in clause 6.

Messages for transmission of applicative acknowledgement of the above messages covered by the scope of this ENV are defined at an application level (ISO 9735-6:1999). They do not interfere with similar messages at lower levels. These messages are reports that the target applicant has received the message, and whether or not the message can be processed normally.

Implementable message specifications (IMS) [**3.37**] shall conform to the GMDs defined in this ENV. They shall support both mandatory and optional objects, attribute [**3.1**] groups and attributes as defined in the GMDs of this ENV. They shall also support the relationships between objects as defined by the GMDs.

Implementable message specifications should be expressed in terms of a syntax that is an International Standard [**3.55**] except where the healthcare user requirements cannot be met by using such a standard syntax.

When implementing information exchange based upon this ENV, all generated messages must be acknowledged by the receiver.

When implementing information exchange based upon this ENV, data protection and confidentiality principles have to be guaranteed according to the laws actually in force in the different CEN member countries. The mechanisms needed to secure data integrity [**3.24**], data protection and confidentiality, authentication [**3.3**] of communicating parties and subjects of care are outside the scope of this ENV.

While the messages specified in this ENV may convey clinical and administrative information concerning subjects of care, the way in which this information is treated in this ENV does not constrain the development of future standards for the electronic healthcare record [**3.27**] or for other clinical and administrative messages.

The provisions of this ENV have been validated for the purposes described above. However, since the messages described in this ENV are designed for general application in the blood transfusion domain, the users are required to decide for themselves whether or not these messages meet their particular requirements. A requirement for using other messages, e.g. generic messages for cancellation or acknowledgement, in addition to or instead of messages specified in this ENV, does not invalidate the use of this ENV.

2 Normative references

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

ISO 2382-4:1987	Information processing - Vocabulary Part 4: Organisation of data
ISO 5281 : 1997	Information interchange - Representation of human sexes
ISO/IEC 7826-1 : 1994	Information technology - General structure for the interchange of code values - Part 1 : Identification of coding schemes
ISO/IEC 7826-2 : 1994	Information technology - General structure for the interchange of code values - Part 1 : Registration of coding schemes
ENV 12539: 1997	Medical informatics – Request and report messages for diagnostic services departments
ENV 1613 : 1995	Medical informatics - messages for exchange of laboratory informations

3 Terms, definitions and abbreviations

For the purposes of this European Prestandard (ENV), the following terms and definitions (listed in alphabetical order) apply:

3.1
attribute
characteristic of an object or entity

3.2
audit trail
record of the resources which were accessed and/or used by whom.
Note: This may involve a formal monitoring technique for comparison between the actual use of a medical information system and pre-established criteria

[ISO 7498 – 2]

3.3
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

[ISO 7498 –2]

3.4
autologous transfusion
transfusion of any blood component that was donated by a blood donor who is also the subsequent recipient

3.5
availability
property of being accessible and useable upon demand by an authorised entity

[ISO 7498-2]

3.6
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance requirements and produced during a defined validated process of manufacture

NOTE A labile blood product batch is identified by a unique blood donation or pool number

[EN 375:1992 E][EN 376:1992 E]

3.7
blood
blood is a complex fluid, consisting of cellular components (approximately 45% of the total volume) suspended in a fluid environment, the plasma. It circulates in the arteries and veins of human beings, animals, blood donors (subjects of care) and acts both as a transport system and as a defence mechanism, fighting infection

3.8
blood/blood components collector
authorised healthcare party who collects blood/blood components from a blood donor to be forwarded to a blood manufacturer for the production of blood components. In addition the blood collector forwards a sample of the donated blood to a laboratory service provider for classification

3.9
blood component (BC)
blood component is supplied in accordance with a national specification and/or an order furnished by a user and/or a blood components dispenser, giving it an (unique) component type identifier taken from approved national or international lists and a unique donation number

EXAMPLE Blood components are whole blood, red cells, plasma, platelets, or cryoprecipitate

3.10
blood components dispenser
person or other entity who obtains blood components from one or more providers

NOTE The blood components dispenser stores and dispenses blood components in order to assemble, prepare or dispense a blood component in accordance with a specification furnished by a blood components manufacturer. (In UK and Scandinavia a blood components dispenser is a Hospital Blood Bank)

3.11
blood components manufacturer
authorised healthcare party qualified to manufacture blood components from blood donor and issue to a blood components dispenser or blood processor

NOTE Blood is collected in sterile packs by the collector, subsequently forwarded to the manufacturer where it undergoes manufacturing processes to produce blood components such as red cells, platelets and plasma

3.12
blood components processor
authorised healthcare party who receives blood components from a blood components manufacturer for processing into blood products, e.g. irradiation

3.13

blood donor
healthy person with a good medical history selected to give blood for therapeutic use

NOTE Medical selection of blood donors excludes anyone whose blood might harm the recipient, for example by transmitting infection. In various countries tests for example, may be completed for evidence of infection with Hepatitis B, Hepatitis C, HIV-1, HIV-2 and syphilis. Each donation is tested to determine the most important blood groups (ABO and RhD)

3.14
blood group
one of several classifications into which the blood may be grouped

NOTE It is determined by the presence or absence of specific antigens on the surface of the erythrocytes

3.15
blood product
therapeutic product derived by the fractionation of large volumes of plasma

NOTE It is identified by a product description and a batch number

3.16
blood transfusion
administration of blood components obtained and processed from blood donors into the bloodstream of a recipient

3.17
classification of blood donation
set of biological tests performed by laboratory services provider, aimed to establish the immuno-haematologic characteristics of the blood donated and to evaluate the safety of the blood donated to prevent the transfusion of transmitted diseases, based on formal legal requirements

3.18
clinical information
refers to a subject of care or a blood donor, relevant to the health or treatment of that subject of care or the processing and use of the collected blood

NOTE 1 The information concerning clinical information is recorded by or on behalf of a healthcare professional

NOTE 2 Clinical information about a blood donor, may include information about the blood donor's environment, or related persons where this is relevant

3.19
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 7826] [ISO/IEC 7826][ISO 2382:1987, modified]

3.20
coding scheme
collection of rules that map the elements of one set on to the elements of a second set

[ISO/IEC 7826][ISO 2382-1987, modified]

3.21
collected item
information which identifies donated blood collected by the blood collector

3.22
collection of blood/blood components
process of a collection of blood/blood components from a blood donor to be forwarded to a blood manufacturer for the production of blood components

3.23
confidentiality
property that information is not made available or disclosed to unauthorised individuals, entities or processes

[ISO 7498-2]

3.24
data integrity
property that data or a message's content has not been altered or destroyed in an unauthorised manner

NOTE 1 In order to achieve this requirement for the data, the integrity of all system assets must be preserved including hardware, system design, software design, implementation and maintenance

NOTE 2 This definition includes both accidental and intentional events and actions

[ISO 7498-2]

3.25
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

[CR 12587]

3.26
EDIFACT
Electronic Data Interchange for Administration, Commerce and Transport

NOTE They comprise a set of internationally agreed standards, directories and guidelines for the electronic interchange of structured data. (Also referred to as UN/EDIFACT)

3.27
electronic healthcare record
healthcare record concerning the subject of care in computer readable form

[CEN ENV 13606-1]

3.28
general message description
subset of a domain information model [**3.25**] prescribing the information content and semantic structure of a healthcare message used to meet one or more identified information interchange requirements

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

[CR 12587][ENV 1613]

3.29
healthcare
provision of health related services

NOTE This includes more than performing procedures on subjects of care. It includes also e.g. the management of information about patients, their health status and their relationship with their healthcare framework

[CEN TC/251 ENV 13606,1-4]

3.30
healthcare agent
healthcare professional [**3.34**], healthcare organisation [**3.32**], healthcare device or healthcare software component that performs a particular role in a healthcare activity

[CEN TC/251 ENV 13606,1-4]

3.31
healthcare informatics
scientific discipline that is concerned with the cognitive, information processing and communication tasks of healthcare practice, education and research, including the information science and technology to support these tasks

[Directory of the European Standardization requirements for Healthcare Informatics and Telematics (version 2.1 1996.08.15)]

3.32
healthcare organisation
organisation involved in the direct or indirect provision of healthcare services to an individual, or to a population or in the provision of healthcare related services

EXAMPLE Hospital, clinic

NOTE Groupings or subdivisions of an organisation, such as departments or sub-departments, may also be considered as organisations where there is a need to identify them

[ENV 1613, modified]

3.33
healthcare party
organisation or person involved in the direct or indirect provision of healthcare services to an individual, or to a population or involved in the provision of healthcare related services

NOTE Organisations responsible for the funding, payment, or reimbursement of healthcare provision are healthcare parties

[ENV 1613]

3.34
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care

EXAMPLE Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk

[ENV 1613:1995]