SLOVENSKI STANDARD
SIST EN ISO 13606-1:2012

01-december-2012

Nadomešča:
SIST EN 13606-1:2008

Zdravstvena informatika - Komunikacija z elektronskimi zapisi na področju zdravstva - 1. del: Referenčni model (ISO 13606-1:2008)

Health informatics - Electronic health record communication - Part 1: Reference model (ISO 13606-1:2008)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 1: Referenzmodell (ISO 13606-1:2008)

Informatique de santé - Communication du dossier de santé informatisé - Partie 1: Modèle de référence (ISO 13606-1:2008)

Ta slovenski standard je istoveten z: **EN ISO 13606-1:2012**

ICS:

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

SIST EN ISO 13606-1:2012 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13606-1

October 2012

ICS 35.240.80

Supersedes EN 13606-1:2007

English Version

Health informatics - Electronic health record communication - Part 1: Reference model (ISO 13606-1:2008)

Informatique de santé - Communication du dossier de santé informatisé - Partie 1: Modèle de référence (ISO 13606-1:2008)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 1: Referenzmodell (ISO 13606-1:2008)

This European Standard was approved by CEN on 24 August 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

The text of ISO 13606-1:2008 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13606-1:2012 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13606-1:2007.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13606-1:2008 has been approved by CEN as a EN ISO 13606-1:2012 without any modification.

INTERNATIONAL STANDARD

ISO 13606-1

FIrst edition
2008-02-15

Health informatics — Electronic health record communication —

Part 1: Reference model

Informatique de santé — Communication du dossier de santé informatisé —

Partie 1: Modèle de référence

Reference number
ISO 13606-1:2008(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13606-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 13606 consists of the following parts, under the general title *Health informatics — Electronic health record communication*:

— *Part 1: Reference model*

— *Part 2: Archetype interchange specification*

— *Part 3: Reference archetypes and term lists*

— *Part 5: Interface specification*

0 Introduction

0.1 Preface

The overall goal of ISO 13606 is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:

— preserving the original clinical meaning intended by the author;

— reflecting the confidentiality of that data as intended by the author and patient.

ISO 13606 is not intended to specify the internal architecture or database design of EHR systems or components. Nor is it intended to prescribe the kinds of clinical application that might require or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. The information model in this part of ISO 13606 is an ISO Reference Model for Open Distributed Processing (RM-ODP) RM-ODP Information Viewpoint of the EHR Extract.

ISO 13606 considers the EHR to be the persistent longitudinal and potentially multi-enterprise or multi-national record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject's future healthcare and to provide a medico-legal record of care that has been provided. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc., ISO 13606 has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

ISO 13606 may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems.

This part of ISO 13606 is the first part to be published of a five-part series. In this part of ISO 13606 dependency upon one of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

ISO 13606 has drawn on the practical experience that has been gained in implementing a European precursor prestandard, ENV 13606, other EHR-related standards and specifications, commercial systems and demonstrator pilots in the communication of whole or part of patients' EHRs, and on fifteen years of research findings in the field. ISO 13606 builds on ENV 13606, in order to provide a more rigorous and complete specification, to accommodate new requirements identified, to incorporate a robust means of applying the generic models to individual clinical domains, and to enable communication using HL7 version 3 messages. A mapping from the European prestandard is also provided to support implementers of systems that conformed to it. The technical approach to producing ISO 13606 has taken into account several contemporary areas of requirement.

a) In addition to a traditional message-based communication between isolated clinical systems, the Electronic Health Record will in some cases be implemented as a middleware component (a record server) using distributed object technology and/or web services.

b) “Customers” of such record services will be not only other electronic health record systems but also other middleware services such as security components, workflow systems, alerting and decision support services and other medical knowledge agents.

c) There is wide international interest in this work, and this part of ISO 13606 has been drafted jointly through CEN and ISO with significant input from many member countries.

d) Mapping to HL7 version 3 has been considered an important goal, to enable conformance to this part of ISO 13606 within an HL7 version 3 environment.

e) The research and development (R & D) inputs on which ENV 13606 was based have moved forward since 1999 and important new contributions to the field have been taken into account. The *open* EHR foundation, integrating threads of R & D in Europe and Australia, is one such example.

Given the diversity of deployed EHR systems, ISO 13606 has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4, and through normative term lists (defined in Part 3).

ISO 13606 will, in practice, usually be adopted alongside other health informatics standards that define particular aspects of health data representation. Annex B explains how ISO 13606 can be used alongside key complementary standards, including the HL7 Version 3 Reference Information Model (RIM), EN 14822-1, EN 14822-2, EN 14822-3, CEN/TS 14822-4 (GPIC), prEN 12967 (HISA) and prEN13940 (CONTSYS).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalized approach to representing every conceivable kind of health record data structure *in a consistent way*. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates, etc. required by different healthcare domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of *semantic interoperability*.

The approach adopted by ISO 13606 distinguishes a reference model, defined in this part of ISO 13606 and used to represent the generic properties of health record information, and archetypes (conforming to an archetype model, defined in Part 2), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5).

This generic information model needs to be complemented by a formal method of communicating and sharing the organizational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively precoordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organizations. An archetype is a formal expression of a distinct, *domain-level concept*, expressed in the form of constraints on data whose instances conform to the *reference model.* For an EHR_Extract, as defined in this part of ISO 13606, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This part of ISO 13606 recognises that archetypes might be used to support communication between some EHR systems in the future, or might be used as a knowledge specification by some EHR system external interfaces when mapping parts of an EHR to an EHR_EXTRACT, or might not be used at all between some EHR systems. The use of archetypes is therefore supported, but not made mandatory, by this part of ISO 13606. A specification for communicating archetypes is defined by Part 2.

0.4 Requirements basis for this part of ISO 13606

From the early 1990s it was recognised that a generic representation is required for the communication of arbitrary health record information between systems, and in Europe this has resulted in a succession of EU sponsored R & D projects and two generations of CEN health informatics standards prior to this International Standard. These projects and standards have sought to define the generic characteristics of EHR information and to embody these in information models and message models that could provide a standard interface between clinical systems. The vision of such work has been to enable diverse and specialist clinical systems to exchange whole or parts of a person's EHR in a standardized way that can rigorously and generically represent the data values and contextual organization of the information in any originating system. A complementary goal has been to accommodate the evolving nature of medical knowledge and the inherent diversity of clinical practice.

Many investigations of user and enterprise requirements for the EHR have taken place over this period, which have sought to span the information needs of diverse specialties across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, mainly within Europe, in order to identify the basic information that needs to be accommodated within an EHR information architecture to:

- capture faithfully the original meaning intended by the author of a record entry or set of entries;
- provide a framework appropriate to the needs of professionals and enterprises to analyse and interpret EHRs on an individual or population basis;
- incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on the same or different sites.

This work includes the GEHR [41, 48, 57], EHCR-SupA [36-38], Synapses [42, 43], I4C and Nora projects and work by the Swedish Institute for Health Services Development (SPRI). These key requirement publications are listed in the Bibliography [51]. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO/TS 18308[9].

In this reference model the key EHR contextual requirements for such faithfulness are related to a set of logical building block classes, with suitable attributes proposed for each level in the EHR extract hierarchy. ISO/TS 18308 has been adopted as the reference set of requirements to underpin the features within this EHR communications reference model, and a mapping of these requirements statements to the constructs in the reference model is given in Annex D.

0.5 Overview of the EHR extract record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organized under headings, and contained in "documents" such as consultation notes, letters and reports. These documents are usually filed in folders, and a patient may have more than one folder within a healthcare enterprise (e.g. medical, nursing, obstetric).

The EHR extract reference model needs to reflect this hierarchical structure and organization, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organized within heterogeneous EHR systems.

These parts are summarised in Table 1.

Table 1 — Main hierarchy components of the EHR Extract Reference Model

EHR hierarchy component	Description	Examples
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care, for communication between an EHR provider system and an EHR recipient.	Not applicable
FOLDER	The high level organization within an EHR, dividing it into compartments relating to care provided for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, schizophrenia, cholecystectomy, paediatrics, St Mungo's Hospital, GP folder, Episodes 2000-2001, Italy
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, laboratory test result form, radiology report, referral letter, clinic visit, clinic letter, discharge summary, functional health assessment, diabetes review
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, past history, family history, allergy information, subjective symptoms, objective findings, analysis, plan, treatment, diet, posture, abdominal examination, retinal examination
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement
CLUSTER	The means of organizing nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight

An EHR_EXTRACT contains EHR data as COMPOSITIONs, optionally organized by a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

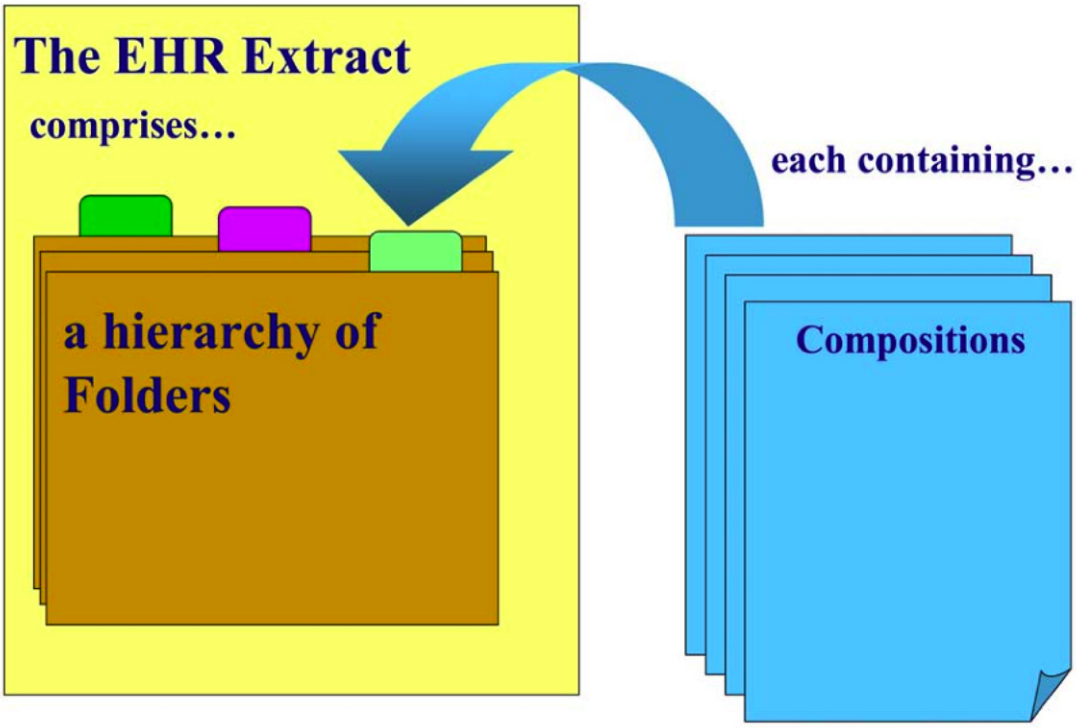

Figure 1 — Diagram of the EHR Extract hierarchy (Part 1)

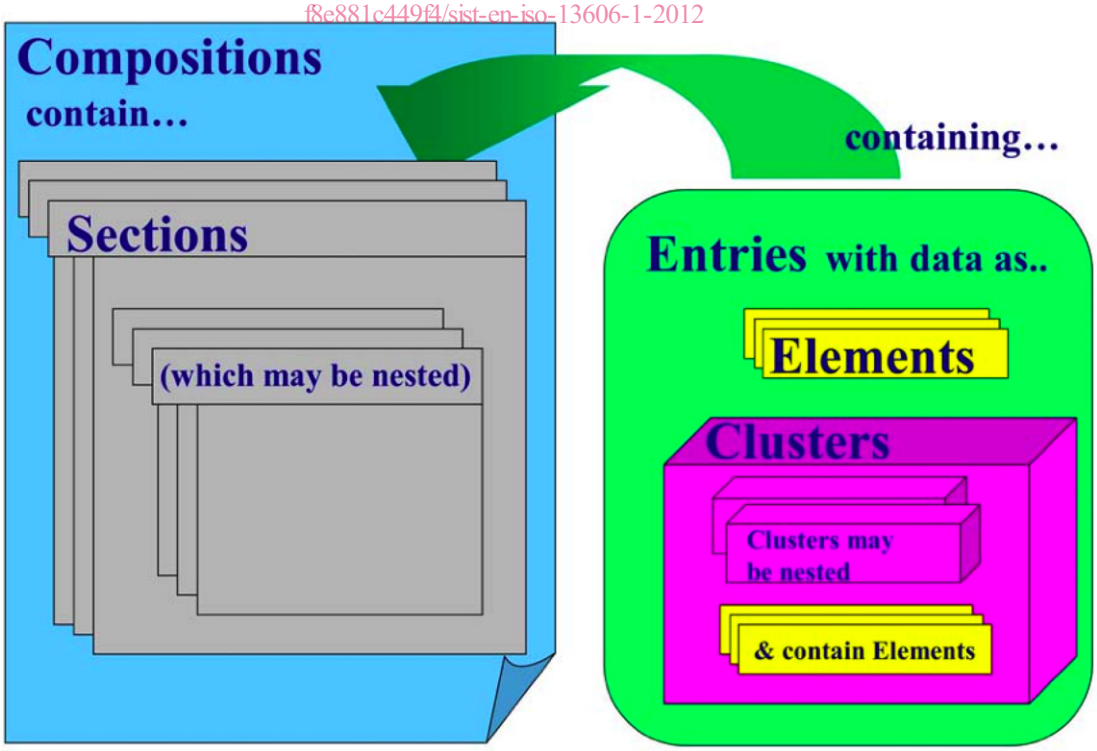

Figure 2 — Diagram of the EHR Extract hierarchy (Part 2)