

CEN Standards

EN13606 - a Standard for EHR System Communication

This five part standard (near to final adoption at European and International levels) defines the logical models and interfaces required to support the generic communication of EHR data and archetypes between heterogeneous EHR systems. Its content builds on many years of *openEHR* work, and adopts many of its constructs in a simplified form that are perhaps better suited to the more simple architectures within most contemporary EHR systems.

The five parts of the standard are summarised below.

- Part 1: Reference Model
 - comprehensive, generic model for communicating part or all of an EHR between heterogeneous systems
- Part 2: Archetype Specification
 - constraint-based approach for defining clinical “business objects” that are built from the Reference Model - adopted from *openEHR*
- Part 3: Reference Archetypes and Term Lists
 - an initial set of inter-reference model conversion archetypes, mapping to *openEHR* and to the HL version 3 RIM Act classes
 - vocabularies for the Part 1 model
- Part 4: Security
 - measures and models to share the access control, consent and auditability of EHR communications
- Part 5: Interface specification
 - message and service interfaces to enable EHR and archetype communication

The table below summarises the progress towards adoption of each of the five parts in CEN and ISO, as of October 2008.

13606 Part Standard	Status in CEN	Status in ISO
1: EHR Reference Model	EN published in February 2007	Published in February 2008
2: Archetype Interchange Specification	EN published in July 2007	Out for FDIS ballot
3: Reference Archetypes and Term Lists	EN published in February 2008	Out for FDIS ballot
4: Security	EN published in March 2007	Passed DTS ballot: comments under review
5: Interface Specification	Passed ENQ/DIS ballot, under Vienna Agreement (CEN lead): comments under review	

The main EHR Reference Model defines the following core classes, which closely align with those in

the *openEHR* 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 organisation 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 organising 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.

Dipak Kalra (UCL) led the EHRcom CEN Task Forces in CEN and ISO that developed and balloted these standards, and key input was provided by David Lloyd, Sam Heard, Tom Beale and originally by Peter Schloeffel. The standard has used ISO TS 18308 (Requirements for an Electronic Health Record Reference Architecture) as its requirements basis, and Part 1 includes a mapping to the ISO TS 18308 statements. A collaboration with HL7, in recent years endorsed and supported by ISO, has resulted in

mapping work (not yet finalised) between 13606-1 and the HL7 v3 RIM and Clinical Document Architecture (Release 2). Work is ongoing towards an implementation guide to enable ISO EN 13606 EHR Extracts to be communicated within HL7 v3 messages. Further harmonisation is intended during 2008-9 to align ISO EN 13606 with the forthcoming ISO Health Data Type Standard (ISO 21090, presently a Draft international Standard).

Several countries have begun pilot projects to implement the 13606 standard, evaluations of which will be published as they mature.

The standards themselves are copyright and may be purchased from national standard bodies (e.g. www.bsi-global.com¹), or directly from ISO (www.iso.org²). A summary of the standard has been published in Methods of Information in Medicine:

- Kalra D. Electronic Health Record standards. Methods of Information in Medicine 2006; 45 Suppl 1: S136-44.

HISA

The 1999 CEN ‘Standard Architecture for Healthcare Information Systems’ (ENV 12967, commonly known as “HISA”) seeks to enable the development of modular open systems to support healthcare.

The HISA standard builds on the extensive work of RICHE, NUCLEUS, EDITH and HANSA in this field. The architecture of any generic healthcare information system is described as a federation of heterogeneous applications, interacting and co-operating through a middleware layer of common services. It specifies the structure of the data maintained and retrieved by each service, without prescribing its internal structure. Both applications and the middleware rely on a set of technological facilities (a bitways layer) to enable the physical connection and interaction of various modules.

Two main classes of common services are identified:

1. Healthcare-related Common Services (HCS) meeting the particular requirements and activities of users in the healthcare business domain. These relate to the subject of care, activities, resources, authorisation, health characteristics, concepts.
2. Generic Common Services (GCS) which may be common to any information system in any business domain.

This standard is presently being revised by CEN, and is expected to be published as a full standard (EN 12967) in 2005.

1. <http://www.bsi-global.com>

2. <http://www.iso.org>