

ISO EHR Standards

ISO 18308 - "Requirements for an Electronic Health Record Reference Architecture"

The work item to develop a standard set of EHR reference architecture requirements began in August 1999 with Peter Schloeffel of Australia as project leader. The project is now near completion and the requirements document will go to international ballot in January 2003 as an ISO Technical Specification.

It is important to emphasise that these are not functional requirements for an EHR system but rather, "...a set of clinical and technical requirements for a record architecture that supports using, sharing, and exchanging electronic health records across different health sectors, different countries, and different models of healthcare delivery."

The primary users of this requirements standard will therefore be developers of EHR architecture standards (e.g. CEN 13606) and other reference architectures such as the *openEHR* Reference Model. The first known compliance test against the 18308 requirements has been done for the *openEHR* RM. This can be downloaded at [ISO 18308 Mapping](#)¹.

The development of ISO 18308 was undertaken in three separate stages. The first stage involved an extensive literature search and direct contact with domain experts in many countries to identify as many existing sources of EHR requirements as possible. Material from over 35 primary sources was obtained, including 20 sources originally collected by the EHCR Support Action project (EHCR-SupA) in Europe.

Stage 2 of the project involved collation of the more than 700 requirements identified in the first stage and the development of a suitable hierarchical framework of headings under which the requirements could be organised. By the end of stage 2, 590 source requirements remained after exclusion of redundant requirements and EHR system requirements. The identification and exclusion of requirements which relate to EHR systems rather than to the record was in some cases obvious but in others quite challenging since there is a fine line between the record and the system at the margins.

The final stage of the project was the development of a consolidated set of EHR requirements from the 590 source requirements which remained at the end of stage 2. This resulted in a final set of 123 requirements listed under a framework of ten major headings and 60 sub-headings. The process of consolidation involved exclusion of many requirements which were overlapping or identical and the separation of requirements from the many compound source statements which actually embodied two or more requirements. The consolidated requirements statements were also worded in a consistent manner and in a normative form to enable upgrade of the Technical Specification to a full normative International Standard at a later date.

The latest version of ISO 18308 can be downloaded at [ISO Requirements](#)².

ISO/DTR 20514 – Electronic Health Record Definition, Scope and Context

This project began in August 2001 and is due for completion by mid-2004. Its target deliverable is an ISO Technical Report which:

- describes a pragmatic classification of electronic health records;

1. http://www.openehr.org/svn/specification/TRUNK/publishing/requirements/iso18308_conformance.pdf

2. <http://www.openehr.org/downloads/standards/iso/ISOEHRRequirements.zip>

- provides simple definitions for the main categories of EHR; and
- provides supporting descriptions of the characteristics of electronic health records and EHR systems.

Previous attempts to develop a definition for the Electronic Health Record (EHR) have foundered due to the difficulty of encapsulating all of the many and varied facets of the EHR in a single comprehensive definition.

The approach taken in this Technical Report is to make a clear distinction between the content of the EHR and its form or structure. This is achieved by first defining the EHR in terms of its structure (i.e. as a container). This definition (to be called the “basic-generic EHR”) is intentionally concise and generic to ensure the broadest applicability to the widest range of existing and future users of EHRs and EHR systems. Such a definition must also be able to support legislative and access control requirements that apply to all ‘forms’ of EHR.

The basic-generic EHR definition is supplemented by a more detailed and specialised definition to cover two of the most essential characteristics of the EHR not covered by the basic-generic definition. These are the ability to share patient health information between authorised users of the EHR and the primary role of the EHR in supporting continuing, efficient and quality integrated health care. There are of course many other important characteristics of the EHR dependent on the scope and context of care, which will not be explicitly expressed in a single supplementary definition. It would be possible to develop a whole series of formal definitions to capture all of the nuances of different care contexts. However, the approach taken in this Technical Report is to keep the number of formal definitions of EHR types to an essential minimum and to demonstrate the inclusiveness of these definitions through explanatory text and examples.

The principle definition of the EHR, which is a specialisation of the basic-generic EHR definition, is called the Integrated Care EHR (ICEHR). The ICEHR is based on a standardised or commonly agreed logical information model which supports semantic interoperability. The *openEHR* Reference Model and the CEN 13606 Reference Model are examples of models which fit this definition.

The [2005 final version of ISO/DTR 20514](#)³.

3. [http://www.openehr.org/downloads/standards/iso/isotc215wg3_N202_ISO-TR_20514_Final_\[2005-01-31\].pdf](http://www.openehr.org/downloads/standards/iso/isotc215wg3_N202_ISO-TR_20514_Final_[2005-01-31].pdf)