*open*EHR / ISO 18308 Conformace Statement

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1. Ocean Informatics Australia

The *open*EHR foundation

is an independent, non-profit community, facilitating the creation and sharing of health records by consumers and clinicians via open-source, standards-based implementations.

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Amendment Record

Issue	Details	Who	Date
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1 Introduction

1.1 Purpose

This document describes the compliance of the *open*EHR architecture to the draft ISO TC 215 Technical Specification ISO/WD 18308, “Requirements for an Electronic Health Record Reference Architecture”. These requirements have been developed from numerous sources. Quoting from the 2002-06-28 draft:

> An extensive search of the literature and direct contact with domain experts in many countries has been undertaken to identify as many existing sources of EHR requirements as possible. Material from over 35 primary sources has been obtained. This includes 20 sources originally collected by the EHCR Support Action Project (EHCR-SupA) in Europe. This project was established to support the work of CEN in developing a four part EHR communication standard [CEN 13606, 1999) and one of its Deliverables [SupA1.4, 2000] was to provide "…a consolidated classification of the requirements for the Electronic Health Care Record (EHCR) and EHCR architecture (EHCRA)." The 20 different primary EHR requirements documents used by EHCR-SupA came from many sources including relevant projects from the EU's Third and Fourth Framework AIM programmes and from CEN. The 15 newly identified sources come from the United States, The Netherlands, Australia, and New Zealand.

As implied by the title, the ISO EHR requirements relate to EHR “reference architectures”, which include the architectures such as that published by *open*EHR. It is therefore appropriate to show how the *open*EHR architecture satisfies or deviates from the the ISO requirements.

1.2 Status

1.2.1 Versions

This document compares the ISO requirements draft document identified as `ISO/WD 18308`, published by ISO TC 215 WG1, dated 2002-06-28 with the *open*EHR deliverables:

- *open*EHR EHR Reference Model (RM) revision 4.3 draft
- *open*EHR EHR Demographic Reference Model revision 1.4.1 draft
- *open*EHR EHR Common Reference Model revision 1.4.3
- *open*EHR EHR Data Structures revision 1.3.1
- *open*EHR EHR Data Types revision 1.7.2
- *open*EHR archetype draft documents corresponding to these RM versions

In the future it is expected that this list will be expanded to include the following document:

- *open*EHR consent/policy reference model

The latest version of this document can be found in PDF and HTML formats at http://www.openEHR.org. New versions are announced on openehr-announce@openehr.org.

1.2.2 Completeness

In the conformance column of the tables, the systems listed as having verified each feature in the architecture are not exhaustive, and undoubtedly do not include systems which have in fact verified the feature. These can be added over time.

1.3 Acronyms, Abbreviations and Definitions

For the most part, definitions of EHR-related concepts are to be found in ISO/WD 18308, which includes a comprehensive set of definitions. Abbreviations used in describing conformance are described below. A few key acronyms are repeated here for convenience.

EHR - Electronic Health Record. There is currently no single definition of “EHR” in ISO;

EHRRA - EHR Reference Architecture, i.e. a formal model of EHR semantics as derived from a set of requirements, and containing no design particularities, or features specific to any jurisdiction, style of medicine, or culture;

RM - reference model; any formal model derived from requirements by analysis, but prior to the application of system design activities.

1.4 Methodology

The approach taken in this document is to show for each ISO requirement what feature(s) of the openEHR reference architecture satisfy the requirement.

The information is presented in a table of the form shown below. All ISO original content is shown in blue. All ISO numbering is preserved. Each requirement includes a number in parentheses denoting the heading number in a heading framework developed by ISO WG1 for the purpose of classifying requirements. The numbers refer to version 5.3 of the heading framework .

ISO Req’t	Description	*open*EHR artifact	Conformance
IDN.N	ISO description, verbatim from the current ISO draft document. (ISO source reference number)	Detail of how openEHR meets the requirement	Level of conformance (see below).

Conformance

Conformance is described in two dimensions. The conformance of the *open*EHR models to the requirement is indicated by paragraphs like the following in the “conformance” column.

Design: X

The following values of the letter ‘X’ are used:

Full: Full conformance - the requirement is believed to be completely satisfied by the reference architecture in a direct way, e.g. with a class or other feature specifically designed for the purpose;

Qual: Qualified - the requirement is believed to be completely satisfied by the architecture;

Part: Partial - the requirement is partially met by the current architecture;

Fut: Future - the requirement will be met by a future revision of the architecture;

No: No conformance - the requirement is not met by the architecture and is not intended to be satisfied in the future;

N/A: Not Applicable - In some cases, the current ISO requirement is not considered a valid requirement for EHR reference architectures;

Unk: Unknown - it is currently not known if the architecture caters for the requirement, or if it does it in a manner desirable for implementation and information management.

Design conformance essentially indicates whether, in the *open*EHR design process, there has been conscious consideration of the ISO requirement or one which is very similar or a superset, or use cases which are implied by the ISO requirement.

However, the best intentions of design do not always guarantee success in implemented systems, due to factors such as complexity, novelty (never before implemented), or difficulty of testing (e.g. requires large clinical trials). Hence, the second dimension indicates whether the *open*EHR reference architecture feature, or one like it (e.g. in one of the architectures on which *open*EHR is based, such as CEN 13606, GEHR or SynEx) has been shown to work in practice. This is shown by “Validated” paragraphs like the following.

Val: xxxx

The values here include the names of any of the following projects where a) the *open*EHR design feature was present and b) it was known to have fulfilled the ISO requirement.

CEN: Any CEN ENV 13606 implementation

GEHR: The Australian Good Electronic Health Record project [9]. (It should be noted that the Australian GEHR project (1997 - 2002) was heavily implementation oriented, while the original Good European Health Record project (1992 - 1995) was a requirements-oriented project, and one of the precursors to the ISO 18308 technical specification described here);

HL7: ....

OMG CorbaMed (HDTF): ...

SNX: SynEx & Synapses European projects [4], [5]

The conformance assessments provide a guide to what elements of the *open*EHR architecture need to be addressed in order to meet the ISO requirements. Non-conforming requirements are summarised in a hyperlinked list at the end of this document.

1.5 Recommendations

Three general rules of thumb should be respected by any requirement in a set of requirements, as follows:

- each statement expresses one requirement only;
- it is clear how each statement would be tested, i.e. it would be easy to write a test case corresponding to the requirement;
- each statement expresses a requirement about the object of the requirements, not about something else (usually related).

The current version of the ISO requirements does not always follows these rules. Some requirements (e.g. 3.9, 3.15) actually express several requirements, and it is recommended that these be split out. Any requirement where multiple “design” entries are included in the conformance column.

Some requirements are unclear or vague, and the meaning is not obvious, nor is a way to state a test case. Finally, in a few cases, a few requirements are not considered to apply to an EHR reference architecture. In both casesm these are indicated with a “TBR” (to be reviewed) paragraph of the following form:
TBR 1: example TBR paragraph

These paragraphs may indicate the need for further review of the ISO requirement, either within ISO TC 215 (in order to state the requirement more clearly, or correct it) or within *open*EHR, in order to better interpret the requirement. A hyperlinked summary list of TBR paragraphs is provided at the end of this document.

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2 Mappings

ISO Section 1 Structure

ISO Section 1.1 Record organisation

ISO Section 1.1.1 Sections

ISO Req't	Description	*open*EHR artifact	Conformance
STR1.1	The EHRRA must enable information in the EHR to be organised in different sections allowing navigation by users and views of sections to be returned as the result of queries. (1.1)	*open*EHR EHR RM: `TRANSACTIONs` provide coarse-grained buckets. `FOLDERs` reference `TRANSACTIONs`, providing course-grained views. `ORGANISERs` provide navigational headings inside `TRANSACTIONs`; the `ENTRY` subtype `VIEW` allows views to be constructed. Queries return PATHs, which are URI-style references.	**Design:** Full **Val:** GEHR, CEN

ISO Section 1.1.2 EHR format

ISO Req't	Description	*open*EHR artifact	Conformance
STR1.2	The EHRRA must ensure that the 'format' of the EHR as it appears to the clinician or user is able to conform to specifications set by standards organisations, regulatory and accreditation agencies, professional groups, local healthcare institutions and users. (1.1)	*open*EHR EHR RM: The reference model architecture provides generic structures which are configured by domain-authored archetypes, which can be devised to reflect relevant standards in structuring.	**Design:** Full

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ISO Section 1.1.3 Portability

ISO Req't	Description	*open*EHR artifact	Conformance
STR1.3	The EHRRA must support an EHR which is moveable and mergeable between individuals and institutions independent of hardware, software (application programs, operating systems, programming languages), databases, networks, coding systems, and natural languages. (2.6)	*open*EHR all models: All models are defined in platform-independent UML, and can be expressed in any object-oriented formalism for implementation, including XML-schema or other XML schema languages (RDF, Schematron etc). Moving and merging semantics are defined by the `VERSIONED_TRANSACTION` and `EHR_EXTRACT` classes.	**Design:** Full

ISO Section 1.1.4 Secondary uses

ISO Req't	Description	*open*EHR artifact	Conformance
STR1.4	The EHRRA must enable information in the EHR to be organised and retrieved in a manner that facilitates its secondary uses. (1.1)	*open*EHR EHR RM: Paths, `FOLDERs`, `TRANSACTIONs`, `ORGANISERs` and `VIEWs` all provide means of retrieving EHR data in arbitrary ways.	**Design:** Full

ISO Section 1.1.5 Archiving

ISO Req't	Description	*open*EHR artifact	Conformance
STR1.5	The EHRRA must support archiving (5.4)	*open*EHR EHR RM: The 'contribution' concept, implemented with versioned `TRANSACTIONs` which contain a `VERSION_AUDIT` for each change enable each successive change to the EHR to be unambiguously identified; each change can therefore be retrieved and processed by an archiving system.	**Design:** Full

ISO Section 1.2 Data Organisation

ISO Section 1.2.1 Structured Data

ISO Req't	Description	*open*EHR artifact	Conformance
STR2.1	The EHRRA must enable storage of data as lists such that the order of the data is preserved when the data is displayed. (1.2.1)	*open*EHR Data Structures RM: `LIST_S` subtype of `STRUCTURE`.	**Design:** Full **Val:** GEHR
STR2.2	The EHRRA must enable storage of data in tables such that the relationships of the data with the row and column headings are preserved. (1.2.1)	*open*EHR Data Structures RM: `TABLE_S` subtype of `STRUCTURE`.	**Design:** Full **Val:** GEHR
STR2.3	The EHRRA must enable storage of data in hierarchies such that the relationship between the node parents and children are preserved. (1.2.1)	*open*EHR Data Structures RM: `TREE_S` subtype of `STRUCTURE`.	**Design:** Full **Val:** GEHR
STR2.4	The EHRRA must enable storage of data such that simple name / value pairing is preserved. (1.2.1)	*open*EHR Data Structures RM: `SINGLE_S` subtype of `STRUCTURE`.	**Design:** Full **Val:** GEHR
STR2.5	The EHRRA must enable the storage of multiple values of the same measurement taken at closely proximate times at the same contact, or at different contacts and at different locations. The context of these measurements must be preserved - such as who took the measurement, what method was used etc. These values should be able to be returned in a query and ordered in different ways. (1.1)	*open*EHR Data Structures RM: classes `HISTORY<T:STRUCTURE>`, `EVENT_SERIES`, `STATE_SERIES`, etc enable recording of time-series data of any complexity, along with their times. Other context data is recorded on the owning `ENTRY`. Recordings by different people, using different protocols etc are not considered scientific time-series data due to variability of samples, and are recorded using successive, distinct `ENTRY`s.	**Design:** Full

ISO Section 1.2.2 Non-structured data

ISO Req't	Description	*open*EHR artifact	Conformance
STR2.6	The EHRRA must support the inclusion of narrative free text and there should be no logical limit to the size of this text. (1.2.2.1)	*open*EHR Data Types: `DV_TEXT` and `DV_PARAGRAPH` types for plain or text with basic font formatting; `DV_ENCAPSULATED` for encapsulated rich text.	**Design:** Full **Val:** CEN, GEHR, SNX
STR2.7	The EHRRA must support searching within non-structured data (text and non-text) and the inclusion of structured text within this data. (1.2.2.1)	*open*EHR Data Types: Searching is not strictly an EHR reference model facility - it can be performed on any `DV_TEXT` or `DV_PARAGRAPH` item, as converted to e.g. XML or any other database or representation format. The `DV_PARAGRAPH` type can include any number and mixture of `DV_CODED_TEXT`s (coded terms) and `DV_TEXT`s.	**Design:** Full **Val:** GEHR

ISO Req't	Description	*open*EHR artifact	Conformance
STR2.8	The EHRRA must support the inclusion of comments within the data stored - enabling the clinician to qualify structured information appropriately. Comments must be able to be linked to specific data attributes. (1.2.2.2)	*open*EHR Reference Model: Comments are expressed as text data items in distinct `ELEMENT`s in structured data. Associating a comment with a specific datum means using archetypes to define the relevant structure (e.g. `TREE_S` etc) to allow comments to be associated with original data items. *open*EHR does not include a blanket facility to include comments in all data value types as such because experience has shown that this kind of feature tends to be abused, and perverts capture of well-structured data (i.e. it allows systems to work around the intention of the model).	**Design:** Qual
STR2.9	The EHRRA must provide a means for different levels of emphasis to be associated with comments and other entries - this may alter the way they are displayed or their returning in a query. (1.2.2.2)	The `DV_TEXT` type provides a facility to associate a platform-standard font string with one or more text items.	**Design:** TBD

ISO Section 1.2.3 Clinical Data

ISO Req't	Description	*open*EHR artifact	Conformance
STR2.10	The EHRRA must allow for comprehensive information storage and retrieval regarding patient care. The EHRRA must at a minimum allow for the recording of all data on: • Patient history • Physical examination • Psychological, social, environmental, family, and self care information • Allergies and other therapeutic precautions • Preventative and wellness measures such as vaccinations and lifestyle interventions • Diagnostic tests and therapeutic interventions such as medications and procedures • Clinical observations, interpretations, decisions, and clinical reasoning • Requests/orders for further investigation, treatments, or discharge • Problems, diagnoses, issues, conditions, preferences and expectations • Healthcare plans, health and functional status, and health summaries • Disclosures and consents • Suppliers, model and manufacturer of devices (e.g. implants or prostheses)	*open*EHR EHR RM: All of these categories except "Disclosures and consents" would be recorded by the normal means in `TRANSACTIONS` (mostly "persistent" `TRANSACTIONs`), which can be thematically defined as required. "Disclosures" are not strictly part of the *open*EHR EHR model, but would be recorded in the EHR system (i.e. *open*EHR has no particular model for how disclosures are recorded). "consents" are expressed using instances of the `INSTRUCTION` `ENTRY` type, and may also be further used by an access control service in mediating access to the EHR.	**Design:** Qual

ISO Section 1.2.4 Administrative data

ISO Req't	Description	*open*EHR artifact	Conformance
STR2.11	The EHRRA must support the recording (and classifying for identification purposes) of patient identification, location, demographic, contact, employment and other administrative data. (1.3.3)	*open*EHR Demographic RM: The demographic model defines the class `PARTY` and various subtypes, all archetypable to whatever particular form is required.	**Design:** Full **Val:** CEN, GEHR, SNX

ISO Req't	Description	*open*EHR artifact	Conformance
STR2.12	The EHRRA must support standards for information which enable the unambiguous identification of the subject of care, the clinicians involved in care (including their role and context of care), the location of care, the date/time and duration of care, and third parties such as next of kin and non-clinical contacts. There should be no limit on the storage of such information. (1.3.3)	*open*EHR Demographic RM: The demographic model defines the class `PARTY` and various subtypes, all archetypable to whatever particular form is required. *open*EHR EHR RM: The class `CLINICAL_CONTEXT`, and the context attributes of the `ENTRY` class define all of the attributes mentioned. Both classes can include unlimited further context data, with meaning defined by archetyping.	**Design:** Full **Val:** CEN, GEHR, SNX
STR2.13	The EHRRA must support the administration of healthcare processes and episodes of care as well as the organisation of visit and encounter data. (1.3.3)	*open*EHR EHR RM: Episodes can be represented using `FOLDERs` for grouping all event transactions which occur during an episode. Encounters are represented using "event" `TRANSACTIONs`.	**Design:** Full
STR2.14	The EHRRA must support the recording of financial and other commercial information such as health plan enrolment, eligibility and coverage information, guarantor, costs, charges, and utilisation. (1.3.3)	*open*EHR EHR RM: All of these items can be recorded as persistent transactions using appropriately designed archetypes, although in distributed systems (and particularly outside North America), this information is more likely to be in other systems in the environment.	**Design:** Full
STR2.15	The EHRRA must support the recording of legal status and consents relevant to the patient's healthcare (e.g. legal status of guardianship order, consents for operations and other precedures).	*open*EHR EHR RM: All such details can be modelled using archetypes which describe the subject of the record. The data should probably be recorded in a dedicated persistent transaction.	**Design:** Full
STR2.16	The EHRRA must be amenable to querying for the purpose of data aggregation to support information gathering required for population and public health initiatives, surveillance, and reporting.	*open*EHR EHR RM & archetypes: Archetypes provide the basis for formulating intelligent queries. As long as information which is of interest in population queries (e.g. lifestyle, chronic disease etc) has been stored using archetypes in the first place, very efficient querying is possible, based on the use of paths extracted from archetypes.	**Design:** Qual

ISO Section 1.3 Type and form of data

ISO Section 1.3.1 Support for different types of data

ISO Req't	Description	*open*EHR artifact	Conformance
STR 3.1	The EHRRA must allow for the incorporation of data types defined elsewhere, such as DICOM, MIME, EKG. (1.3.1)	*open*EHR Data Types: The DV_ENCAPSULATED type caters for all data types defined in other standards.	**Design:** Full

ISO Section 1.3.2 Data types

The EHRRA must define the following data types:

ISO Req't	Description	*open*EHR artifact	Conformance
STR 3.2	Numeric and Quantifiable data. The EHRRA must support the definition of the logical structure of numeric and quantifiable data, including the handling of units. (1.3.4.2)	*open*EHR Data Types: DV_QUANTITY (including units), DV_CUSTOMARY_QUANTITY, DV_DATE/TIME types	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.3	Quantities should include a measure of precision related to the method of measurement. (1.3.4.2)	*open*EHR Data Types: precision is included as an attribute in the type DV_QUANTITY. More complex measurement information can be included in the OBSERVATION.*protocol* attribute which is of type STRUCTURE (i.e. any complexity)	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.4	Percentages must be able to be expressed as quantities. (1.3.4.2)	*open*EHR Data Types: Percent is a valid unit in the Unified Code for Units of Measure (UCUM) specification [7], which provides the semantics for units in the DV_QUANTIFIED types.	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.5	Quantity ranges The EHRRA must support the definition of the logical structure of ranges - that is high and low values. (1.3.4.2)	*open*EHR Data Types: Ranges are provided for with the DV_INTERVAL<T:DV_ORDERED> type, which caters for ranges of any ordered data types.	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.6	Quantity ratios The EHRRA must support the definition of the logical structure of quantity ratios (i.e. x of a per y of b). (1.3.4.2)	*open*EHR Data Types: The DV_QUANTITY_RATIO type provides for ratios of the form <{val_1, units_1}/{val_2, units_2}>. What the quantities are of can be recorded in the name or in an associated attribute, but are not recorded inside the quantity ratio data item as such.	**Design:** Qual **Val:** CEN, GEHR, SNX

ISO Req't	Description	*open*EHR artifact	Conformance
STR 3.7	Dates and times The EHRRA must support the definition of the logical structure of dates and times. (1.3.4.3)	*open*EHR Data Types: The subtypes of `DV_CUSTOMARY_QUANTITY`, provide for dates and times, namely `DV_DATE`, `DV_TIME`, `DV_DATE_TIME`, `DV_PARTIAL_DATE`, `DV_PARTIAL_TIME`, `DV_DURATION`	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.8	The EHRRA must support approximate, partial, and fuzzy dates and times such as: · approximate dates/times: e.g., sometime yesterday, last week; · partial dates: e.g. ??/May/1997, ??/??/1928	*open*EHR EHR RM / Data types: These requirements are satisfied with the following elements of the *open*EHR models: · text data types · `DV_PARTIAL_DATE`	**Design:** Qual **Design:** Full
STR 3.9	The EHRRA must support the recording of future planned events or actions such as: · periods of day or time: e.g., morning, afternoon, evening, shifts (AM, PM, NOC), while awake; · points of time: e.g., upon awakening, at mealtime (breakfast, lunch, dinner), at bedtime; · relative points of day or time: e.g., before breakfast, after lunch, before bedtime, two days post discharge, one week after last dose; · alternating and patterned dates/times: e.g., alternate every 8 hours, alternate every 3 days, every Monday/Wednesday/Friday, every Sunday, every third Tuesday. (1.3.4.3)	*open*EHR EHR RM / Data types: These requirements are satisfied with the following elements of the *open*EHR models: · `DV_INTERVAL<>` of any date/time type; `DV_TIME_SPECIFICATION` type · `DV_TIME_SPECIFICATION` (with event alignment) · `DV_TIME_SPECIFICATION`. One week after last dose: `HISTORY<T>` with reference event set to "last dose" · `DV_TIME_SPECIFICATION`	**Design:** Full **Design:** Full **Design:** Full **Design:** Full
STR 3.10	The EHRRA must support the recording of time as an absolute time, an elapsed time since a particular event, and as a duration. (1.3.4.3)	*open*EHR Data types: Absolute time: `DV_DATE_TIME`; elapsed time: `DV_DURATION`. *open*EHR EHR RM: `HISTORY<T>` allows events to be recorded with respect to a reference even.	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.11	The EHRRA must support the recording of the time-zone in which the recording took place. (1.3.4.3)	*open*EHR Data types: Timezone is an attribute of `DV_DATE_TIME` `DV_DATE`, and `DV_TIME`.	**Design:** Full
STR 3.12	The EHRRA must support recording of time in all units down to milliseconds. (1.3.4.3)	*open*EHR Data types: to be supported in the future.	**Design:** Fut

ISO Section 1.3.3 Reference data

ISO Req't	Description	*open*EHR artifact	Conformance
STR 3.13	The EHRRA must support the recording of references such as normal ranges and attributes relevant to a particular observation or measurement. (1.3.5)	*open*EHR Data types: DV_ORDERED.*reference_ranges* and *normal_range* attributes.	**Design:** Full

ISO Section 1.3.4 Contextual Data

ISO Req't	Description	*open*EHR artifact	Conformance
STR 3.14	The EHRRA must support the recording of contextual data associated with the date/time the event occurred.	*open*EHR EHR RM: EHR RM attribute HISTORY.*origin*, EVENT.*offset*	**Design:** Full
STR 3.15	The EHRRA must support the recording of contextual data associated with the date/time the event was committed to the record.	*open*EHR EHR RM: EHR RM attribute VERSION_AUDIT.*time_committed*	**Design:** Full
STR 3.16	The EHRRA must support the recording of contextual data associated with the subject.	*open*EHR EHR RM: EHR RM attribute ENTRY.*subject*	**Design:** Full
STR 3.17	The EHRRA must support the recording of contextual data associated with the person responsible for recording and committing the event.	*open*EHR EHR RM: EHR RM attribute ENTRY.*committer*	**Design:** Full
STR 3.18	The EHRRA must support the recording of contextual data associated with the healthcare facility.	*open*EHR EHR RM: EHR RM attribute CLINCAL_CONTEXT . *health_care_facility*	**Design:** Full
STR 3.19	The EHRRA must support the recording of contextual data associated with the location where the event was recorded.	*open*EHR EHR RM: EHR RM attribute CLINCAL_CONTEXT . *location*	**Design:** Full
STR 3.20	The EHRRA must support the recording of contextual data associated with the reason for recording the information associated with the event.	*open*EHR EHR RM: EHR RM attribute ENTRY . *reasoning*	**Design:** Full
STR 3.21	The EHRRA must support the recording of contextual data associated with the protocol associated with the event.	*open*EHR EHR RM: EHR RM attribute ENTRY . *protocol*	**Design:** Full

ISO Section 1.3.5 Links

ISO Req't	Description	*open*EHR artifact	Conformance
STR 3.22	The EHRRA must define the semantic representation of links between different information in the EHR. (1.3.7)	*open*EHR Data types: `LINK` data type, including *meaning* attribute.	**Design:** Full **Val:** CEN, GEHR, SNX
STR 3.23	The EHRRA must support links to 'externally referenced data' which is not able to be stored within the EHR, providing patient safety is not compromised. (1.3.7)	*open*EHR EHR RM: `EXTERNAL_ID` type references complex data (e.g. demographic, terminological) in external repositories. *open*EHR Data Types: `DV_ENCAPSULATED` can include a URL for its data item which is not included by value in the EHR; `DV_TEXT` can include a URL as a hyperlink for a section of narrative text.	**Design:** Full

ISO Section 1.4 Supporting health concept representation

ISO Section 1.4.1 Support for multiple coding systems

ISO Req't	Description	*open*EHR artifact	Conformance
STR 4.1	The EHRRA must support multiple coding systems (entry or interface terminologies, reference terminologies and classifications) by creating interfaces with electronic tools such as terminology browsers, terminology editors and terminology servers. (1.4.1)	The *open*EHR models do this in several ways. Coded terms in EHR data are represented using the `DV_CODED_TEXT` type, which records the identity of the terminology from which codes come, using a `TERMINOLOGY_ID` object. The ids and codes refer to indentifiers and terms in the *open*EHR Terminology Model, which models the minimum semantics of the interface between the EHR and terminologies.	**Design:** Full **Val:** CEN, GEHR, SNX
STR 4.2	At the data attribute level, the EHRRA must support the capture of the code, the coding scheme (e.g., coding/classification system), version and original language.	*open*EHR Data Types: The `DV_CODED_TEXT` & `COORDINATED_TERM` types record code, rubric (textual expansion) and terminology_id. Original language is recorded at the `TRANSACTION` level in `VERSION_AUDIT`, because transactions are not allowed to be of mixed language.	**Design:** Full **Val:** CEN, GEHR, SNX
STR 4.3	The EHRRA must enable storage of data from terminologies and preserve the information about the terminology set from which it was chosen (see section 1.4 below). (1.2.1)	*open*EHR Data Types & EHR RM: `COORDINATED_TERM.`*terminology_id*: `TERMINOLOGY_ID`.	**Design:** Full

ISO Section 1.4.2 Unique representation of information

ISO Req't	Description	*open*EHR artifact	Conformance
STR 4.4	Where information is not represented uniquely in only one place and one way, the EHRRA shall support explicit rules to avoid ambiguity (e.g. is must be clear what [not] [pedal pulses absent] means).	*open*EHR Data Types `DV_CODED_TEXT` type.	**Design:** TBD
STR 4.5	The EHRRA must support a means of mapping between objects in information and inference models corresponding to a well-defined set of concepts in the foundation reference terminology (or concept) model. (1.4.1)	*open*EHR Data Types `DV_CODED_TEXT` and `TERM_MAPPING` types.	**Design:** Full

ISO Section 1.4.3 Language independence

ISO Req't	Description	*open*EHR artifact	Conformance
STR 4.6	The EHRRA must support the use of a comprehensive reference terminology that enables the recording/translation of multilingual terms. [This does not imply that a given EHR implementation must support more than one language].	The approach to handling language translation has not yet been finalised, as the requirements have not been sufficiently developed.	**Design:** TBD
STR 4.7	The EHRRA must support the identification of information that has been translated from the language in which it was originally recorded. Such identification must describe the faithfulness or reliability of the translation. (1.4.3)		

ISO Section 1.4.4 Representation of text

ISO Req't	Description	*open*EHR artifact	Conformance
STR 4.8	The original textual representation as entered by the clinician must be retained in the EHR when information is translated from one natural language to another or when terms are mapped from one coding/classification system to another.	The approach to handling language translation has not yet been finalised, as the requirements have not been sufficiently developed.	**Design:** TBD

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ISO Section 2 PROCESS

Preamble

The EHRRA must support clinical processes such as ordering, care planning, clinical guidelines, and decision support. It must also support processes associated directly with the record including the capture, retrieval, querying, presentation, and automatic processing of patient data. Good quality data is essential for good quality decision support and most other aspects of patient care, so uniform data capture methods and data definitions should be used whenever possible in EHR systems. The EHRRA should also support local clinical and workflow processes to ensure maximum usability and acceptability of EHR systems by clinicians and other users.

ISO Section 2.1 Clinical processes

ISO Section 2.1.1 Support for clinical processes

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.1	The EHRRA must support the recording of any type of clinical event, encounter, or episode relevant to the care of a patient (3.1)	The *open*EHR models are generic in nature, and do not directly model concepts such as "encounter" or "episode" - these are modelled by using archetypes, FOLDERs, TRANSACTIONs and other elements of the architecture. All clinical events result in an "event" TRANSACTION, which contains relevant context in an attached CLINICAL_CONTEXT object.	**Design:** Full **Val:** CEN, GEHR, SNX
PRO 1.2	The EHRRA must support the creation, instantiation, and maintenance of clinical processes that support the activities of its users (3.3.5)	*open*EHR EHR RM: Archetypes can be used to define specific structures of the various kinds of ENTRY (OBSERVATION, EVALUATION and INSTRUCTION) and links between them describing causality or other relationships. As more events happen in a clinical process, changes to the states of INSTRUCTIONs/ACTIONs and the addition of links can be made, creating a growing picture of the real-world process as it unfolds in time.	**Design:** Full
PRO 1.3	The EHRRA must support the continuity of a clinical process, the ability to query the status of a process, modify an existing process, and verify that a process has been completed (3.3.5)	*open*EHR EHR RM: The INSTRUCTION type allow the state of fine-grained processes to be recorded using the DV_STATE data type. The state machines are defined in archetypes. When a process changes state, a new version of a TRANSACTION is made which records the state change. The status of coarse-grained processes such as care-plans is more likely to be recorded by clinicians as narrative.	**Design:** Full
PRO 1.4	The EHRRA must be able to accommodate partial completion of a clinical process. (3.3.5)	*open*EHR EHR RM: The INSTRUCTION types include a state indicator, which make take on any values, including states such as "suspended", "aborted" etc, as defiined by the relevant archetype.	**Design:** Full

ISO Section 2.1.2 Problems/issues and health status

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.5	The EHRRA must support the recording and presentation of holistic health status, functional status, problems, conditions, environmental circumstances and issues (3.2.1)	*open*EHR EHR RM: all of these would be recorded in the appropriate "persistent" transactions, according to appropriate archetypes.	**Design:** Full **Val:** GEHR
PRO 1.6	The EHRRA must support the recording and presentation of data in a problem-oriented structure including problem status, resolution plans and targets (problem-oriented here includes conditions and issues) (3.2.1)	*open*EHR EHR RM: particular types of persistent transaction are used to record problem list, issues, care plans etc; appropriate Organiser archetypes are used to support problem-oriented recording.	**Design:** Full **Val:** GEHR
PRO 1.7	The EHRRA must support a patient's lifetime, longitudinal record of health status and care interventions which can be viewed as a chronological health record. The patient EHR is at once (simultaneously): 1. retrospective: an historical view of health status and interventions (e.g., completed health service events/acts); 2. concurrent: a "now" view of health status and active interventions (e.g., health service events/acts now underway); and 3. prospective: a future view of planned interventions (e.g., health service events/acts scheduled or pending).	The *open*EHR models are designed to express the semantics of a longitudinal EHR, and are based on a number of core design principles [2]. The three views are supported by three subtypes of `ENTRY`, namely `OBSERVATION`, `EVALUATION` and `INSTRUCTION`, types which are based on some years of research and experience, including by GEHR, PEN&PAD (U. Manchester), and by CEN and HL7.	**Design:** Full **Val:** CEN, GEHR, SNX.

ISO Section 2.1.3 Clinical reasoning

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.8	The EHRRA must support the recording of the clinical reasoning including automated processes for all diagnoses, conclusions, and actions regarding the care of a patient (3.2.2)	*open*EHR EHR RM: Archetypes are used to define particular diagnoses and care plan information structures. Actions are described with `INSTRUCTIONs`. Specific allowance is made for interaction with guidelines via the `INSTRUCTION` class, which allows guideline 'profiles' and execution state to be stored.	**Design:** Full

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ISO Section 2.1.4 Decision support, guidelines, and protocols

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.9	The EHRRA must support the automatic presentation of warnings, alerts and reminders such as patient infective status, allergies and other therapeutic precautions, outstanding interventions, and urgent results (3.2.1)	*open*EHR EHR RM: Important items such as allergies, problems etc are most likely to be stored in a small number of oten-accessed "persistent" transactions in the EHR, each of which is identified by purpose, e.g. "therapeutic precautions", "problem list" etc. In addition, any element of an *open*EHR EHR can be accessed via a URI-style path, allowing individual identification of important items. The actual detection and actioning of warnings and alerts is up to the calling application, such as a decision support system.	**Design:** Full
PRO 1.10	The EHRRA must support systematic population-based recalls and reminders including public and population health programs such as immunisation and epidemiological surveillance (3.3.5)	*open*EHR EHR RM: The `INSTRUCTION` type in the EHR RM have been specifically designed to support automated recall management, including modelling of recall types with individual archetype-defined state machines. Paths to all recalls in an EHR would be added to a persistent transaction when they are first defined. This enables triggers to be created for each recall, based on its state machine and state data.	**Design:** Full
PRO 1.11	The EHRRA must be able to support guidelines, protocols, and decision support systems (3.3.5)	The `INSTRUCTION` type in the EHR RM have been specifically designed to support automated guideline interaction. In particular: · paths to items in the EHR needed by guidelines can be stored in the `INSTRUCTION.`*guideline_id* object for the guideline; · execution state of a guideline can be stored in the `INSTRUCTION.`*state* object for the guideline. Further experience and testing is needed in this area to determine whether the architecture needs to provide other support for decision support and other automated processing.	**Design:** Qual
PRO 1.12	The EHRRA must enable semantic interoperability of clinical concepts to support decision support processing.	Archetypes can be shared between the EHR and decision support systems, enabling decision support to search for semantically meaningful concepts rather than just atomic data items.	**Design:** Qual

ISO Section 2.1.5 Care Planning

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.13	The EHRRA must support care planning, including the management of process states (eg planned, ordered, scheduled, in progress, on hold, pending, completed, amended, verified, cancelled), within the care planning process (3.2.4)	*open*EHR EHR RM: The EHR RM `EVALUATION ENTRY` subtype allows plans to be expressed, while the `INSTRUCTION ENTRY` type enables specific actions to be prescribed. The information defining any such action is expressed in an appropriate archetype, including the state machine definition for the process state. *open*EHR Data Types: The `DV_STATE` data type directly implements the concept of a state machine, and is designed to be driven by state machines defined on a per-archetype basis.	**Design:** Full

ISO Section 2.1.6 Orders & service processes

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.14	The EHRRA must support the recording and tracking of clinical orders and requests such as prescriptions and other treatment orders, investigation requests, and referrals (3.3.6)	*open*EHR EHR RM: orders and other requests are recorded usng the `INSTRUCTION ENTRY` type. Prescriptions are actually documents containing medication order requests from a provider to a filler such as a pharmacy. There may be an arbitrary relationship between medications and prescriptions from a given clinical session, due to a) prescriptions required for different fillers (e.g. a special drug may only be available from a specialist pharmacy), and b) due to legislation, e.g. in Australia, there can be a maximum of 3 medications on a prescription; and c) not all proposed medications or therapies need to be included in a prescription. Prescriptions should therefore be managed separately, and are most likely to be represented in *open*EHR as separate transactions, or just with prescription ids from a prescribing system.	**Design:** Full
PRO 1.15	The EHRRA must support the linking of orders with the observations that arise as a result (e.g. the results of an investigation or administration of a medication with the order for these interventions).	*open*EHR EHR RM and Data Types: The `LINK` data type is provided for exactly this purpose, and may be used to create a named link between any archetyped data entities, i.e. `TRANSACTIONs`, `ORGANISERs`, `ENTRYs`. Such links may be used to create causal chains or "problem threads" through the data.	**Design:** Full **Val:** CEN, GEHR, SNX

ISO Section 2.1.7 Integrated care

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 1.16	The EHRRA must support integrated patient care including continuing collaborative multi-disciplinary care and case management across different healthcare sectors and settings (e.g. primary care, acute hospitals, allied health, home-based care) (3.2.3)	The EHR is actually agnostic about who records information in it and uses it. Access and care across different sectors are possible within the one EHR, since the architecture is generic, and does not correspond to any particular model or subdomain of care. However, it is up to EHR systems to actually enable access across different sectors, people etc.	**Design:** Full **Val:** CEN, GEHR, SNX

ISO Section 2.1.8 Quality assurance

ISO Req't	Description	*open*EHR artifact	Conformance
PRO1.17	The EHRRA must support the recording and querying of data to enable the measurement of operational and clinical performance, to ensure compliance with standards of care, to ensure quality process and to measure outcomes.	There are no specific features of the reference models for supporting this. Any such data would be modelled using archetypes, and queried in the normal way.	**Design:** TBD

ISO Section 2.2 Record processes

ISO Section 2.2.1 Data capture

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 2.1	The EHRRA must support clear and consistent rules for entry, amendment, verification, transmittal, receipt, translation, and deletion of data. This requirement does not imply that it is necessary for a given implementation to allow deletion of EHR content. Local data retention rules will apply. (3.3.1)	*open*EHR EHR RM: all change to the EHR is governed by the semantics of version control built into the `VERSIONED_TRANSACTION` and `TRANSACTION` classes. The fact of transmittal of EHR extracts to other users is not recorded in the EHR itself, since this is deemed to be the same as any other kind of non-modifying access. Where receipt of EHR extracts or other data such as messages causes changes to the EHR, the audit trailing indicates clearly where the data was acquired from. Where translation occurs..... (currently unknown)	**Design:** Part

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 2.2	The EHRRA must support the implementation of rules for data validation (3.3.1)	Archetypes: The openEHR archetypes are a key way of expressing constraints on data, including on type, value, structure and names, as well as on more esoteric things like allowed state transitions, fuzzy value mappings. These constraints provide a means of high-quality data validation.	**Design:** Full
PRO 2.3	The EHRRA must support the ability to review information of all types recorded in the past, including via the use of query and filter facilities, during the data capture process (3.3.1)	*open*EHR EHR RM: The version control mechanism ensures that all previous states of Folders and Transactions in the EHR are preserved, and therefore any previous state of the EHR can be recreated.	**Design:** Full **Val:** CEN, GEHR

ISO Section 2.2.2 Retrieval/query/views of data

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 2.4	The EHRRA must support selective retrieval and customized views of the same information for specific needs (e.g. decision support, data analysis) (3.3.2)	*open*EHR EHR RM: views can be created in various ways, including: · using the `VIEW ENTRY` type, which enables the specification and optionally results of a query to be stored in the EHR; · using `FOLDERs` to create coarse-grained views of transactions in the record All references in views are defined as EHR Paths, using a standard URI-like textual referencing mechanism for any node or leaf in the EHR.	**Design:** Full **Val:** CEN, SNX

ISO Section 2.2.3 Presentation of data

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 2.5	The EHRRA must support the ability to display data marked as clinical summary without the need for manual searching (3.3.3)	Clinical summaries are likely to be stored in one or a small number of persistent transactions based on a "clinical summary" archetype. Since persistent transactions are likely to be stored in their own `FOLDER`, they are easy to find. Alternative approaches include: any transaction in which a clinical summary is included can have an entry in an index of archetype ids->Transactions, whereby Transactions containing any particular kind of information can be quickly found based on archetype id.	**Design:** Full
PRO 2.6	The EHRRA must support the ability to convey the nature of devices on which information should by preference be presented where this may affect the clinical interpretation (eg viewing a colour image on a monochrome viewer, viewing a digital diagnostic image on a low resolution viewer) (3.3.3)	*open*EHR EHR RM: presumably this means that a clinical instruction about what kind of device to view the information on in order not to diminish its clinical utility should be included in the observation. Currently observation protocol can be recorded; should a "viewing protocol" also be included? This would seem to apply only for very particualar circumstances.	**Design:** TBD

ISO Section 2.2.4 Scalability

ISO Req't	Description	*open*EHR artifact	Conformance
PRO 2.7	The EHRRA should not impede efficient processing of very large records or very large numbers of records.	*open*EHR EHR RM: Each EHR consists of `VERSIONED_TRANSACTIONs` whose most natural implementation is as separate entities in a database, ensuring performance does not diminish with size. Performance of systems containing large numbers of records is mostly a system issue, but is probably improved by the use of separate transactions.	**Design:** Full

ISO Section 3 COMMUNICATION

Preamble

The principle underlying the requirements in this section is to enable data stored in EHRs to be transferred between different EHR systems and other clinical systems. Similarly, EHRs must be able to accept data transferred from different EHR systems and other clinical systems.

There are two distinct forms of transfer possible: messaging and record exchange. Messaging is necessary when data is transferred between systems which do not conform to the same EHR architecture standard. Messaging requires the use of agreed protocols such as HL7, UN/EDIFACT and DICOM. The format and methods of disseminating data must be standardised wherever possible.

Record exchange can occur where data is transferred between two EHR Systems that share a common architecture. Record exchange includes the movement or copying of all or part of an EHR.

ISO Section 3.1 Messaging

ISO Req't	Description	*open*EHR artifact	Conformance
COM1.1	The EHRRA must support the export and import of data received using messaging protocols such as HL7, UN/EDIFACT and DICOM. (4)	Data from any other source can be incorporated into the record and represented in native *open*EHR form, as long as a mapping can be developed from the source form to *open*EHR. Transformations from CEN and HL7v2 and HL7v3 have been studied, and should be possible. Data in another format which cannot be converted can always be represented in encapsulated form.	**Design:** Fut

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ISO Section 3.2 Record exchange

ISO Req't	Description	*open*EHR artifact	Conformance
COM 2.1	The EHRRA must allow for the exchange of a complete EHR or a part of an EHR (an extract) between EHRRA compliant systems. (4.4)	The semantics of `EHR_EXTRACTs` are formally defined, and allow any subset of the latest `TRANSACTIONs` of an EHR to be transmitted elsewhere. Transmitting a whole EHR means transmitting all its previous versions, and presumably has the semantics of "moving" rather than copying. This would be achieved by serialising the entire EHR according to the EHR & `VERSIONED_TRANSACTION` classes (rather than the `EHR_EXTRACT` class) and transmitting it. However, the problem of transmitting demographic and terminology information also has to be addressed, and depends on what the intention is: is it about moving an entire EHR environment elsewhere, or just one patient?	**Design:** Qual **Val:** CEN, GEHR, SNX
COM 2.2	The EHRRA must support serialisation of data for interoperability purposes (e.g. via XML, CORBA, SOAP, etc). (4.3)	The *open*EHR EHR RM supports any standard serialisation mechanism, such as XML, CORBA, .NET etc.	**Design:** Full **Val:** CEN, GEHR, SNX
COM 2.3	The EHRRA must define the semantics of to merging data from an EHR extract with the EHR resident in the receiving system. (4.7)	*open*EHR EHR RM: the `FEEDER_AUDIT` (revision history) class and associated semantics are provided for just this purpose.	**Design:** Full
COM 2.4	The EHRRA must provide an audit trail of exchange processes, including authentication, to enable identification of points of EHR extract transmittal and receipt. This needs to account for merging processes. (4.3)	*open*EHR EHR RM: the `EHR_LOG` object is designed to provide this facility. It has not been fully analysed.	**Design:** Fut
COM 2.5	The rules covering the exchange of an extract must be the same as those for exchanging the complete record. (4.4)	*TBR 1: that depends - if the intention is to send a copy of the current state of an entire record for clinical/shared care purposes, this is true, and an EHR_EXTRACT can be used. If the intention is to move the whole record (e.g. to another jurisdiction, another inforation guardian), including previous versions, relevant demographic, terminological and access control data, the semantics will be different.*	**Design:** TBD
COM 2.6	The EHRRA must enable semantic interoperability of clinical concepts between EHR systems to support automatic processing of data at the receiving system. (3.3.4)	The use of archetypes which are shared by both EHR systems in communication enables semantic interoperability between these parties.	**Design:** Full

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ISO Section 4 PRIVACY AND SECURITY

Preamble

The EHR must support the ethical and legal use of personal information, in accordance with established privacy principles and frameworks, which may be culturally or jurisdictionally specific. Key issues include control of access to the EHR to ensure personal health information can be kept confidential - ie used only for approved purposes and shared only among authorised people; and informed consent.

Key issues in relation to security include authentication, data integrity, confidentiality, non-repudiation and auditablility.

ISO Section 4.1 Privacy and confidentiality

ISO Req't	Description	*open*EHR artifact	Conformance
PRS1.1	The EHRRA must support the application of prevailing privacy and confidentiality rules. (5.2)	No specific facility has yet been included for this purpose. It is expected that further research and development experience is required before this requirement can be analysed well enough to be implemented.	**Design:** No
PRS1.2	The EHRRA must support the labelling of the whole and/or sections of the EHR as restricted to authorised users and/or purposes. This should include restrictions at the level of reading, writing, amendment, verification, and transmission/disclosure of data and records (5.2)		
PRS1.3	The EHRRA must support privacy and confidentiality restrictions at the level of both data sets and discrete data attributes.		

ISO Section 4.2 Consent

ISO Req't	Description	*open*EHR artifact	Conformance
PRS2.1	The EHRRA must support recording of informed consent for the creation of a record. (5.3)	It appears that the consent data in all of these requirements can be adequately captured in a combination of `INSTRUCTION` and `OBSERVATION ENTRY` types. It is not yet known whether all access control requirements would be covered. This requires further real-world experience.	**Design:** Qual
PRS2.2	The EHRRA must support obtaining, recording and tracking the status of informed consent to access the whole and/or sections of the EHR, for defined purposes. (5.3)		
PRS2.3	The EHRRA must support recording of the purposes for which consent is obtained. (5.3)		
PRS2.4	The EHRRA must support recording of the time frames attached to each consent. (5.3)		

ISO Section 4.3 Access control

ISO Req't	Description	*open*EHR artifact	Conformance
PRS3.1	The EHRRA must support measures to define, attach, modify and remove access rights to the whole and/or sections of the EHR. (5.1.1)	*open*EHR EHR RM: Access control settings can be attached to any archetyped structure, including the `EHR`, a `VERSIONED_TRANSACTION`, an `ORGANISER` and an `ENTRY`. The access control settings are defined outside the EHR architecture. These may be changed at any time.	**Design:** Full
PRS3.2	The EHRRA must support measures to define, attach, modify and remove access rights for classes of users of the EHR. (5.1.1)	The *open*EHR architecture does not define any particular model of access control, it just provides places to put access control settings at the lowest meaningful level of granularity, i.e. archetyped structures.	**Design:** Qual
PRS3.3	The EHRRA must support measures to enable and restrict access to the whole and/or sections of the EHR in accordance with prevailing consent and access rules. (5.1.1)	The details of how consent and access control are represented are not yet completed in the *open*EHR EHR RM.	**Design:** TBD
PRS3.4	The EHRRA must support measures to separately control authorities to add to and/or modify the EHR from authorities to access the EHR (5.1.1)	*open*EHR EHR RM: This presumably means that access versus modification should be distinguished in the access control settings. Currently the facility exists to record any access rights, but not to force these two types to always be there.	**Design:** TBD

ISO Section 4.4 Data integrity

ISO Req't	Description	*open*EHR artifact	Conformance
PRS4.1	The EHRRA must support measures to ensure the integrity of data stored in and transferred to and from EHRs (2.8.3)	The model for EHR Extracts does not include methods to guarantee integrity as such, since it is thought that these need to be applied to the serialised form of the data, which is dependent on the target technology, e.g. XML, CORBA etc. A model for general semantics of serialised form of extracts, including signing, may need to be described. Transactions may need a "digest", i.e. a content-derived hash.	**Design:** TBD

ISO Section 4.5 Auditability of access

ISO Req't	Description	*open*EHR artifact	Conformance
PRS5.1	The EHRRA must support recording of an audit trail of access to and modifications of data within the whole or sections of the EHR. (5.5)	*open*EHR EHR RM: Modifications are audit trailed in the `VERSION_AUDIT` of each `TRANSACTION`. Accesses can be recorded in the `EHR_LOG` object.	**Design:** Full/Fut
PRS5.2	The EHRRA must support recording of the nature of each access and/or transaction. (5.5)	*open*EHR EHR RM: All modifications are audit-trailed in the `VERSION_AUDIT` object of a `TRANSACTION`. Accesses can be recorded in the `EHR_LOG` object.	**Design:** Full/Fut
PRS5.3	The EHRRA must support audit capability sufficient to track accountability for each step or task in the clinical or operational processes recorded in the record. (5.5)	*open*EHR EHR RM: Each distinct clinical observation, evaluation or analysis, and action recorded is represented using an `ENTRY`, which ensures the relevant context information for each such action is recorded.	**Design:** Full

Author: T Beale

ISO Section 5 MEDICO-LEGAL

Preamble

Requirements for the medico-legal aspects of the EHRRA are essential if EHRs are to be trusted by both consumers and clinicians and accepted in courts of law as evidence of care provided, compliance with legislation, and the competence of clinicians. Many of the medico-legal requirements are related to and have implications for both privacy and security of the EHR but are nevertheless a distinct category.

For medico-legal purposes it is essential that every addition, amendment or alteration to the EHR be permanently recorded and preserved for an indefinite period. To maintain its originality, information must not be subject to later alteration or erasure. It is also essential that every actor be unambiguously identified and inextricably linked to the information for which they attest.

Legal requirements will vary widely among jurisdictions. In recognising these variances the EHR must not attempt to impose legal obligations of one society upon another. The EHRRA should ensure that the EHR can be a legally acceptable document in the jurisdiction in which it is created.

ISO Section 5.1 Support for legal requirements

ISO Req't	Description	*open*EHR artifact	Conformance
MEL1.1	The EHRRA must support measures to ensure an accurate reflection of the chronology of clinical events and information availability in the EHR (6.3)	*open*EHR EHR RM: the model specifically distinguishes between date/times of clinical events and acts, and interactions with the EHR system, ensuring that the chronology of events in the real world is clear, as well as the chronology of changes to the EHR.	**Design:** Full
MEL1.2	The EHRRA must enable the viewing of an accurate representation of the EHR at any particular date and time since its creation (6.4)	*open*EHR EHR RM: the model explicitly includes versioning semantics in the `VERSIONED_TRANSACTION` and related classes.	**Design:** Full

ISO Section 5.2 Actors

ISO Section 5.2.1 Subject of healthcare

ISO Req't	Description	*open*EHR artifact	Conformance
MEL2.1	The EHRRA must cater for the subject of care of the EHR to be one or more persons (6.1.1)	Currently any situation in which health information for a subject other than the subject of the record, e.g. a family member, a donated organ, or a foetus is well-understood and catered for via the subject & subject_relationship attributes in `ENTRY`. Requirements for families, tribes, or other social groupings have not been widely described or analysed.	**Design:** TBD

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ISO Section 5.2.2 Patient identification

ISO Req't	Description	*open*EHR artifact	Conformance
MEL2.2	The EHRRA must cater for the recording of appropriate patient identification attributes and clinically relevant patient attributes such as date of birth, sex, ethnicity etc (6.1.2)	*open*EHR Demographic RM: all PERSONs, include patients can have any number of identifiers and other data recorded for them.	**Design:** Full **Val:** CEN, GEHR, SNX

ISO Section 5.2.3 User Identification

ISO Req't	Description	*open*EHR artifact	Conformance
MEL2.3	The EHRRA must ensure that users who attest and commit any particular information to the record are uniquely and reliably identified (6.1.3)	The EHR guarantees that distinct identifiers which occur in the EHR correspond to distinct demographic entities, i.e. that identifiers are not re-used.	**Design:** Full **Val:** GEHR, SNX
MEL2.4	The EHRRA must support the on-going ability to identify users, even if they change their name, profession, sex, or address. (6.1.3)	*open*EHR EHR RM: identifiers in the EHR referring to demographic entities managed in a demographic service always refer to the current information in that service.	**Design:** Full

ISO Section 5.2.4 Healthcare parties

ISO Req't	Description	*open*EHR artifact	Conformance
MEL2.5	The EHRRA must support measures to ensure that all clinical parties referred to in the EHR are uniquely identified (6.1.4)	*open*EHR EHR RM: Subtypes of the OBJECT_ID class are used to refer uniquely to demographic entities, including all clinical parties.	**Design:** Full
MEL2.6	The EHRRA must support the recording of the clinical roles of any parties with respect to any clinical activity recorded. (6.1.4)	*open*EHR EHR RM: Currently roles and other demographic details are defined in the demographic model and its archetypes. Roles and relationships are not yet included in the EHR architecture, but should be, in a manner similar to HL7's Act/Participation approach.	**Design:** Fut

ISO Section 5.2.5 Author responsibility

ISO Req't	Description	*open*EHR artifact	Conformance
MEL2.7	The EHRRA must support measures which ensure that every record entry is dated, its author identified. (6.1.6)	*open*EHR EHR RM: all additions to the record are in the form of `TRANSACTIONs`, which indicate the author's identity, date.time of addition.	**Design:** TBD
MEL2.8	The EHRRA must support measures to ensure that there is an absolute requirement that each contribution to the record is attributed to a responsible healthcare party whether in the role of author or not. (6.1.5)	*open*EHR EHR RM: each `TRANSACTION` in the record identifies, via its sub-objects: • participations, e.g. including HCA legally responsible (`CLINICAL_CONTEXT`) • committer (`VERSION_AUDIT`) • information_provider (`ENTRY`)	**Design:** Full **Val:** GEHR

ISO Section 5.2.6 Attestation/Authorization of entries

ISO Req't	Description	*open*EHR artifact	Conformance
MEL2.9	The EHRRA must support measures which ensure that every contribution to the record must be attested by a responsible person . (6.1.6)	*open*EHR EHR RM: every `TRANSACTION` includes a `VERSION_AUDIT` object which contains the mandatory attribute *committer*:`PARTY_REF`.	**Design:** Full **Val:** CEN, GEHR, SNX
MEL2.10	The EHRRA must support measures which ensure that amendments are attributed to a responsible person and the date and time and the reason for the amendment are recorded. (6.6)	*open*EHR EHR RM: amendments and new information are done by the same mechanism, namely `TRANSACTIONs`, which always include these details..	**Design:** Full **Val:** CEN, GEHR, SNX

ISO Section 5.3 Clinical competence/governance

ISO Req't	Description	*open*EHR artifact	Conformance
MEL3.1	The EHRRA must support the demonstration of clinical competence and accountability of clinicians (6.2)	The *open*EHR approach ensures that any addition that clinicians make to the record identifies the author, the context of care and of recording, and allows reasons for doing things to be recorded (e.g. identifying guidelines etc). Links used to represent causal and other relationships enable chains of events to be followed back in time, ensuring that, as long as all actions are recorded in the record, the record will support the clinicians' claims to have performed those actions. The ability to recreate any prior state of the record guarantees that any clinician's claim about what information was available can be supported.	**Design:** Full

ISO Section 5.4 Faithfulness

ISO Req't	Description	*open*EHR artifact	Conformance
MEL4.1	The EHRRA must ensure that information intended to supersede that already recorded and attested must be separately collected and attested as a new transaction version. (6.5.1)	*open*EHR EHR RM: this is exactly the way the *open*EHR `TRANSACTION` concept works.	**Design:** Full **Val:** GEHR
MEL4.2	The EHRRA must ensure that the exact state of the record can be re-created for any given point of time since the original creation of the EHR.	*open*EHR EHR RM: this is enabled by the versioning mechanism.	**Design:** Full

ISO Section 5.5 Preservation of context

ISO Req't	Description	*open*EHR artifact	Conformance
MEL5.1	Where coded terms in the EHR have been mapped to another coded terminology, the EHRRA must provide a means of indicating the faithfulness of the translation (6.5.2).	The *open*EHR Data Types RM: mappings between any text item (coded or not) and a coded term are explicitly modelled by the `TERM_MAPPING` class. The *match* attribute indicates the closeness of the match (broader, narrower, equivalent).	**Design:** Full
MEL5.2	The EHRRA must maintain the original context of all elements of the record irrespective of the potential separate distribution of elements (6.5.2)	The *open*EHR EHR model is based on a theory of context [2] which ensures that this exact requirement is always met.	**Design:** Full

ISO Section 5.6 Permanence

ISO Req't	Description	*open*EHR artifact	Conformance
MEL6.1	The EHRRA must ensure that attested information shall be stored in a protected mode, disallowing any changes or deletions. (6.6)	*open*EHR EHR RM: The `VERSIONED_TRANSACTION` class performs this function.	**Design:** Full **Val:** GEHR
MEL6.2	The EHRRA will ensure that amendments are attributed to a clinician and the date and time, and the reason for the amendment are recorded. (6.6)	*open*EHR EHR RM: The `VERSION_AUDIT` class records the clinician authorising committal, and date/time of committal, among other things.	**Design:** Full **Val:** GEHR

ISO Section 5.7 Version control

ISO Req't	Description	*open*EHR artifact	Conformance
MEL7.1	The EHRRA must incorporate a method of version control that supports information at the level at which it was attested (6.8)	*open*EHR EHR RM: The `VERSIONED_TRANSACTION` class performs this function.	**Design:** Full **Val:** GEHR
MEL7.2	The EHRRA must support measures to discern modification or updating of the record using version control (6.8)	*open*EHR EHR RM: The `VERSIONED_TRANSACTION` class performs this function.	**Design:** Full **Val:** GEHR

ISO Section 6 ETHICAL

Preamble

The ethical and moral justification for the creation, storage and processing of health records derives from the fact that they are instrumental for the protection of health. The foundations of the relationship between a clinician and a patient are the delivery of clinical care to the highest standard and the respect for patient autonomy. This inevitably leads to the conclusion that the right to informed consent and the right to confidentiality are also ethical/moral principles of the highest importance.

ISO Section 6.1 Support for ethical justification

ISO Req't	Description	*open*EHR artifact	Conformance
ETH1.1	The EHRRA must be able to record ethical approval for secondary uses of patient information held in the EHR (8)	No specific facility has been included for this purpose. It is expected that further research and development experience is required before this requirement can be analysed well enough to be implemented.	**Design:** No

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ISO Section 7 CONSUMER/ CULTURAL

ISO Section 7.1 Consumer issues

Preamble

Benefits of EHRs for consumers

EHRs have the potential to significantly improve quality of care and health outcomes for consumers, primarily through availability to clinicians of accurate, current information about a consumer's healthcare history. Improved access to information for both consumers and clinicians has the potential to improve communication between consumers and clinicians, resulting in more meaningful consumer participation in the healthcare process. Having access to such information is empowering, enabling people to interact as informed consumers and make sensible choices within the healthcare system.

Accommodating the needs and interest of consumers raises issues of privacy, security, confidentiality and access.

Consumer aspects of privacy, security and confidentiality

Consumers of healthcare services must be secure in the knowledge that the information they share with their clinician is treated with respect for their privacy and kept secure and confidential. Otherwise, they will be unwilling to seek appropriate care or to provide accurate and complete information. This will not only compromise their own healthcare, but will also confound programmes of clinical and health services research, health professional education and public health promotion.

Consumers' point of view

EHRs will not only be accessible to consumers but also incorporate their views and comments resulting from self-monitoring of illness, dietary notes, notes on self-monitoring of sport and exercise performance, behavioural activities and moods, etc. Consumers may also use EHRs to seek advice about improving their health or ask questions about the management of their care. A consumer's point of view is important, supporting consumer involvement and promoting communication between consumers and clinicians.

Cultural issues

Cultural issues are an essential category of information to be recognised and accommodated in the requirements for EHRs. Many cultures do not support the idea of sharing patient information. Others share information and decision making on health matters at the level of the extended family or larger group.

Some components of clinical competence are closely related to the role of clinicians in the societies in which they practice. The EHRRA must not impose the clinical practice of one society on the clinical practice of another, although it should promote ways of learning about different styles of clinical practice.

EHR development, therefore, needs to focus on community issues involving culture and consent, expectations, language, religious beliefs, individual identification and all these will determine the subsequent healthcare model.

ISO Section 7.1.1 Support for consumer issues

ISO Req't	Description	*open*EHR artifact	Conformance
COC1.1	The EHRRA must support the production of a consumer oriented view. (9.1)	*open*EHR EHR RM: Since all contributions to the record are marked with the author's identification, a view of patient-added data are easily possible. If simplification of data & presentation is required, either software applications or particular consumer-oriented archetypes would have to be developed.	**Design:** Qual

Date of Issue:20 Mar 2003

ISO Req't	Description	*open*EHR artifact	Conformance
COC1.2	The EHRRA must support consumers' right of access to all EHR information subject to jurisdictional constraints. (9.1)	The *open*EHR models do not predetermine any particular model of access; they support whichever access control model is required to be used in a given usage scope.	**Design:** Qual
COC1.4	The EHRRA must support consumers being able to incorporate self-care information, their point of view on personal healthcare issues, levels of satisfaction, expectations and comments they wish to record in EHRs. (9.1)	*open*EHR EHR RM: Self-care information is added in the same way as any information is added by a clinician. Personal comments, expectations etc can be added according to consumer-oriented archetypes which are developed for this purpose.	**Design:** Qual

ISO Section 7.2 Cultural issues

ISO Section 7.2.1 Support for cultural issues

ISO Req't	Description	*open*EHR artifact	Conformance
COC2.1	The EHRRA must support interoperability in a way that is truly global, yet respects local customs and culture. It follows that the process must be both simple and amenable to customisation in different jurisdictions. (9.2)	General support for interoperability occurs with the approach of using a generic model which does not describe any specific clinical or medical concepts. *open*EHR Data Types: Data interoperability is supported as follows: · all coded terms include terminology identifier · all text types use UNICODE *open*EHR EHR RM: Other aspects of interoperability: · the structure of the record is essentially container/headings/structured data, and data may be as minimally or maximally structured as desired. *open*EHR Archetype systems: The archetpe system provides the most powerful basis for semantic interoperability, while allowing local definition and customisation of archetypes according to required medical and social cultures.	**Design:** Full

ISO Section 8 EVOLUTION

Preamble

To enable the creation and maintenance of life-time longitudinal electronic health records, it is necessary to ensure that both EHRs and EHR software are "future proof". Technology will continue to change rapidly. This means that the EHRRA must be effectively technology independent. The EHR architecture must therefore be able to accommodate new forms of clinical knowledge (e.g. genomics and proteomics) which may include not only new clinical content but also completely new types of data. On the other hand, legacy systems will persist long into the future and it is therefore necessary that a standard-compliant EHRRA must be able to support legacy data.

ISO Section 8.1 Support for EHR architecture and EHR system evolution

ISO Req't	Description	*open*EHR artifac
EVO1.1	Backwards compatibility of EHR software: Any implementation of the EHRRA must be able to process EHRs created under older versions of the EHRRA (10.1.1)	This requirement is satisfied by the use o what constitutes a new version of the *op* New software versions are not allowed t data model elements, only add new ones wards compatibility of software.
EVO1.2	Backwards compatibility of the EHR: Software built on a previous version of the EHRRA must be capable of processing EHRs created under a newer version of the EHRRA (10.1.1)	This requirement is satisfied by the use o what constitutes a new version of the *op* New versions are not allowed to invalidat el elements, only add new ones, guarante ibility of data.
EVO1.3	The EHRRA must be able to accommodate the recording of information due to new forms of clinical knowledge, new clinical disciplines, and new clinical practices and processes (10.1.1)	The *open*EHR two-level modelling appr reference models; second level = domai archetypes) is designed precisely to satis a formal, systematic way.

3 Summary of Conformance Exceptions

4 ISO Requirements Requiring Review

A References

Publications

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4 Kalra D. (Editor). The Synapses User Requirements and Functional Specification (Part A). EU Telematics Application Programme, Brussels; 1996; The Synapses Project: Deliverable USER 1.1.1a. 6 chapters, 176 pages.

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Resources

9 GEHR Australia: http://www.gehr.org.

10 GEHR - Good European Health Record. Available at http://www.chime.ucl.ac.uk/.

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