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Second edition
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Health informatics — Electronic health record communication —

Part 5: Interface specification

Informatique de santé — Communication du dossier de santé informatisé —

Partie 5: Spécification d'interfaces

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*.

This second edition cancels and replaces the first edition (ISO 13606-5:2010), which has been technically revised. The main changes compared to the previous edition are as follows:

— Removal of properties from the interface specifications that no longer correspond to properties in the Reference Model defined in ISO 13606-1.

A list of all parts in the ISO 13606 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

This document is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement. In this document, dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Preface

This document defines the interfaces by which an EHR_EXTRACT, an ARCHETYPE or an EHR_AUDIT_LOG_EXTRACT may be requested and provided.

The scope of this document has been considered carefully in order to achieve several objectives:

— to specify those interfaces that are unique to the 13606 context, and not to include more generic health information communication interfaces that might be the scope of other standards and specifications;

— to specify the interfaces in ways that are compatible with the HISA standard series (ISO 12967 all parts);

— to specify the interfaces as computational viewpoints, in order to support the wide range of engineering viewpoints that might be adopted by individual vendors or eHealth programmes; (it should be noted that ISO 13606-1, ISO 13606-2 and ISO 13606-4 define the corresponding information viewpoints, and that ISO 18308 defines the corresponding enterprise viewpoint);

— to construct these interfaces such that they might easily be implemented as specialisations of standard interfaces within the commonly used engineering languages such as Java, Visual Basic, dotnet, SOAP, ebXML etc.;

— to work through the joint SDO Initiative and Council on the production of Engineering Viewpoint Implementation Guides, that will define more specifically how to implement these interfaces, for example in HL7 version 3; these guides will be published separately from ISO 13606-5, to enable them to be maintained and updated more frequently (to reflect implementation experience) than is possible for a standards document;

— to recognise that EHR communication will be implemented within a healthcare communications infrastructure, usually nationally, that will define a generalised approach to many other complementary and necessary services such as patient demographics registries, provider registries, authentication and authorisation policies and services etc.; these are therefore not part of the formal scope of ISO 13606-5 but are referred to as being assumed and necessary complementary services;

— to require an ISO/TS 22600 series (PMAC) compatible architecture or its equivalent will be used for managing security services, and not to duplicate or conflict with these services in this document;

— to further support the protection of patient privacy by avoiding the need to reveal if any EHR data has been withheld by the provider when responding to a request;

— to enable each interface and term set to be extended locally to cater for specialised circumstances of EHR communication, in which additional requirements constraints might apply.

This document defines a set of interfaces by which the artefacts defined in ISO 13606-1, ISO 13606-2 and ISO 13606-4 may be requested and provided:

a) ISO 13606-1 defines a reference model for an EHR_EXTRACT: part or all of the EHR of a subject of care;

b) ISO 13606-2 defines an information model for an ARCHETYPE, and optionally a serialised form represented using Archetype Definition Language;

c) ISO 13606-4 defines an EHR_AUDIT_LOG_EXTRACT to communicate the audit log activity history pertaining to part or all of an EHR.

(ISO 13606-3 defines term lists and reference archetypes, to which a direct interface is not required. ISO 13606-4 defines an access policy model to which a direct interface is also not required.)

This document defines three interfaces, one for each of a-c above, as a communication between an *EHR_requester* (wishing to and authorising the communication of the artefact), an *EHR_provider* (a repository service that contains and can return the requested artefact) and an *EHR_recipient* who is intended and authorised to receive the artefact (usually but not always the same as the *EHR_requester*).

These interfaces are all expressed as Computational Viewpoint specifications and aim to support implementation through many different Engineering Viewpoint (transport) formalisms, such as message protocols (e.g. EDIFACT, HL7 version 3) or service protocols (e.g. SOAP, Java RMI). This document therefore specifies only the "payload" information to be communicated at each interface. Attributes such as message identifiers, message time-stamping and message version management are normally defined and handled by each kind of transport protocol in particular ways, and this document therefore does not define its own duplication of this kind of information. It should be noted that the EHR_EXTRACT defined in ISO 13606-1, the ARCHETYPE defined in ISO 13606-2, and the EHR_AUDIT_LOG_EXTRACT defined in ISO 13606-4 all include time-stamping, authorship and version management information of the payload data as part of their information models.

Request acknowledgements and system/communication error messages are routinely handled by most engineering transport protocols. It is also not appropriate that this document duplicates these. An optional exception is defined to communicate back to the EHR_requester a reason why a request has been received but refused, if it is legitimate to reveal this without breaching confidentiality.

The EHR_requester will need to authenticate to the EHR_provider in ways that are to be locally determined, and will present authorisation credentials that are also beyond the scope of this document but are specified in the ISO 22600 series (PMAC). It is recognised that there might be times when an EHR_requester wishes the EHR_provider to "send" the EHR_EXTRACT to a third party. This document may be used within a delegation architecture, in which an EHR_requester acts on behalf of another party, but the representation and communication of the hierarchy of authorisations involved in delegation is a matter for the privilege management and access control architecture and does not directly impact on this document. Alternatively, local arrangements may be made to securely communicate to a third party a unique reference for any particular RECORD_COMPONENT (e.g. for a particular letter or discharge summary, via the ehr-id and rc_id of the COMPOSITION) that the third party is recommended to and has permission to access directly, without therefore requiring the use of delegation.

Health informatics — Electronic health record communication —

Part 5: Interface specification

1 Scope

This document specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. This document is not intended to specify the internal architecture or database design of such systems.

The subject of the record or record extract to be communicated is an individual person, and the scope of the communication is predominantly with respect to that person's care.

Uses of healthcare records for other purposes such as administration, management, research and epidemiology, which require aggregations of individual people's records, are not the focus of this document but such secondary uses could also find the document useful.

This document defines a set of interfaces to request and provide:

— an EHR_EXTRACT for a given subject of care as defined in ISO 13606-1;

— one or more ARCHETYPE(s) as defined in ISO 13606-2;

— an EHR_AUDIT_LOG_EXTRACT for a given subject of care as defined in ISO 13606-4.

This document defines the set of interactions to request each of these artefacts, and to provide the data to the requesting party or to decline the request. An interface to query an EHR or populations of EHRs, for example for clinical audit or research, are beyond its scope, although provision is made for certain selection criteria to be specified when requesting an EHR_EXTRACT which might also serve for population queries.

This document defines the Computational Viewpoint for each interface, without specifying or restricting particular engineering approaches to implementing these as messages or as service interfaces.

This document effectively defines the payload to be communicated at each interface. It does not specify the particular information that different transport protocols will additionally require, nor the security or authentication procedures that might be agreed between the communicating parties or required by different jurisdictions.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13606-1, *Health informatics — Electronic health record communication — Part 1: Reference model*

ISO 13606-2, *Health informatics — Electronic health record communication — Part 2: Archetype interchange specification*

ISO 13606-4, *Health informatics — Electronic health record communication — Part 4: Security*

ISO TS 14265, *Health Informatics — Classification of purposes for processing personal health information*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13606-1, ISO 13606-2, ISO 13606-4 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
electronic health record requester
entity initiating a request for electronic health record communication to take place between an electronic health record provider and an electronic health record recipient

3.2
electronic health record recipient
entity to whom electronic health record data is communicated by an electronic health record provider

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

CORBA	Common Object Request Broker Architecture
ebXML	Electronic Business XML
EDIFACT	Electronic Data Interchange For Administration, Commerce and Transport
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HISA	Health Information Systems Architecture
HL7	Health Level Seven
ISO	International Organization for Standardization
PMAC	Privilege Management and Access Control
RMI	Remote Method Invocation
SDO	Standards Development Organisation
SOAP	Simple Object Access Protocol
UML	Unified Modelling Language
XML	Extensible Mark-up Language

5 Conformance

5.1 A message or service interface that serves to request part or all of the Electronic Health Record (EHR) of a subject of care shall include all of the information specified as mandatory in 7.1, and shall include any of the information specified as optional in 7.1. An EHR_provider shall be able to receive

and process all of the mandatory and optional parameters in the request. The provision of an EHR_EXTRACT in response to this request, or the refusal to do so, shall conform to 7.1.

5.2 A message or service interface that serves to request one or more Archetypes shall include all of the information specified as mandatory in 7.2, and shall include any of the information specified as optional in 7.2. An EHR_provider shall be able to receive and process all of the mandatory and optional parameters in the request. The provision of ARCHETYPES in response to this request, or the refusal to do so, shall conform to 7.2.

5.3 A message or service interface that serves to request part or all of the Audit Log pertaining to an Electronic Health Record (EHR) of a subject of care shall include all of the information specified as mandatory in 7.3, and shall include any of the information specified as optional in 7.3. An EHR_provider shall be able to receive and process all of the mandatory and optional parameters in the request. The provision of an EHR_AUDIT_LOG_EXTRACT in response to this request, or the refusal to do so, shall conform to 7.3.

5.4 The information specified in 7.1 to 7.3 shall be included as parameters, arguments or message segments within the communications artefact, as appropriate to the engineering paradigm adopted. These interfaces can be locally extended to include additional information that is locally relevant, but such extensions cannot be mandated outside of the jurisdiction in which they have been agreed.

6 Interactions

6.1 Introduction

The five parts of ISO 13606 define the way in which the following may be communicated:

— part or all of the EHR (an EHR_EXTRACT, as defined in ISO 13606-1);

— an Archetype (an ARCHETYPE, as defined in ISO 13606-2);

— an Audit Log (an EHR_AUDIT_LOG_EXTRACT, as defined in ISO 13606-4).

ISO 13606-1, ISO 13606-2, ISO 13606-3 and ISO 13606-4 specify the information models and terminology that together define the Information Viewpoint for EHR communication. This document defines the set of communications interfaces (the Computational Viewpoint).

This Computational Viewpoint is deliberately expressed in a way that is generic to the many possible Engineering Viewpoint approaches that might be used to implement these interfaces, for example via messages or services, using standards such as HL7 v3, EDIFACT, ebXML, Java, CORBA, SOAP etc. This document is also generic in terms of the user interaction scenarios it formally supports. There are many use cases in health care that require the communication (or sharing) of EHR data, which can involve many different kinds of actor (e.g. healthcare professionals, patients, families and carers, managers, researchers and legal representatives) and system (e.g. clinical application, hand-held application, EHR system, decision support, reporting, security or audit systems). The communication can take place within or between organisations, or across a health care network.

Several examples of these use cases are listed below.

A clinician looking after a subject of care in a district hospital wishing to read any recent COMPOSITIONS in the EHR system of the subject's GP; in this case the parameters in the request will include a date range.

A GP looking after a subject of care wishing to read any COMPOSITIONS documenting recent progress made in the management of the subject's cancer care in the EHR system of the local hospital; in this case the parameters in the request will include a date range and could specify the inclusion of certain kinds of clinical entry through the inclusion of certain archetypes (using the *archetype_ids* parameter).

An emergency triage nurse wishing to identify all medications prescribed to the subject of care over the past year right across the health system by requesting EHR_EXTRACT(S) that contain medication entries from a national EHR repository or national virtual EHR.

A GP retrieving the full EHR for a subject of care held in the EHR system of another GP (including all versions of each COMPOSITION) in order to effect a complete transfer of care between the GPs.

A physiotherapist wishing to retrieve a COMPOSITION (not held locally) that is the target of a LINK within a COMPOSITION already held locally in the EHR system, for example to the consultation that was the presentation of an injury that triggered the physiotherapy referral; the request will include a specific rc_id as the value of the *rc_ids* parameter.

A clinical system administrator who has been asked to develop a new screen and reports for the management of diabetic ketoacidosis, wishing to request and download the most recent archetypes for representing this information from the certified archetype repository maintained by a national diabetes professional organisation.

A subject of care who is also a member of staff at a hospital, wishing to examine the audit log of their recent in-patient stay to see who has accessed their EHR.

All of these scenarios have in common that EHR data (an EHR Extract, an Archetype or an Audit Log) are being requested by one process and provided by another process, or the request may be declined. In this document, the party or service making the request is termed the *EHR_requester*, the party or service with capability to provide EHR data of a kind defined by this document is termed the *EHR_provider,* the party or service who will receive the data is termed the *EHR_recipient*. Although many different concrete scenarios will exist for EHR Communication, at a logical level they can all be subsumed by the following interaction diagram (see Figure 1).

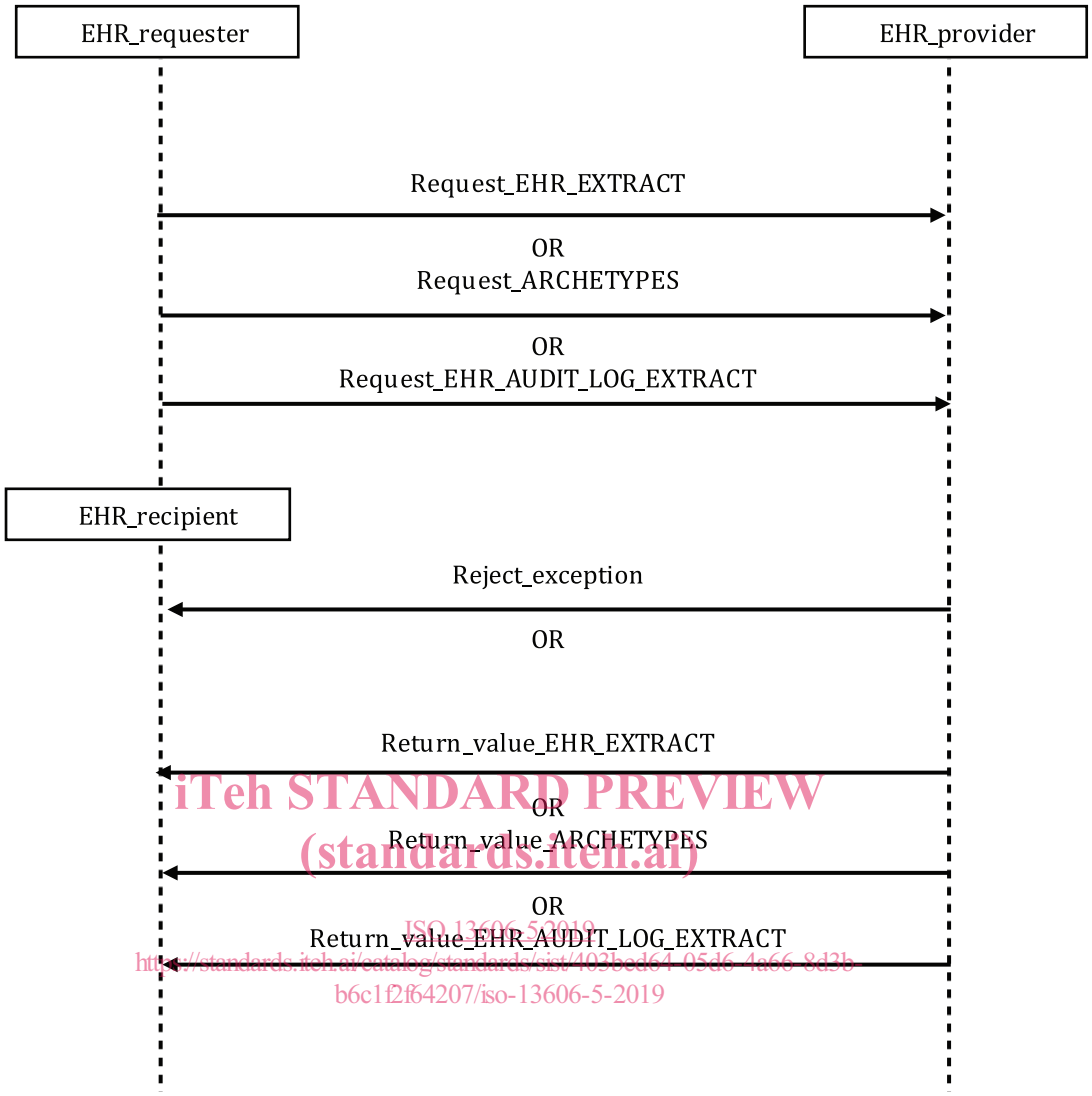

Figure 1 — Interaction Diagram to depict the set of interfaces that are in scope for this document

In order to implement and operationalise these interactions, several additional steps will need to be taken that are beyond the scope of this document.

The EHR_provider will need to be located, and the services it supports established, via a published directory, service locator or through prior knowledge of the EHR_requester. Once located the relevant service interfaces needs to be accessible to the communicating parties (e.g. relevant authorizations need to be in place).

The authentication and authorisations (privileges) of the EHR_requester will need to be known in advance by the EHR_provider or the latter will require access to a means of verifying these at the time of the request.

Any more detailed security policies and security measures that are necessary to comply with organisational, professional or jurisdictional regulations will need to be in place to support the communication.

Certain identifiers used in the request, such as that for the subject of care, will need to be agreed in advance or be capable of de-referencing to demographic traits or cross-referencing to alternative identifiers at the time of the request.