BSI Standards Publication

Health informatics - Electronic health record communication

Part 5: Interface specification

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 13606-5:2019. It is identical to ISO 13606-5:2019. It supersedes BS EN ISO 13606-5:2010, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2019

ISBN 978 0 580 81953 7

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2019.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD EN ISO 13606-5

NORME EUROPÉENNE

EUROPÄISCHE NORM July 2019

ICS 35.240.80 Supersedes EN ISO 13606-5:2010

English Version

Health informatics - Electronic health record communication - Part 5: Interface specification (ISO 13606-5:2019)

Informatique de santé - Communication du dossier de santé informatisé - Partie 5: Spécification d'interfaces (ISO 13606-5:2019)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 5: Interface Spezifikation (ISO 13606-5:2019)

This European Standard was approved by CEN on 2 July 2019.

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 13606-5:2019: E

European foreword

This document (EN ISO 13606-5:2019) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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

This document supersedes EN ISO 13606-5:2010.

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

Endorsement notice

The text of ISO 13606-5:2019 has been approved by CEN as EN ISO 13606-5:2019 without any modification.

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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*