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del: Varnost (ISO/FDIS 13606-4:2026)

Health informatics - Electronic health record communication - Part 4: Security (ISO/FDIS 13606-4:2026)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 4: Sicherheit (ISO/FDIS 13606-4:2026)

Informatique de santé - Communication du dossier de santé informatisé - Partie 4: Sécurité (ISO/FDIS 13606-4:2026)

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FINAL DRAFT

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ISO/FDIS 13606-4

Health informatics — Electronic health record communication —

Part 4: Security

Informatique de santé — Communication du dossier de santé informatisé —

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviations	2
5 Conformance	2
6 Record Component Sensitivity and Functional Roles	3
6.1 RECORD_COMPONENT sensitivity	3
6.2 Functional roles	3
6.3 Mapping of Functional Role to COMPOSITION sensitivity	4
7 Representing access policy information within an EHR_EXTRACT	4
7.1 Overview	4
7.2 UML representation of the archetype of the access policy COMPOSITION	6
7.3 Access policy model properties	7
7.3.1 Access policy	7
7.3.2 Target	7
7.3.3 Request criterion	8
7.3.4 Sensitivity constraint	9
7.3.5 Attestation information	10
7.4 Archetype of the access policy COMPOSITION	11
8 Representing audit log information	11
8.1 General	11
8.2 EHR audit log extract	12
8.3 Audit log constraint	12
8.4 EHR audit log entry	13
8.5 EHR extract description	14
8.6 Demographic extract	15
Annex A (informative) Illustrative access control example	16
Annex B (informative) Relations of this document to alternative approaches	20
Bibliography	22

ISO/FDIS 13606-4:2026(en)

Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 13606-4:2019), of which it constitutes a minor revision. The changes are as follows:

- the tables in [Clause 7](#) and [Clause 8](#) have been numbered;
- the examples in [Annex B](#) have been anonymized;
- corrections were made to [Clause 2](#) and [Clause 3](#) to reflect the technical content of the document.

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.

ISO/FDIS 13606-4:2026(en)

Introduction

0.1 General

This document is part of a series including five parts. In this document, dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Challenge addressed by this document

The communication of electronic health records (EHRs) in whole or in part, within and across organisational boundaries, and sometimes across national borders, is challenging from a security perspective. Health records should be created, processed and managed in ways that assure the confidentiality of their contents and legitimate control by patients in how they are used. Around the globe, these principles are progressively becoming enshrined in national data protection legislation. These instruments declare that the subject of care has the right to play a pivotal role in decisions on the content and distribution of their EHR, as well as the right to be informed of its contents. The communication of health record information to third parties should take place only with patient consent (which can be any freely-given specific and informed indication of their wishes, by which the data subject signifies their agreement to personal data relating to them being processed in an ethically-acceptable way). More details can be found in ISO 22600-3 [1]. For EHR communication across national borders, ISO 22857 [2] provides guidance that can be used to define appropriate security policy specifications.

Ideally, each fine-grained entry in a patient's record should only be accessed by those persons who have permissions to view that information, specified by or approved by the patient and reflecting the dynamic nature of the set of persons with legitimate duty of care towards the patient through their lifetime. The access control list will ideally also include those persons who have permissions to access the data for reasons other than a duty of care (such as health service management, epidemiology and public health, consented research) but exclude any information that they do not need to see or which the patient feels is too personal for them to access. On the opposite side, the labelling by patients or their representatives of information as personal or private should ideally not hamper those who legitimately need to see the information in an emergency, nor accidentally result in genuine health care providers having such a filtered perspective that they are misled into managing the patient inappropriately. Patients' views on the inherent sensitivity¹⁾ of entries in their health records can evolve over time, as their personal health anxieties alter or as societal attitudes to health problems change. Patients might wish to offer some heterogeneous levels of access to family, friends, carers and members of their community. Families might wish to provide a means by which they are able to access parts of each other's records (but not necessarily to equal extents) in order to monitor the progress of inherited conditions within a family tree.

Such a set of requirements is arguably more extensive than that required of the data controllers in most other industry sectors. It is in practice made extremely complex by:

- the large number of health record entries made on a patient during the course of modern health care;
- the large number of health care personnel, often rotating through posts, who can potentially come into contact with a patient at any one time;
- the large number of organisations with which a patient can come into contact during their lifetime;
- the difficulty (for a patient or for anyone else) of classifying in a standardized way how sensitive a record entry can be;
- the difficulty of determining how important a single health record entry can be to the future care of a patient, and to which classes of user;
- the logically indelible nature of the EHR and the need for revisions to access permissions to be rigorously managed in the same way as revisions to the EHR entries themselves;

1) The term sensitivity is widely used in the security domain for a broad range of safeguards and controls, but in this document the term refers only to the characteristic of a resource (EHR data) that implies its value or importance (and by implication the extent of confidentiality and therefore to the functional roles that should have access to it).

ISO/FDIS 13606-4:2026(en)

- the need to determine appropriate access very rapidly, in real time, and potentially in a distributed computing environment;
- the high level of concern expressed by a growing minority of patients to have their consent for disclosure recorded and respected;
- the low level of concern the majority of patients have about these requirements, which has historically limited the priority and investment committed to tackling this aspect of EHR communications.

To support interoperable EHRs, and seamless communication of EHR data between health care providers, the negotiation required to determine if a given requester for EHR data should be permitted to receive the data should be capable of automation. If this were not possible, the delays and workload of managing human decisions for all or most record communications would obviate any value in striving for data interoperability.

The main principles of the approach to standards development in the area of EHR communications access control are to match the characteristics and parameters of a request to the EHR provider's policies, and to any access control or consent declarations within the specified EHR, to maintain appropriate evidence of the disclosure, and to make this capable of automated processing. In practice, efforts are in progress to develop international standards for defining access control and privilege management systems that would be capable of computer-to-computer negotiation. However, this kind of work is predicated upon health services agreeing a mutually consistent framework for defining the privileges they wish to assign to staff, and the spectrum of sensitivity they offer for patients to define within their EHRs. This requires consistency in the way the relevant information is expressed, to make this sensibly scalable at definition-time (when new EHR entries are being added), at run-time (when a whole EHR is being retrieved or queried), and durable over a patient's lifetime. It is also important to recognize that, for the foreseeable future, diversity will continue to exist between countries on the specific approaches to securing EHR communications, including differing legislation, and that a highly prescriptive approach to standardization is not presently possible.

This document therefore does not prescribe the access rules themselves. It does not specify who should have access to what and by means of which security mechanisms; these need to be determined by user communities, national guidelines and legislation. However, it does define a basic framework that can be used as a minimum specification of EHR access policy, and a richer generic representation for the communication of more fine-grained detailed policy information. This framework complements the overall architecture defined in ISO 13606-1 [3], and defines specific information structures that are to be communicated as part of an EHR_EXTRACT defined in ISO 13606-1 [3]. Some of the kinds of agreement necessary for the security of EHR communication are inevitably outside the scope of this document, and are covered more extensively in the ISO 22600 [4] series.

It should be noted that there are a number of explicit and implicit dependencies on use of other standards alongside this document, for overall cohesion of an interoperable information security deployment. In addition to agreement about the complete range of appropriate standards, a relevant assurance regime would be required (which is beyond the scope of this document).

0.3 Communication scenarios

0.3.1 Data flows

The interfaces and message models required to support EHR communication are the subject of ISO 13606-5 [5]. The description here is an overview of the communications process in order to show the interactions for which security features are needed. [Figure 1](#) illustrates the key data flows and scenarios that are considered by this document. For each key data flow there will be an acknowledgement response, and optionally a rejection may be returned instead of the requested data.

ISO/FDIS 13606-4:2026(en)

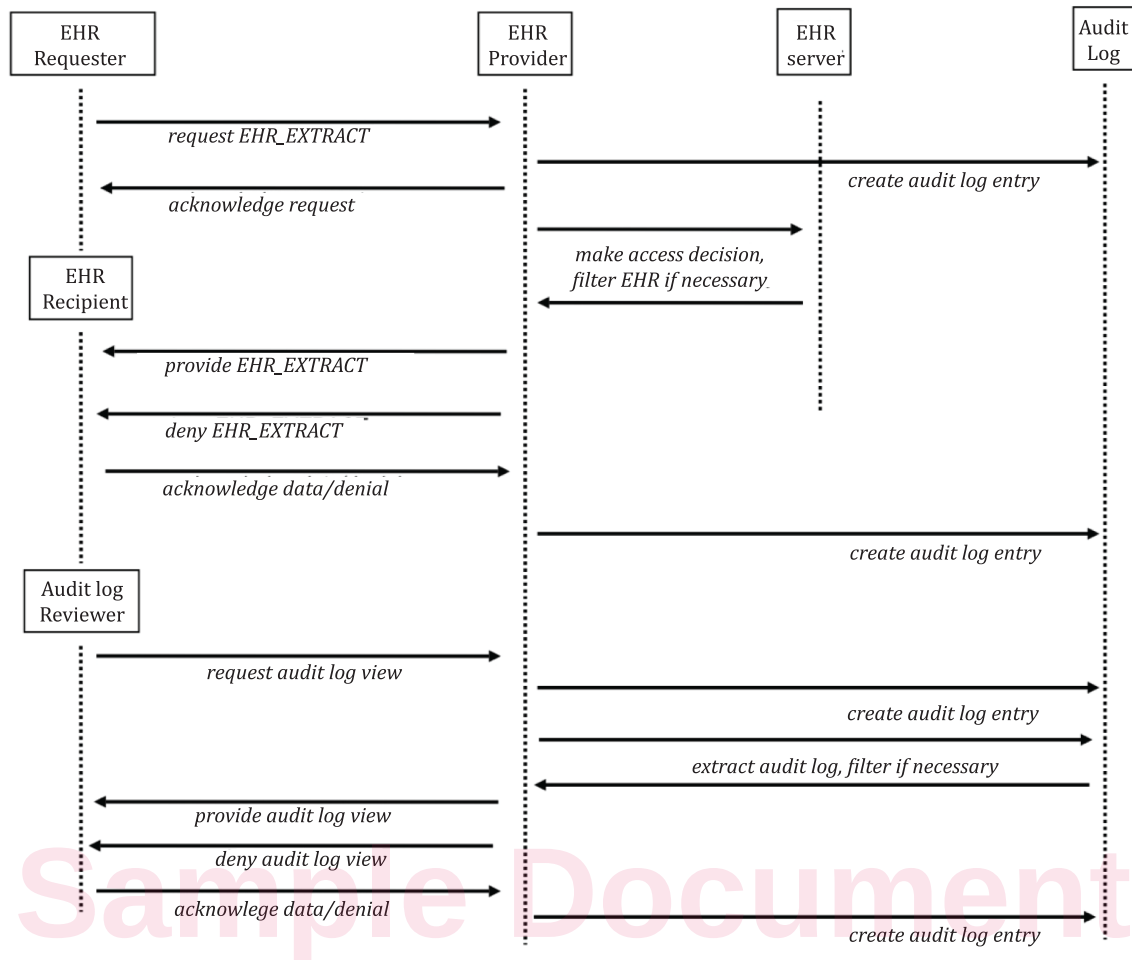


Figure 1 — Principal data flows and security-related business processes covered by this document

The EHR Requester, EHR Recipient and Audit Log Reviewer can be healthcare professionals, the patient, a legal representative or another party with sufficient authorization to access healthcare information. Both the EHR_EXTRACT and the audit log, if provided, might need to be filtered to limit the disclosure to match the privileges of the recipient. This aspect of access control is discussed later in this introduction (all parties shown here will need to maintain an audit log, not just the EHR Provider. However, for readability the other audit log processes are not shown or described here).

The following subclauses describe each data flow in [Figure 1](#).

0.3.2 Request EHR data

This interaction is not always required (for example, EHR data might be pushed from Provider to Recipient as in the case of a discharge summary). The request interface needs to include a sufficient profile of the Requester to enable the EHR Provider to be in a position to make an access decision, to populate an audit log, and provide the appropriate data to the intended Recipient. In some cases the EHR Requester might not be the same party as the EHR Recipient – for example a software agent might trigger a notification containing EHR data to be sent to a healthcare professional. In such cases it is the EHR Recipient's credentials that will principally determine the access decision to be made.

An EHR request might need to include or reference consents for access and mandates for care, for example by providing some form of explicit consent from the patient, or a care mandate.

The negotiation between Requester and Provider of EHR data will increasingly be automated, and the information included in this interaction should be sufficient to enable a fully computerised policy negotiation.

ISO/FDIS 13606-4:2026(en)

The requirements for this interaction will be reflected in the REQUEST_EHR_EXTRACT interface model defined in ISO 13606-5 [5].

0.3.3 Generate EHR access log entry

This is assumed practice in any EHR system, but it is not specified as a normative interface because of the diverse approaches and capabilities in present-day systems. The internal audit systems within any EHR system are not required to be interoperable except in support of the model defined in [Clause 8](#) of this document and the corresponding interface defined in ISO 13606-5 [5].

0.3.4 Acknowledge receipt of the EHR request

No healthcare-specific security considerations.

0.3.5 Make access decision, filter EHR data

When processing the EHR request, policies pertaining to the EHR Provider and access policies in the EHR itself all need to be taken into account in determining what data are extracted from the target EHR. This document cannot dictate the overall set of policies that might influence the EHR Provider, potentially deriving from national, regional, organisation-specific, professional and other legislation.

A decision to filter the EHR data on the basis of its sensitivity and the privileges of the EHR Requester and Recipient will need to conform to relevant policies and might need to balance the clinical risks of denying access to information with the medico-legal risks of releasing information.

This document however does define an overall framework for representing in an interoperable way the access policies that might relate to any particular EHR, authored by the patient or representatives. These might not be stored in the physical EHR system in this way; they might instead, for example, be integrated within a policy server linked to the EHR server.

This access decision is discussed in more detail in [Clause 7](#).

0.3.6 Deny provision of the EHR_EXTRACT

If the access decision is to decline, a coarse-grained set of reasons needs to be defined in order to frame a suitable set of responses from the EHR Provider. However, it is important that the denial and any reason given does not imply to the recipient that the requested EHR data does exist – even the disclosure of its existence could itself be damaging to a patient.

No healthcare-specific security considerations – the interface model is defined in ISO 13606-5 [5].

0.3.7 Provide the EHR_EXTRACT

It should be noted that the EHR Recipient need not be the same as an EHR Requester, and indeed the provision of an EHR need not have been triggered by a request. It might instead have been initiated by the provider as part of shared care pathway or to add new data to an existing EHR.

The EHR_EXTRACT is required to conform to the Reference Model defined in ISO 13606-1 [3], and to the interface model defined in ISO 13606-5 [5].

The EHR_EXTRACT should include or reference any relevant access policies, represented in conformance with this document, to govern any onward propagation of the EHR data being communicated. Policies may only be referenced if the EHR recipient is known to have direct access to the same information by another means.

0.3.8 Acknowledge receipt of EHR_EXTRACT

No healthcare-specific security considerations.

0.3.9 Generate EHR access log entry

As described in 0.3.3.

0.3.10 Request EHR access log view

ISO/FDIS 13606-4:2026(en)

This is now considered to be desirable practice, to enable a patient to discover who has accessed part or all of their EHR in an information-sharing environment. The scope of this interface, as defined in this document, is to request a view of the audit log that informs the recipient about who has accessed what parts of his or her EHR within a given EHR system, and when. This interface is not intended to support situations where a full inspection of an audit log is required for legal purposes or for other investigations. This interface is discussed in [Clause 6](#).

The interface model is defined in ISO 13606-5 [\[5\]](#).

0.3.11 Generate EHR access log entry

As described in 0.3.3.

0.3.12 Provide EHR access log view

This is desirable practice, and requires an interoperable representation of such an entry (or set of entries). This interface is discussed in [Clause 6](#).

Although a legal investigation will require that an audit log is provided in a complete and unmodified form, the presentation of an audit log view to a patient or to a healthcare professional might require that some entries are filtered out (such as those referring to EHR data to which the patient does not have access).

The interface model is defined in ISO 13606-5 [\[5\]](#).

0.3.13 Deny EHR access log view

If the request is not to be met, a coarse-grained set of reasons needs to be defined. However, it is important that the denial and any reason given does not imply to the recipient that the requested EHR data does exist – even the disclosure of its existence could itself be damaging to a patient.

No healthcare-specific security considerations – the interface model is defined in ISO 13606-5.

0.3.14 Acknowledge receipt of EHR access log view

No healthcare-specific security considerations.

0.3.15 Generate EHR access log entry

As described in 0.3.3.

0.4 Requirements and technical approach

0.4.1 Generic healthcare security requirements

The most widely accepted requirements for an overall security approach in domains handling sensitive and personal data are published in ISO/IEC 27002 [\[6\]](#). This specifies the kinds of measures that should be taken to protect assets such as EHR data, and ways in which such data might safely be communicated as part of a distributed computing environment. A health specific guide to this general standard has been published in ISO 27799 [\[7\]](#). This will facilitate the formulation of common security policies across healthcare, and should help promote the adoption of interoperable security components and services. The ISO 22600 [\[8\]](#) series defines a comprehensive architectural approach to formally and consistently defining and managing such policies. For EHR communication across national borders ISO 22857 [\[2\]](#) provides guidance that can be used to define appropriate security policy specifications.

The exact security requirements that need to be met to permit any particular EHR communication instance will be governed by a number of national and local policies at both the sending and receiving sites, and at any intermediate links in the communications chain. Many of these policies will apply to healthcare communications in general, and will vary between countries and clinical settings in ways that cannot and should not be directed by this document. The approach taken in drafting this document has therefore been to assume that generic security policies, components and services will contribute to a negotiation phase (the “access decision”) prior to sanctioning the communication of an EHR Extract, and will protect the actual EHR data flows.

ISO/FDIS 13606-4:2026(en)

This document therefore requires that an overall security policy or set of policies conforming to ISO 27799 [7] is in place at all of the sites participating in an EHR communication, and assumes that these policies conform to national or trans-border data protection legislation. Additional policies might be required to conform to specific national, local, professional or organisation regulations applicable to the communication or use of EHR data. Defining such policies is beyond the scope of this document.

0.4.2 Relationship to other related security standards

Legitimate access to EHR data will be determined by a wide range of policies, some of which might exist as documents, some will be encoded within applications, and some within formal authorization system components. It is recognized that vendors and organisations differ in how they have implemented access control policies and services, and the extent to which these are presently computerized.

The ISO 22600 [8] series defines a generic logical model for the representation of the privileges of principals (entities), of access control policies that pertain to potential target objects, and of the negotiation process that is required to arrive at an access decision. Figure 2 depicts the concepts of Role Based Access Control defined in the ISO 22600 [8] series.

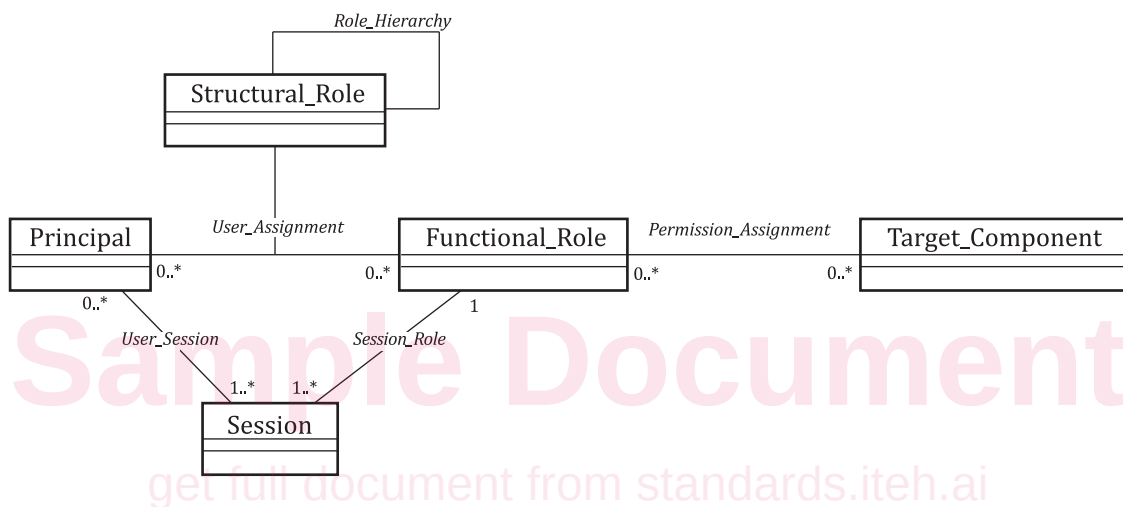


Figure 2 — Main concepts and policy types defined in Role Based Access Control [ISO 22600 [8] series]

Defining constraints on roles, processes, target objects and related privileges by policies, Figure 2 turns into Figure 3, according to the ISO 22600 [8] series.

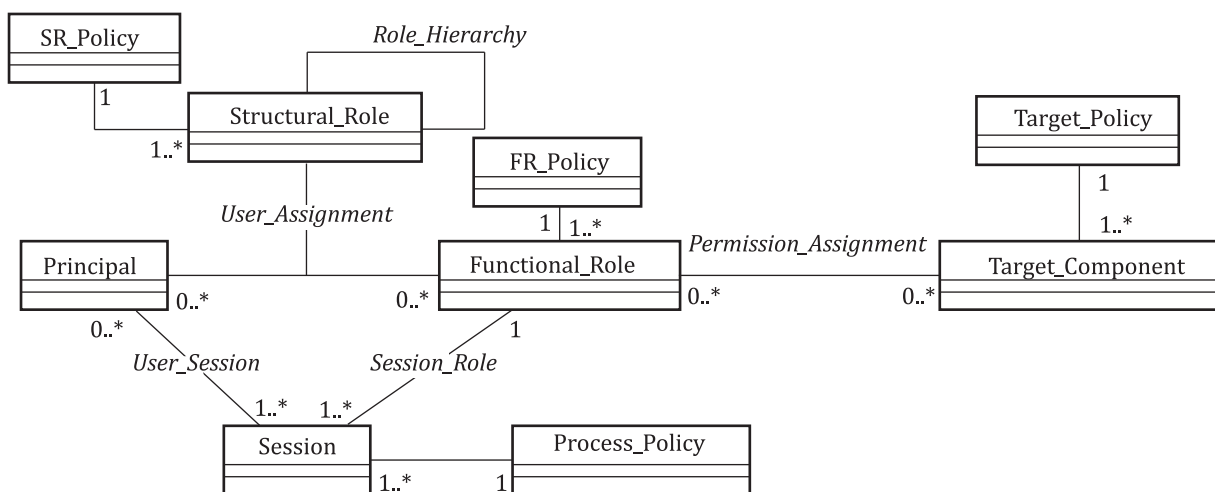


Figure 3 — Policy-driven RBAC Schema