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Irish Standard
I.S. EN ISO 13606-4:2019

Health informatics - Electronic health record communication - Part 4: Security (ISO 13606-4:2019)

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National Foreword

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13606-4

July 2019

ICS 35.240.80

Supersedes EN 13606-4:2007

English Version

Health informatics - Electronic health record communication - Part 4: Security (ISO 13606-4:2019)

Informatique de santé - Communication du dossier de santé informatisé - Partie 4: Sécurité (ISO 13606-4:2019)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 4: Sicherheit (ISO 13606-4:2019)

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Ref. No. EN ISO 13606-4:2019 E

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European foreword

This document (EN ISO 13606-4:2019) 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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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INTERNATIONAL STANDARD

ISO 13606-4

First edition
2019-06

Health informatics — Electronic health record communication —

Part 4: Security

Informatique de santé — Communication du dossier de santé informatisé —

Partie 4: Sécurité

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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).

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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 first edition of ISO 13606-4 cancels and replaces the first edition of ISO/TS 13606-4:2009, which has been technically revised. The main changes compared to the previous edition are as follows:

— Functional Roles

  — Some terms for functional roles have been updated to align with CONTSYS.

  — The rules for using this vocabulary now state that jurisdictions can nominate alternatives or specialisations of these terms if needed.

— Access policy model

  The access policy model now also permits jurisdictional alternative terms to be used where appropriate.

— Audit log model

  The audit log model now aligns with the ISO 27789 standard for EHR audit trails. It contains more information than is present in ISO 27789: it is a kind of specialisation specifically dealing with the communication of EHR information and audit log information. It therefore includes information about the EHR extract or the audit log extract being communicated, which is beyond the scope of ISO 27789.

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.

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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 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 his or her electronic health record, as well as rights 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 his or her wishes by which the data subject signifies his or her agreement to personal data relating to him or her being processed). More details can be found in ISO 22600-3. For EHR communication across national borders, ISO 22857 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 his or her 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 sensitivity[1)] of entries in their health record 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 might potentially come into contact with a patient at any one time;

— the large number of organisations with which a patient might come into contact during his or her lifetime;

— the difficulty (for a patient or for anyone else) of classifying in a standardized way how sensitive a record entry might be;

— the difficulty of determining how important a single health record entry might be to the future care of a patient, and to which classes of user;

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 access controls.

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