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**Health informatics — Trusted end-to-end  
information flows**

*Informatique de santé — Flux d'informations “trusted end-to-end”*

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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.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 21089 was prepared by Technical Committee ISO/TC 215, Health informatics.

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# Health informatics — Trusted end-to-end information flows

## 1 Scope

Health(care) records form persistent evidence of health status and the provision and completeness of health(care) services, being retained in electronic and/or other media. Health(care) records often contain Protected Health Information (PHI), typically defined as "individually-identifiable health information", and thus incur safeguards exceeding the ordinary.

The prime unit of health(care) record-keeping is the Entity/Act Record, the authenticatable unit of the health record, evidencing (documenting) the performance/completion of an Act by an Entity and preserving the Accountability Context of the Entity for the Act. (Note that the Entity/Act is central to Health Level Seven's Version 3 Reference Information Model.)

Trusted stewardship, retention and interchange of Entity/Act Records/PHI requires vital safeguards such as traceability and audit. This Technical Report offers an information flow methodology for units of the health(care) record/PHI, particularly the Entity/Act Record, and specifies critical Trace Points (audit events) in that flow including: record/PHI origination, authentication, amendment, translation, access/use, transmittal/disclosure, receipt, de-identification/re-identification, archival, etc.

This Technical Report offers an informative guide to trusted end-to-end information flow for health(care) records and to the key Trace Points and audit events in the electronic Entity/Act Record lifecycle (from point of record origination to each ultimate point of record access/use). It also offers recommendations regarding the trace/audit detail relevant to each.

This Technical Report offers recommendations of best practice for healthcare providers, health record stewards, software developers and vendors, end users and other stakeholders, including patients.

## 2 References

ISO/IEC Guide:1996, Guide 2: definition 3.2

ISO/IEC 2382-8:1998, Information technology — Vocabulary — Part 8: Security

ISO 6523-1:1998, Information technology — Structure for the identification of organizations and organization parts — Part 1: Identification of organization identification schemes

ISO 7498-2:1989, Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture

ISO/IEC 10746-2:1996, Information technology — Open Distributed Processing — Reference Model: Foundations

ISO/IEC 10746-3:1996, Information technology — Open Distributed Processing — Reference Model: Architecture

ISO/IEC 10746-4:1998, Information technology — Open Distributed Processing — Reference Model: Architectural Semantics

ISO/IEC 15408-1:1999, Information technology — Security techniques — Evaluation criteria for IT security — Part 1: Introduction and general model

ISO/IEC 17799, Information technology — Code of practice for information security management

### 3 Terms and definitions

#### 3.1

##### access

ability or the means necessary to read, write, modify, or communicate data/information or otherwise make use of any system resource  
[HIPAA]

provision of an opportunity to approach, inspect, review, make use of data or information  
[CPR]

specific type of interaction between a subject and an object that results in the flow of information from one to the other  
[GCST]

#### 3.2

##### access control

means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways  
[ISO/IEC 2382-8]

prevention of an unauthorized use of a resource, including the prevention of use of a resource in an unauthorized manner  
[ISO 7498-2]

policies and procedures preventing access by those who are not authorized to have it  
[IOM]

#### 3.3

##### accountability

property that ensures that the actions of an entity can be traced uniquely to the entity  
[ISO 7498-2]

concept that individual persons or entities can be held responsible for specified actions  
[NRC]

obligation to disclose periodically, in adequate detail and consistent form, to all directly and indirectly responsible or properly interested parties, the purposes, principles, procedures, relationships, results, incomes and expenditures involved in any activity, enterprise, or assignment so that they can be evaluated by the interested parties  
[JCAHO]

#### 3.4

##### actor

•with respect to an action •an enterprise object (or entity) that participates in the action  
[ISO/IEC 15414]

#### 3.5

##### agent

enterprise object (or entity) that has been delegated (authority, a function, etc.) by and acts for another (in exercising the authority, performing the function, etc.)

#### 3.6

##### application

identifiable computer running a software process

NOTE 1 In this context, it may be any software process used in healthcare information systems including those without any direct role in treatment or diagnosis.

NOTE 2 In some jurisdictions, including software processes may be regulated medical devices.



## 3.7

## architecture

set of principles on which the logical structure and interrelationships to an organization and business context are based

NOTE Software architecture is the result of software design activity.

## 3.8

## archived (records)

## archival (records)

healthcare data saved for later reference or use, possibly off-line

[COACH]

## 3.9

## assurance

grounds for confidence, surety, certitude

grounds for confidence that an entity meets its security objectives

[ISO/IEC 15408-1:1999]

development, documentation, testing, procedural and operational activities carried out to ensure a system's security services do in fact provide the claimed level of protection

[OMG 97]

## 3.10

## audit control

mechanisms employed to record and examine system activity

## 3.11

## audit trail

record of the resources which were accessed and/or used by whom

[ISO 7498-2]

documentary evidence of monitoring each operation (of healthcare entities) on health information

[NRC]

chronological record of system activities that is sufficient to enable the reconstruction, reviewing and examination of the sequence of environments and activities surrounding or leading to an operation, a procedure, or an event in a transaction from its inception to final results

[GCST]

## 3.12

## authentication of health record entries

process used to verify that an entry is complete, accurate and final

[JCAHO]

## 3.13

## authentication

providing assurance regarding the identity of a subject (author) or object (information)

[ASTM E1762]

## 3.14

## authentication (data)

verification of the integrity of data that have been stored, transmitted or otherwise exposed to possible unauthorized modification

[GCST]

## 3.15

## authentication (data source)

corroboration that the source of data received is as claimed

[ISO 7498-2]

## 3.16

authentication (user)  
provision of assurance of the claimed identity of an entity  
[ISO/IEC 10181-2]

3.17  
authorize  
authorization  
granting of rights, which includes granting of access based on access rights  
[ISO 7498-2]

prescription that a particular behaviour must not be prevented  
[ISO/IEC 15414]

3.18  
authorized user  
user who may, in accordance with the Security Policy, perform an operation

3.19  
availability  
property of being accessible and useable upon demand by an authorized entity  
[ISO 7498-2]

prevention of the unauthorized withholding of information or resources  
[ITSEC]

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3.20  
business unit  
discrete and accountable function or sub-function within an organization

NOTE For example, a business unit includes a department, service or speciality of a healthcare provider organization.

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3.21  
care  
provision of accommodations, comfort and treatment to an individual subject of care (patient), also implying responsibility for safety  
[JCAHO]

3.22  
caregiver  
cf. healthcare professional

3.23  
clinical information  
information about a subject of care, relevant to the health or treatment of that subject of care, that is recorded by or on behalf of a healthcare person  
[CEN ENV 1613:1995]

data/information related to the health and healthcare of an individual collected from or about an individual receiving healthcare services: includes a caregiver's objective measurement or subjective evaluation of a patient's physical or mental state of health; descriptions of an individual's health history and family health history; diagnostic studies; decision rationale; descriptions of procedures performed; findings; therapeutic interventions; medication prescribed; description of responses to treatment; prognostic statements; and descriptions of socio-economic and environmental factors related to the patient's health  
[ASTM E1769, CPRI]

3.24  
code set  
any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes

3.25  
coding scheme

collection of rules that maps the elements of one set on to the elements of a second set

## 3.26

complete health record

final, assembled and authenticated, health record for an individual

(health) record is complete when a) its contents reflect the diagnosis, results of diagnostic tests, therapy rendered, condition and progress (of the subject of care), and condition (of the subject of care) at discharge, and b) its contents, including any required clinical résumé or final progress notes, are assembled and authenticated, and all final diagnoses and any complications are recorded without use of symbols or abbreviations

[JCAHO]

## 3.27

confidentiality

property that information is not made available or disclosed to unauthorized individuals, entities or processes [ISO 7498-2]

condition in which information is shared or released in a controlled manner

[NRC]

prevention of the unauthorized disclosure of information

[ITSEC]

restriction of access to data and information to individuals who have a need, a reason and permission for access

[JCAHO]

status accorded to data or information indicating that it is sensitive for some reason, and that therefore it needs to be protected against theft or improper use and must be disseminated only to individuals or organizations authorized to have it

[OTA]

## 3.28

credentials (for identity)

data that are transferred to establish the claimed identity of an entity

[ISO/IEC 2382-8]

## 3.29

credentials (for healthcare practice)

documented evidence of (a healthcare professional's) licensure, education, training, experience, or other qualifications

[JCAHO]

## 3.30

criteria

expected level(s) of achievement, or specifications against which performance can be assessed

[JCAHO]

## 3.31

data attribute, element or item

single unit of data that in a certain context is considered indivisible

## 3.32

data transmission

data transmittal

sending of data or information from one location to another location

[JCAHO]

exchange of data between person and program, or program and program, when the sender and receiver are remote from each other

[CPRI]

3.33

de-identified data

data resulting from personally identifiable information after the process of removing or altering one or more attributes so that the (direct or indirect) identification of the relevant person without knowledge of the initial information is either impossible or requires an unreasonable amount of time and manpower

[MEDSEC]

3.34

digital signature

data appended to, or a cryptographic transformation (see cryptography) of a data unit that allows a recipient of the data unit to prove the source and integrity of the data unit and protect against forgery e.g. by the recipient

[ISO 7498-2]

electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified

[HIPAA]

NOTE This term is usually reserved for digital values or checksums calculated using asymmetric techniques, where only the originator of the message can generate the digital signature but many people can verify it.

3.35

disclosure (of health information)

release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information

[HIPAA]

release of information to third parties within or outside the healthcare provider organization from an individual's (health) record with or without the consent of the individual to whom the record pertains

[CPR]

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3.36

documentation

process of recording information in the (health) record

[JCAHO]

3.37

electronic health record

EHR

electronic healthcare record

ECHR

health record concerning the subject of care in computer-readable form

[CEN ENV13606-1]

3.38

entity

object modelling a natural person or any other entity considered to have the same rights, powers and duties of a natural person

[ISO/IEC 15414]

3.39

episode of care

identifiable grouping of healthcare related activity characterized by the entity relationship between the subject of care and a healthcare provider, such a grouping determined by the healthcare provider

3.40

health information

any information, whether oral or recorded in any form or medium, that a) is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearing-house; and b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment

for the provision of healthcare to an individual  
[HIPAA]

3.41

health record

healthcare record

account compiled [by healthcare entities (e.g., healthcare professionals)] of a variety of (subject of care) health information, such as the (subject of care's) assessment findings, treatment details and progress notes  
[JCAHO]

3.42

health record entry

healthcare record entry

dataset, suitably attributed, which forms part of, or a whole, contribution to a health(care) record at one place and time

[CEN ENV 13606-2]

3.43

healthcare

care, services, or supplies related to the health of an individual

[HIPAA]

NOTE Includes any: a) preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counselling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; b) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or c) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients.

3.44

healthcare agent

medical devices (e.g. instruments, monitors) and software (e.g. applications, components) which: a) perform a role in the provision of healthcare services, and/or b) are accountable for actions related to, and/or ascribed in, the health record

[CEN ENV12265, modified]

3.45

healthcare data

data which are input, stored, processed or output by the automated information system which support the clinical and business functions of a healthcare organization; these data may relate to person identifiable records or may be part of an administrative system where persons are not identified

[HL7]

3.46

healthcare informatics

scientific discipline that is concerned with the cognitive, information processing and communication tasks of healthcare practice, education and research, including the information science and technology to support these tasks

[Directory of the European Standardization Requirements for Healthcare Informatics and Telematics v2.1, 1994]

3.47

healthcare organization

generic term used to describe many types of organizations that provide healthcare services

[JCAHO]

3.48

healthcare entity

individuals, organizations or business units, including: a) subjects of care (patients, health plan members); b) those involved in the direct or indirect provision of healthcare services to an individual or to a population; and/or c) those accountable for actions related to, and/or ascribed in, the health record

[CEN ENV 1613:1995, modified]

3.49

healthcare professional

person that is authorized by a nationally recognized body to be qualified to perform certain health services  
individual who is entrusted with the direct or indirect provision of defined healthcare services to an individual  
subject of care or to populations  
[CEN ENV 1613: 1995]

NOTE 1 The types of registering or accrediting bodies differ in different countries and for different professions. Nationally recognized bodies include local or regional governmental agencies, independent professional associations and other formally and nationally recognized organizations. They may be exclusive or non-exclusive in their territory.  
NOTE 2 Examples of health professionals are physicians, registered nurses and pharmacists.

3.50  
healthcare provider  
healthcare organization or healthcare professional responsible for the provision of healthcare to a subject of  
care or to a population  
[CEN 13940:2000]

3.51  
health plan  
individual or group plan that provides, or pays the cost of, medical care  
[HIPAA]

3.52  
identifier  
piece of information used to claim an identity, before a potential corroboration by a corresponding  
authenticator  
[CEN ENV 13608-1]

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3.53  
indelible  
indelibility  
impossible to remove or erase, permanent

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3.54  
indicator (of performance)  
measure used to determine over time, (an organization's) performance of functions, processes and  
outcomes  
[JCAHO]

3.55  
individually identifiable health information  
any information, including demographic information collected from an individual, that a) is created or  
received by a healthcare provider, health plan employer, or healthcare clearing-house; and b) relates to the  
past, present or future physical or mental health or condition of an individual, the provision of healthcare to  
an individual, or the past, present, or future payment for the provision of healthcare to an individual, and i)  
identifies the individual, or ii) with respect to which there is a reasonable basis to believe that the information  
can be used to identify the individual  
[HIPAA]

3.56  
information  
interpreted set(s) of data that can assist in decision making  
[JCAHO]

data to which meaning is assigned, according to context and assumed conventions  
[NSC]

3.57  
integrity (data)  
property that data has not been altered or destroyed in an unauthorized manner  
[ISO 7498-2]

accuracy, consistency and completeness of data  
[JCAHO]

3.58

integrity (message)

proof that the message content has not altered, deliberately or accidentally in any way, during transmission  
[ISO/IEC 7498-2]

3.59

interface

process that permits the flow of data from one system to another in a structured manner

3.60

interoperability

with regard to a specific task is said to exist between two applications when one application can accept data from the other and perform the task in an appropriate and satisfactory manner (as judged by the user of the receiving system) without the need for extra operator intervention  
[CEN]

ability of software and hardware on multiple machines from multiple vendors to communicate; ability of a system to use the parts or equipment of another system

3.61

longitudinal or lifetime personal health record

permanent, coordinated record of significant information, in chronological sequence; it may include all historical data collected or be retrieved as a user designated synopsis of significant demographic, genetic, clinical and environmental facts and events maintained within an automated system  
[ASTM E1384]

3.62

master file

dataset containing definitional entries in common across system, business units and, in some cases, organizational boundaries

NOTE For example, master files may include data group and attribute definitions, security policy and domain definitions, security classification and clearance definitions, healthcare service definitions, care protocol definitions.

3.63

measure

measurement

collect quantifiable data about a function or process  
[JCAHO]

3.64

message

logically ordered dataset designed to communicate essential information between systems

3.65

need-to-know

legitimate requirement of a prospective recipient of data to know, to access, or to possess any sensitive information represented by these data  
[ISO/IEC 2382-8]

users should have access only to the data he or she needs to perform a particular function  
[HIPAA]

3.66

network

electronic data transmission facility which can comprise of just a point-to-point wire link between two devices, or a complex arrangement of transmission lines

3.67

organization

unique framework of authority within which a person or persons act, or are designated to act towards the