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Health informatics — Cloud computing considerations for the security and privacy of health information systems

Informatique de santé — Considérations relatives à l'informatique en nuage pour la sécurité et la confidentialité des systèmes d'information de santé

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	6
5 Cloud computing	6
5.1 General	6
5.2 Overview of cloud computing	6
5.3 Cloud computing roles and activities	8
5.4 Cloud capabilities types and cloud service categories	8
5.5 Cloud deployment models	9
5.6 Cloud computing information system security capabilities	11
6 Considerations for health information in cloud computing environment	12
6.1 Overview	12
6.2 Health information security	14
6.2.1 Overview of Teleworking Policies and Procedures	14
6.2.2 Telework and portable devices	14
6.3 Information security policies	15
6.3.1 Overview	15
6.3.2 Information security and protection of PII and PHI	15
6.3.3 Availability	16
6.3.4 Cloud deployment models considerations	17
6.3.5 Audit trail and logs	17
6.3.6 Cryptography and obfuscation	18
6.3.7 Retention, backup, and deletion	19
6.3.8 Access control and multi-client segmentation	19
6.3.9 Change management	21
6.3.10 Disaster recovery	21
6.3.11 Testing and evaluation	22
6.3.12 Information management	22
Annex A (informative) Example guidance from the UK for selecting and risk managing cloud based digital health services	24
Annex B (informative) Detailed advice and guidance	30
Annex C (informative) Service classification recommendations	50
Bibliography	52

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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For an explanation of 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 www.iso.org/iso/foreword.html.

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

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

This document identifies core Electronic Health Record (EHR) security and privacy requirements where cloud computing services are utilized. Additional requirements may also be needed where local legal or regulatory requirements exist. Potential additions or modifications can be considered by the cloud service providers in their contractual arrangements.

Cloud computing usage and adoption is becoming popular for healthcare applications worldwide. However, there are health information systems in the market that were not originally designed to operate in such an environment. The appeal and reasons for use that lead to cloud computing adoption are varied, but the available solutions do not always take into account the necessary security and privacy precautions and the necessary measures for secure use of this platform. Migration is a key consideration, as is the design of new systems to account for this type of environment.

The security and privacy of EHRs are paramount considerations for organizations that use health information systems based on cloud services, and for the patient's trust and confidence that their information is processed and stored safely and securely.

This document includes perspective of health information on cloud computing and health informatics requirements. It also provides guidance on selecting service providers in the public cloud for safely locating healthcare data, and confidential patient information (including solutions on handling of data off-shoring).

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Health informatics — Cloud computing considerations for the security and privacy of health information systems

1 Scope

This document provides an overview of security and privacy considerations for Electronic Health Records (EHR) in a cloud computing service that users can leverage when selecting a service provider.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

application capabilities type

cloud capabilities type (3.2) in which the *cloud service customer* (3.8) can use the *cloud service provider's* (3.11) applications

[SOURCE: ISO/IEC 17788:2014, 3.2.1] [ISO/TR 21332:2021](#)

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3.2

cloud capabilities type

classification of the functionality provided by a *cloud service* (3.5) to the *cloud service customer* (3.8), based on resources used

Note 1 to entry: The cloud capabilities types are *application capabilities type* (3.1), *infrastructure capabilities type* (3.24) and *platform capabilities type* (3.31).

[SOURCE: ISO/IEC 17788:2014, 3.2.4]

3.3

cloud computing

paradigm for enabling network access to a scalable and elastic pool of shareable physical or virtual resources with self-service provisioning and administration on-demand

Note 1 to entry: Examples of resources include servers, operating systems, networks, software, applications, and storage equipment.

[SOURCE: ISO/IEC 17788:2014, 3.2.5]

3.4

cloud deployment model

way in which *cloud computing* (3.3) can be organized based on the control and sharing of physical or virtual resources

Note 1 to entry: The cloud deployment models include community cloud, hybrid cloud, private cloud and public cloud.

[SOURCE: ISO/IEC 17788:2014, 3.2.7]

3.5

cloud service

one or more capabilities offered via *cloud computing* (3.3) invoked using a defined interface

[SOURCE: ISO/IEC 17788:2014, 3.2.8]

3.6

cloud service category

group of *cloud services* (3.5) that possess some common set of qualities

Note 1 to entry: A cloud service category can include capabilities from one or more *cloud capabilities types* (3.2).

[SOURCE: ISO/IEC 17788:2014, 3.2.10]

3.7

cloud service customer data

class of data objects under the control, by legal or other reasons, of the *cloud service customer* (3.8) that were input to the *cloud service* (3.5), or resulted from exercising the capabilities of the *cloud service* (3.5) by or on behalf of the *cloud service customer* (3.8) via the published interface of the *cloud service* (3.5)

Note 1 to entry: An example of legal controls is copyright.

Note 2 to entry: It may be that the *cloud service* (3.5) contains or operates on data that is not *cloud service customer* data; this might be data made available by the *cloud service providers* (3.11), or obtained from another source, or it might be publicly available data. However, any output data produced by the actions of the *cloud service customer* (3.8) using the capabilities of the *cloud service* (3.5) on this data is likely to be *cloud service customer data* (3.7), following the general principles of copyright, unless there are specific provisions in the *cloud service* (3.5) agreement to the contrary.

[SOURCE: ISO/IEC 17788:2014, 3.2.12]

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3.8

cloud service customer

<https://standards.itcb.si/catalog/standards/iso/43b11b87-6314-45d4-b725-1c8cd2721e68/iso-tr-21332-2021>
CSC party which is in a business relationship for the purpose of using *cloud services* (3.5)

Note 1 to entry: A business relationship does not necessarily imply financial agreements.

[SOURCE: ISO/IEC 17788:2014, 3.2.11]

3.9

cloud service derived data

class of data objects under *cloud service provider* (3.11) control that are derived as a result of interaction with the *cloud service* (3.5) by the *cloud service customer* (3.8)

Note 1 to entry: *Cloud service* (3.5) derived data includes log data containing records of who used the service, at what times, which functions, types of data involved and so on. It can also include information about the numbers of authorized users and their identities. It can also include any configuration or customization data, where the *cloud service* (3.5) has such configuration and customization capabilities.

[SOURCE: ISO/IEC 17788:2014, 3.2.13]

3.10

cloud service partner

party which is engaged in support of, or auxiliary to, activities of either the *cloud service provider* (3.11) or the *cloud service customer* (3.8), or both

[SOURCE: ISO/IEC 17788:2014, 3.2.14]

3.11**cloud service provider**

party which makes *cloud services* (3.5) available

[SOURCE: ISO/IEC 17788:2014, 3.2.15]

3.12**communications as a service****CaaS**

cloud service category (3.6) in which the capability provided to the *cloud service customer* (3.8) is real time interaction and collaboration

Note 1 to entry: CaaS can provide both *application capabilities type* (3.1) and *platform capabilities type* (3.31).

[SOURCE: ISO/IEC 17788:2014, 3.2.18]

3.13**community cloud**

cloud deployment model (3.4) where *cloud services* (3.5) exclusively support and are shared by a specific collection of *cloud service customers* (3.8) who have shared requirements and a relationship with one another, and where resources are controlled by at least one member of this collection

[SOURCE: ISO/IEC 17788:2014, 3.2.19]

3.14**compute as a service****Compaas**

cloud service category (3.6) in which the capabilities provided to the *cloud service customer* (3.8) are the provision and use of processing resources needed to deploy and run software

Note 1 to entry: To run some software, capabilities other than processing resources may be needed.

[SOURCE: ISO/IEC 17788:2014, 3.2.20]

3.15

[ISO/TR 21332:2021](https://www.iso.org/standard/43b11b87-631d-45d4-b725-1c8cd3721e68/iso-tr-21332-2021.html)

cyber-incident
https://www.iso.org/standard/43b11b87-631d-45d4-b725-1c8cd3721e68/iso-tr-21332-2021.html
cyber-event that involves a loss of information security or impacts business operations

[SOURCE: ISO/IEC 27102:2019, 3.1]

3.16**cyber-insurance**

insurance that covers or reduces financial loss to the insured caused by a *cyber-incident* (3.15)

[SOURCE: ISO/IEC 27102:2019, 3.2]

3.17**cyber-risk**

risk caused by a *cyber-threat* (3.18)

[SOURCE: ISO/IEC 27102:2019, 3.4]

3.18**cyber-threat**

threat that exploits a *cyberspace* (3.19)

[SOURCE: ISO/IEC 27102:2019, 3.5]

3.19**cyberspace**

interconnected digital environment of networks, services, systems, and processes

[SOURCE: ISO/IEC 27102:2019, 3.6]

3.20

insured

entity that shares or considers sharing *cyber-risk* (3.17) with an insurer

[SOURCE: ISO/IEC 27102:2019, 3.7]

3.21

data storage as a service

DSaaS

cloud service category (3.6) in which the capability provided to the *cloud service customer* (3.8) is the provision and use of data storage and related capabilities

Note 1 to entry: DSaaS can provide any of the three *cloud capabilities types* (3.2).

[SOURCE: ISO/IEC 17788:2014, 3.2.22]

3.22

hybrid cloud

cloud deployment model (3.4) using at least two different *cloud deployment models* (3.4)

[SOURCE: ISO/IEC 17788:2014, 3.2.23]

3.23

infrastructure as a service

IaaS

cloud service category (3.6) in which the *cloud capabilities type* (3.2) provided to the *cloud service customer* (3.8) is an *infrastructure capabilities type* (3.24)

Note 1 to entry: The *cloud service customer* (3.8) does not manage or control the underlying physical and virtual resources, but does have control over operating systems, storage, and deployed applications that use the physical and virtual resources. The *cloud service customer* (3.8) may also have limited ability to control certain networking components (e.g. host firewalls).

[SOURCE: ISO/IEC 17788:2014, 3.2.24]

[ISO/TR 21332:2021](#)

3.24

infrastructure capabilities type

cloud capabilities type (3.2) in which the *cloud service customer* (3.8) can provision and use processing, storage or networking resources

[SOURCE: ISO/IEC 17788:2014, 3.2.25]

3.25

network as a service

NaaS

cloud service category (3.6) in which the capability provided to the *cloud service customer* (3.8) is transport connectivity and related network capabilities

Note 1 to entry: NaaS can provide any of the three *cloud capabilities types* (3.2).

[SOURCE: ISO/IEC 17788:2014, 3.2.28]

3.26

personally identifiable information

PII

any information that (a) can be used to establish a link between the information and the natural person to whom such information relates, or (b) is or can be directly or indirectly linked to a natural person

Note 1 to entry: The “natural person” in the definition is the PII principal. To determine whether a PII principal is identifiable, account should be taken of all the means which can reasonably be used by the privacy stakeholder holding the data, or by any other party, to establish the link between the set of PII and the natural person.

[SOURCE: ISO/IEC 29100:2011/Amd.1:2018, 2.9]

3.27**PII controller**

privacy stakeholder (or privacy stakeholders) that determines the purposes and means for processing *personally identifiable information (PII)* (3.26) other than natural persons who use data for personal purposes

Note 1 to entry: A PII controller sometimes instructs others (e.g. *PII processors* (3.29)) to process *PII* (3.26) on its behalf while the responsibility for the processing remains with the PII controller.

[SOURCE: ISO/IEC 29100:2011, 2.10]

3.28**PII principal**

natural person to whom the *personally identifiable information (PII)* (3.26) relates

Note 1 to entry: Depending on the jurisdiction and the particular *PII* (3.26) protection and privacy legislation, the synonym “data subject” can also be used instead of the term “*PII principal*” (3.28).

[SOURCE: ISO/IEC 29100:2011, 2.11]

3.29**PII processor**

privacy stakeholder that processes *personally identifiable information (PII)* (3.26) on behalf of and in accordance with the instructions of a *PII controller* (3.27)

[SOURCE: ISO/IEC 29100:2011, 2.12]

3.30**platform as a service****PaaS**

cloud service category (3.6) in which the *cloud capabilities type* (3.2) provided to the *cloud service customer* (3.8) is a *platform capabilities type* (3.31)

[SOURCE: ISO/IEC 17788:2014, 3.2.30]

[ISO/TR 21332:2021](https://standards.iteh.ai/catalog/standards/iso/43b11b87-631d-45d4-b725-1c8cd3721e68/iso-tr-21332-2021)

[3.31](https://standards.iteh.ai/catalog/standards/iso/43b11b87-631d-45d4-b725-1c8cd3721e68/iso-tr-21332-2021) *platform capabilities type*

cloud capabilities type (3.2) in which the *cloud service customer* (3.8) can deploy, manage and run customer-created or customer-acquired applications using one or more programming languages and one or more execution environments supported by the *cloud service provider* (3.11)

[SOURCE: ISO/IEC 17788:2014, 3.2.31]

3.32**private cloud**

cloud deployment model (3.4) where *cloud services* (3.5) are used exclusively by a single *cloud service customer* (3.8) and resources are controlled by that *cloud service customer* (3.8)

[SOURCE: ISO/IEC 17788:2014, 3.2.32]

3.33**public cloud**

cloud deployment model (3.4) where *cloud services* (3.5) are potentially available to any *cloud service customer* (3.8) and resources are controlled by the *cloud service provider* (3.11)

[SOURCE: ISO/IEC 17788:2014, 3.2.33]

3.34

software as a service

SaaS

*cloud service category (3.6) in which the *cloud capabilities type (3.2)* provided to the *cloud service customer (3.8)* is an *application capabilities type (3.1)**

[SOURCE: ISO/IEC 17788:2014, 3.2.36]

3.35

reversibility

process for *cloud service customers (3.8)* to retrieve their *cloud service customer data (3.7)* and application artefacts and for the *cloud service provider (3.11)* to delete all *cloud service customer data (3.7)* as well as contractually specified *cloud service derived data (3.9)* after an agreed period

[SOURCE: ISO/IEC 17788:2014, 3.2.35]

4 Abbreviated terms

EHR Electronic Health Record

NHS National Health System

PHI Personal Health Information

SDO Standard Development Organizations

SIEM Security Information and Event Management

WAN Wide Area Network

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5 Cloud computing

[ISO/TR 21332:2021](#)

5.1 General <https://standards.iteh.ai/catalog/standards/iso/43b11b87-631d-45d4-b725-1c8cd3721e68/iso-tr-21332-2021>

Cloud computing is an evolving paradigm. This is not intended to prescribe or constrain any particular method of deployment, service delivery, or business operation.

There are known risks to confidentiality and security using a cloud computing environment. However, the use of a cloud computing architecture over advanced technologies can produce valuable benefits. The challenge for health informatics is what deployment method to use with the available resources to maintain a trusted yet useful service.

5.2 Overview of cloud computing

This overview introduced the following.

a) Six key cloud computing characteristics:

i) Broad network access

It is a feature where the physical and virtual resources are available over a network and accessed through standard mechanisms that promote use by heterogeneous client platforms. The focus of this key characteristic is that cloud computing offers an increased level of convenience in that users can access physical and virtual resources from wherever they need to work, as long as it is network accessible, using a wide variety of clients, including devices such as mobile phones, tablets, laptops, and workstations.

ii) Measured service

It is a feature where the metered delivery of cloud services is such that usage can be monitored, controlled, reported, and billed. This is an important feature needed to optimize and validate the delivered cloud service. The focus of this key characteristic is that the customer only pays for the resources that they use. From the customers' perspective, cloud computing offers the users value by enabling a switch from a low efficiency and asset utilization business model to a high efficiency one.

iii) Multi-tenancy

It is a feature where physical or virtual resources are allocated in such a way that multiple tenants and their computations and data are isolated from and inaccessible to one another. Typically, and within the context of multi-tenancy, the group of cloud service users that form a tenant will all belong to the same cloud service customer organization. There might be cases where the group of cloud service users involves users from multiple different cloud service customers, particularly in the case of public cloud and community cloud deployments. However, a given cloud service customer organization might have many different tenancies with a single cloud service provider representing different groups within the organization.

iv) On-demand self-service

It is a feature where a cloud service customer can provision computing capabilities, as needed, automatically or with minimal interaction with the cloud service provider. The focus of this key characteristic is that cloud computing offers users a relative reduction in costs, time, and effort needed to take an action, since it grants the user the ability to do what they need, when they need it, without requiring additional human user interactions or overhead.

v) Rapid elasticity and scalability

These are features where physical or virtual resources can be rapidly and elastically adjusted, in some cases automatically, to quickly increase or decrease resources. For the cloud service customer, the physical or virtual resources available for provisioning often appear to be unlimited and can be purchased in any quantity at any time automatically, subject to constraints of service agreements. Therefore, the focus of these key characteristics is that cloud computing means that the customers no longer need to worry about limited resources and might not need to worry about capacity planning.

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vi) Resource pooling

It is a feature where a cloud service provider's physical or virtual resources can be aggregated in order to serve one or more cloud service customers. The focus of this key characteristic is that cloud service providers can support multi-tenancy while at the same time use abstraction to mask the complexity of the process from the customer. From the customer's perspective, all they know is that the service works, while they generally have no control or knowledge over how the resources are being provided or where the resources are located. This offloads some of the customer's original workload, such as maintenance requirements, to the provider. Even with this level of abstraction, it can be noted that users might still be able to specify location at a higher level of abstraction (e.g. country, state, or data centre).

b) **Three cloud capabilities types:**

- 1) Application capabilities type
- 2) Infrastructure capabilities type
- 3) Platform capabilities type

c) **An extensible set of cloud service categories including but not limited to the following:**

- Software as a Service (SaaS)
- Platform as a Service (PaaS)
- Infrastructure as a Service (IaaS)

- Network as a Service (NaaS)
- Communications as a Service (CaaS)
- Compute as a Service (CompaaS)
- Data Storage as a Service (DSaaS)

d) Four cloud deployment models:

- 1) Public cloud
- 2) Private cloud
- 3) Community cloud
- 4) Hybrid cloud

5.3 Cloud computing roles and activities

Within the context of cloud computing, it is often needed to differentiate requirements and issues for certain parties. These parties are entities that play roles, which set of competencies and/or performances that are associated with a task. Tasks, in turn, have sets of activities and those activities are implemented by components. All cloud computing-related activities can be categorized into three main groups: activities that use services, activities that provide services and activities that support services. It is important to note that a party can play more than one role at any given point in time and can only engage in a specific subset of activities of that role. [Table 1](#) shows a set of roles and describes their main characteristics.

[\(https://standards.iteh.ai/\)](https://standards.iteh.ai/)
Table 1 — The major roles of cloud computing

Role	Description
Cloud service customer	The business relationship is with a cloud service provider or a cloud service partner. Key activities for a cloud service customer include, but are not limited to, using cloud services, performing business administration, and administering use of cloud services.
Cloud service partner	A cloud service partner's activities vary depending on the type of partner and their relationship with the cloud service provider and the cloud service customer. Examples of cloud service partners include cloud auditor and cloud service broker.
Cloud service provider	The cloud service provider focuses on activities necessary to provide a cloud service and activities necessary to ensure its delivery to the cloud service customer as well as cloud service maintenance. The cloud service provider includes an extensive set of activities (e.g. provide service, deploy and monitor service, manage business plan, provide audit data, etc.) as well as numerous sub-roles (e.g. business manager, service manager, network provider, security and risk manager, etc.).

5.4 Cloud capabilities types and cloud service categories

A cloud capabilities type is a classification of the functionality provided by a cloud service to the cloud service customer, based on the resources used. There are three different cloud capabilities types:

- a) application capabilities type;
- b) infrastructure capabilities type;
- c) platform capabilities type.

These are different because they follow the principle of separation of concerns, i.e. they have minimal functionality overlap between each other.

[Table 2](#) describes the cloud capabilities.