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Health informatics — Public key infrastructure —

Part 1: Overview of digital certificate services

Informatique de santé — Infrastructure de clé publique —

Partie 1: Vue d'ensemble des services de certificat numérique

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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 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*.

This third edition cancels and replaces the second edition (ISO 17090-1:2013), of which it constitutes a minor revision. The changes compared to the previous edition are as follows:

— update to references;

— editorial update.

A list of all parts in the ISO 17090 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

The healthcare industry is faced with the challenge of reducing costs by moving from paper-based processes to automated electronic processes. New models of healthcare delivery are emphasizing the need for patient information to be shared among a growing number of specialist healthcare providers and across traditional organizational boundaries.

Healthcare information concerning individual citizens is commonly interchanged by means of electronic mail, remote database access, electronic data interchange, and other applications. The Internet provides a highly cost-effective and accessible means of interchanging information, but it is also an insecure vehicle that demands additional measures be taken to maintain the privacy and confidentiality of information. Threats to the security of health information through unauthorized access (either inadvertent or deliberate) are increasing. It is essential to have available to the healthcare system reliable information security services that minimize the risk of unauthorized access.

How does the healthcare industry provide appropriate protection for the data conveyed across the Internet in a practical, cost-effective way? Public key infrastructure (PKI) and digital certificate technology seek to address this challenge.

The proper deployment of digital certificates requires a blend of technology, policy, and administrative processes that enable the exchange of sensitive data in an unsecured environment by the use of "public key cryptography" to protect information in transit and "certificates" to confirm the identity of a person or entity. In healthcare environments, this technology uses authentication, encipherment, and digital signatures to facilitate confidential access to, and movement of, individual health records to meet both clinical and administrative needs. The services offered by the deployment of digital certificates (including encipherment, information integrity, and digital signatures) are able to address many of these security issues. This is especially the case if digital certificates are used in conjunction with an accredited information security standard. Many individual organizations around the world have started to use digital certificates for this purpose.

Interoperability of digital certificate technology and supporting policies, procedures, and practices is of fundamental importance if information is to be exchanged between organizations and between jurisdictions in support of healthcare applications (for example between a hospital and a community physician working with the same patient).

Achieving interoperability between different digital certificate implementations requires the establishment of a framework of trust, under which parties responsible for protecting an individual's information rights may rely on the policies and practices and, by extension, the validity of digital certificates issued by other established authorities.

Many countries are deploying digital certificates to support secure communications within their national boundaries. Inconsistencies will arise in policies and procedures between the certification authorities (CAs) and the registration authorities (RAs) of different countries if standards development activity is restricted to within national boundaries.

Digital certificate technology is still evolving in certain aspects that are not specific to healthcare. Important standardization efforts and, in some cases, supporting legislation are ongoing. On the other hand, healthcare providers in many countries are already using or planning to use digital certificates. This document seeks to address the need for guidance of these rapid international developments.

This document describes the common technical, operational, and policy requirements that need to be addressed to enable digital certificates to be used in protecting the exchange of healthcare information within a single domain, between domains, and across jurisdictional boundaries. Its purpose is to create a platform for global interoperability. It specifically supports digital certificate-enabled communication across borders, but could also provide guidance for the national or regional deployment of digital certificates in healthcare. The Internet is increasingly used as the vehicle of choice to support the movement of healthcare data between healthcare organizations and is the only realistic choice for cross-border communication in this sector.

This document should be approached as a whole, with the three parts all making a contribution to defining how digital certificates can be used to provide security services in the health industry, including authentication, confidentiality, data integrity, and the technical capacity to support the quality of digital signature.

This document defines the basic concepts underlying the use of digital certificates in healthcare and provides a scheme of interoperability requirements to establish digital certificate-enabled secure communication of health information.

ISO 17090-2 provides healthcare specific profiles of digital certificates based on the International Standard X.509[14] and the profile of this specified in IETF/RFC 3280 for different types of certificates.

ISO 17090-3 deals with management issues involved in implementing and using digital certificates in healthcare. It defines a structure and minimum requirements for certificate policies (CPs) and a structure for associated certification practice statements. ISO 17090-3 is based on the recommendations of the informational IETF/RFC 3647 and identifies the principles needed in a healthcare security policy for cross border communication. It also defines the minimum levels of security required, concentrating on the aspects unique to healthcare.

Health informatics — Public key infrastructure —

Part 1: Overview of digital certificate services

1 Scope

This document defines the basic concepts underlying the use of digital certificates in healthcare and provides a scheme of interoperability requirements to establish a digital certificate-enabled secure communication of health information. It also identifies the major stakeholders who are communicating health-related information, as well as the main security services required for health communication where digital certificates can be required.

This document gives a brief introduction to public key cryptography and the basic components needed to deploy digital certificates in healthcare. It further introduces different types of digital certificates — identity certificates and associated attribute certificates for relying parties, self-signed certification authority (CA) certificates, and CA hierarchies and bridging structures.

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 17090-2, *Health informatics — Public key infrastructure — Part 2: Certificate profile*

ISO 17090-3, *Health informatics — Public key infrastructure — Part 3: Policy management of certification authority*

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 Healthcare context terms

3.1.1
application
identifiable computer running software process that is the holder of a private encipherment key

Note 1 to entry: Application, in this context, can be any software process used in healthcare information systems, including those without any direct role in treatment or diagnosis.

Note 2 to entry: In some jurisdictions, including software, processes can be regulated medical devices.

3.1.2
device
identifiable computer-controlled apparatus or instrument that is the holder of a private encipherment key

Note 1 to entry: This includes the class of regulated medical devices that meet the above definition.

Note 2 to entry: Device, in this context, is any device used in healthcare information systems, including those without any direct role in treatment or diagnosis.

3.1.3
healthcare actor
actor
regulated health professional, non-regulated health professional, sponsored healthcare provider, supporting organization employee, patient/consumer, healthcare organization, device, or application that acts in a health-related communication and requires a certificate for a digital certificate-enabled security service

3.1.4
healthcare organization
officially registered organization that has a main activity related to healthcare services or health promotion

EXAMPLE Hospitals, Internet healthcare website providers, and healthcare research institutions.

Note 1 to entry: The organization is recognized to be legally liable for its activities but need not be registered for its specific role in health.

Note 2 to entry: An internal part of an organization is called here an organizational unit, as in X.501.

3.1.5
non-regulated health professional
person employed by a healthcare organization who is not a regulated health professional

EXAMPLE Medical receptionist who organizes appointments or nurses aid who assists with patient care.

Note 1 to entry: The fact that the employee is not authorized by a body independent of the employer in his/her professional capacity does, of course, not imply that the employee is not professional in conducting his/her services.

3.1.6
organization employee
person employed by a healthcare organization or a supporting organization

EXAMPLE Medical records transcriptionists, healthcare insurance claims adjudicators, and pharmaceutical order entry clerks.

3.1.7
patient
consumer
person who is the receiver of health-related services and who is an actor in a health information system

3.1.8
privacy
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[SOURCE: ISO/IEC 2382:2015, 2126263]

3.1.9
regulated health professional
person who is authorized by a nationally recognized body to be qualified to perform certain health services

EXAMPLE Physicians, registered nurses, and pharmacists.

Note 1 to entry: 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 to entry: A nationally recognized body in this definition does not imply one nationally controlled system of professional registration but, in order to facilitate international communication, it would be preferable for one nationwide directory of recognized health professional registration bodies to exist.

3.1.10
sponsored healthcare provider
health services provider who is not a regulated professional in the jurisdiction of his/her practice, but who is active in his/her healthcare community and sponsored by a regulated healthcare organization

EXAMPLE A drug and alcohol education officer who is working with a particular ethnic group, or a healthcare aid worker in a developing country.

3.1.11
supporting organization
officially registered organization which is providing services to a healthcare organization, but which is not providing healthcare services

EXAMPLE 1 EXAMPLE

EXAMPLE 2 Healthcare financing bodies such as insurance institutions, suppliers of pharmaceuticals and other goods.

3.2 Security services terms

3.2.1
access control
means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

[SOURCE: ISO/IEC 2382:2015, 2126294, modified — Notes to entry removed.]

3.2.2
accountability
property that ensures that the actions of an entity may be traced uniquely to the entity

[SOURCE: ISO 7498-2:1989, 3.3.3]

3.2.3
asymmetric cryptographic algorithm
algorithm for performing encipherment or the corresponding decipherment in which the keys used for encipherment and decipherment differ

[SOURCE: ISO/IEC 10181-1:1996, 3.3.1, modified — Note to entry removed.]

3.2.4
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

[SOURCE: ISO 7498-2:1989]

Note 1 to entry: See also data origin authentication and peer entity authentication.

3.2.5
authorization
granting of rights, which includes the granting of access based on access rights

[SOURCE: ISO 7498-2:1989, 3.3.10]

3.2.6
availability
property of being accessible and useable upon demand by an authorized entity

[SOURCE: ISO 7498-2:1989, 3.3.11]

3.2.7
ciphertext
data produced through the use of encipherment, the semantic content of which is not available

[SOURCE: ISO 7498-2:1989, 3.3.14, modified — Note to entry removed.]

3.2.8
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities, or processes

[SOURCE: ISO 7498-2:1989, 3.3.16]

3.2.9
cryptography
discipline which embodies principles, means, and methods for the transformation of data in order to hide its information content, prevent its undetected modification, and/or prevent its unauthorized use

[SOURCE: ISO 7498-2:1989, 3.3.20, modified — Note to entry removed.]

3.2.10
cryptographic algorithm
cipher
method for the transformation of data in order to hide its information content, prevent its undetected modification, and/or prevent its unauthorized use

[SOURCE: ISO 7498-2:1989]

3.2.11
data integrity
property that data have not been altered or destroyed in an unauthorized manner

[SOURCE: ISO 7498-2:1989, 3.3.21]

3.2.12
data origin authentication
corroboration that the source of data received is as claimed

[SOURCE: ISO 7498-2:1989, 3.3.22]

3.2.13
decipherment
decryption
process of obtaining, from a ciphertext, the original corresponding data

[SOURCE: ISO/IEC 2382:2015, 2126281, modified — Notes 2 and 3 to entry removed.]

Note 1 to entry: A ciphertext may be enciphered a second time, in which case a single decipherment does not produce the original plaintext.

3.2.14
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

[SOURCE: ISO 7498-2:1989, 3.3.26]

3.2.15
encipherment
encryption
cryptographic transformation of data (see cryptography) to produce ciphertext

[SOURCE: ISO 7498-2:1989, 3.3.27]

3.2.16
identifier
piece of information used to claim an identity, before a potential corroboration by a corresponding authenticator

[SOURCE: ENV 13608-1]

3.2.17
integrity
proof that the message content has not been altered, deliberately or accidentally, in any way during transmission

Note 1 to entry: Adapted from ISO 7498-2:1989.

3.2.18
key
sequence of symbols that controls the operations of encipherment and decipherment

[SOURCE: ISO 7498-2:1989, 3.3.32]

3.2.19
key management
generation, storage, distribution, deletion, archiving, and application of keys in accordance with a security policy

[SOURCE: ISO 7498-2:1989, 3.3.33]

3.2.20
non-repudiation
service providing proof of the integrity and origin of data (both in an unforgeable relationship), which can be verified by any party

Note 1 to entry: Adapted from Reference [18].

3.2.21
private key
key that is used with an asymmetric cryptographic algorithm and whose possession is restricted (usually to only one entity)

[SOURCE: ISO/IEC 10181-1:1996, 3.3.10]

3.2.22
public key
key that is used with an asymmetric cryptographic algorithm and that can be made publicly available

[SOURCE: ISO/IEC 10181-1:1996, 3.3.11]

3.2.23
role
set of behaviours that is associated with a task

3.2.24
security
combination of availability, confidentiality, integrity, and accountability

[SOURCE: ENV 13608-1]

3.2.25
security policy
plan or course of action adopted for providing computer security

[SOURCE: ISO/IEC 2382:2015, 2126246, modified — Notes to entry removed.]

3.2.26
security service
service, provided by a layer of communicating open systems, which ensures adequate security of the systems or of data transfers

[SOURCE: ISO 7498-2:1989, 3.3.51]

3.3 Public key infrastructure related terms

3.3.1
attribute authority
AA
authority which assigns privileges by issuing attribute certificates

[SOURCE: RFC 5280]

3.3.2
attribute certificate
data structure, digitally signed by an attribute authority, that binds some attribute values with identification about its holder

[SOURCE: RFC 5280]

3.3.3
authority certificate
certificate issued to a certification authority or to an attribute authority

Note 1 to entry: Adapted from RFC 5280.

3.3.4
certificate
public key certificate

3.3.5
certificate distribution
act of publishing certificates and transferring certificates to security subjects

3.3.6
certificate extension
extension fields (known as extensions) in X.509 certificates that provide methods for associating additional attributes with users or public keys and for managing the certification hierarchy

Note 1 to entry: Certificate extensions may be either critical (i.e. a certificate-using system has to reject the certificate if it encounters a critical extension it does not recognize) or non-critical (i.e. it may be ignored if the extension is not recognized).

3.3.7
certificate generation
act of creating certificates

3.3.8
certificate profile
specification of the structure and permissible content of a certificate type

3.3.9
certificate revocation
act of removing any reliable link between a certificate and its related owner (or security subject owner) because the certificate is not trusted any more, even though it is unexpired

3.3.10
certificate holder
entity that is named as the subject of a valid certificate

3.3.11
certification
procedure by which a third party gives assurance that all or part of a data processing system conforms to security requirements

[SOURCE: ISO/IEC 2382:2015, 2126258, modified — Notes to entry removed.]

3.3.12
certification authority
CA
certificate issuer
authority trusted by one or more relying parties to create and assign certificates and which may, optionally, create the relying parties' keys

Note 1 to entry: Adapted from ISO/IEC 9594-8:2021.

Note 2 to entry: Authority in the CA term does not imply any government authorization but only denotes that it is trusted.

Note 3 to entry: Certificate issuer may be a better term, but CA is very widely used.

3.3.13
certificate policy
CP
named set of rules that indicates the applicability of a certificate to a particular community and/or class of application with common security requirements

[SOURCE: IETF/RFC 3647]