INTERNATIONAL STANDARD

ISO 17090-1

Third edition
2021-02

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

Reference number
ISO 17090-1:2021(E)

© ISO 2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**
3.1 Healthcare context terms 1
3.2 Security services terms 3
3.3 Public key infrastructure related terms 6

4 Abbreviations **9**

5 Healthcare context **9**
5.1 Certificate holders and relying parties in healthcare 9
5.2 Examples of actors 10
5.2.1 Regulated health professional 10
5.2.2 Non-regulated health professional 10
5.2.3 Patient/consumer 10
5.2.4 Sponsored healthcare provider 10
5.2.5 Supporting organization employee 10
5.2.6 Healthcare organization 10
5.2.7 Supporting organization 11
5.2.8 Devices 11
5.2.9 Applications 11
5.3 Applicability of digital certificates to healthcare 11

6 Requirements for security services in healthcare applications **12**
6.1 Healthcare characteristics 12
6.2 Digital certificate technical requirements in healthcare 12
6.2.1 General 12
6.2.2 Authentication 13
6.2.3 Integrity 13
6.2.4 Confidentiality 13
6.2.5 Digital signature 13
6.2.6 Authorization 13
6.2.7 Access control 13
6.3 Healthcare-specific needs and the separation of authentication from data encipherment 14
6.4 Health industry security management framework for digital certificates 14
6.5 Policy requirements for digital certificate issuance and use in healthcare 14

7 Public key cryptography **14**
7.1 Symmetric vs. asymmetric cryptography 14
7.2 Digital certificates 15
7.3 Digital signatures 15
7.4 Protecting the private key 16

8 Deploying digital certificates **17**
8.1 Necessary components 17
8.1.1 General 17
8.1.2 CP 17
8.1.3 CPS 17
8.1.4 CA 17
8.1.5 RA 17
8.2 Establishing identity using qualified certificates 18
8.3 Establishing speciality and roles using identity certificates 18
8.4 Using attribute certificates for authorization and access control 19

© ISO 2021 – All rights reserved

9 Interoperability requirements **20**
9.1 Overview 20
9.2 Options for deploying healthcare digital certificates across jurisdictions 20
9.2.1 General 20
9.2.2 Option 1 — Single hierarchy of CAs 20
9.2.3 Option 2 — Relying party management of trust 20
9.2.4 Option 3 — Cross-recognition 21
9.2.5 Option 4 — Cross-certification 21
9.2.6 Option 5 — Bridge CA 22
9.3 Option usage 22
Annex A (informative) **Scenarios for the use of digital certificates in healthcare** **23**
Bibliography **40**

 © ISO 2021 – All rights reserved

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.

© ISO 2021 – All rights reserved

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.

 © ISO 2021 – All rights reserved

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.

© ISO 2021 – All rights reserved

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.

© ISO 2021 – All rights reserved