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Health informatics — Public key infrastructure —

Part 3: Policy management of certification authority

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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 second edition cancels and replaces the first edition (ISO 17090-3:2008), 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. The ISO 17090 series seeks to address the need for guidance of these rapid international developments.

The ISO 17090 series 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.

The ISO 17090 series should be approached as a whole, with the five 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.

ISO 17090-1 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[9] and the profile of this, specified in IETF/RFC 5280 for different types of certificates.

This document 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. This document 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 17090-4 supports interchangeability of digital signatures and the prevention of incorrect or illegal digital signatures by providing minimum requirements and formats for generating and verifying digital signatures and related certificates.

ISO 17090-5 defines the procedural requirements for validating an entity credential based on PKI defined in the ISO 17090 series, used in healthcare information systems including accessing remote systems.

Health informatics — Public key infrastructure —

Part 3:
Policy management of certification authority

1 Scope

This document gives guidelines for certificate management issues involved in deploying digital certificates in healthcare. It specifies a structure and minimum requirements for certificate policies, as well as a structure for associated certification practice statements.

This document also identifies the principles needed in a healthcare security policy for cross-border communication and defines the minimum levels of security required, concentrating on aspects unique to healthcare.

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 17090-1:2021, *Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services*

ISO 17090-2:2015, *Health informatics — Public key infrastructure — Part 2: Certificate profile*

ISO/IEC 27002, *Information technology — Security techniques — Code of practice for information security controls*

IETF/RFC 3647, *Internet X.509 Public Key Infrastructure Certificate Policy and Certification Practices Framework*

IETF/RFC 4211, *Internet X.509 Public Key Infrastructure Certificate Request Message Format (CRMF)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 17090-1 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/

4 Abbreviations

AA attribute authority

CA certification authority

CP certificate policy

CPS certification practice statement

CRL certificate revocation list

OID object identifier

PKC public key certificate

PKI public key infrastructure

RA registration authority

TTP trusted third party

5 Requirements for digital certificate policy management in a healthcare context

5.1 General

Deployment of digital certificates in healthcare shall meet the following objectives in order to be effective in securing the communication of personal health information:

— the reliable and secure binding of unique and distinguished names to individuals, organizations, applications and devices that participate in the electronic exchange of personal health information;

— the reliable and secure binding of professional roles in healthcare to individuals, organizations and applications that participate in the electronic exchange of personal health information, insofar as those roles may be used as the basis of role-based access control to such health information;

— (optionally) the reliable and secure binding of attributes to individuals, organizations, applications and devices that participate in the electronic exchange of personal health information, insofar as those attributes may further the secure communication of health information.

The above objectives shall be accomplished in a manner that maintains the trust of all who rely upon the integrity and confidentiality of personal health information that is securely communicated by use of digital certificates.

To do this, each CA issuing digital certificates for use in healthcare shall operate according to an explicit set of publicly stated policies that promote the above objectives.

5.2 Need for a high level of assurance

The security services that are required for health applications are specified in Clause 6 of ISO 17090-1:2021. For each of these security services (authentication, integrity, confidentiality, digital signature, authorization, access control), a high level of assurance is required.

5.3 Need for a high level of infrastructure availability

Emergency healthcare is a round-the-clock endeavour and the ability to obtain certificates, revoke certificates and check revocation status is in no way bound by the normal working hours of most businesses. Unlike e-commerce, healthcare imposes high availability requirements on any deployment of digital certificates that will be relied upon to secure the communication of personal health information.

5.4 Need for a high level of trust

Unlike electronic commerce (where a vendor and a customer are often the only parties to an electronic transaction and are reliant upon its security and integrity), healthcare applications that store or transmit personal health information may implicitly require the trust of the patients whose information

is being exchanged, as well as that of the general public. It is unlikely that either healthcare providers or patients will cooperate in the electronic exchange of personal health information if such exchanges are believed to be insecure.

5.5 Need for Internet compatibility

As the purpose of this document is to define the essential elements of a healthcare digital certificate deployment to support the secure transmission of healthcare information across national or regional boundaries, it is based as much as possible upon Internet standards so as to effectively span those boundaries.

5.6 Need to facilitate evaluation and comparison of CPs

Approaches for using digital certificates to facilitate the secure exchange of health information across national boundaries are discussed in 9.2 of ISO 17090-1:2021. These approaches (such as cross-recognition and cross-certification) are greatly facilitated if healthcare CPs follow a consistent format so that comparisons may be readily drawn between the provisions of one CP and another.

Healthcare CPs also constitute a basis for the accreditation of CAs (a CA being accredited to support one or more CPs which it proposes to implement). While accreditation criteria are beyond the scope of this document, the entire process of accreditation of healthcare CAs is expedited by the consistency of format and the minimum standards which this document promotes.

6 Structure of healthcare CPs and healthcare CPSs

6.1 General requirements for CPs

When a CA issues a certificate, it provides a statement to a relying party that a particular public key is bound to a particular certificate holder. Different certificates are issued following different practices and procedures, and may be suitable for different applications and/or purposes.

The CA is responsible for all aspects of the issuance and management of a certificate, including control over the registration process, verification of information contained in a certificate, the certificate manufacture, publication, revocation, suspension and renewal. The CA is responsible for ensuring that all aspects of the CA services and operations are performed in accordance with the requirements, representations and warrantees of this CP and with the CA's CPS.

A CA issuing digital certificates for healthcare use shall have policies and procedures available for the services they provide. These policies and procedures shall cover:

— registering potential certificate holders prior to certificate issuance, including, where applicable, the certificate holder's role in accordance with Clause 6 of ISO 17090-2:2015;

— authenticating the identity of potential certificate holders prior to certificate issuance;

— maintaining the privacy of any personal information held about the people to whom certificates are given;

— distributing certificates to certificate holders and to directories;

— accepting information about possible private key compromise;

— distributing CRLs (frequency of issue, and how and where to publish them);

— other key management issues, including key size, key generation process, certificate lifespan, re-keying, etc.;

— cross-certifying with other CAs;

— security controls and auditing.

In order to perform these functions, each CA within the infrastructure will need to provide some basic services to its certificate holders and relying parties. These CA services are listed in the CP.

Digital certificates contain one or more registered CP OIDs, which identify the CP under which the certificate was issued, and may be used to decide whether or not a certificate is trusted for a particular purpose. The registration process follows the procedures specified in some ISO/IEC and ITU standards. The party that registers the OIDs also publishes the CP for examination by certificate holders and relying parties.

Because of the importance of a CP in establishing trust in a PKC, it is fundamental that the CP be understood and consulted not only by certificate holders but by any relying party. Certificate holders and relying parties shall therefore have ready and reliable access to the CP under which a certificate was issued.

The following requirements apply to all CPs specified in accordance with this document.

a) Each digital certificate issued in accordance with this document shall contain at least one registered CP OID, which identifies the CP under which the certificate was issued.

b) The structure of CPs shall be in accordance with IETF/RFC 3647.

c) CPs shall be accessible to certificate holders and relying parties.

While CP and CPS documents are essential for describing and governing CPs and practices, many digital certificate holders, especially consumers, find these detailed documents difficult to understand. These certificate holders and other relying parties may benefit from access to a concise statement of the elements of a CP that require emphasis and disclosure and a model PKI disclosure statement is given in Clause 8 for this purpose.

6.2 General requirements for CPSs

A CPS is a comprehensive description of such details as the precise implementation of service offerings and detailed procedures of certificate life-cycle management and will generally be more detailed than the associated CP.

The following requirements apply to all CPSs specified in accordance with this document.

a) CPSs shall be in accordance with IETF/RFC 3647.

b) A CA with a single CPS may support multiple CPs (used for different application purposes and/or by different groups of relying parties).

c) A number of CAs with non-identical CPSs may support the same CP.

d) A CA may choose not to make its CPS accessible to certificate holders or relying parties or may choose to make portions of its CPS available.

6.3 Relationship between a CP and a CPS

A CP states what assurance can be placed in a certificate (including restrictions on certificate use and limitations on liability). A CPS states how a CA establishes that assurance. A CP may apply more broadly than to just a single organization, whereas a CPS applies only to a single CA. CPs best serve as the vehicle on which to base common interoperability standards and common assurance criteria industry-wide (or possibly more global). A detailed CPS alone does not form a suitable basis for interoperability between CAs operated by different organizations.

6.4 Applicability

This document applies to CPs and CPSs that are used for the purpose of issuing healthcare certificates as specified in ISO 17090-2:2015, Clause 5.

