INTERNATIONAL STANDARD

ISO 17090-1

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

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 17090-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 17090-1:2008), of which it constitutes a minor revision.

ISO 17090 consists of the following parts, under the general title *Health informatics — Public key infrastructure*:

— *Part 1: Overview of digital certificate services*

— *Part 2: Certificate profile*

— *Part 3: Policy management of certification authority*

Annex A of this part of ISO 17090 is for information only.

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 organisational 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 unauthorised access (either inadvertent or deliberate) are increasing. It is essential to have available to the healthcare system reliable information security services that minimise the risk of unauthorised 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 organisations 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 organisations 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 standardisation 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 International Standard seeks to address the need for guidance of these rapid international developments.

This International Standard 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 organisations and is the only realistic choice for cross-border communication in this sector.

This International Standard 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.

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 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, *Internet X.509 Public Key Infrastructure Certificate Policy and Certification Practices Framework,* 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.

Comments on the content of this International Standard, as well as comments, suggestions, and information on the application of these standards may be forwarded to the ISO/TC 215 secretariat.

Health informatics — Public key infrastructure —

Part 1: Overview of digital certificate services

1 Scope

This part of ISO 17090 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 may be required.

This part of ISO 17090 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 17090-2:2008, *Health informatics — Public key infrastructure — Part 2: Certificate profile*

ISO 17090-3:2008, *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.

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.