International Standard

ISO 17090-4

Health informatics — Public key infrastructure —

Part 4:
Digital signatures for healthcare documents

Informatique de la santé — Infrastructure clé publique —

Partie 4: Signatures numériques pour les documents des soins médicaux

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

This third edition cancels and replaces the second edition (ISO 17090-4:2020), which has been technically revised.

The main changes are as follows:

— update of the reference standard and addition of JAdES definitions.

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 that reliable information security services that minimize the risk of unauthorized access be available to the healthcare system.

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 can rely on the policies and practices and, by extension, on 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 to support these rapid international developments.

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, contributes to defining how digital certificates can be used to provide security services in the healthcare industry, including authentication, confidentiality, data integrity, and the technical capacity to support the quality of digital signature.

This document is in line with ISO/ETSI standards for long-term signature formats to improve and guarantee interoperability in the healthcare field.