

BS ISO 17090-4:2014



BSI Standards Publication

Health informatics — Public key infrastructure

Part 4: Digital Signatures for healthcare
documents

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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**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*



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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

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*
- *Part 4: Digital Signatures for healthcare documents*

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 be 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 International Standard seeks to address the need for guidance to support 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 organizations and is the only realistic choice for cross-border communication in this sector.

This International Standard can be approached as a whole, with the four parts all making a contribution 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.

ISO 17090-4 provides healthcare-specific profiles of digital signature based on the ETSI Standard and the profile of the ETSI Standard specified in CADES and XAdES.

Health informatics — Public key infrastructure —

Part 4: Digital Signatures for healthcare documents

1 Scope

This part of ISO 17090 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.

Furthermore, it defines the provable compliance with a PKI policy necessary in the domain of healthcare. This part of ISO 17090 adopts long-term signature formats to ensure integrity and non-repudiation in long-term electronic preservation of healthcare information.

This part of ISO 17090 conforms to ISO/ETSI standards for long-term signature formats to improve and guarantee interoperability in the healthcare field.

There is no limitation regarding the data format and the subject for which the signature is created.

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 17090-1:2008, *Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services*

ISO 17090-3:2008, *Health informatics — Public key infrastructure — Part 3: Policy management of certification authority*

3 Terms and definition

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

3.1 certification path

connection of a series of certificates binding the certificate which is to be validated to a trusted root trust anchor

3.2 certification path validation

path to be validated to a trusted root trust anchor including revocation checking

3.3 hash function

computation method used to generate a random value of fixed length from the data of any optional length

Note 1 to entry: The generated value is called a “hash value”, which has the properties of being uni-directional (the original data cannot be back calculated from it) and of having a low probability of having been generated from two different data (collision).

Note 2 to entry: Because of these properties, when sending/receiving data, if the hash value generated on the sending side and the hash value of the data obtained by the receiving side match on comparison, it can be confirmed with a high degree of confidence that the data were not tampered with during transmission.

4 Scope of application

4.1 Target system

The target systems of this part of ISO 17090 are as follows:

- a) the digital signature library with the digital signature function and the digital signature verification function for the medical treatment application;
- b) the digital signature program and the digital signature verification program as the stand-alone software or with the medical treatment application;

The following are out of scope:

- a) the medical treatment application that does not process the digital signature data directly;
- b) the medical treatment application that processes the digital signature and the result of signature verification with the digital signature library, the specific digital signature program, or the specific digital signature verification program;
- c) the application interface and user interface; [Figure 1](#) shows an example of the processing layer. The digital signature application layer (the digital signature library, the digital signature program, or the digital signature verification program) is the target scope of this example. Therefore, the following layer, CSP, and PKCS#11, is not within the targeted scope of this International Standard.

In HPKI, it is assumed that 'Storage modules of the end entity subscriber private key shall conform to standards of levels equal to or higher than US FIPS 140-2 level 1' by ISO 17090-3:2008, 7.6.2.12. Also, in addition to the smart card, as illustrated, a system could use a USB token, software token, etc., as the medium that stores the private key.

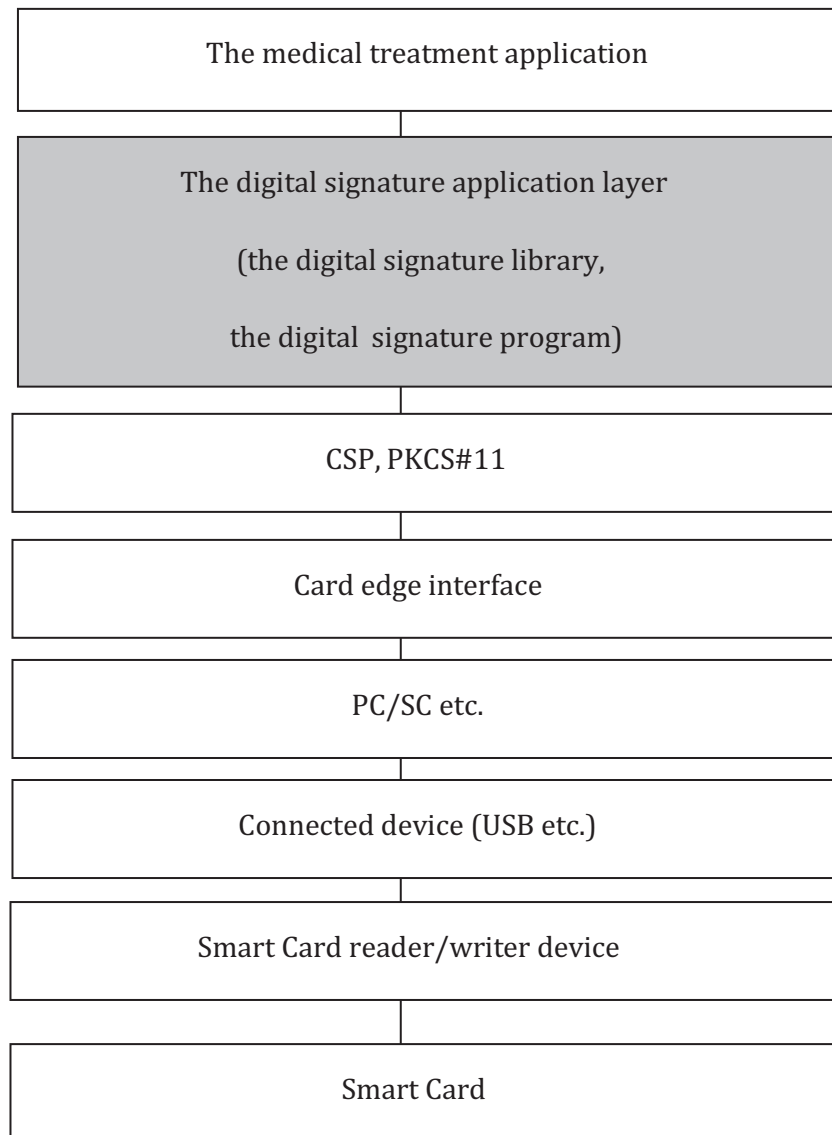


Figure 1 — Example of processing layer digital signature specification

4.2 Generation process

The digital signature format is based on ETSI advanced digital signatures, where CADES (CMS Advanced Digital Signature)^[5] and XAdES (XML Advanced Digital signature)^[6] are described in this International Standard.

These specifications define the various formats according to purpose of operation.

- ES: The format that has the digital signature value, data itself, and information about the signer.
- ES-T: The format that has the Signature Timestamp in addition to the ES format. Signature Timestamp is a trusted timestamp provided by a timestamp authority to prove the existence of the signature.
- ES-C: The format that has validation data references in addition to the ES-T format.
- ES-X: The format that has ES-C Timestamp to protect validation data references.
- ES-X Long: The format that has the ES-C format and revocation information for verification.

- ES-A: The format that has an Archive Timestamp to protect the signature, the timestamps, and the validation data.

See [Figure 2](#) for the different format types of digital signature.

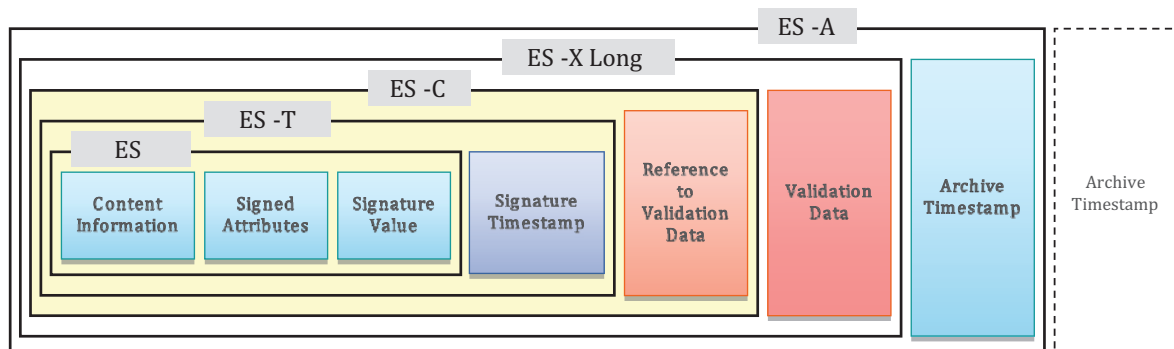


Figure 2 — Format types of digital signature

This specification only defines the profile of ES-T and ES-A. The other formats are considered to be intermediate formats to generate ES-T or ES-A, and they are out of scope of this part of ISO 17090.

The digital signature format is based on ETSI advanced digital signatures, where CADES^[5] based on a CMS (Cryptographic Message Syntax) and XAdES^[6] based on an XML Advanced Digital signature are described in this International Standard.

The CADES profile that specifies elements required/allowed to generate ES-T and ES-A is described in [4.4](#); [4.5](#) describes the XAdES profile of ES-T and ES-A.

4.3 Verification process

This section describes an overview of the basic verification processes. This part of ISO 17090 does not provide verification methods for optional attributes. If the signature data contains any optional attributes, the optional attributes must be correctly verified in accordance with other specifications, policies, or guidelines.

4.3.1 Verification of ES

4.3.1.1 Verification processes of ES

The verification processes of ES are described below, and the order of the processes should not be changed. See [Figure 3](#).

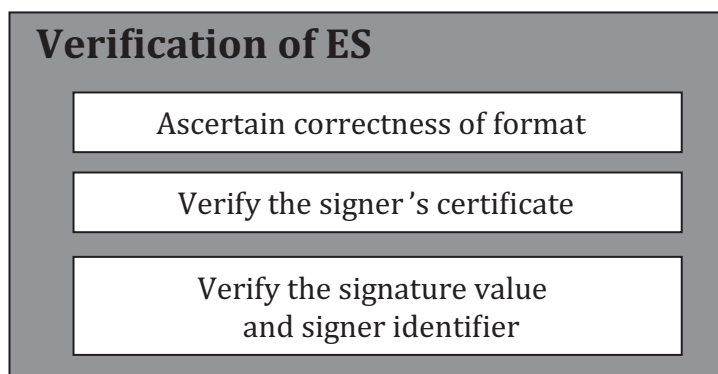


Figure 3 — Verification processes of ES

a) Verify the format of the signing data.

Verify if the digital signature format is correct.

b) Verify the signer's certificate.

The following steps are performed to ascertain the validity of the signer's certificate.

- 1) Certification path validation described in RFC5280.
- 2) Verify signer's certificate extensions regarding HPKI.

c) Verify the signature value of the signer.

The following steps are performed.

- 1) Verify the signature value using the signer's public key.
- 2) Verify the identifier of the signer's certificate.

The above processes are explained in [Annex A](#).

4.3.1.2 Description of verification processes

Verification process	Description
a) Ascertain correctness of format.	<p>The following conditions shall be checked.</p> <ul style="list-style-type: none"> — If the structure of the signature data complies to the defined format. — If the signature data contain all elements required in the profile. — If the version number of the signature data is correct.
b) Verify the signer's certificate.	<ol style="list-style-type: none"> 1) Certification path validation described in RFC5280. <ul style="list-style-type: none"> — Build and verify the certification path for the signer's certificate. 2) Ascertain extensions regarding HPKI contained in the signer's certificate. <ul style="list-style-type: none"> — Implementations are required to support functions to check the following elements. — HPKI certificate policy identifier. — The value of the hcRole attribute in the signer's certificate. — The ascertainment method is out of scope of this part of ISO 17090. It is possible to choose suitable methods for applications.

c) Verify the signature value and signer identifier.	1) Verify the signature value using the signer's public key. The following steps shall be performed. — Calculate the hash value of the content data and ascertain that it matches the value of the message digest contained in the signature. — Verify the signature value with signed attributes using the signer's public key.
	2) Verify the correspondence of the identifier information of the signer's certificate. — Ascertain that the signer identifier matches the signer's certificate attributes contained in the signature data.

4.3.2 Verification of ES-T

4.3.2.1 Verification process of ES-T

This section describes the process to verify a signature in ES-T format.

The verification processes of ES-T are described below, and the order of the processes should not be changed. See [Figure 4](#).

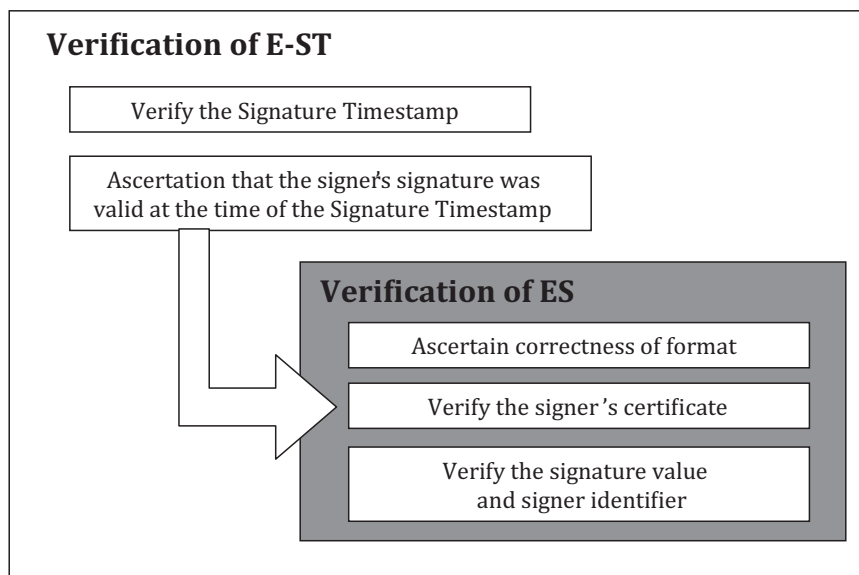


Figure 4 — Verification processes of ES-T

- a) Verify the Signature Timestamp.
 - 1) Verify the certificate of the TSA that provides the Signature Timestamp.
 - 2) Verify the signature value of the TSA that provides the Signature Timestamp.
 - 3) Verify the message imprint of the timestamp token.
- b) Verify the signer's signature at the time of the signature timestamp.
 - 1) Ascertain that the signer's signature was valid at the time of the Signature Timestamp.

- 2) Ascertain that the signer's trust anchor is appropriate.

The above processes are explained in [Annex A](#).

4.3.2.2 Description of a verification process

Verification process	Description
a) Verify the Signature Timestamp.	<p>1) Verify the certificate of the TSA that provides the Signature Timestamp.</p> <p>The following steps shall be performed for the TSA certificate.</p> <ul style="list-style-type: none"> — Certification path validation as described in RFC5280. — Ascertain that the certificate contains extended key usage for TSA purpose. <p>2) Verify the signature of the TSA that provides the Signature Timestamp.</p> <p>Verify the signature value of the timestamp token using the public key of a TSA certificate.</p> <p>3) Verify the message imprint of the timestamp token.</p> <ul style="list-style-type: none"> — Calculate the hash value of the signer's signature value and ascertain that it matches the value of the message imprint within the timestamp token.
b) Verify the ES at the time of the Signature Timestamp.	<p>1) Verify the ES at the time of the Signature Timestamp.</p> <ul style="list-style-type: none"> — Verify that the certificate of the signer was valid at the time of the Signature Timestamp. <p>2) Verify that the trust anchor is appropriate.</p> <ul style="list-style-type: none"> — Verification could be performed in a long period of time after the ES-T data were created. The trust anchor that was valid at the time of signature might be expired or compromised at the time of verification. In this case, the verifier must verify that the trust anchor is appropriate. — For example, the signer and the verifier specify an agreement about the trust anchor (for example, the signature policy) and manage it under protection against CA compromise, or the verifier refers to a trusted third party that manages the history of verification information of certificates. Specific methods are out of the scope of this part of ISO 17090.

4.3.3 Verification of ES-A

4.3.3.1 Verification process of ES-A

The verification processes of ES-A are described below, and the order of the processes should not be changed. See [Figure 5](#).

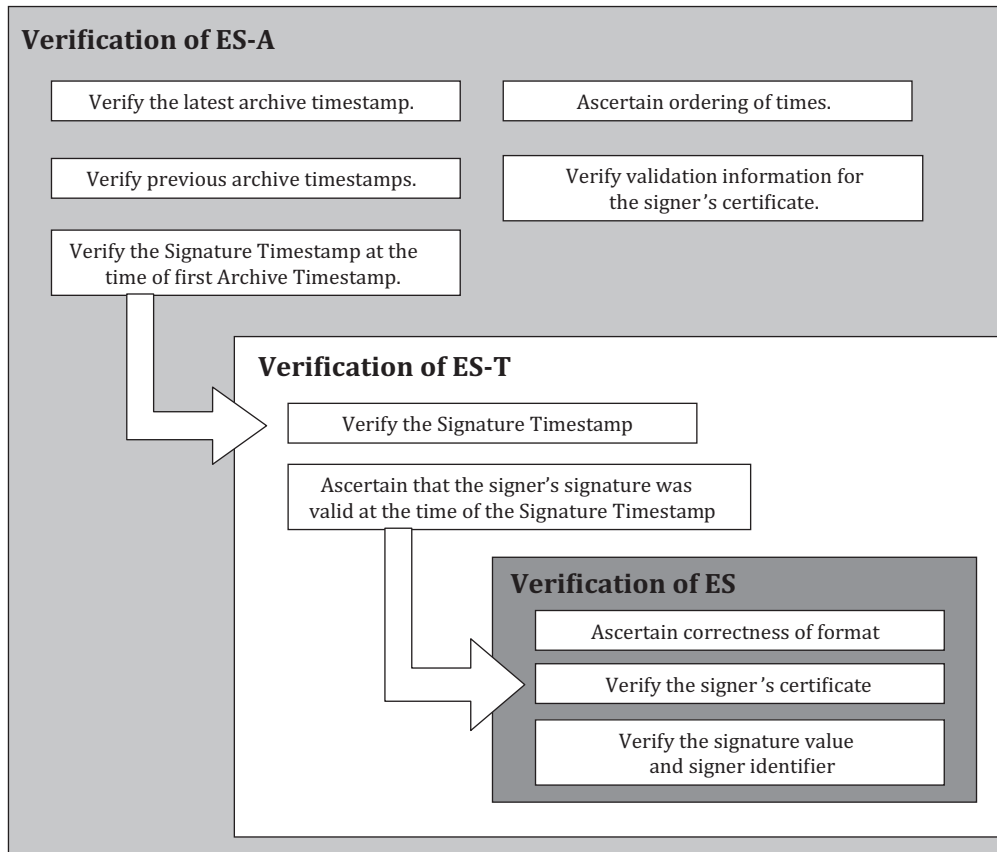


Figure 5 — Verification processes of ES-A

- a) Verify the latest Archive Timestamp.
Verify that the latest Archive Timestamp is valid at the time of verification.
 - 1) Verify the certificate of the TSA that provides the latest Archive Timestamp.
 - 2) Verify the signature of the TSA that provides the latest Archive Timestamp.
 - 3) Verify the correspondence of the latest Archive Timestamp and the target data of the timestamp.
- b) Verify the previous Archive Timestamps, if present.
Verify that the timestamp was valid at the time when the data was archived.
 - 1) Verify the certificate of the TSA that provides the Archive Timestamp.
 - 2) Verify the signature of the TSA that provides Archive Timestamp
 - 3) Verify the correspondence of the Archive Timestamp and the target data of the timestamp.
 - 4) Verify that the trust anchor of the Archive Timestamp is appropriate.
- c) Verify the validation data of the signer's certificate.
 - 1) Verify the validity of the certificate chain archived in the validation data.
 - 2) Verify that the trust anchor is appropriate.
 - 3) Verify the validity of revoke information archived in the validation data.

- 4) Verify that the trust anchor of revoke information is appropriate.
 - d) Verify the Signature Timestamp.
 Verify that the timestamp is appropriate.
 - 1) Verify that the Signature Timestamp was valid at the time it was archived.
 - 2) Verify that the trust anchor of the Signature Timestamp is appropriate.
 - e) Verify the ES at the time of the Signature Timestamp.
 - 1) Verify that the ES was valid at the time of the Signature Timestamp.
 - 2) Verify that the trust anchor is appropriate.
 - f) Verify the ordering of the times of timestamps and the issued time of validation data.
- The above processes are explained in [Annex A](#).

4.3.3.2 Description of Verification Process

Verification process	Description
a) Verify the latest Archive Timestamp.	1) Verify the certificate of the TSA that provided the latest Archive Timestamp. The following steps shall be performed for the TSA certificate. <ul style="list-style-type: none"> — Verify the validity of the certificate at the time of verification. — Ascertain that the purpose of the key usage of the TSA certificate is appropriate.
	2) Verify the signature of the TSA that provides the latest Signature Timestamp. <ul style="list-style-type: none"> — Verify the signature value of the timestamp token using the public key of the TSA certificate.
	3) Verify the message imprint of the timestamp token. <ul style="list-style-type: none"> — Calculate the hash value of the target fields for the archive and verify that it matches the value of the message imprint within the timestamp token.

<p>b) Verify the previous Archive Timestamp, if it is present.</p>	<p>1) Verify the certificate of the TSA that provides the Archive Timestamp.</p> <p>— Verify the validity of the TSA certificate of the archive timestamp at the time that is shown in the next generation archive timestamp.</p> <p>The relationship of time for verification is shown in Figure 6.</p> <p>2) Verify the signature of the TSA that issued the archive timestamp.</p> <p>3) Verify the correspondence between the archive timestamp and the imprint data.</p> <p>4) Verify that the trust anchor of the TSA certificate is appropriate.</p> <p>— The validity of the certificate at the trust point could be expired at the time of verification of the TSA certificate for the archive timestamp.</p> <p>— In order to verify the trust anchor of b) 1), confirm that the certificate at the trust point is appropriate. Specific methods are out of the scope of this part of ISO 17090.</p>
<p>c) Verify validation data for the signer's certificate.</p>	<p>1) Ascertain the validity of the certificate chain archived in the validation data.</p> <p>2) Ascertain that the trust anchor of the certificate is appropriate.</p> <p>3) Ascertain the validity of revoke information archived in the validation data.</p> <p>— Compare the issued time of revoke information with the time of archiving and confirm that the revoke information is appropriate.</p> <p>4) Ascertain that the trust point of the revoke information is valid.</p> <p>— Confirm that the trust point certificate is appropriate at the time of verification of validity of the certificate used for signing the revoke information.</p>

<p>d) Verify the Signature Timestamp at the time of the first Archive Timestamp.</p>	<p>1) Ascertain that the Signature Timestamp was valid at the time of the first Archive Timestamp.</p> <p>— Execute 4.3.3.2 assuming the time of the first archive timestamp. Verify that the TSA certificate was valid at the time of the first archive timestamp.</p> <p>2) Verify that the trust anchor of the Signature Timestamp was appropriate at the time of first Archive Timestamp.</p> <p>— The validity of the certificate at the trust point could be expired at the time of verification of the TSA certificate for the signature timestamp.</p> <p>— In order to verify the trust anchor of d) 1), confirm that the certificate at the trust point is appropriate. Specific methods are out of the scope of this part of ISO 17090.</p>
<p>e) Verify the signer's signature at the time of the Signature Timestamp.</p>	<p>1) Verify the signer's signature based upon Annex A using validation data that is verified by process (c) and ascertain that the certificate was valid at the time of the Signature Timestamp.</p> <p>2) Ascertain that the trust anchor is appropriate.</p> <p>— The validity of the certificate at the trust point could be expired at the time of verification of the signer's certificate.</p> <p>— In order to verify the trust anchor of e) 1), confirm that the certificate at the trust point is appropriate. Specific methods are out of the scope of this part of ISO 17090.</p>
<p>f) Verify the ordering of times. Confirm the correspondence of time.</p>	<p>Ascertain the correspondence of times that is not in the flow of the process above.</p> <p>— Ascertain the correspondence of signature timestamps and archive timestamps.</p>

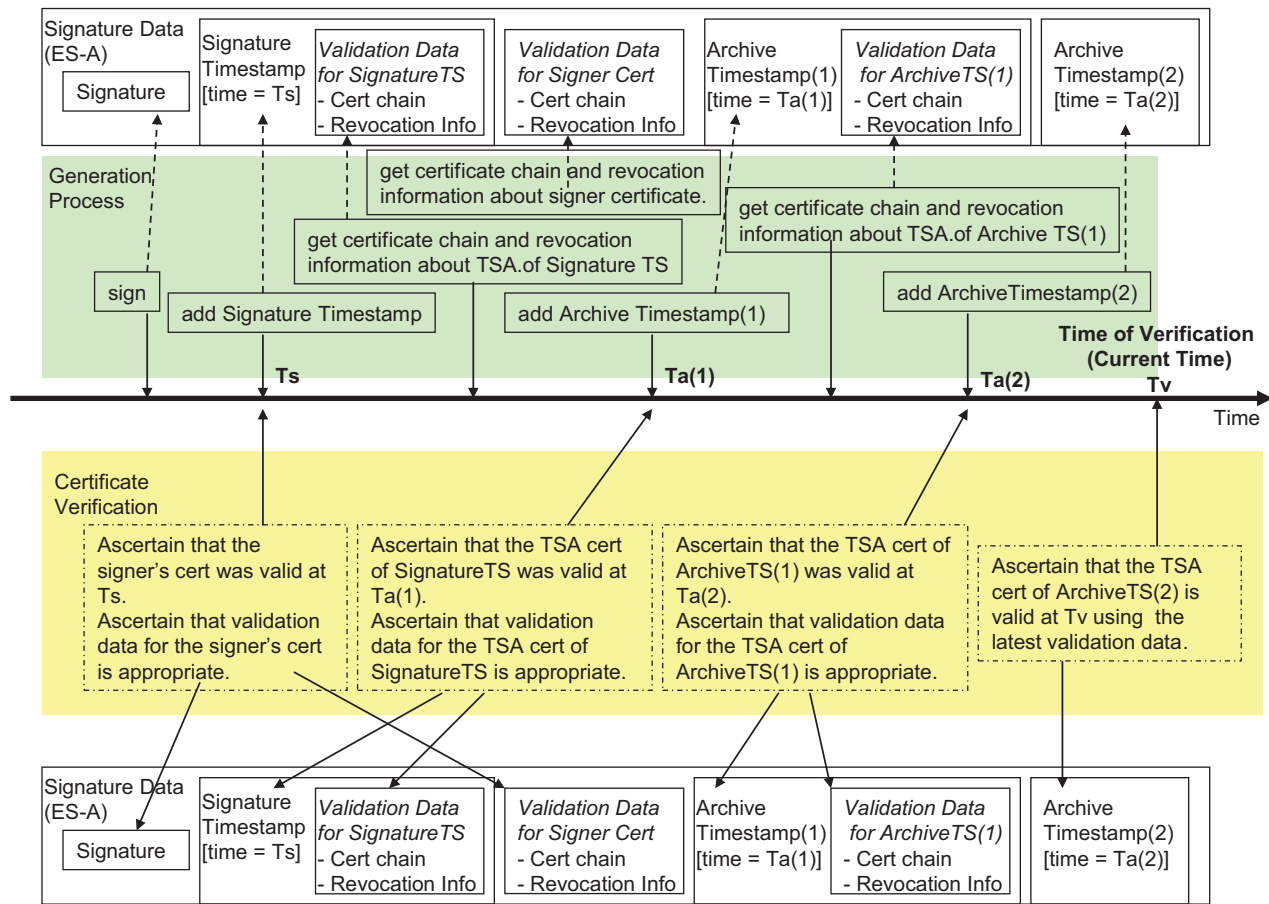


Figure 6 — The relationship of time for ES-A verification (the case of 2 Archive Timestamps)

4.4 CADES specification

This section describes requirements for the generation or validation of CADES data.

[Table 1](#) describes the relationships of profiles defined by this International Standard, and [Table 2](#) describes the data structure of CADES. [Table 3](#), [Table 4](#), and [Table 5](#) describe profiles defined by this part of ISO 17090, and [Table 6](#) describes elements of the CADES data.

4.4.1 Long-term signature profile

In order to make digital signatures verifiable for the long term, SigningTime should be identifiable, any illegal alterations of information pertaining to signatures should be detectable, including the subject of information and validation data, and interoperability should be ensured. By defining the following two profiles, this International Standard satisfies the previous requirements for CADES.

a) CADES-T profile

A profile pertaining to the generation and validation of CADES-T data.

b) CADES-A profile

A profile pertaining to the generation and validation of CADES-A data.

[Figure 7](#) shows the relationship between CADES-T data and CADES-A data.

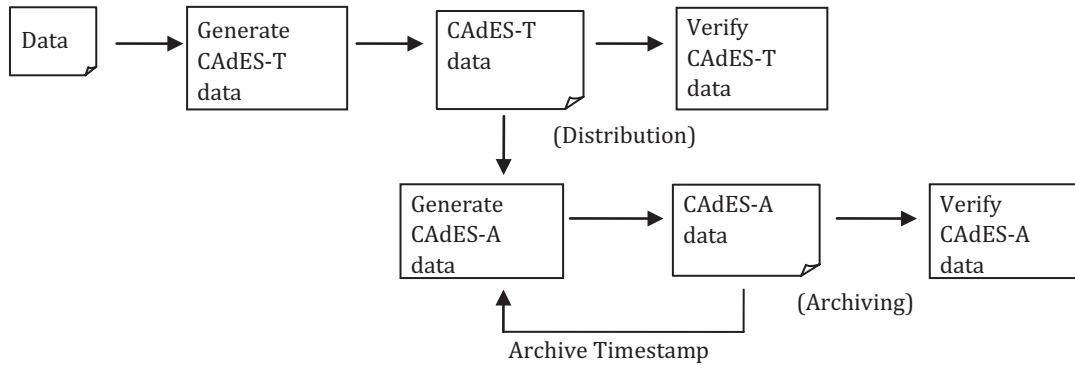


Figure 7 — Relationship between CAdES-T data and CAdES-A data

4.4.2 Representation of the required level

This part of ISO 17090 defines the following representation methods for the required level (as a profile) of each element constituting CAdES-T data and CAdES-A data.

a) **Mandatory (M)**

Elements whose required level is ‘Mandatory’ must be implemented. If such an element has optional subelements, at least one subelement must be selected. Any element whose required level is ‘Mandatory’ and is one of the subelements of an optional element must be selected whenever the optional element is selected.

b) **Optional (O)**

Elements whose required level is ‘Optional’ may be implemented at the discretion of the implementer.

c) **Conditional (C)**

Elements whose required level is ‘Conditional’ may be implemented at the discretion of the implementer. Detailed specifications pertaining to the processing of any element whose required level is ‘Conditional’ shall be provided. For example, the implementer provides the specifications for any ‘Conditional’ elements by disclosing a supplier’s declaration of conformity and its attachment (see ISO 14533-1:2012, Annex A or ISO 14533).

d) **Prohibited (P)**

Elements whose required level is ‘Prohibited’ must not be in the data. The prohibited element may be ignored in validation processes.

4.4.3 CAdES-T profile

Table 1 — ContentInfo

Element	Required level	Value
ContentType	M	Id-signedData
Content	M	SignedData

Table 2 — SignedData

Element	Required level	Value
CMSVersion	M	
DigestAlgorithmIdentifiers	M	
EncapsulatedContentInfo	M	
—eContentType	M	
—eContent	O	
CertificateSet (Certificates)	O	
—Certificate	O	
—AttributeCertificateV2	P	
—OtherCertificateFormat	P	
RevocationInfoChoices (crls)	O	
—CertificateList	O	
—OtherRevocationInfoFormat	C	
SignerInfos	M	
—single	O	
—parallel	O	

Table 3 — SignerInfo

Element	Required level	Value
CMSVersion	M	
SignerIdentifier	M	
—IssuerAndSerialNumber	O	
—SubjectKeyIdentifier	O	
DigestAlgorithmIdentifier	M	
SignedAttributes	M	
SignatureAlgorithm	M	
SignatureValue	M	
UnsignedAttributes	M	

The required level shall be 'Conditional' for any signed and unsigned attribute elements not listed in [Table 4](#) and [Table 5](#).

Table 4 — SignedAttributes

Element	Required level	Value
ContentType	M	
MessageDigest	M	
SigningCertificateReference	M	
^a ESSSigningCertificate or ESSSigningCertificateV2 shall be selected. ^b When the element is not implemented, it may be ignored.		

Table 4 (continued)

Element	Required level	Value
—ESSSigningCertificate	O ^a	
—ESSSigningCertificateV2	O ^a	
—OtherSigningCertificate	P	
SignatureAlgorithmIdentifier	C	
SigningTime	O ^b	
ContentReference	C	
ContentIdentifier	C	
ContentHint	C	
CommitmentTypeIndicatio	C	
SignerLocation	C	
SignerAttribute	C	
ContentTimestamp	C	
^a ESSSigningCertificate or ESSSigningCertificateV2 shall be selected. ^b When the element is not implemented, it may be ignored.		

Table 5 — Additional Unsigned Attributes

Element	Required level	Value
CounterSignature	O	
Signing time information	M	
—SignatureTimestamp	M	TimeStamp defined in RFC3161
—Time Mark etc.	P	

4.4.4 CADES-A profile

The CADES-A profile is defined as an extended form of the CADES-T profile to which the unsigned attributes specified in [Table 6](#) are added. The required level shall be 'Conditional' for any element not specified in [Table 6](#).

Table 6 — Additional Unsigned Attributes

Element	Required level	Value
CompleteCertificateRefs	M (O for validation)	
CompleteRevocationRefs	M (O for validation)	
—CompleteRevRefs CRL	O	
—CompleteRevRefs OCSP	O	
—OtherRevRefs	P	
Attribute certificate references	P	
Attribute revocation references	P	
CertificateValues	M	
—CertificateValues	O	

Table 6 (continued)

Element	Required level	Value
—Certificates maintained by trusted service	P	
RevocationValues	M	
—CertificateList	O	
—BasicOCSPResponse	O	
—OtherRevVals	P	
—Revocation information maintained by trusted service	P	
CAdES-C-timestamp	P	
Time-stamped cert and crls reference	P	
Archiving	M	
—ArchiveTimestampV2 id-aa-48	O	TimeStamp defined in RFC3161
—ArchiveTimestamp id-aa-27	O	TimeStamp defined in RFC3161
—Time Mark etc.	P	

4.5 XAdES specification

This section details the requirements for the generation and verification of XAdES.

Subclause [4.5.1](#) shows the outline of the profile that this part of ISO 17090 defines and subclause [4.5.2](#) shows the structure of XAdES. Subclauses [4.5.3](#) and [4.5.4](#) and [Table 11](#) show the requirements for a profile.

4.5.1 Defined long-term signature profiles

In order to make digital signatures verifiable for the long term, interoperability should be ensured, Signing Time should be identifiable, and any illegal alterations of information pertaining to signatures should be detectable, including the subject of information and validation data. By defining the following two profiles, this part of ISO 17090 satisfies the previous requirements for XAdES.

a) XAdES-T profile:

A profile pertaining to the generation and validation of XAdES-T data.

b) XAdES-A profile:

A profile pertaining to the generation and validation of XAdES-A data.

[Figure 8](#) shows the relationship between XAdES-T data and XAdES-A data.

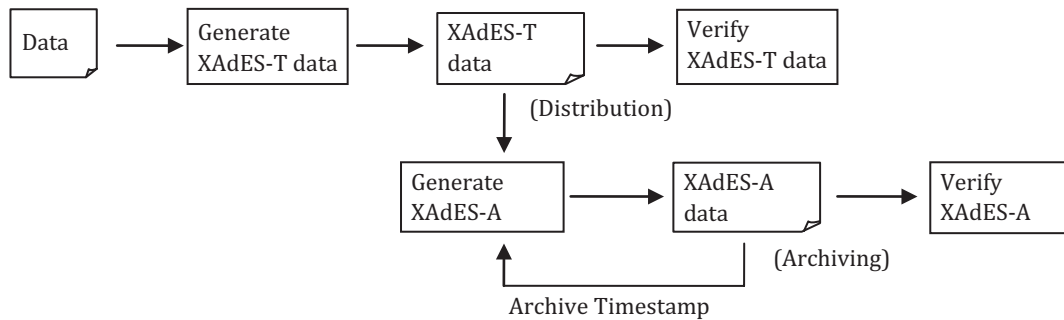


Figure 8 — Relationship between XAdES-T data and XAdES-A data

4.5.2 Representation of the required level

This part of ISO 17090 defines the following representation methods for the required level (as a profile) of each element constituting XAdES-T data and XAdES-A data.

a) Mandatory (M)

Elements whose required level is ‘Mandatory’ must be implemented without fail. If such an element has optional subelements, at least one subelement must be selected. Any element whose required level is ‘Mandatory’ and is one of the subelements of an optional element must be selected whenever the optional element is selected.

b) Optional (O)

Elements whose required level is ‘Optional’ may be implemented at the discretion of the implementer.

c) Conditional (C)

Elements whose required level is ‘Conditional’ may be implemented at the discretion of the implementer. Detailed specifications pertaining to the processing of any element whose required level is ‘Conditional’ shall be provided. For example, the implementer provides the specifications for any ‘Conditional’ elements by disclosing a supplier’s declaration of conformity and its attachment (see ISO 14533-1:2012, Annex A or ISO 14533).

d) Prohibited (P)

Elements whose required level is ‘Prohibited’ must not be implemented. The elements may be ignored in validation processes.

4.5.3 Requirement for XAdES-T

The required level shall be ‘Conditional’ for any elements not listed in [Table 7](#), [Table 8](#), [Table 9](#), and [Table 10](#).

Table 7 — Signature element

Element or attribute	Required level	Condition
ID attribute of ds:Signature	M (See Note 1)	
ds:SignedInfo	M	
NOTE 1 ‘Optional’ in an XML signature, but ‘Mandatory’ in XAdES.		
NOTE 2 Either ds:KeyInfo or SigningCertificate (see Table 9) is required. If ds:KeyInfo is selected (Mandatory in XAdES v1,1,1), an X,509 data element defined in the XML signature shall be included as a subelement.		

Table 7 (continued)

Element or attribute	Required level	Condition
—ds:CanonicalizationMethod	M	C14n
—ds:SignatureMethod	M	
—ds:Reference	M	
—ds:Transforms	O	
—ds:DigestMethod	M	
—ds:DigestValue	M	
ds:SignatureValue	M	
ds:KeyInfo	O (See Note 2)	
ds:Object	M	

NOTE 1 'Optional' in an XML signature, but 'Mandatory' in XAdES.

NOTE 2 Either ds:KeyInfo or SigningCertificate (see [Table 9](#)) is required. If ds:KeyInfo is selected (Mandatory in XAdES v1,1,1), an X,509 data element defined in the XML signature shall be included as a subelement.

Table 8 — Object element

Element	Required level	Condition
QualifyingProperties	M	The ID attribute value of the signature element shall be entered in the target attribute.
—SignedProperties	M	
—UnsignedProperties	O	
QualifyingPropertiesRefernece	C	

Table 9 — Signed Properties element

Element	Required level	Condition
SignedSignatureProperties	M	
—SigningTime	O (See Note 1)	
—SigningCertificate	O (See Note 1, Note 2)	
—SignaturePolicyIdentifier	C	
—SignatureProductionPlace	C	
—SignerRole	C	
SignedDataObjectProperties	C	
—DataObjectFormat	C	
—CommitmentTypeIndication	C	
—AllDataObjectsTimeStamp	C	
—IndividualDataObjectTimeStamp	C	

NOTE 1 Mandatory in XAdES v1,1,1.

NOTE 2 Either SigningCertificate or ds: KeyInfo (see [Table 7](#)) is required.

Table 10 — Unsigned Properties element

Element	Required level	Condition
UnsignedSignatureProperties	M	
—CounterSignature	O	
—Trusted signing time	M	
—SignatureTimeStamp	M	TimeStamp defined as RFC3161 ^a
—TimeMark or other method	P	
UnsignedDataObjectProperties	C	

^a TimeStamp is defined as RFC3161 because the method of acquiring a TimeStamp and storing it in XAdES data and the method of verifying the TimeStamp are clearly shown by standards.

4.5.4 Requirement for XAdES-A

The XAdES-A profile is defined as an extended form of the XAdES-T data. The required level of each element of the UnsignedSignatureProperties defined as XAdES shall be as specified in [Table 11](#). The required level shall be 'Conditional' for any element not specified in [Table 11](#).

Table 11 — Unsigned Signature Properties element

Element or Processing method	Required level	Condition
CompleteCertificateRefs	O (See Note 1)	
CompleteRevocationRefs	O (See Note 1)	
—CRLRef	O	
—OCSPRef	O	
—OtherRef	P	
AttributeCertificateRefs	P	
AttributeRevocationRefs	P	
SigAndRefsTimeStamp	P	
— <i>not distributed case</i>	P	
— <i>distributed case</i>	P	
RefsOnlyTimeStamp	P	
— <i>not distributed case</i>	P	
— <i>distributed case</i>	P	
CertificateValues	M	
—EncapsulatedX509Certificate	O	
—OtherCertificate	P	
— <i>Certificates maintained by trusted service</i>	P	

^a TimeStamp is defined as RFC3161 because the method of acquiring a TimeStamp and storing it in XAdES data and the method of verifying the TimeStamp are clearly shown by standards.

NOTE 1 Mandatory in XAdES v1,1,1.

NOTE 2 Italic type describes the processing method.

NOTE 3 AttrAuthoritiesCertValues, AttributeRevocationValues, not distributed cases and distributed cases are not defined in XAdES v1,1,1 and v1,2,1. AttributeCertificateRefs and AttributeRevocationRefs are also not defined in v1,1,1.

Table 11 (continued)

Element or Processing method	Required level	Condition
RevocationValues	M	
—CRLValues	O	
—OCSPValues	O	
—OtherValues	P	
<i>—Revocation information maintained by trusted service</i>	P	
AttrAuthoritiesCertValues	P	
AttributeRevocationValues	P	
<i>Archiving</i>	M	
—ArchiveTimeStamp	M	
— <i>not distributed case</i>	M	TimeStamp defined as RFC3161 ^a
— <i>distributed case</i>	P	
— <i>Time mark or other method</i>	P	
Any unsigned signature property defined in any other version of XAdES	C	
^a TimeStamp is defined as RFC3161 because the method of acquiring a TimeStamp and storing it in XAdES data and the method of verifying the TimeStamp are clearly shown by standards. NOTE 1 Mandatory in XAdES v1,1,1. NOTE 2 Italic type describes the processing method. NOTE 3 AttrAuthoritiesCertValues, AttributeRevocationValues, not distributed cases and distributed cases are not defined in XAdES v1,1,1 and v1,2,1. AttributeCertificateRefs and AttributeRevocationRefs are also not defined in v1,1,1.		

Annex A (informative)

A.1 Targeted use cases

Digital signatures are included in the original electronic data for the purpose of 'non-repudiation.' In actual activities in the healthcare field, the targeted use cases are categorized as follows.

- a) The digital signatures for the external documents, such as REFERRAL (medical examination and treatment information) and treatment information.
- b) The digital signature for the purpose of the electronic preservation of documents for which preservation was required for a decree.
- c) The digital signature for other internal documents, such as the laboratory reports and radiological image reading reports.
- d) The digital signature added when paper documents are preserved as electronic documents by scanning.
- e) The digital signature for the access logs.

Use cases are described based upon the above-mentioned classification; however, note that these are not comprehensive but are examples of typical use cases.

A.1.1 The digital signatures for the external documents

There are various documents ("print outs") issued by medical organizations to external organizations. The following documents should be converted to an electronic format as external documents:

- leaving certificate;
- medical certificate;
- REFERRAL;
- request for a medical record;
- clinical trial result.

When these documents are converted to an electronic format, long-term preservation is assumed. Therefore, the long-term signature defined by this part of ISO 17090 seems to be applicable. The use cases in which signatures are applied are as follows:

- leaving certificate;
- medical certificate.

An application may require valid signatures when the recipient side needs to clarify the authenticity and the attributes of a document's author, such as a physician's legal qualification.

When these documents are converted to an electronic format, adding the digital signature enables the authenticity and the attribute of the author (hcRole) to be easily clarified by the recipient side. Therefore this can be an effective use case.

— REFERRAL

In medical institutions that share information with other organizations, REFERRAL documents issued by hospitals/clinics need a physician's signature or affixing seal stipulated. When the documents are converted to an electronic format, the digital signature is also required. At the recipient side, validation of the signature is required for as long as the data are retained. Therefore, this can be an effective use case.

— Request for a medical record

This is a use case describing information retrieved by a request for the disclosure of medical records pertaining to a specific patient to that patient. It is transfer of the information from the medical institution to the patient, requiring both the assurance of the authenticity of the contents and a strong property of non-repudiation. Therefore, this can be an effective use case.

— Clinical trial results

When clinical trial results are created in electronic format, the treatment of personal information shall comply with the regulation applicable in each nation. As clinical trial results are preserved for the long term, the long-term signature standardized by this part of ISO 17090 will be useful.

A.1.2 The digital signature for the electrical preservation of documents

For example, the documents for which preservation is required in Japan are the following:

- medical care histories (physicians, dentists, etc.);
- birthing assistance records (midwives);
- instruction sheets stipulated (dental technicians);
- emergency medical care records (emergency life guards);
- application records (dental hygienists);
- irradiation records (radiology technicians);
- prescription (physician);
- dispensing records (pharmacists);
- hospital diary (hospitals);
- medical treatment diary (hospitals);
- prescription (hospitals);
- operation records (hospital);
- diagnosis reports (hospital).

Regarding the digitalization of these documents, the use cases are considered as follows. In general, the valid period of certificates is shorter than the legal preservation period; however, the verification shall be ensured during the legal period. Therefore, the long term signature defined by this part of ISO 17090 is required.

- Documents for which preservation is obliged by the law

The addition of digital signature is required from the legal requirements.

In this case, the procedure to add digital signature is as follows.

- a) Add the digital signature of the issuer when the document is issued.
- b) Integrity and non-repudiation shall be kept when information using digital signatures is preserved.

— Documents for which preservation is not obliged by the law.

Because the preservation of these documents is not in response to a legal obligation, the addition of a digital signature is not required. However, from the point of view of integrity and non-repudiation, the digital signature should be required. The procedure to add the signature is the same as in the case, "Documents whose preservation is obliged by law."

A.1.3 The digital signature for internal documents

"Internal documents" exclude documents written in the "Documents whose preservation is obliged by law." For example, internal documents would include "laboratory reports" and "radiological image reading reports" specified individually by medical institutes. Although various checks may be included in this category, it may not be the case that these are treated separately because the order entry systems are operated in the medical institutions as integrated components of the electronic health records systems. For the use of "hcRole" management, "Contracts" may be included in this category.

A.1.4 Using a digital signature for the electronic storage of paper documents with an image scanner and disposing of the original paper documents

In the case of converting a medical record into an electronic format using an image scanner and disposing of the original paper documents, an operator (or an administrator) shall sign so that one can trace the responsibility. Medical records in electronic format can be verified in case of falsification. Converting the clinical record from a paper format into an electronic format requires a higher degree of confidence in the chain of authorization as compared with the case where a record is created from the beginning in an electronic format.

A.1.5 Using a digital signature for an access log

The access logs of electronic health records contain significant amounts of data. Therefore, data that exceed a pre-determined retention period should be preserved in an archival system. The system administrator's signature may be required to ensure that the access log has not been falsified.

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