

Australian Standard™

**Health informatics—Public key
infrastructure**

Part 1: Framework and overview

This Australian Standard was prepared by Committee IT-014, Health Informatics. It was approved on behalf of the Council of Standards Australia on 30 March 2003 and published on 16 May 2003.

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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

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Published as AS ISO 17090.1—2003.

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Published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001

ISBN 0 7337 5189 X

PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee IT-014, Health Informatics. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

This Standard is identical with, and has been reproduced from, the International Technical Specification ISO/TS 17090-1:2002, *Health informatics—Public key infrastructure—Part 1: Framework and overview*.

Committee IT-014 provided input to the International Organization for Standardization (ISO) Committee, ISO/TC 215 on Health Informatics, in the preparation of the ISO 17090 family of International Standards.

The objective of this Standard is to define the basic concepts of a healthcare public key infrastructure (PKI) and to provide a scheme of interoperability requirements to establish a PKI enabled secure communication of health information. It also identifies the major stakeholders who are communicating in health, as well as the main security services required for health communication where PKI may be required.

This Standard is Part 1 of AS ISO 17090, *Health informatics—Public key infrastructure*, which is published in parts as follows:

- Part 1: Framework and overview (this Standard)
- Part 2: Certificate profile
- Part 3: Policy management of certification authority

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from an international standard, the following applies:

- (a) Its number appears on the cover and title page while the international standard number appears only on the cover.
- (b) In the source text ‘this part of ISO/TS 17090’ should read ‘this Australian Standard’.
- (c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

| <i>Reference to International Standard</i> | | <i>Australian or Australian/New Zealand Standard</i> | |
|--|---|--|---|
| ISO | | AS | |
| 7498 | Information processing systems—Open Systems Interconnection—Basic reference model | 2777 | Information processing systems—Open Systems Interconnection—Basic reference model |
| 7498-2 | Part 2: Security architecture | 2777.2 | Part 2: Security architecture |

(continued)

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|------------------|---|-------------------------|---|
| ISO 9594 | Information technology—Open Systems Interconnection—The Directory | AS/NZS 4019 | Information technology—Open Systems Interconnection—The Directory |
| 9594-8 | Part 8: Public-key and attribute certificate frameworks | 4019.8 | Part 8: Authentication framework |
| ISO/TS 17090 | Health informatics—Public key infrastructure | AS ISO 17090 | Health informatics—Public key infrastructure |
| 17090-2 | Part 2: Certificate profile | 17090.2 | Part 2: Certificate profile |
| 17090-3 | Part 3: Policy management of certification authority | 17090.3 | Part 3: Policy management of certification authority |
| ISO/IEC 17799 | Information technology—Code of practice for information security management | AS/NZS ISO/IEC 17799 | Information technology—Code of practice for information security management |

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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) technology seeks to address this challenge.

PKI is 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, PKI 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 a PKI (including encipherment, information integrity and digital signatures) are able to address many of these security issues. This is especially the case if PKI is used in conjunction with an accredited information security standard. Many individual organizations around the world have started to apply PKI for this purpose.

Interoperability of PKI 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 PKI schemes 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 adopting PKIs 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 PKI standards development activity is restricted to within national boundaries.

PKI technology is still rapidly 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 PKI. This Technical Specification seeks to address the need for guidance of these rapid international developments.

This technical document is being issued in the Technical Specification series of publications (according to the ISO/IEC Directives, Part 1, 3.1.1.1) as a prospective standard for the use of PKI in the field of healthcare because there is an urgent need for guidance on how standards in this field should be used to meet an identified need. This document is not to be regarded as an International Standard. It is proposed for provisional application so that information and experience of its use in practice may be gathered. ISO/TC 215 intends to revise it into a full International Standard after a three-year period.

This Technical Specification describes the common technical, operational and policy requirements that need to be addressed to enable PKI 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 PKI enabled communication across borders, but could also provide guidance for the establishment of healthcare PKIs nationally or regionally. 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 Technical Specification should be approached as a whole, with the three parts all making a contribution to defining how PKIs 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/TS 17090-1 defines the basic concepts of a healthcare public key infrastructure (PKI) and provides a scheme of interoperability requirements to establish a PKI enabled secure communication of health information.

ISO/TS 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 2459 for different types of certificates.

ISO/TS 17090-3 deals with management issues involved in implementing and operating a healthcare PKI. It defines a structure and minimum requirements for certificate policies (CPs) and a structure for associated certification practice statements. This part is based on the recommendations of the IETF/RFC 2527, *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 document, as well as comments, suggestions and information on the application of these technical specifications may be forwarded to the ISO/TC 215 secretariat: tsandler@astm.org and the WG4 secretariat w4sec215@medis.or.jp.

AUSTRALIAN STANDARD

Health informatics — Public key infrastructure —**Part 1:
Framework and overview****1 Scope**

This part of ISO/TS 17090 defines the basic concepts of a healthcare public key infrastructure (PKI) and provides a scheme of interoperability requirements to establish a PKI enabled secure communication of health information. It also identifies the major stakeholders who are communicating in health, as well as the main security services required for health communication where PKI may be required.

This part of ISO/TS 17090 gives a brief introduction to public key cryptography and the basic components of a healthcare PKI. It further introduces different types of certificates, public key 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 normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO/TS 17090. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO/TS 17090 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 7498-2:1989, *Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture*

ISO/IEC 9594-8:2001, *Information technology — Open Systems Interconnection — The Directory: Public-key and attribute certificate framework — Part 8*

ISO/TS 17090-2:2002, *Health informatics — Public key infrastructure — Part 2: Certificate profile*

ISO/TS 17090-3:2002, *Health informatics — Public key infrastructure — Part 3: Policy management of certification authority*

ISO/IEC 17020:2000, *Information technology — Code of practice for information security management*

INTERNET-DRAFT October 1999 4.1, *X.509 Attribute Certificate*