LICENCE

for

DR AS 2828.2:2018, Health records, Part 2: Digitized health records

Document Licence Agreement
(Public Comment Publications)

Standards Australia Limited (ABN 85 087 326 690) (**Standards Australia**) provides public access to draft standards and other documents for the purpose of obtaining public comment. Standards Australia provides the downloaded Publication(s) to You in PDF format on the following terms and conditions of use (**Agreement**).

By downloading the Publication(s) and checking the box "I have read and accept the terms of the Document Licence Agreement" and clicking "Accept", You accept and agree to the terms and conditions of this Agreement.

1. Definitions

1.1 **Authorised User** — if You are a company: a single end user who is nominated by You to access (including to view) or use the Publication.

1.2 **Intellectual Property Rights** — means all present and future rights conferred by statute, at common law or in equity and wherever existing, including:
(a) patents, designs, copyright, rights in circuit layouts, trademarks, know how, brand names, domain names, inventions, product names, trade secrets and any other rights subsisting in the results of intellectual effort in any field, whether or not registered and capable of registration;
(b) any application or right to apply for registration of any of these rights;
(c) any registration of any of those rights or any registration of any application referred to in

To read the full licence agreement, click within the box above and scroll through using the scroll bar

Draft

Australian Standard

Public Comment is invited for:

DR AS 2828.2:2018, *Health records*, Part 2: *Digitized health records*

Public Comment period:

Start date: 31 October 2018

Close date: 02 January 2019

To submit comments please use the following link:

https://hub.standards.org.au/hub/public/listOpenCommentingPublication.action

During their development process, Australian Standards are available in draft form during the public consultation period to allow any interests concerned with the application of the proposed Standard to review the draft and submit their comments.

This draft is liable to alteration. It is not to be regarded as an Australian Standard until finally issued as such by Standards Australia.

Upon successful conclusion of the Public Comment period it is proposed to publish this Standard as AS 2828.2:201X.

STANDARDS Australia

How to submit comments

To submit comments on this proposed identical adoption of this Australian Standard:

1. Register
   Register at the Standards Australia Standards Hub site:
   https://hub.standards.org.au/hub/public/listOpenCommentingPublication.action

2. Enter
   There are two submission options depending on the following:

   Option A: If you have fewer than 10 comments, fill in the online form.

   Option B: If you have more than 10 comments, download the Word form and type in your comments.

3. Submit
   Submit comments by clicking on the blue 'Online Comment' button or 'Upload' button.

Conditions for comment

Comments are welcome on the technical content, wording and general arrangement of the draft. How the requirements of this draft coordinate with other Standards is of particular importance and you are invited to point out any areas where changes or additions to this draft may be necessary. Editorial matters (i.e. spelling, punctuation, grammar, etc.) will be corrected before final publication.

Please provide supporting reasons and suggested wording for each comment. Where you consider that specific content is too simplistic, too complex or too detailed please provide an alternative.

If the proposed Standard is acceptable for Australia without change, an acknowledgement to this effect would be appreciated.

If you know of other persons or organizations that may wish to comment on this draft Australian Standard, please advise them of its availability. Copies of drafts and other publications from Standards Australia are available from SAI Global at www.saiglobal.com

Only comments submitted via the Standards Australia Standards Hub site before midnight on the closing date will be reviewed by the committee. The Hub automatically submits comments to the committee. Any other communication will not be considered by the committee.

At the expiry of the comment period, the committee responsible for the document is obliged to give serious consideration to all comments received. However, normally no acknowledgement of comment is sent.

Preface

This Standard was prepared by Standards Australia Technical Committee HE-025, Health Records, to supersede AS 2828.2(Int)—2012, *Health records*, *Part 2*: *Digitized (scanned) health record system requirements*.

The objective of this Standard is to specify requirements to be met by processes and systems used to digitize paper health records, to ensure that digitized health records are fit for purpose, easy to use, and address legal, safety, quality and security requirements. The Standard is intended for persons and organizations that create, maintain and curate digitized health records, and for suppliers of digitizing health record systems.

This Standard is one of a series of Standards, as follows:

AS 2828.1, *Health records, Part 1: Paper health records* (Under preparation. At Public Comment at the time of publication.)

AS 2828.2, *Health records, Part 2: Digitized (scanned) health records* (this Standard).

These documents should be read as a set to gain a better appreciation of the context.

In writing this Standard, concepts from AS/NZS ISO 13028—2012, *Information and documentation—Implementation guidelines for digitization of records* were taken into consideration.

Contents

Introduction

Electronic health records (EHR) development in Australia is proceeding in conjunction with the digitization of health records. Systems to digitize health records improve record-handling processes and improve access to the information contained in paper health records. The introduction of digitized record systems complements the health record and often serves as a transitionary phase between the paper record and EHRs, such as those maintained in electronic medical record (EMR) systems and practice management systems

As digitized systems and EHRs are used together in many organizations, multiple sources of patient information should be well integrated. Health record principles should apply irrespective of media and processes used to collect, maintain, access and archive the health record. Information should appear seamless and non-fragmented, to decrease risks in both patient care and organizational decision-making.

The need to scan paper records into health records will continue; even health services that implement a fully electronic health record will need to digitize paper received from external sources.

Future integration of digitized records into electronic records should be considered when implementing a digitized health record.

Australian Standard®

Health records

Part 2: Digitized health records

Section 1 Scope and General

1.1 Scope

This Standard specifies the requirements for digitization (scanning) of paper health records. It provides technical specifications, data capture and implementation principles as well as quality control measures.

In addition, it provides guidelines on best practice for safe storage, security, conformance and reproducibility of digitized health records.

This Standard is also intended to cover requirements for processes and systems for digitization of health record documents that may be accessed within the context of an electronic health record (EHR).

This Standard excludes any aspects of clinical information systems and electronic health records that are not primarily related to information in the form of scanned documents and captured images.

1.2 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.

NOTE Documents referenced for informative purposes are listed in the Bibliography.

AS 4846, *Person and provider identification in healthcare*

AS ISO 15489-1, *Information and documentation — Records management, Part 1: Concepts and principles*

AS ISO 23081-1, *Information and documentation — Records management processes — Metadata for records, Part 1: Principles*

AS/NZS ISO 13028, *Information and documentation—Implementation guidelines for digitization of records*

AS/NZS ISO 23081-2, *Information and documentation — Records management processes — Metadata for records, Part 2: Conceptual and implementation issues*

ISO 27789, *Health informatics — Audit trails for electronic health records*

ISO/IEC 646, *Information technology — ISO 7-bit coded character set for information interchange*

ISO/IEC 15417, *Information technology — Automatic identification and data capture techniques — Code 128 bar code symbology specification*

ISO/IEC 15424, *Information technology — Automatic identification and data capture techniques — Data Carrier Identifiers (including Symbology Identifiers)*

ISO/IEC 16022, *Information technology — Automatic identification and data capture techniques — Data Matrix bar code symbology specification*

ISO/IEC 16388, *Information technology — Automatic identification and data capture techniques — Code 39 bar code symbology specification*

1.3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Additional definitions and terms can be found at the Joint Initiative for Global Standards Harmonization Health Informatics Document Registry and Glossary website (www.skmtglossary.org).

1.3.1
audit trail
process that captures details of additions, deletions, views or alterations of information in a record without obliterating the original record

Note 1 to entry: The audit trail facilitates the reconstruction of the history of actions relating to the record.

1.3.2
born digital
materials that originate in digital form (digitally native), not created on paper or any other analogue source

Note 1 to entry: Born digital applies only to digital media. Subsequent analogue representations of born digital material such as print-outs or other hard copies are not born digital media.

1.3.3
clinical information system (CIS)
system dedicated to collecting, storing, manipulating, and making available clinical information that applies at the point of care

Note 1 to entry: Clinical information systems include electronic medical record systems, clinical data repositories, and decision support programs such as clinical guidelines and drug interaction checking. They may also incorporate devices for collecting data and viewing reference material, imaging modalities and communication tools, e.g. electronic messaging systems. This includes mobile access to the systems above.

Note 2 to entry: Information in a clinical information system may be used for secondary purposes.

1.3.4
conversion
process of translating the content of a record from one format to another

Note 1 to entry: This includes —

(a) digitization of a paper original;

(b) microfilming of a paper original;

(c) digitization of a microfilm;

(d) changing a digitized record from one software format to another;

(e) changing a database to a set of PDF files or a spreadsheet; and

(f) printing material from a digital source to paper or film.

1.3.5
digitization
process of converting paper or other non-digital records into digital format

Note 1 to entry: Includes scanning or imaging, taking digital photographs of the non-digital source records, or converting analogue voice recordings to digital media.

1.3.6
digitized health record
health record produced by converting source records into digital format

Note 1 to entry: “Digitized health record” and “scanned health record” are synonymous in this Standard.

1.3.7
digitizing health record system (DHRS)
information technology system for digitization of health records

1.3.8
digitizing health record service
external capability for digitization of health records

1.3.9
electronic discovery (e-discovery)
discovery in legal proceedings where the information sought is in electronic format

Note 1 to entry: For the purposes of this Standard, legal proceedings may include: government investigations and freedom-of-information requests as well as litigation.

1.3.10
electronic form (e-form)
computerized template of a health record form used to capture data which may be responsive to the data entered

Note 1 to entry: e Forms can be filled out faster because the programming associated with the form can automatically format, calculate, look up and validate information for the user.

Note 2 to entry: Some systems do this by overlaying text on top of a form template and may do rudimentary calculations.

1.3.11
electronic health record (EHR)
health record with data structured and represented in a manner suited to computer calculation and presentation

Note 1 to entry: Use of this term implies the ability to compute the content of the record. The EHR is often described as representing a lifetime record of health and care. An EHR may include digitized information, as well as born digital records and other database entries.

1.3.12
embedded object
an object physically stored in the compound document, along with all other information needed to manage the object, so it forms part of the compound document in which it is situated

Note 1 to entry: An embedded object may consist of any "non-text" element in a PDF (e.g. an image, a video or a file attachment), or be a link to an external file.

1.3.13
episode of care
identifiable grouping of healthcare-related activities characterized by the entity relationship between the subject of care and a healthcare provider, such grouping determined by the healthcare provider

Note 1 to entry: A common example is a patient's stay in a hospital related to a particular clinical problem.

1.3.14
encounter
interaction between a subject of care and one or more healthcare providers

Note 1 to entry: This can include communication events that do not occur face to face or occur on behalf of the healthcare provider or the subject of care for the benefit of the subject of care.

1.3.15
health record
collection of data and information gathered or generated to record the clinical care and health status of an individual or group

Note 1 to entry: This includes information such as assessment findings, treatment details, progress notes, registration and information associated with care and health status.

Note 2 to entry: The term "health record" includes paper health records, clinical records, medical records, digitized health records, EHR, healthcare records and personal health records.

Note 3 to entry: Personal health records have specific variations that should be taken into consideration when applying this Standard.

1.3.16
health record document
document held in a health record

Note 1 to entry: Examples include health record forms, clinical documents, legally authenticated documents, and clinical referral letters received from clinical providers.

1.3.17
health record form
template used to record information in a health record

Note 1 to entry: Examples include forms to record information about assessment, diagnosis, management or professional advice given to a person.

Note 2 to entry: The term "health record form" includes clinical forms and case record forms.

Note 3 to entry: Forms should receive endorsement through the appropriate Forms Committee.

Note 4 to entry: An e-form is a type of health record form.

1.3.18
health record number
unique identifier of a given patient for a health record within an organization

Note 1 to entry: The term "health record number" includes the medical record number (deprecated), healthcare record number, Unit Record number (deprecated), clinical record number, client record number and local record number.

Note 2 to entry: The health record number is typically used to support filing and retrieval of healthcare records within the healthcare organization's record system. It is used for patient and information identification as the unique identifier within the organization.

1.3.19
healthcare record
health record produced for and used within a healthcare organization or by a healthcare provider

Note 1 to entry: This is the traditional health record. The term can be associated with specific formats to represent different meanings, e.g. medical record, EHR, and digitized healthcare record. A personal health record may include healthcare record information but is not limited to that content.

Note 2 to entry: The term "healthcare record" includes medical records and clinical records.

1.3.20
hybrid health record
health record comprising paper, digitized and electronic formats, created and accessed using both manual and electronic processes

Note 1 to entry: A hybrid health record often arises as a transitional health record during migration from digitized format to a full EHR.

1.3.21
individual healthcare identifier (IHI)
identifying number assigned to an individual eligible to receive healthcare in Australia

Note 1 to entry: This identifier is used by the Australian healthcare system and is specific to Australian legislative requirements.

Note 2 to entry: This is not to be confused with any local health record number.

Note 3 to entry: Refer to ISO/TS 22220, which defines a healthcare identifier as including the organization that issued the identifier.

1.3.22
information technology system (IT System)
set of one or more computers, associated software, peripherals, terminals, human operations, physical processes, and information transfer means that form an autonomous whole, capable of performing information processing and/or information transfer

[SOURCE: ISO/IEC 15944-1:2011(E), 3.32]

1.3.23
lossless compression
mechanism for reducing file sizes while retaining all original data

1.3.24
lossy compression
mechanism for reducing file sizes that discards data

1.3.25
may
indicates the existence of an option

1.3.26
metadata
data that defines and describes other data or processes

Note 1 to entry: Examples include data that describes the context, content and structure of records and their management through time.

1.3.27
non-digital source record
analogue document or record, or digital data that has been copied, converted or migrated into an analogue format, to be the source of a process

Note 1 to entry: A non-digital source record can be an original paper record or it can be an analogue reproduction generated by an earlier copying, conversion or migration process.

1.3.28
personal health record (PHR)
a health record (paper-based or electronic) controlled by the person, or a representative of the person, to whom it pertains

Note 1 to entry: A PHR may have contributions from providers of healthcare and the person, or their representatives.

1.3.29
shall
indicates that a statement is mandatory

1.3.30
should
indicates a recommendation

1.3.31
subject of care
one or more persons to receive, receiving, or having received a health service

Note 1 to entry: Synonyms — patient, client, consumer.

1.3.32
temporary record
record not of permanent value to the organizational archives

1.3.33
user
person who makes use of an artefact or system

Note 1 to entry: In the digitized health record context this would include, but is not restricted to, a scanning operator, a quality control person, or a clinician who reads or views the documents in the system.

Section 2 Digitization of health records

2.1 General

Success in implementing digitized health records within a healthcare organization requires effective processes and systems for creating and managing digitized health records.

2.2 Processes for digitization of health records

An organization's processes for creating and managing digitized health records shall address requirements for —

(a) organizing and managing digitized health records activities (Clause 3.1);

(b) clinical relevance of digitized health records (Clause 3.2);

(c) design of health records, documents and forms (Clause 3.3);

(d) support of legal processes (Clause 3.4);

(e) quality control measures (Clause 3.5);

(f) cybersecurity and access control (Clause 3.6);

(g) retention and disposal of health records (Clause 3.7);

(h) maintenance and operation of digitizing health record systems (Clause 3.8); and

(i) planning for data capture (Clause 3.9).

2.3 Digitizing health record systems

A DHRS used to capture and manage digitized health records shall provide functionality to address —

(a) key characteristics of a digitizing health system as required by Clause 4.1;

(b) scanning of documents and capture of other material (Clause 4.2);

(c) processing of electronic images arising from digitization of health records (Clause 4.3);

(d) managing metadata to describe the content of digitized health record (Clause 4.4);

(e) capturing data document images and managing digitized health records (Clause 4.5);

(f) retrieving and viewing digitized health records (Clause 4.6);

(g) reliably storing digitized health records (Clause 4.7);

(h) reproducing digitized health records (Clause 4.8); and

(i) controlling and logging access to digitized health records (Clause 4.9).

2.4 Digitizing health record services

A digitizing health record service should meet the requirements of this Standard as applicable to a DHRS.

Section 3 Processes for digitization of health records

3.1 Organization and management

3.1.1 General

The processes used by an organization for creating and managing digitized health records shall —

(a) be defined, documented and implemented;

(b) specify organizational roles and responsibilities for the capture, management and disposal of digitized health records;

(c) align with the organization's broader policies, processes, procedures and obligations for managing health records;

(d) set out operational procedures and quality criteria for health record digitization and maintenance activities to ensure authenticity, confidentiality, integrity, accessibility and quality of digitized health records and associated metadata;

(e) maximize integration and interoperability between the DHRS and other present and proposed information systems used by the organization (including patient administration systems, practice management systems and CISs);

(f) take into account the requirements of AS ISO 15489.1 and the guidance provided in AS/NZS ISO 13028;

(g) specify how to define and use metadata elements and associated value domains to support the effective storage, management and retrieval of information in digitized health records, taking into account —

(i) requirements for support of clinical users and clinical workflows (see Clause 3.2) and for the effective management of digitized health records;

(ii) the requirements of AS ISO 23081.1; and

(iii) the requirements of AS/NZS ISO 23081.2;

(h) ensure continuity of timely access to all (past and present) health record information both during and after the introduction of digitized health records; and

(i) identify the role of any proposed DHRS in managing and providing access to printable extracts from CISs (such as hospital EMR applications).

3.1.2 Metadata and value domains

An organization's processes for selecting, defining, documenting and using metadata elements and associated value domains with digitized health records —

(a) should maximize automatic capture of transactional metadata, minimizing the need for manual assignment; and

(b) may adapt metadata elements to maximize the ability to inherit data values from existing systems and equipment.

3.1.3 Planning for implementation

An organization's plan for the implementation of digitized health records should include —

(a) the organization's goals and strategy for introducing digitized health records;

(b) the processes, activities, digitization volumes and capability, time frames and the human and financial resources required to achieve its goals for digitization of health records;

(c) a strategy for acquiring and implementing the digitization capability required; and

(d) strategies and processes for identifying and capturing the content of historic health records for various classes of subjects of care.

NOTE Digitization can involve extensive document preparation and requirements for indexing. Digitization undertaken purely for saving space is rarely justified.

3.2 Clinical relevance

In order to be clinically relevant, particularly at the point of care, the digitized health record should be as complete, accurate and up-to-date as possible and be accessible in ways that reflect the specific needs of different groups of clinical personnel.

While digitized health records have advantages such as the ability to be viewed simultaneously from different physical locations, in most organizations there will be a time lag between when information is recorded at a point of care and when it has been captured in the digitized health record. In some cases, it may take some time for the existence of paper documents to become known and incorporated into the digitized health record.

Increasingly, clinical information is being generated, captured and accessed via CISs (i.e. born digital) rather than on paper, and may only be rendered on paper when required for incorporation into a health record. Even when such information is available as electronic documents, these need to be curated into the digitized health record for the digitized health record to be complete and accurate.

To support clinical relevance and be acceptable to clinical personnel:

(a) The processes used by an organization for planning, implementation and use of digitized health records shall constructively integrate processes for capture and use of information in digitized health records into clinical work flows.

(b) Documents captured in a digitized health record shall —

  (i) be accurately identified by and displayed with metadata identifying the document type, document source and date of creation;

  (ii) be associated with any further metadata required to support clinical purposes; and

(iii) be subjected to quality control checks (see Clause 3.5.2) to reduce the likelihood of errors or omissions arising from digitization or the capture of data and metadata.

(c) Documents stored in a digitized health record should be rendered —

(i) in a consistent way for viewing on each class of viewing device (and in accordance with Clause 4.6); and

(ii) with a transaction completion latency (speed) that meets performance metrics defined in collaboration with clinical personnel as being adequate to support clinical workflow.

(d) Processes and systems for digitization of health records should —

(i) ensure that information from health records required for delivery of care is available at the point of care as and when required;

(ii) provide a means of accessing the content of a digitized health record relevant to the delivery of clinical care at times when the DHRS holding the primary version of the digitized health record is unavailable;

(iii) provide a means of ensuring that clinical information generated during a period when the DHRS or the paper health record is unavailable —

(A) continues to be available at the point of care; and

(B) is tracked and subsequently incorporated into the digitized health record;

(iv) minimize the need for clinical personnel to re-enter data that already exists in other clinical and administrative systems; and

(v) allow reproduction of digitized health record content in a manner that meets legal requirements (as required by Clauses 3.4 and 4.8).

3.3 Design of paper health records, documents and forms

3.3.1 Application of barcodes and other OCR-readable identifiers

3.3.1.1 General

Documents and forms intended for digitization should provide for barcodes or other OCR-compatible markings which indicate —

(a) the type of health record form or health record document;

(b) the subject of care to which the health record form or health record document relates;

(c) the encounter or episode of care to which the health record form or health record document relates; and

(d) the page number of each page within a health record form or health record document.

NOTE In many cases the relevant barcode or other identifier will be on a label affixed to the form.

Organizations should be aware of any legislative requirements that mandate the nature and location of barcodes or other forms of identification on paper health record forms. Where not precluded by any such legislative requirements, barcodes and other machine-readable identifiers used on health record forms should conform with the requirements of this clause and the requirements and guidance in AS 2828.1.

3.3.1.2 Use of barcodes and OCR

When a barcode or OCR-compatible marking is used on a health record form or health record document metadata elements likely to be represented by the barcode or captured by OCR should follow a uniform, documented structure.

A barcode shall conform to ISO/IEC 15424 (the general and overarching Standard on symbology); ISO/IEC 16388 (Code 39); and ISO/IEC 15417 (Code 128); and be either:

(a) a data matrix barcode (2D-barcode) conforming to ISO/IEC 16022; or

(b) a linear barcode conforming to ISO/IEC 16388 (Code 39) or ISO/IEC 15417 (Code 128).

The information encoded in a barcode shall:

(i) be representable using ISO/IEC 646, *Information technology — ISO 7-bit coded character set for information interchange*; and

(ii) be printed in human-readable form along with the barcode.

A barcode should be surrounded by a 5 mm quiet zone without dark marks or lines.

New copies of the health record form or health record document should be reproduced directly from the digital template, rather than being photocopied or printed from copies of the health record form or health record document.

NOTE Refer to AS/NZS ISO 12029 for more information on the design of forms to accommodate data to be captured using barcodes and OCR.

3.3.2 Barcodes specifying type of form or document

A barcode containing information specifying the type of a health record form or health record document shall be located in the binding margin on the front of the health record form or health record document.

NOTE 1 Many organizations may have mandated the barcode be placed in either the top, middle or lower position in the binding margin.

NOTE 2 Refer to AS 2828.1:2018, Appendix A, for examples of layout.

3.3.3 Labels identifying subject of care and episode of care

Labels identifying the subject of care (patient labels) should be in the top right hand corner of the front page of each health record form or health record document.

The barcode on a patient label shall contain the unique identifier for the subject of care (normally health record number).

Information identifying the episode of care should be included in a barcode on either the patient label or elsewhere on the health record form or health record document.

3.3.4 Use of intelligent character recognition (ICR), optical character recognition (OCR) and optical mark recognition (OMR)

ICR is a technology for translating handwritten or printed text into machine-encoded text, whereas OCR is intended for translation of printed text. OMR is the machine recognition of a mark such as a tick, cross or spot based on a minimum area being marked rather than from the shape of the mark.

OCR, ICR or OMR can be performed at the time that a document is captured in electronic form (scanned) or subsequently from the captured images.

The ability of ICR, OCR and OMR to provide an accurate translation depends on factors, including:

(a) the quality of the original document and text;

(b) the predictability, layout and content of the original text;

(c) the accuracy of document image alignment;

(d) the level of operator oversight; and

(e) the level of quality control.

ICR, OCR and OMR are typically less reliable than capturing data directly from users using electronic forms, but can be suitable for less critical applications such as customer satisfaction surveys.

Organizations implementing ICR, OCR and OMR to capture computable data from paper health records should:

(i) Adopt a risk-managed approach to each proposed use of these technologies, considering the maturity of the technology at the time of the implementation, the consequences of errors in the data captured, and any measures proposed to detect and correct such errors.

(ii) Perform robust testing of the proposed application of ICR, OCR or OMR technology to confirm the suitability of the technology, the observed error rate, and the adequacy of processes and procedures for handling errors.

(iii) Retain copies of document images from which computable data has been captured using ICR, OCR or OMR technology.

(iv) Design forms for use with ICR, OCR or OMR technology in accordance with relevant standards, such as AS/NZS ISO 12029.

3.4 Support for legal obligations

It is important that processes for creating and managing digitized health records support conformance with a record-holders' various legal obligations, including the production and attestation of copies of material held in digitized health records on request.

The processes used by an organization for managing digitized health records shall ensure the following:

(a) A digitized health record is retained at least until the time required to satisfy all applicable legal requirements (refer also to AS 2828.1).

(b) A comprehensive audit trail or other record is retained to demonstrate the provenance of all material held in a digitized health record for as long as the digitized health record continues to exist.

(c) The content of a digitized health record, once captured and validated, is not altered.

(d) Any amendment to the content of a digitized health record is authorized, logged in the audit trail, and presented in conjunction with or in place of the amended content.

(e) The organization can demonstrate the following to experts in the area of data storage and digitizing health record systems:

(i) the provenance and completeness of material held in a digitized health record and of any extract reproduced from a digitized health record; and

(ii) the state of a digitized health record at any previous point in time.

NOTE Evidence as to the provenance of original entries reflected in a digitized health record will rely on being able to produce attested evidence of the accuracy of the content of the digitized health record as a reflection of the underlying record.

(f) Original copies of material (original material) from which part or all of a digitized health record has been produced are not destroyed until quality control processes validating the completeness and accuracy of the record are completed, and the provenance of the record can be proven.

(g) Performance criteria for the completeness and accuracy of digitized health records and associated metadata are established and met.

(h) Processes, procedures and logs are maintained (by means of an audit trail or otherwise) that enable the organization to review and report on all persons who accessed a digitized health record or any identifiable copies of material extracted from a digitized health record.

(i) Privacy consents provided by subjects of care are recorded.

(j) Material held in any digitized health record for a subject of care (or copy of such digitized health record) is only accessed, used and maintained in accordance with the most up-to-date privacy consents provided by the subject of care.

(k) Procedures and systems for collection, management and use of digitized heath records are in accordance with the organization's privacy policy and support its obligations to monitor for data breaches and provide notification of actual or suspected data breaches.

(l) Personnel responsible for the management of digitized health records have knowledge of —

(i) the obligation for all health service providers to give notification of eligible data breaches under Part IIIC of the *Privacy Act 2010* (Cth); and

(ii) their responsibilities and obligations under the organization's privacy breach response plan.

3.5 Quality processes

3.5.1 General

An organization's processes for managing the quality of digitized health records should:

(a) Be documented.

(b) Align with or form part of the organization's overall quality management system.

(c) Address —

(i) quality planning, specifying overall quality objectives for digitization of health records and the means of checking the achievement of these objectives;

(ii) quality control, checking that digitized health records and associated metadata fulfil specified quality criteria (e.g. by testing/validating samples of outputs and by capturing key performance indicators); and

(iii) quality assurance, providing confidence that quality control processes are operating effectively and that quality requirements are and will continue to be fulfilled.

(d) Ensure that the results of quality control checking performed on its health record digitization processes are recorded and retained.

(e) Require the following:

(i) Completion of basic quality control checking to confirm the integrity of digitized material and associated metadata before it is accepted into a digitized health record.

NOTE Such checking often comprises a combination of visual and automated inspection of captured images of health record documents, validation checks on metadata captured from digitized health records, and reconciliation of page counts.

(ii) Additional quality control checking to be performed on samples of material after being digitized and accepted into digitized health records, but before disposal of the material that was digitized.

(iii) Key performance measures to be recorded on —

(A) the throughput, reliability and effectiveness of the digitization processes and systems;

(B) the capture and/or assignment of metadata associated with digitized health records; and

(C) the utilization and management of digitalized health records and associated metadata;

(iv) Results of quality assurance processes to be documented and reviewed as part of the organization's quality improvement activities.

(v) An ongoing commitment to training and competency assessment to ensure that personnel engaged in the digitization of health records and the application of associated quality control measures have the skills required to perform their roles.

(vi) Records to be kept on the nature and frequency of training provided to personnel engaged in the digitization of health records and the application of associated quality control measures.

(f) Be reviewed and improved to confirm that they continue to meet business requirements.

NOTE For more detailed information on quality control for digitization of records, refer to AS/NZS ISO 13028.

3.5.2 Quality control

3.5.2.1 Quality control requirements

Quality control processes shall:

(a) Be defined, documented and maintained.

(b) Establish whether each digitized health record and its associated metadata are a complete and accurate representation of the source records from which it was digitized.

(c) Be built into the ongoing, end-to-end, operation of health record digitization processes.

(d) Address the quality of both the digitized health record images and the associated metadata.

(e) Verify that —

(i) the quantity of digitized output for each health record matches the quantity of non-digital input; and

(ii) digitized health records are no less legible than the source paper records.

3.5.2.2 Desirable characteristics of quality control processes

Quality control processes should:

(a) Have mechanisms in place to minimize errors, such as:

(i) reviewing incoming health record documents to identify poor quality input and prepare it for digitization;

(ii) re-sequencing documents that are not in the correct order;

(iii) correctly labelling mislabelled documents;

(iv) capturing metadata and identification information that cannot be read from barcodes; and

(v) recording on an audit trail any changes made as a result of error minimization.

(b) Stipulate the extent and frequency of any sampling of digitized images.

(c) Stipulate measures and criteria for checking image quality.

(d) Stipulate the frequency and criteria for checks on metadata.

(e) Describe re-processing of documents and material that failed quality control.

(f) Stipulate the nature and frequency of processes for testing and calibration of scanning equipment used for digitizing health records.

(g) Address the quality control recommendations contained in AS/NZS ISO 13028.

(h) Identify and record where there has been any variation from normal digitization procedures that affected the quality or integrity of a digitized health record and the nature of any consequent corrective actions taken.

3.5.3 Quality assurance

Quality assurance activities should provide confidence that quality requirements for the health record digitization processes (including quality control) are being fulfilled. Quality assurance measures may include —

(a) quality audits / conformity audits;

(b) inspection of process documentation;

(c) inspection of quality control records and audit trails;

(d) benchmarking; and

(e) investigation of incident reports raised by quality audits.

3.5.4 Key performance indicators

Key performance indicators (KPIs) to be captured as part of quality control for digitization of health records should include the following:

(a) Throughput measures (e.g. number of documents scanned per timeframe, counts of pages output by scanner).

(b) Clinically-relevant turn-around times for digitization of health record documents following various types of clinical events.

(c) Productivity of key processes (e.g. whether turn-around times have been met, priority scanning completed within the agreed timeframes, completeness and timeliness of metadata).

(d) Errors or exceptions by type (e.g. incorrect name, divider or document type).

(e) Level of incomplete information encountered (e.g. numbers of identifier number missing).

(f) System availability reliability measures (e.g. scanner failure).

3.6 Cybersecurity and access control

3.6.1 General

Cybersecurity refers to the measures and tools that safeguard health information and health information systems in a computerized environment from any unauthorized access to or modification of information, the denial of service to authorized users, and the provision of service to unauthorized users.

Cybersecurity comprises —

(a) measures to safeguard data and computed programs from undesired occurrences and exposures; and

(b) system security associated with hardware, software and enterprise-wide institutional policies.

A cybersecurity strategy for protection of digitized health records should address the following security domains:

(i) Security and risk management.

(ii) Asset security.

(iii) Security engineering.

(iv) Communications and network security.

(v) Identity and access management.

(vi) Security assessment and testing.

(vii) Security operations.

(viii) Software development security.

NOTE 1 These security domains are those identified by the International Information Systems Security Certification Consortium.

NOTE 2 Refer to ISO 27799.

3.6.2 Unique access credentials

Each person accessing DHRS functions or digitized health records shall be assigned an access credential (e.g. usercode/password) that is unique to that person, which will allow access to DHRS functions and digitized health records needed by that person to perform their roles and responsibilities. Access credentials should not be shared amongst users and there should be no generic logons.

3.7 Retention and disposal

Digitized health records shall be retained for at least the retention period required to meet legal requirements (see Clause 3.4(a)).

A DHRS (including any archival subsystem) used to store digitized health records should have sufficient capability and capacity to hold and reproduce every digitized health record for its required retention period.

An organization's processes for retention and disposal of digitized health records should:

(a) Ensure that all health records that have been disposed of are recorded in a register, noting the relevant disposal authority, whether a copy has been retained as a digitized health record, and the retention period (as set out in disposal schedules).

NOTE 1 Proof of disposal may be required for legal purposes.

NOTE 2 Both the disposal of the original non-digital source record and any subsequent disposal of the digitized health record produced from it should be noted on the register.

(b) Confirm the accuracy of digitized health records before disposal of the corresponding non-digital source records.

(c) Be reviewed to ensure that they are up to date with legislative and other regulatory requirements, as retention periods are subject to change.

NOTE For more guidelines regarding disposal of health records, refer to AS 2828.1.

3.8 Maintenance and operation of a digitizing health record system

The processes used to manage, maintain and operate a DHRS and/or other equipment for digitizing and viewing health records should provide for —

(a) hardware and software used for digitization of health records being replaced as upgrades and improvements in technology become available;

(b) DHRS software and the operating environments in which a DHRS is used being kept up to date through the regular application of software updates as they become available;

(c) digitized health records continuing to be available in both online and archival forms through upgrades and updates of the DHRS;

(d) scanning equipment used for digitizing health records being routinely calibrated and adjusted to ensure that it continues to meet quality control criteria, including tests for resolution, noise, dynamic range, tone and colour reproduction; and

(e) retention of records of the calibration and adjustment of scanning equipment for inspection and review, including records of the scanner number, operator, date and time, and outcomes.

NOTE Most scanning equipment will be calibrated and tested using test patterns and software provided by the supplier of the scanning equipment or DHRS. Guidance on alternatives and best practice for in-house regimes is available from independent suppliers of testing services and the following:

(a) ISO/TS 19264-1.

(b) ISO/TR 19263-1.

(c) Federal Agencies Digitization Guidelines Initiative, FADGI Guidelines.

(d) Metamorfoze Preservation Imaging Guidelines.

3.9 Planning for data capture

When planning for the digitization of health records:

(a) Potential benefits may be achievable by incorporating innovative data capture techniques, including:

(i) Use of online e-forms with interactive feedback to capture data more accurately at source.

(ii) Greater use of mobile data capture technology at point of activity.

(iii) Seeking opportunities for real-time data capture by improving alignment of processes.

(b) Processes may be required for capturing both content and metadata from older documents (back-scanning or retrospective scanning).

Key principles include:

(i) Where source material is already in electronic form, it should not have to be converted to paper in order to be converted back as part of a digitized health record.

NOTE Email, fax and web forms are all forms of electronic information.

(ii) Capture of digitized records should be processed at source in order to minimize delays in digitization and processing.

Section 4 Digitizing health record system (DHRS)

4.1 Key Characteristics

A DHRS shall:

(a) Capture and store images at the highest resolution delivered by the equipment used in the digitization process.

(b) Retain all captured information without loss of resolution except as specifically permitted or required by this Standard.

(c) Generate and retain metadata about digitized records and their content, including meeting the requirements of Clause 4.4.

(d) Structure information captured about a subject of care into a single digitized health record for that subject of care, irrespective of the media on which information is provided and the processes used to collect, maintain and access the information (i.e. apply the unit record principle).

(e) Deliver the content of digitized health records electronically for viewing or processing in one or more Standards-based formats that —

(i) can be stored, processed and viewed using commonly available software applications capable of running on personal computing devices; and

(ii) do not contain embedded objects.

(f) Enable a DHRS operator to use a combination of parameters to select part or all of a digitized health record for viewing or for replication as an electronic extract.

(g) Be able to capture document metadata by reading and interpreting barcodes printed on the documents in accordance with Clause 3.3.

(h) Exchange information on subjects of care with other health information systems (e.g. patient administrative systems, hospital EMR systems, laboratory information systems and practice management systems) for the purposes of verifying identifiers and capturing relevant information into the digitized health record.

(i) Be capable of accepting and categorizing appropriately identified digitized documents from other health information systems, and other external sources and incorporating them into the correct digitized health record.

(j) Control the ability of system operators and other users to access digitized health records, other data within the DHRS, and DHRS system functions according to definable rules, based on a person's membership of one or more definable groups of user (e.g. supporting role-based access).

NOTE This would need to encompass rights to administer the DHRS, view/print contents of particular classes of digitized health records, and to accept, rectify or change a digitized health record, or its contents, at a minimum.

(k) Provide a help function that is:

(i) Available to system operators and other users as and when they require assistance in the correct configuration, operation and use of DHRS functions.

(ii) Comprehensive and up-to-date in its coverage of the full range of functions supported by any given implementation of the DHRS.

(iii) Supported by a regularly updated knowledge base accessible via an intelligent search function.

(l) Be supported by information technology systems and networks having sufficient capacity, speed and redundancy to ensure that digitized health records are continuously available during periods

of normal operation and that any required outages, such as for system maintenance, can be addressed in a controlled way with minimum or no impact on front-line clinical services.

4.2 Scanning and image capture

4.2.1 Scanning equipment

Scanning equipment used by a DHRS to digitize paper health records should:

(a) Without the need for operator intervention, automatically feed documents:

(i) of varied paper weights (e.g. from 60gsm to 150 gsm); and

(ii) of different paper sizes (e.g. A4 and A3).

(b) Operate in duplex mode, capturing both the front and back of each page in a single pass.

(c) Have sensors to prevent double feeds.

NOTE The features required in a scanning system will depend on the amount and complexity of scanning required, which may range from —

(a) *ad hoc low volume digitizing* — using flat-bed scanners and all-in-one printers designed for low volume and ad hoc digitizing at a general workstation; to

(b) *heavy duty bulk digitizing* — high volume scanning that requires automatic feed trays that are designed for bulk, multi-page, duplex digitizing.

There may also be differences in the level of requirements for network connectivity; on-board storage/folder options; and interaction between scanning equipment and the DHRS digitization functions.

4.2.2 Calibration features

A DHRS, its associated calibration system (if any) and the scanning equipment used to digitize paper health records should:

(a) Automatically prompt the user to calibrate the machine on a routine and pre-defined basis.

(b) Keep a log of when scanning equipment has been calibrated, which includes —

(i) the identifier of the scanning equipment;

(ii) date and time of calibration;

(iii) the calibration system and/or Standard that was used;

(iv) the name of the operator responsible for the calibration; and

(v) the outcome of the calibration, including any adjustments to settings or parameters.

4.3 Image processing

4.3.1 Required image processing functions

The image processing functions provided as part of a DHRS should:

(a) Automatically rotate scanned document images according to document type and in accordance with parameters that may be customised by a system operator.

(b) Automatically de-skew images using algorithms that ensure no document content is lost from either the front or rear of any document page as a result of de-skewing (e.g. by using edge detection with or instead of document content to adjust de-skew angle and zoom parameters).

(c) Automatically recognize and hide one-sided pages and blank content, to ensure correct page sequence numbering and reduce demands on network bandwidth and storage capacity.

(d) Correctly sequence images from multi-page documents.

(e) Provide operational modes that include —

(i) automatically optimising the brightness, contrast and colour of the image captured from each page of a document to maximize its legibility;

(ii) providing the ability for a system operator to control the colour, brightness and contrast of captured images by —

(A) setting default values for image-capture parameters;

(B) setting image-capture parameters to be applied automatically in place of default settings for specific types of document; and

(C) using colour tables to customise image capture parameters (such as during calibration).

(f) Be able to —

(i) automatically de-speckle images;

(ii) automatically scale images for optimal image quality;

(iii) identify and decode barcodes in defined zones anywhere on a document to include, for example, health record numbers, document numbers or page numbers; and

(iv) produce different types of digital output files (e.g. a TIFF, a PDF and a JPG) from a single scan and in accordance with the document type.

(g) Enable system operators to efficiently review captured images and to assign or correct document, patient and episode metadata, particularly for situations where this metadata could not be captured automatically from barcoding.

(h) Provide the ability to crop and scale images:

(i) According to cropping parameters separately defined for —

(A) the front and rear sides of pages; and for

(B) colour and black and white images.

(ii) By allowing a system operator to select and apply complementary combinations of the following operating modes —

(A) *automatic (for batches of mixed-size documents)* — dynamically adjusting the cropping window and scaling for documents of different sizes;

(B) *fixed (for batches of same-size documents)* — allowing the areas or zones to be imaged to be defined by the operator;

(C) *aggressive (for batches of mixed-size documents)* — eliminating residual black borders on any image edge; and

(D) *relative to document* or *zone processing (for batches of same-size documents)* — allowing defined parts of an image to be captured in colour with the remainder being captured in black and white, thereby saving storage space.

4.3.2 Desirable image processing functions

The image processing functions provided as part of a DHRS may also include the following capabilities:

(a) Ability to deliver high-quality images from a large range of poor contrast, high-contrast or glossy documents, thereby reducing the need to pre-sort, rescan and perform post-image processing.

(b) *Auto colour detection* — automatically detecting when material is to be captured in colour or greyscale rather than in black and white.

(c) *Fixed thresholding* for more legible capture of black and white and other high-contrast documents — allowing the DHRS to be configured with a threshold density that determines which pixels will be captured as white and those that will be black.

(d) *Background smoothing* — producing colour or greyscale images with more uniform background colours.

(e) *Long doc mode* — ability to accept and process scans of long documents (e.g. cardiotocograph charts).

(f) *Colour/greyscale and bi-tonal* — ability to preconfigure the DHRS to capture defined areas of specified types of documents as colour, bi-tonal, greyscale, or black and white images.

4.4 Metadata

4.4.1 Role of metadata

Metadata needs to be assigned to all digitized images and to all digitized health records, to suppport their management and use.

Metadata helps establish authenticity and integrity of digitized health records and to allow selective retrieval, viewing and reproduction of record contents.

Organizations need to be able to configure the metadata that is assigned to digitized health records by customising and adding metadata objects and value sets as required (e.g. to maximize the inheritance of data values from existing systems and equipment).

Significant operational efficiencies can be obtained by designing digitization processes to maximize the automatic capture of metadata, minimizing the need for manual attribution of values to metadata items.

The following Standards provide requirements and guidance on the role of metadata in relation to the management of records, information and documents, and are applicable to the role of metadata in the capture and management of digitized health records:

(a) AS ISO 23081.1

(b) AS ISO 23081.2

(c) AS ISO 15489.1

(d) AS/NZS ISO 13028—2012, Clause 6.3.4, Metadata.

4.4.2 DHRS metadata functionality

4.4.2.1 Required metadata functionality

A DHRS shall:

(a) Provide metadata capabilities and metadata objects sufficient to enable the requirements of this Standard to be met.

(b) Grant DHRS operators sufficient access privileges to —

(i) manage the default metadata objects and associated value domains that are supplied with the DHRS;

(ii) create additional user-defined metadata objects and value sets, and manage them in the same way as the metadata objects and associated value domains that are supplied with the DHRS; and

(iii) specify how metadata items are to be obtained from DHRS processes relating to —

(A) capture of images;

(B) capture of documents;

(C) capture, structure and management of digitized health records;

(D) capture and incorporation of material from other sources into digitized health records;

(E) accessing, viewing and reproducing digitized health record content;

(F) retrieval of information (e.g. patient identification details and status) from other health information systems; and

(G) populating a comprehensive audit trail meeting the requirements of Clause 4.9.

(iv) modify document-level metadata for health record documents (subject to a permanent non-repudiable record being kept of any such modification).

(c) Capture, accept and process image-level metadata as specified in Clause 6.3.4.2 of AS/NZS ISO 13028—2012 (including date and time of digitizing, scanner identification, and scanning system operator).

(d) Capture, accept and process document-level metadata related to each document or other item for incorporation into a digitized health record, including —

(i) the type of document (e.g. by health record form identifier);

(ii) the principal health record identifier that uniquely identifies the subject of care to which the document relates (including the identity of the healthcare facility that issued the identifier, and the type of identifier, as required by AS 4846).

(iii) episode-level metadata, where the document can be related to an episode of care.

(e) Capture, accept and process record-level metadata that —

(i) uniquely identifies each digitized health record and the subject of care to which the digitized health record relates; and

(ii) can be used to track versions of the digitized health record and assist in reproducing earlier versions of a digitized health record.

(f) Capture, accept and process metadata related to the access, viewing and reproduction of digitized health records.

(g) Capture, accept, process and permanently retain transactional metadata that tracks changes in digitized health records (including amendments to record content after it has been accepted, movement of content within a record or from one record to another) and the person/system responsible for making each change.

NOTE Metadata relating to record access and viewing of records, and transactional metadata are commonly maintained by the audit trail function.

(h) Use assigned metadata to record key characteristics of digitizing processes, assist with document identification, match access permissions, and structure the presentation of the digitized health record to meet user requirements.

4.4.2.2 Desirable metadata functionality

A DHRS should

(a) Capture all image-level metadata automatically.

(b) Facilitate the automated capture of document-level metadata —

(i) using barcodes and/or OCR where provided on the face of the source document; and

(ii) to include, where available:

(A) The person who is responsible for the creation of the source document.

(B) The date and time that the source document was authorized.

(C) Episode-level metadata meeting the requirements of Clause 4.4.2.3.

(c) Be able to accept, recognize, process and retain record-level metadata and document-level metadata supporting multiple personal identifiers (e.g. the Individual Health Identifier [IHI] and regional and State/Territory healthcare identifiers, where they exist), in addition to the principal health record number used in conjunction with records within an organization.

NOTE The ability to recognize and use multiple identifiers is particularly relevant where records, documents or their contents might be shared with other health services.

(d) Facilitate the provision of document-level metadata and health-record level metadata to support workflow applications and information sharing.

4.4.2.3 Episode-level metadata

Where episode-level metadata are captured by a DHRS, it shall include:

(a) a unique identifier (e.g. admission number, appointment-ID) for the episode of care to which the document relates;

(b) the date and time when the episode of care took place or commenced;

(c) the healthcare organization and/or unit that delivered the identified episode of care; and

(d) the episode type, where users of the DHRS have defined episode types.

Episode-level metadata may include —

(i) where available and relevant, the date and time on which the episode of care concluded;

(ii) metadata associating the document with additional episode types or other characteristics of the episode of care, such as clinical unit, discipline/speciality, individual healthcare provider, a clinical trial, or other program of activities to which the document relates.

NOTE Image metadata, e.g. date of digitizing, is not equivalent to episode identification.

4.4.3 Identification of digitized health records and documents

Patient identification information, including a unique health record number, is required on all health records, including digitized health records and documents intended for incorporation into a health record.

It is essential that each document in a health record is accurately and reliably associated with the correct subject of care to ensure the integrity of the record and avoid a potential source of misinformation leading to clinical errors.

Where possible, each document in a digitized health record should also be associated with an episode of care, visit, program of events, and/or clinical trial in order to maximize the potential for automated indexing and retrieval of record contents using various criteria.

NOTE For further guidance on best practice in the use of identifiers in healthcare, refer to —

(a) AS 2828.1;

(b) ISO/TS 22220; and

(c) METeOR (the AIHW Metadata Online Registry, at http://meteor.aihw.gov.au).

4.5 Digitized health record data capture and document management

Data capture is the conversion of information from document images into a form that can be used by an information technology system for computation (and includes the capture of metadata that can be used to index and retrieve digitized documents).

A DHRS should provide data capture, indexing and document management functionality that:

(a) Interoperates with DHRS image capture and processing functionality (see Clauses 4.2 and 4.3), and with other information technology systems to facilitate capture of identifiers, document types and other key metadata items, and to support the validation and extension of these data at the point of digitization.

(b) Automatically assigns document metadata to digitized documents based on technologies such as barcodes and/or OCR and/or intelligent character recognition (ICR).

NOTE See Clause 3.3.4 for further discussion of these technologies.

(c) Can retrieve additional metadata values and assign them to a digitized document by using captured document-level metadata to obtain the additional metadata values (e.g. patient demographics, form characteristics) from other information technology systems and/or user-defined reference tables.

(d) Highlights unassigned mandatory metadata fields requiring operator intervention and flags or holds a document pending completion of required interventions.

(e) Assigns a metadata value (e.g. a date or document type) to multiple documents based on identified document characteristics, with the ability for this functionality to be applied to individual documents in real time or to the members of a batch of documents.

(f) Provides shortcuts for manual entry or automated capture of metadata fields common to a sequence of documents (e.g. digitization date, system operator and/or document type).

(g) Provides the ability for a system operator with sufficient privileges to define business rules and document-level metadata to be used by the DHRS to realize one or more logical structures for the storage, indexing, retrieval and viewing of documents within a digitized health record.

NOTE Such a logical structure is the means by which the sections and order of "filing" of digitized documents within a digitized health record can be defined for any given implementation of a DHRS. Nevertheless, this logical structure would not necessarily correspond to the physical data structures used by the DHRS to hold images and metadata representing documents and digitized health records.

(h) Correctly incorporates digitized documents into digitized health records by applying the business rules and document-level metadata defined in Clause 4.5(f).

(i) Allows the incorporation of born digital information into digitized health records.

(j) Enables a system operator with sufficient privileges to:

(i) Annotate a digitized document (e.g. in the event that the paper health record has been destroyed, or to indicate the document is part of a merged patient record).

(ii) Merge digitized data from patient records automatically for an entire record or by selection of individual documents from within a source record.

(iii) Unmerge patient records (by means of a system operator selectively assigning digitized documents from one source patient to two destination patients).

(k) Enables a process by which images, documents and associated metadata from existing digitized health records (e.g. from a legacy DHRS) can be —

(i) converted into digitized health records managed by a DHRS; implemented under this Standard (the "incoming DHRS"); or

(ii) accessed as a part of the collection of digitized health records managed by the incoming DHRS.

NOTE Where such a process exists, it is likely to be complex and involve a combination of:

(a) Identifying and documenting existing file structures, metadata objects, value sets, and the differences between these and those required by the incoming DHRS.

(b) Mapping metadata objects and associated data sets between the different DHRS implementations.

(c) Establishing the means of accessing material in existing data and image repositories, and of incorporating this material into the digitized health records managed by the incoming DHRS.

(d) Undertaking any upgrading of file formats, reformatting of digital image files or other conversions necessary to enable access or use by the incoming DHRS.

4.6 Retrieval and viewing of digitized health records

A DHRS should be intuitive to operate based on contemporary design, user experience and human factor principles, and provide functionality for retrieval and viewing of digitized health records that:

(a) Presents the content of digitized health records —

(i) in a tree or section/divider structure to simulate the paper health record;

(ii) grouped by clinical domain and/or document type to facilitate clinical review; or

(iii) in any other logical structure defined in accordance with Clause 4.5(g).

(b) Clearly differentiates document types within the structure being presented.

NOTE Logical structures for retrieval and presentation of digitized health record contents may vary as healthcare organizations move away from paper records.

(c) Enables clinical document images and associated metadata to be viewed on different types and sizes of viewing workstations (desktop, laptop, tablet, split screen or multiple screen viewing workstations).

(d) Gives users a selection of intuitive, easy to use functions for:

(i) Zooming in and out of images and moving around a zoomed image, (e.g. via mouse or touchscreen).

(ii) Rotating images of documents and/or a selection of pages at least by +90 °, 180 ° and −90 °.

(iii) Adjusting the brightness, contrast and colour balance of images.

(iv) Selecting images to view from a document or digitized health record by —

(A) scrolling through full images in a default or selected sequence;

(B) reviewing images as thumbnails; or

(C) selecting an image from a list/folder tree populated with image metadata.

(v) Searching for digitized health records and/or associated documents by subject of care, episode of care, episode of care date range, document type and other selectable health record-level metadata and document-level metadata.

(vi) Searching for specific document types for a specified period of time and presenting the output in a defined sequence, including either chronological or reverse chronological order.

(e) Automatically presents pages in portrait, landscape or booklet orientation.

(f) Provides a default option to exclude blank pages when viewing a document.

(g) Provides a default option of displaying the identifier (health record number) and demographic details of the subject of care along any image being viewed from a digitized health record.

NOTE In some instances, the health record number that a document is indexed to may be different to the record number appearing on the digitized image (e.g. due to a duplicate patient merge). Therefore, it is important that the user can view the patient-identifying details for the subject of care that the document is indexed to, and not just the digitized label on the digitized image.

NOTE 1 The need for particular viewing features and rights to use particular features of the DHRS may vary between various groups of clinical users and various groups of users responsible for capture and management of digitized health documents, and also the quality and types of viewing workstations available to the different groups for any given DHRS implementation. Requirements for different types of users should be considered when assessing products and viewing products.

NOTE 2 Consideration should also be given, where relevant, to the requirements of —

(a) *National Guidelines for On-screen Presentations of Discharge Summaries*; and

(b) *National Guidelines for On-Screen Display of Medicines Information*.

4.7 Storage of digitized health records

4.7.1 General

Digitized health records and their metadata shall be:

(a) Maintained on media which is stored securely in formats that are readily readable and periodically refreshed to ensure that they remain current.

(b) Securely held in facilities and on systems that are capable of detecting, logging and providing notification of unauthorized attempts at access.

(c) Readily retrievable from any off-line storage within a time that is designed to ensure that there is no unacceptable risks to clinical workflow and health service operations.

(d) Addressed in the organization's data back-up and disaster recovery plans.

NOTE Both paper health records and digitized health records require storage and maintenance, of an appropriate standard, whether on premises or off-site. Backup processes need to consider the ongoing availability of required records, be secure, and be regularly tested to ensure that they (and the responsible personnel) are capable of operating as intended.

4.7.2 Requirements for storage of digitized health records

Facilities and services (including any cloud-based DHRS application) used for storage of digitized health records shall:

(a) Be designed to provide for the privacy and security of digitized health records and their content.

(b) Keep the primary copy and any secondary or backup copies of the digitized health records on digital storage devices physically located within Australia.

(c) Support e-discovery for legal proceedings and freedom of information requests.

NOTE Storage may be provided by the healthcare organization itself, in-house, or by a third party service provider, including use of Storage as a Service (SaaS). In either case the same functional requirements should be met.

4.7.3 Desirable measures for storage of digitized health records

Facilities and services for storage of digitized health records should:

(a) Use lossless encryption of digitized health record data.

(b) Ensure that keys and codes needed for encryption are protected and held securely.

(c) Have established means of user authentication and identity management, and for control, monitoring and reporting of all user access to digitized health record data.

(d) Have measures in place to:

(i) Monitor, report and minimize overall system down time.

(ii) Regularly back up and protect copies of digitized health record data, with a demonstrated and regularly tested capacity to recover copies of the data.

(iii) Provide for recovery of services within an agreed timeframe in the event of a system malfunction.

(iv) Ensure that copies of digitized health record data are held in an unalterable form on all storage media.

(v) Protect the security of the networks supporting the storage facilities and services.

(vi) Apply timely updates to operating systems, applications software, and network operating systems, devices and firmware.

NOTE Refer to ISO/IEC 17825 for information on the management of cloud computing in relation to storage of digitized health records

4.8 Reproduction of digitized health records

4.8.1 Requirements for reproduction of digitized health records

Reproduction of digitized health records may be required for purposes such as sharing of information with subjects of care, responding to legal action and for appropriately authorized clinical and non-clinical research.

Copies of a digitized health record are to be provided in forms that are widely acceptable to potential users.

A DHRS shall enable a complete, authentic (a true and accurate) reproduction of part or all of a digitized health record.

4.8.2 Desirable features for reproduction of digitized health records

When producing a reproduction of a digitized health record, a DHRS should:

(a) Permit DHRS operators with sufficient privileges to —

(i) print single or multiple pages;

(ii) bulk print extracts from a digitized health record based on selected key terms;

(iii) print to a variety of media/formats — paper, CD, USB etc;

(iv) scale a document to ensure it is readable regardless of its original size (e.g. ECG outputs, A3 pages);

(v) offset the size of a document, e.g. zoom to 90 %;

(vi) include a header or footer on each page;

(vii) select an option to include page numbers in printed headers or footers for ease in handling (by default), or to omit them; and

(viii) include a watermark to indicate output is a copy of a digitized document.

(b) Include a date and time stamp on every page of a reproduction.

(c) Log all printing or other generation of reproductions directly from the DHRS.

(d) Provide the option of limiting or allowing access to printing or further copying of reproductions created in digital format (such as pdf files).

(e) Produce reproductions that, when reconstituted to paper format, align with the record layout and format depicted in AS 2828.1. In particular, each printed page should clearly define the form name, identification details and patient ID details and be able to be reproduced in A4 and, in special circumstances, A3 size.

4.9 Control and logging of access

A DHRS shall:

(a) Support each user being assigned unique access credentials that determine which DHRS functions and digitized health records the user may access.

(b) Allow DHRS system operators with sufficient privileges to define user work groups with access to defined sets of DHRS functions and/or particular classes of digitized health records.

(c) Allow a user to be assigned to one or more user work groups for the purposes of allowing access to DHRS functions and/or particular classes of digitized health records.

(d) Allow DHRS system operators with sufficient privileges to identify and authorize access and/or use by trusted processes.

(e) Maintain an audit trail applying ISO 27789, to log each access to a document within a digitized health record or for each DHRS function used, capturing the following:

(i) Date and time of access/use.

(ii) Unique identifier for the user or trusted process accessing a digitized health record or DHRS function.

(iii) Unique identifier (e.g. health record number) for the subject of care to which an accessed digitized health record relates.

(iv) Identifier and description of each document accessed within a digitized health record.

(v) The DHRS function used or action performed, e.g. print document, copy document to file, make changes to data, make changes to metadata, create/upload/scan document, enter data, archive/delete document, delete data, create user work group, assign privileges.

(vi) The details of any additions, updates or deletions made to a digitized health record or to its associated record-level metadata and/or document-level metadata.

(vii) Time spent viewing a document or, where possible, time spent on each section or page of a document (in hours, minutes, seconds, milliseconds).

(viii) The name and/or IP address of any workstation being used to access the DHRS.

NOTE 1 All access by users should be logged, including access by technical, administrative, clinical personnel and by other parties or systems.

NOTE 2 As noted in ISO 27789, the term audit trail does not necessarily require all access to be logged in a single audit log, but may include entries being made across several different audit logs.

NOTE 3 Not all accesses and actions logged on the audit trail will relate to a digitized health record; some will record the use of DHRS functions that alter the configuration or operation of the DHRS itself, in which case the details of such changes should be logged on the audit trail.

(f) Enable the production of reports on the use of DHRS functions and on access to particular digitized health records by selective filtering, extracting and summarizing of audit trail entries.

(g) Enable access to various classes of digitized health records to be restricted to particular users or groups of users (e.g. sexual assault, child protection, VIP records).

(h) Operate in a secure network environment in which —

(i) unauthorized attempts to access a DHRS and/or its digitized health records are tracked, monitored, and notified to DHRS system operators; and

(ii) actual or potential data breaches may be identified for purposes of mandatory reporting of data breaches.

Bibliography

AS 2828-1, *Health records, Part 1: Paper-based health records*

AS/NZS ISO 12029, *Document management—Machine-readable paper forms—Optimal design for user friendliness and electronic document management systems (EDMS)*

ISO 27799, *Health informatics — Information security management in health using ISO/IEC 27002*

ISO/IEC 15944-1, *Information technology — Business Operational View — Part 1: Operational aspects of Open-edi for implementation*

ISO/IEC 17825, *Information technology — Security techniques — Testing methods for the mitigation of non-invasive attack classes against cryptographic modules*

ISO/TR 19263-1, *Photography — Archiving systems — Part 1: Best practices for digital image capture of cultural heritage material*

ISO/TS 19264-1, *Photography — Archiving systems — Image quality analysis — Part 1: Reflective originals*

ISO/TS 22220, *Health informatics — Identification of subjects of health care*

Australian Commission on Safety and Quality in Health Care. *National Guidelines for On-screen Presentations of Discharge Summaries*, August 2016. Available at https://www.safetyandquality.gov.au/wp-content/uploads/2017/02/Guidelines-on-screen-presentation-of-discharge-summaries.pdf

Australian Commission on Safety and Quality in Health Care. *National Guidelines for On-Screen Display of Medicines Information*, January 2016. Available at https://www.safetyandquality.gov.au/wp-content/uploads/2016/03/National-guidelines-for-onscreen-display-of-clinical-medicines-information.pdf

Hans van Dormolen National Library of the Netherlands (KB). *Metamorfoze Preservation Imaging Guidelines: Image Quality*, version 1.0, January 2012. Available at https://www.metamorfoze.nl/sites/metamorfoze.nl/files/publicatie_documenten/Metamorfoze_Preservation_Imaging_Guidelines_1.0.pdf

METeOR (the AIHW Metadata Online Registry), at http://meteor.aihw.gov.au/

United States Government, Federal Agencies Digital Guidelines Initiative (FADGI), *Still Image Working Party, Technical Guidelines for the Still Image Digitization of Cultural Heritage Materials*, September 2016. Available at http://www.digitizationguidelines.gov/guidelines/digitize-technical.html

Standards Australia
Standards Australia develops Australian Standards® and other documents of public benefit and national interest. These Standards are developed through an open process of consultation and consensus, in which all interested parties are invited to participate. Through a Memorandum of Understanding with the Commonwealth Government, Standards Australia is recognized as Australia's peak non-government national standards body.

For further information visit www.standards.org.au

Australian Standards®
Committees of experts from industry, governments, consumers and other relevant sectors prepare Australian Standards. The requirements or recommendations contained in published Standards are a consensus of the views of representative interests and also take account of comments received from other sources. They reflect the latest scientific and industry experience. Australian Standards are kept under continuous review after publication and are updated regularly to take account of changing technology.

International Involvement
Standards Australia is responsible for ensuring the Australian viewpoint is considered in the formulation of International Standards and that the latest international experience is incorporated in national Standards. This role is vital in assisting local industry to compete in international markets. Standards Australia represents Australia at both the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Sales and Distribution
Australian Standards®, Handbooks and other documents developed by Standards Australia are printed and distributed under licence by SAI Global Pty Limited.

Australian Standards are prepared by a consensus process involving representatives nominated by organizations drawn from major interests associated with the subject. Australian Standards may be derived from existing industry Standards, from established international Standards and practices or may be developed within a Standards Australia committee.

Committee HE-025, Health Records, consisting of the following, is responsible for the issue of this draft:

Australasian College of Health Informatics
Australian Information Industry Association
Australian Medical Association
Australian Private Hospitals Association
Catholic Health Australia
Consumers Federation of Australia
Department of Health and Human Services (Vic.)
Health Informatics Society of Australia
Health Information Management Association of Australia
Medical Software Industry Association
NSW Health
Queensland Health
Royal Australian and New Zealand College of Psychiatrists
Royal Australian College of Medical Administrators
Royal College of Pathologists of Australasia
SA Health

For information regarding the sale and distribution of Standards contact:
SAI Global Pty Limited
Phone: 13 12 42
Email: sales@saiglobal.com
Internet: www.saiglobal.com

For information regarding the development of Standards contact:
Standards Australia Limited
GPO Box 476
Sydney NSW 2001
Phone: 02 9237 6000
Email: mail@standards.org.au
Internet: www.standards.org.au

ISBN to be allocated on publication of the final document

Standards Australia

Standards Australia is an independent company, limited by guarantee, which prepares and publishes most of the voluntary technical and commercial standards used in Australia. These standards are developed through an open process of consultation and consensus, in which all interested parties are invited to participate. Through a Memorandum of Understanding with the Commonwealth government, Standards Australia is recognized as Australia's peak national standards body.

Australian Standards

Australian Standards are prepared by committees of experts from industry, governments, consumers and other relevant sectors. The requirements or recommendations contained in published Standards are a consensus of the views of representative interests and also take account of comments received from other sources. They reflect the latest scientific and industry experience. Australian Standards are kept under continuous review after publication and are updated regularly to take account of changing technology.

International Involvement

Standards Australia is responsible for ensuring that the Australian viewpoint is considered in the formulation of international Standards and that the latest international experience is incorporated in national Standards. This role is vital in assisting local industry to compete in international markets. Standards Australia represents Australia at both ISO (The International Organization for Standardization) and the International Electrotechnical Commission (IEC).

Electronic Standards

All Australian Standards are available in electronic editions, either downloaded individually from SAI Global, or via on-line and CD ROM subscription services. For more information phone 131 242 or visit www.saiglobal.com/shop