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for

ATS 5816-2013 Digital images for diagnostic and other clinical purposes: Presentation, communication, display and manipulation

Licensee: Mr Michael Sandow

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Australian Technical Specification

Digital images for diagnostic and other clinical purposes: Presentation, communication, display and manipulation

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PREFACE

This Australian Technical Specification was prepared by the Standards Australia Technical Committee IT-014, Health Informatics.

The Standards Australia Technical Committee IT-014 recognizes the work of the Standards Australia Subcommittee IT-014-12, Telehealth, in the preparation of this Technical Specification.

The objective of this document is to define the technical specifications that will ensure that the digital diagnostic images provided by Australian diagnostic imaging practitioners meet the varying requirements of referring clinicians, including those who require access to images that are of diagnostic quality.

The term ‘informative’ has been used in this Standard to define the application of the appendix to which it applies. An ‘informative’ appendix is for information and guidance only.

Statements expressed in mandatory terms in notes to tables or figures are deemed to be requirements of this Technical Specification.

This publication has been developed with assistance from the Australian Government Department of Health. The Australian Government makes no representation or warranty that the information in this publication is correct and accurate.

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NOTE: This Australian Technical Specification includes extracts from *Digital Diagnostic Imaging, Recommendations on the Delivery of, Access to and Viewing of Diagnostic Quality Images for Clinicians (RACS DDIR)*, used with permission of the Royal Australasian College of Surgeons.

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FOREWORD

Radiological images of patient anatomy are an integral part of the information that clinicians use to guide their patient care decisions. Historically these images have been captured in analogue fashion on transparent film.

Over the last two decades, diagnostic imaging has seen a gradual transition from film-based image delivery to the use of portable devices (e.g. CDs) or networked transmission. This transition has involved substantial changes to the workflow of imaging providers, and potentially to that of referrers, depending on the way they use diagnostic images (Ref. 6, 8, 10).

NOTE: The drivers for the transition to digital diagnostic imaging are discussed in Appendix A.

Diagnostic imaging providers will need to utilize technology that provides clinicians with access to images of appropriate quality in a manner that is fit for purpose. Clinicians need a range of options for accessing and viewing diagnostic images in the clinic, wards and operating theatre, depending on the clinical requirements and technology capabilities.

Requirements for levels of image quality, and the means of access to images, will vary depending on the clinician and clinical needs. The process of providing adequate image access has several aspects, which are described in this Technical Specification. This document identifies appropriate options for managing each of these aspects of the process, so as to ensure the appropriate availability of diagnostic quality images to a clinician who may require such information.

Where access to images is required for a reduced quality review or for educational purposes only, the specifications relating to diagnostic quality do not necessarily apply. Images produced according to specifications other than those in the relevant sections of this Technical Specification, while useful for review or educational purposes, may not be of a sufficient standard to allow optimal diagnostic analysis.

STANDARDS AUSTRALIA

Australian Technical Specification

Digital images for diagnostic and other clinical purposes: Presentation, communication, display and manipulation

S E C T I O N 1 S C O P E A N D G E N E R A L

1.1 SCOPE

This Technical Specification defines the requirements for the presentation, communication, display and manipulation of digital images which are to be used for primary and secondary diagnosis. Such images are required to be of 'diagnostic quality', and this Technical Specification details the particular requirements for the presentation, transmission and display of these images.

This Technical Specification does not define requirements relating to images that are not intended for use for primary or secondary diagnostic purposes, as such images do not need to meet the requirements for 'diagnostic quality'.

This document provides normative elements and recommendations to assist diagnostic imaging practitioners in providing digital images in ways that appropriately meet the needs of clinicians who require access to images of diagnostic quality, and informative material to advise clinicians on how to realize the potential advantages of digital diagnostic medical images.

This Technical Specification defines the elements in the process of providing adequate image access. It defines appropriate options for managing each of these elements of the process, in order to ensure the appropriate availability of diagnostic quality images to a clinician who may require such information.

NOTE: This Technical Specification also provides informative material on the nature and management of digital diagnostic images, and informative advice for clinicians on how best to make use of these images for the purposes for which they were requested (see Appendix A).

1.2 EXCLUSIONS

1.2.1 Mammographic images

Whether obtained by analogue or digital methods, mammographic images have special requirements and are outside the scope of this Technical Specification.

1.2.2 Reports

The nature and content of diagnostic reports that are derived from diagnostic images are outside the scope of this document.

1.2.3 Specific requirements for security of images

Due to the rapidly evolving nature of the field, this document provides only general information on security measures and long-term image storage.

1.2.4 Special use application

Images for which a commonly used DICOM object definition is not available (e.g. those from older operating systems still in use, which are using old operating platforms and systems, and some specialized or novel modalities) are not covered in this document.

1.3 OBJECTIVE

Diagnostic imaging is a crucial part of many treatment decisions, and appropriate access to digital images in a clinically appropriate format and situation is essential to optimize patient care.

This Technical Specifications identifies the details that will ensure the digital diagnostic images provided by Australian diagnostic imaging practitioners meet the varying diagnostic needs of referrers and other clinicians whose work involves the interpretation of such images.

It is recognized that many clinicians may not have had sufficient technical experience to appreciate the complex technical specifications within this document. The intention is to provide a reference and background source to ensure that the transition to digital imaging facilitates optimal patient care that is consistent with the capabilities and resources of both the treating clinicians and imaging providers.

1.4 APPLICATION

Significant technological advances in diagnostic imaging have led to a variety of image formats and functionalities, which require innovative solutions to maximize the effectiveness of delivery, access, manipulation and archiving. Variations in display matrices and bit depth, three-dimensional display methods, multiplanar reconstruction, image fusion, dynamic imaging and colour rendering can all be better supported in digital formats than on film.

However, the transition to digital imaging should not compromise the diagnostic and treatment capabilities of the clinician, and it should facilitate, not hinder, appropriate image access at the patient care interface where required.

This Technical Specification is for use by diagnostic imaging providers (including radiologists, medical imaging technologists and picture archiving and communication system administrators), diagnostic imaging vendors, and the managers of hospitals and clinics in planning and executing the provision of digital imaging studies to clinicians. It also provides the normative information required for referrers to identify hardware and software functionality to ensure the images reviewed are fit for purpose.

Clinicians can refer to this Technical Specification to find the specifications for image provision that are appropriate to their needs, and for the specifications of the appropriate hardware and software needed to view those images.

This Technical Specification does not define who is responsible for the provision of appropriate hardware and software for image viewing.

When patient care decisions depend upon the review of the diagnostic images, all parties need to be constructively involved in any decision to adopt a material change in the way images are provided.

It is important that referrers have realistic expectations when requesting ‘film’ image formats in preference to ‘digital’ image formats. Multi-slice CT studies often create over 1000 images per patient study, and the principle of selection needs to be applied judiciously when key images are saved onto film. When selected images are supplied on film (or other hard copy) they should be appropriate to the clinical setting.

It is not always possible to anticipate all of the potential uses of and requirements for a diagnostic imaging examination at the time of referral and conduct of the initial imaging examination. Although precise communication between the clinical referrer and the imaging provider can minimize difficulties concerning examination type, processing and delivery, there should also be a mechanism whereby requests for access to the image data by a clinician other than the requesting clinician (e.g. those arising from on-referral) will be met expeditiously, provided such requests are made within a reasonable time period after the performance of the imaging study.

1.5 NORMATIVE REFERENCES

The following are the normative documents referenced in this Technical Specification:

1 American College of Radiology, 2012 *ACR AAPM SIIM technical standard for electronic practice of medical imaging* [viewed 8 July 2013]. Available at http://www.acr.org/~/media/AF1480B0F95842E7B163F09F1CE00977.pdf

2 Canadian Association of Radiologists, 2008, CAR *standards for irreversible compression in digital diagnostic imaging within radiology* [viewed 8 July 2013]. Available at http://www.car.ca/uploads/standards%20guidelines/Standard_Lossy_Compression_EN.pdf

3 Integrating the Healthcare Enterprise, 2009, *IHE Radiology technical framework supplement—Basic image review (BIR)* [viewed 8 July 2013]. Available at http://www.ihe.net/Technical_Framework/upload/IHE-RAD_TF_Suppl_Basic_Image_Review_2009-03-23.pdf

4 Integrating the Healthcare Enterprise, 2009, *IHE Radiology technical framework supplement—Extensions to the portable data for imaging (PDI) integration profile* [viewed 8 July 2013]. Available at http://www.ihe.net/Technical_Framework/upload/IHE-RAD_TF_Suppl_PDI_Extensions_2009-03-23.pdf

5 National Electrical Manufacturers Association, 2011, *Digital imaging and communications in medicine (DICOM) part 14: Grayscale standard display function* [viewed 8 July 2013], Available at http://medical.nema.org/Dicom/2011/11_14pu.pdf

6 Royal Australasian College of Surgeons, 2009, *Digital diagnostic imaging—Recommendations on the delivery of, access to and viewing of diagnostic quality digital images for clinicians* [viewed 8 July 2013]. Available at http://www.surgeons.org/media/297029/POS_2009-09-15_Digital_Diagnostic_Imaging_Position_Paper.pdf

7 Sim, LH, Manthey, K and Stuckey, S, 2007, 'Comparison of performance of computer display monitors for radiological diagnosis: "diagnostic" high brightness monochrome LCD 3MP vs "clinical review" colour LCD, 2MP', *Australasian Physical and Engineering Sciences in Medicine*, Vol. 30, No. 2, pp. 101–4. doi:10.1007/BF03178413

8 The Royal Australian and New Zealand College of Radiologists, 2008, *Principles for the provision of digital diagnostic images* (Version 3.2) [viewed 8 July 2013]. Available at http://www.ranzcr.edu.au/component/docman/doc_download/1657-principles-for-the-provision-of-digital-diag-images

9 The Royal Australian and New Zealand College of Radiologists, 2010, *A guideline for the use of image compression in diagnostic imaging* [viewed 8 July 2013]. Available at http://www.ranzcr.edu.au/component/docman/doc_download/574-a-guideline-for-the-use-of-image-compression-in-diagnostic-imaging

10 The Royal Australian and New Zealand College of Radiologists, 2012, *Standards of practice for diagnostic and interventional radiology* (version 9.2) [viewed 8 July 2013]. Available at http://www.ranzcr.edu.au/component/docman/doc_download/510-ranzcr-standards-of-practice-for-diagnostic-and-interventional-radiology

11 The Royal Australian and New Zealand College of Radiologists and Spine Society of Australia, 2009, *Joint guidelines for confirming vertebral levels in spine imaging* [viewed 8 July 2013]. Available at http://www.ranzcr.edu.au/component/docman/doc_download/586-joint-ranzcrssa-guidelines-for-confirming-vertebral-levels-in-spine-imaging

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

1.6 DEFINITIONS

For the purposes of this Technical Specification, the following definitions apply.

1.6.1 Anatomical size

Displayed image of anatomical region or feature shown at the same size as in life; alternative term ‘ADJ100’.

NOTE: This is achieved by an adjustment based on a known reference marker size. Anatomical size is not the same as ‘projected size’.

1.6.2 Basic Image Review (BIR)

IHE (see Clause 1.6.12) profile describing the desirable common elements for software used for DICOM image viewing (see Clause 1.6.8) and manipulation (Ref. 3).

1.6.3 Compression

Mathematical techniques used to reduce the file size of digital images.

NOTE: These may be ‘lossless’ or ‘lossy’ (see Clauses 1.6.13 and 1.6.14) (Ref. 9).

1.6.4 Cross-enterprise Document Sharing for Imaging (XDS-I)

IHE (see Clause 1.6.12) profile that describes how images may be shared between two different sites within a group of healthcare institutions, which may constitute an affinity domain.

1.6.5 Diagnostic imaging provider

Individual who performs or supervises the performance of the diagnostic imaging service, and who usually provides the primary analysis and opinion on the obtained images.

NOTE: This term typically refers to radiologists, but may also include vascular surgeons, cardiologists, obstetricians and any other person who is appropriately accredited by the local regulatory authority.

1.6.6 Diagnostic quality image

Image that can be used for diagnostic purposes and is comparable in quality and presentation to that used by radiologists in reporting.

1.6.7 Diagnostically acceptable image compression (DAIC)

Techniques for 'lossy compression' (see Clause 1.6.14) of diagnostic images, where the diagnostic accuracy of interpretation of these images has been shown to be equivalent to that obtained with losslessly compressed images (Ref. 9).

1.6.8 DICOM (Digital Imaging and Communications in Medicine)

Industry standard protocol for the sharing and distribution of digital images derived from medical imaging devices.

1.6.9 Film

Transparent polyester sheets, coated with thermographic toner (usually grey-scale), on which diagnostic images are distributed in hard copy.

NOTE: While such film can be generated by either photographic/analogue capture or laser printed images derived from a digital image, for the purposes of this document both forms are grouped under the term 'film'.

1.6.10 Greyscale standard display function (GSDF)

Specification of the relationship between digital image pixel values and display luminance values, defined in Part 14 of the DICOM standard (Ref. 5).

NOTE: GSDF calibration is commonly implemented by the use of look-up tables (LUT) in the display software.

1.6.11 Import Reconciliation Work flow (IRWF)

IHE (see Clause 1.6.12) profile describing how to import imaging studies from another system into a local system while ensuring the integrity of patient identification.

1.6.12 Integrating the Healthcare Enterprise (IHE)

Industry and professional consortium, originally established by the Radiological Society of North America and the Health Informatics and Medical Software Society, that develops profiles describing how different devices and software packages from different vendors can be made to interoperate.

1.6.13 Lossless compression

Mechanism for reducing files sizes that retains all original data.

1.6.14 Lossy compression

Mechanism for reducing files sizes in such a way that files recreated from compressed data may not be identical to the original file content or structure.

NOTE: Milder degrees of lossy compression may cause minor changes to the reconstructed images that do not affect diagnostic interpretation ('diagnostically acceptable image compression'), but more severe lossy compression will impair diagnostic interpretation.

1.6.15 May

Indicates the existence of an option.

1.6.16 MPG2

Standard for the generic coding of moving pictures and associated audio information.

1.6.17 MPR

Standard for multiplanar reconstruction.

1.6.18 On-referral

Circumstance where the clinician who originally requested an imaging study refers the patient on to another clinician for further management: this may occur without the knowledge of the imaging provider.

1.6.19 Picture archiving and communications system (PACS)

Software and hardware application or set of applications for managing the storage, transmission and viewing of digital medical images within an organization.

1.6.20 Pixel aspect ratio

Mathematical ratio that describes how the width of a pixel in a digital image compares to the height of that pixel.

1.6.21 Portable Data for Imaging (PDI)

IHE profile describing how digital diagnostic images are recorded on portable devices; includes the specification of the DICOM file format (Ref. 4).

1.6.22 Portable device

Broad term for optical or electronic devices that can store large amounts of digital data.

NOTE: Examples include CDs, DVDs, SD cards and USB drives.

1.6.23 Projected size

Displayed image in which the anatomy is shown magnified to the same extent that it was on the image detector [traditionally photographic film, now usually a computed radiographic (CR) or digital radiographic (DR) electronic detector].

NOTE: Sometimes also referred to as ‘full size’.

1.6.24 Referrer

Clinician who requests a diagnostic imaging service for the patient from the diagnostic imaging provider.

1.6.25 Scout view

Images which show the position of a set of cross-sectional images in relation to one or more key anatomical landmarks.

NOTES:

1 Traditionally, the scout view was a digital projection radiograph. With the increasing use of isotropic 3D acquisitions, cross-sectional images in another plane are increasingly being used instead of the projection image. This can lead to difficulty with correlating the cross-sectional images with a projection image available, for example in the operating theatre.

2 Depending on the equipment vendor, these images may also be termed ‘pilot views’, ‘reference images’, ‘surviews’ or ‘topograms’.

1.6.26 Secure Digital (SD) card

Electronic device for storing digital data.

1.6.27 Service object pair

Class of DICOM data.

1.6.28 Shall

Indicates that a statement is mandatory.

1.6.29 Should

Indicates a recommendation.

1.6.30 Single photon emission computed tomography/computed tomography (SPECT/CT)

Fusion of nuclear medicine imaging and conventional computed tomography.

1.6.31 Solid state drive (SSD)

Portable non-volatile memory devices (such as USB flash memory drives or portable hard drives).

1.6.32 Source data

Data from which an imaging device reconstructs images.

NOTE: Depending on the device and context, these may be thin-section, cross-sectional images in DICOM format. If the device stores 'source data' in a different format it should be able to produce thin-section reconstructions in DICOM format if required.

1.6.33 Universal Serial Bus (USB) drive

Electronic device for storing digital data. Input and output is via a widely used standard connector—the Universal Serial Bus.

1.6.34 Vendor-Neutral Archive (VNA)

Data storage techniques in which images and documents (and potentially any file of clinical relevance) are available in a standard format with a standard interface, so that they can be accessed equally effectively by the systems of other vendors.

NOTE: This includes storage systems that can accept data from a variety of vendors' equipment with similar degrees of difficulty, but excludes systems that can only accept data from one vendor's devices.

1.7 ACRONYMS AND ABBREVIATIONS

For the purposes of this document, the following abbreviated terms apply.

ADIA	Australian Diagnostic Imaging Association
BIR	Basic Image Review
CD	Compact disc
cd/m^2	Candelas per square meter
CR	Computed radiography
CRT	Cathode ray tube
CT	Computed Tomography
DAIC	Diagnostically acceptable image compression
DICOM	Digital Imaging and Communications in Medicine
DVD	Digital video disk/digital versatile disc
GSDF	Greyscale standard display function
ICU	Intensive Care unit
IHE	Integrating the Healthcare Enterprise
LCD	Liquid crystal display
L_{max}	Maximum luminance
L_{min}	Minimum luminance
LUT	Lookup table
lx	Lux—the derived SI unit of illuminance
MB	Megabyte

(*continued*)

1.7 ACRONYMS AND ABBREVIATIONS (continued)

MP	Megapixel
MR	Magnetic resonance
PACS	Picture archiving and communication system
PDI	Portable Data for Imaging
ppi	Pixels per inch
RACS	Royal Australasian College of Surgeons
RANZCR	Royal Australian and New Zealand College of Radiologists
SOE	Standard Operating Environment
SOP	Service Object Pair
SSA	Spine Society of Australia
TCP/IP	Transmission Control Protocol/Internet Protocol
US	Ultrasound
XDS-I	Cross-enterprise Document Sharing for Imaging (from IHE to facilitate clinical image sharing)

SECTION 2 PRODUCTION, VIEWING AND MANAGEMENT OF DIAGNOSTIC IMAGES

2.1 IMAGING PROCESS STEPS

The production, viewing and management of diagnostic images involve the following process steps:

(a) *Image data presentation*—processes the source image data according to defined standards for presenting image data in a standard file format.

(b) *Image data distribution*—provides the digital image files to the radiologist and treating practitioner, by using a computer network, digital storage media, digital imaging communication systems/digital image exchange, or as hard copy on film or paper.

(c) *Image data viewing*—achieved with computer hardware and software (for the display of digital data) or an illuminated view box (for the display of film).

(d) *Image data display* with a digital monitor—a major factor in achieving diagnostic quality imaging. Critical issues relate to luminance response, spatial resolution, contrast, refresh rate and the ability to calibrate the digital display. Image data distributed on film should be viewed on an appropriate light source in appropriate viewing conditions.

(e) *Image data manipulation*—enables measurements of anatomical features to be taken, the creation of different views, usually by reformatting the data in a manipulative environment, and planning for clinical intervention.

(f) *Image data storage*—provides for long term storage of images. This process of archiving was well defined, although it was not always effective during the film era (film was sometimes lost or misfiled, there could be conflict between clinicians for access to a single hard copy, and old films would need to be destroyed due to finite storage capacity). The archiving process is an uncertain and contested area in the transition to digital imaging. Storage may occur at the site of the imaging service or at an imaging archive service. Such storage shall include the capacity for image indexing and retrieval.

2.2 OVERVIEW

Each of these steps in the process of the provision of appropriate quality diagnostic images to the clinician is described in more detail in Clauses 3.1 to 3.6. Compliance with the requirements in this Technical Specification will ensure that digital diagnostic imaging can optimally inform patient care decisions.

Section 4 provides a summary of the current options available for each of these steps to ensure the provision of diagnostic quality images. When the provision of diagnostic quality images is required, one of these options shall be used for each distinct step.

SECTION 3 DIAGNOSTIC IMAGING PROCESS STEPS

3.1 IMAGE DATA PRESENTATION

3.1.1 Primary data format

Diagnostic quality images produced in digital format shall be available as DICOM objects and compliant with IHE PDI profiles if distributed on portable devices (Ref. 4). The digital data can then be distributed as detailed in Clause 3.2.

3.1.2 Other formats

Digital diagnostic images may be made available in formats other than DICOM objects—including those involving the use of lossy compression—if appropriate to the clinical needs of the referrer, and agreed to by the referrer (Ref. 2, 8, 9, 10).

When images have been compressed to an extent greater than that which is diagnostically acceptable, there shall be an annotation stating that lossy compression has been applied and indicating the degree of such compression. Annotations relating to the compression of images which have undergone lossless or diagnostically acceptable lossy compression may be applied.

3.1.3 Reference images

Cross-sectional image sets shall be supplied with means to correlate the location of the cross-sectional images with relevant anatomical landmarks. This may be achieved by the provision of scout views or by the use of cross-sectional images (or reconstructions) obtained in another appropriate plane.

The RANZCR/SSA *Joint guidelines for confirming vertebral levels in spine imaging* provide more detail on these requirements in the field of spine imaging (Ref. 11).

3.2 IMAGE DATA DISTRIBUTION (digital or hard copy)

3.2.1 General

Imaging providers shall consider the needs of the patient and their treating clinician(s) in deciding the means of image distribution, bearing in mind the possibility of on-referral (Ref. 10).

3.2.2 Secondary transmission

In the event of on-referral (the patient being referred to another practitioner), if the referrer of record has been supplied with images on film or physical media, the referrer shall make reasonable efforts to forward the images to the second practitioner, possibly in the care of the patient or the patient's agent. Imaging providers shall be in a position to promptly provide copies of the imaging data, of appropriate quality and via appropriate media, when necessary for patient care.

3.2.3 Change to the means of distribution

When there is to be a change in the means of image transmission or the associated workflow, the needs of all stakeholders shall be considered.

3.2.4 Security and confidentiality

Legislative provisions pertaining to the privacy requirements for the storage and transmission of health information in general should be considered. However, due to the rapidly evolving nature of the field, consensus on specific requirements for digital image security and confidentiality has not yet been reached. Network distribution options shall provide tools to assist ongoing image access within an appropriate patient confidentiality environment for an appropriate period.

3.2.5 Network performance requirements

Because technology evolves continuously, no firm recommendations can be provided with respect to desired or optimal data transmission speed. The acceptability or otherwise will depend on the clinical situation and end user digital functionality, with consideration of the existing technology environment.

3.2.6 Distribution options

The following are the options for the distribution of digital images:

(a) Via computer network using IHE and DICOM compliant protocols (Ref. 6, 8, 10).

(b) On a portable device, using IHE PDI compliant profiles (Ref. 4).

NOTE: CD or DVD media are a practical option when patients are being transferred permanently to another medical care jurisdiction, the clinical workflow is of low volume or the clinical workflow has been appropriately structured to accept such portable devices. It should be noted that access to image data on a CD or DVD is generally limited to a single image data transfer episode. In general, simultaneous direct viewing of image data on more than one CD or DVD is not possible. If such simultaneous viewing is required, the data should be transferred to a PACS and viewed independently of the CD or DVD.

(c) On laser printed transparent film.

NOTE: Laser printed transparent film may not be a practical medium to use for the distribution of many commonly performed studies such as CT, MR, Ultrasound or Nuclear Medicine studies due to the limitations on image display with film, and the number of images to be distributed.

3.2.7 Computer network distribution

3.2.7.1 *General*

Digital diagnostic images made available via electronic networks should be provided at compression levels appropriate to the available bandwidth, preferably at least DAIC.

If a greater degree of lossy compression is employed in the first instance due to network constraints, there shall be a mechanism for provision of diagnostic quality images that are lossless or DAIC images—either through a portable device or as an option on the network interface. The use of streaming and compression techniques in distribution is acceptable, but the degree of the compression of the displayed images should be evident to the viewer.

The time taken to display an image, set of images and multiple patient studies should be acceptable for the reasonable workflow requirements of the referring doctor and the diagnostic imaging provider.

3.2.7.2 *Network transmission*

Network transmission shall comply with legislative requirements and the general principles of computer network security.

The physical accessibility of computing devices and networks shall permit access to images in a variety of clinical locations, with particular emphasis on operating theatres, clinics, emergency departments, wards, clinical meeting rooms and mobile devices.

The interoperability of computer systems and applications shall be maximized through the avoidance of proprietary formats, and systems that may not be compatible with cross-vendor operations.

3.2.8 Portable media distribution

3.2.8.1 *General*

Diagnostic quality images can be stored and distributed on portable devices. Such distribution shall comply with the requirements in Clauses 3.2.8.2, 3.2.8.3 and 3.2.8.4.

3.2.8.2 *Portable devices (file structure)*

Digital diagnostic images supplied on portable devices shall comply with the IHE profile for PDI.

3.2.8.3 *Portable devices (labelling)*

Portable devices used to transmit digital diagnostic images shall be labelled externally with the patient name, date of birth, the name(s) of the imaging examination(s) and the date(s) conducted, and one other identifier (e.g. institutional unit record number or individual healthcare identifier).

3.2.8.4 *Portable devices (accessibility)*

If appropriate, additional measures should be available to ensure that the images stored on portable devices cannot be edited, other than by imaging providers.

The physical accessibility of computing devices should permit access to images in a variety of clinical locations, with particular emphasis on operating theatres, clinics, wards and clinical meeting rooms. The design of healthcare facilities, including that of public and private hospitals, should incorporate such accessibility considerations.

The interoperability of computer systems and applications should be maximized through the avoidance of propriety formats and systems that are not compatible with cross-vendor platforms.

3.2.9 Film distribution

3.2.9.1 *General*

Where distribution of diagnostic quality images over a computer network is not possible or clinically appropriate, diagnostic quality images can be distributed through printing on film or paper.

NOTE: This is more often appropriate for small numbers of radiographic images rather than for cross-sectional studies, for which the limitations of film should be recognized.

3.2.9.2 *Images for templating supplied on film*

Where possible, images supplied on film for templating purposes shall be printed at ‘projected size’.

Where this is not possible due to technical features of the imaging device, there shall be included in the image either an annotation reporting the degree of magnification or minification employed relative to the ‘projected size’, or a marker of known length, placed at the same distance from the detector as the anatomical part in question.

3.2.9.3 *Images for templating—‘fit to film’*

The use of ‘fit to film’ printing is not recommended. If a ‘fit to film’ option is used there shall be included in the image either an annotation reporting the degree of magnification or minification employed relative to the ‘projected size’ or a marker of known length, placed at the same distance from the detector as the anatomical part in question.

3.2.9.4 *Requirements for Printers*

Diagnostic quality images printed on film (or paper) should be printed at high resolution (not less than 300 dots per inch) on a high quality print medium (paper or film) using a printer and software capable of supporting appropriate DICOM SOP classes.

Magnification relative to 'full size' or a 'fit to film' option should not be used unless requested. However, where this is necessitated by equipment constraints, the resulting magnification or minification relative to 'projected size' shall be clearly stated.

3.2.9.5 *Requirements for printed images*

The printed images (transparent sheet film or paper) shall include the following information:

(a) Patient demographics, examination date (in day/month/year format) and imaging provider details and side where appropriate.

(b) Compression ratio and information on whether the image is lossy or lossless; if no compression is being used, annotation of the film or paper is not required.

Although most imaging studies will not be used for specific measurement by the referring practitioner, and will generally be reviewed in conjunction with the radiologist report, such images at 'full size' may be required following the on-referral of the patient to another clinician.

The imaging provider should where possible anticipate and address the need for such eventual image presentation, to avoid the cost of repeating the image distribution or—more adversely—repeating the imaging study.

3.2.9.6 *Requirements for printed images—radiographic images*

Printed images of radiographic examinations shall also include information regarding the magnification or otherwise of the image, in a prominent position on the printed image, in unambiguous terms, including—

(a) 'FC100' (from capture), 'SC100%' (as scanned), 'full size' and 'projected size', which indicate that images are displayed at the actual size at which they were captured); and

(b) 'anatomical size' or 'ADJ100' (which means that the image on the film is the same size as the imaged part in life—this is achieved by an adjustment based on a reference marker of a known and documented size).

The term 'true size' shall not be used, as it is ambiguous.

NOTE: A reference ruler to allow calculation of magnification is optional where images are printed at 'anatomical size' or 'full size', but should be included in all other situations.

3.2.9.7 *Requirements for printed images—cross-sectional images*

Printed images from a cross-sectional imaging from a study using CT, MRI, or similar modalities studies shall also—

(a) include a complete set (showing the whole volume of interest) of cross-sectional images in at least one plane, reconstructed at an appropriate section thickness.

Reconstructed views in additional planes or with additional image display windows should also be included where clinically appropriate;

(b) include at least one representative scout image in at least one orthogonal plane with clearly identifiable anatomical landmarks (where available). For each series this should be printed on at least the first film sheet of that series. A scout image view should be printed on each film in the series;

(c) ensure that, where scout images contain multiple lines to represent cross-sections in an orthogonal plane, the density of the lines does not obscure the underlying relevant anatomical detail (where possible); and

(d) ensure that, where scout images contain multiple lines with numeric labels that reference a section number in an orthogonal plane, the density of the numeric labels and lines is such that the labels remain legible (where possible).

3.3 IMAGE DATA DISPLAY—SOFTWARE

3.3.1 Viewing options

Images received in digital format shall be available as DICOM objects and compliant with IHE PDI profiles if distributed on portable devices. The end user computer will therefore require viewing software that is capable of presenting the image data to the display hardware within the DICOM environment (Ref. 1). The DICOM viewer may be pre-installed on the viewing computer, supplied on the portable device by the diagnostic imaging provider, or made available by the provider via secure download over a network connection.

Options for accessing and reading the digital images are the following:

(a) Use of DICOM reading software with simple intuitive interfaces pre-installed or network downloadable onto the viewer's computer.

Such a viewer shall be compliant with IHE BIR profile for image display (Ref. 3).

(b) DICOM reading software, provided on the portable device containing the images to be viewed. Onboard viewers should comply with the IHE profile for BIR (Ref. 3). If the reading software is likely to be used in a clinical care situation but fails to comply with the relevant benchmarks defined in this Technical Specification, a clear disclaimer that the software is not suitable for diagnostic purposes shall be displayed in the viewing interface when the image is initially displayed.

(c) Direct observation of hard copy film using high quality transparent laser printed images on a suitable light box, in an appropriate viewing environment.

(d) Where performed, comparison studies should be viewed under the same viewer/software conditions where available, to be fit for diagnostic purposes.

The means selected for the viewing of diagnostic quality images produced in digital format shall be suited to the technological capabilities and reasonable limitations of both the provider (media provision) and the referrer (image reading and display). Providers shall also consider the reasonable needs of clinicians likely to be involved in the subsequent management of the particular disease process in question.

Where possible, a DICOM compliant viewer already installed on the referrer's computer should be used. This is particularly relevant where the image data is distributed on a portable device, as it should not be assumed that all portable devices (including CDs, DVDs and solid state drives) will have an appropriate onboard viewer since the presence of a viewer is not required by IHE PDI (Ref. 4).

3.3.2 Digital image DICOM viewing software

DICOM viewers used to review digital diagnostic images should be compliant with the IHE BIR profile. The DICOM viewer may be pre-installed on the reviewing computer or supplied on the portable device by the diagnostic imaging provider.

Where a DICOM viewer complies with the benchmarks defined in this Technical Specification, there shall be a visually obvious statement displayed on the viewing interface that indicates that the display software is '***Suitable for clinical use or diagnostic purposes if displayed on appropriate monitor'***.

DICOM viewers shall have the following functionality implemented with standard IHE BIR consistent pictorial icons (Ref. 3):

(a) Window functions such as thumbnails of available studies, load, clear indicator of active window, tile and window (including automated preset 'window levels').

(b) Movement functions, including pan, measure—linear, angle, density, zoom and scroll.

(c) File functions, including save image, print image, the relevant DICOM header details and close.

(d) Help functions, including simple help menu, abort (allowing the operator to terminate the current action and return to previous function) and refresh (returning the viewer that is the windowing and zoom to default settings).

(e) Animation functions, including the ability to display and play DICOM compliant animations (MPG2), the capacity for export to a DICOM supported cine format of the animation, and the standard animation controls of play, pause, reverse, fast forward and stop.

(f) On screen information that can be hidden or unhidden, including demographic details (e.g. name, date of birth and study number), study details (basic details of study, region and type of study), CR/DR, lossy, lossless and magnification.

Cross-sectional navigation should if possible ensure that all image sets are related to all other image sets in orthogonal planes, such that the position of one image can be displayed in all other image sets in an orthogonal plane. It shall also include at least one representative scout image, in at least one orthogonal plane with clearly identifiable landmarks, that relates to a selected image set and is available for display on the same screen as the image set.

Compliance with the following specifications will enable the optimal viewing of cross-sectional images:

(i) If scout images contain multiple lines to represent sections in an orthogonal plane, the density of the lines shall not obscure the underlying anatomical detail (where available).

(ii) If scout images contain multiple lines with numeric labels that reference a slice number in an orthogonal plane, the density of the numeric lines shall ensure that the labels remain legible.

(iii) The image number on an individual image that corresponds to a scout image line shall be clearly indicated and not obscured by other numerical information.

(iv) If more than one window is open there shall be an option allowing images obtained in the same plane to be synchronized to the same section position. If images in separate windows are orthogonal then scout image lines shall be visible with a simple 'show image position on reference/scout image' command. Synchronization of different CT MPR image sets should be used as a guide only, as accurate location information may not be available due to volumetric data set manipulation. This does not apply to MRI images that are directly acquired in orthogonal planes.

3.3.3 Images supplied on portable devices—autoload

Images received on a portable device (e.g. a CD) may be accompanied by a DICOM viewing software program. Such software shall not autoload upon insertion of the CD, DVD or other portable device into the viewer's computer system.

3.3.4 Transparent film viewing

A light box of adequate luminance in a viewing area with adequate control of ambient light shall be used for viewing diagnostic quality images, as defined in Clause 3.4.3.

3.4 IMAGE DATA DISPLAY—HARDWARE

3.4.1 Display options

The quality of the monitor is a major factor in achieving diagnostic quality imaging. Critical features of a monitor are luminance response, spatial resolution, contrast, refresh rate and the ability to calibrate the digital display. While the LCD monitor has largely taken over from the CRT, alternative digital displays may be suitable depending on their functionality.

Where the images are displayed on a monitor, this shall conform to greyscale standard display function DICOM format (GSDF) (Ref. 1, 5), with a minimum luminance of at least 250 cd/m^2 and a minimum luminescence ratio of 250 (Ref. 1). Unless used only for smaller matrix images, the pixel pitch should be less than 0.250 mm (about 100 pixels per inch).

NOTE: The minimum resolution required for mammograms exceeds that typically required for non-mammography diagnostic image review.

To allow accurate measurement and anatomical assessment, including templating, the pixel aspect ratio of the displayed image shall match the pixel aspect ratio of the captured image. In virtually all situations this is a pixel aspect ratio of 1:1.

The following are the acceptable alternatives for the display of diagnostic quality images:

(a) For larger matrix images (e.g. CR and DR), the use of an appropriate sized LCD (with or without GSDF compliance) and a pixel pitch of 0.250 mm or less (100 ppi) at the clinician's discretion.

(b) For smaller matrix images (e.g. CT and MR), the use of an appropriate sized LCD (with or without GSDF conformance) and a pixel pitch of 0.300 mm or less (80 ppi), at the clinician's discretion.

(c) Where images are transferred on transparent film, the use of direct observation of printed transparent film on light box of suitable intensity and with low ambient light (see Clause 3.4.5.3).

3.4.2 Monitor specification and performance options

There is a spectrum of monitor specifications for different tasks in the clinical environment.

NOTE: This is expanded in Appendix B. This document does not address the issues related to mammography review, where the image display typically has a much higher display specification (see Clause 1.2.1).

Monitors can be differentiated into three grades or tiers:

Tier 1 primary diagnosis

Tier 2 clinical review

Tier 3 basic image viewing

The actual specifications of the appropriate monitor relates to the image quality needs, type of image and clinical circumstances (Ref. 7).

3.4.3 Digital image DICOM display

Diagnostic quality images should be viewed using DICOM compatible display attached to the end user computer. For non-primary image interpretation, diagnostic quality DICOM compatible displays should be GSDF Part 14 compliant, with minimum luminance of 250 cd/m^2, minimum luminance ratio of 1:250, and pixel pitch of 0.250 mm or less (100 ppi or greater). Typically a monitor to this specification would be about 53 cm (21") diagonal with an image matrix of 1600 px × 1200 px (2MP) (Ref. 1, 7).

Depending on imaging modality (i.e. image matrix size), a monitor of lower pixel pitch can provide adequate spatial resolution, as shown in Table 1.

TABLE 1

MONITOR RESOLUTION BY MODALITY

Modality	Minimum pixel pitch	Typical monitor resolution
CR/DR	0.250 mm (100 ppi)	1600 × 1200 monochrome/colour (pixel pitch approximately 0.250 mm (100 ppi) on a 53 cm (diagonal) (21") monitor)
CT	0.300 mm (80 ppi)	1024 × 768 colour/monochrome
US	0.300 mm (80 ppi)	1024 × 768 colour/monochrome
MR	0.300 mm (80 ppi)	1024 × 768 colour/monochrome

The following requirements and recommendations apply to the display of diagnostic quality images:

(a) For optimal review, the spatial resolution of the digital display shall be able to achieve the native resolution of the displayed image [see the note below list item (c)].

(b) If general diagnostic digital image review is anticipated, the monitor resolution should be at a specification level suitable for viewing CR images.

(c) If larger screens are required (such as in an operating theatre or a clinic meeting room) this should be supplemented by a monitor to allow more accurate review, as specified in Table 2.

NOTE: Although the spatial resolution of CR may exceed the monitor pixel pitch (e.g. 250 mm or 100 ppi), the utilization of the zoom function in the viewing software will allow adequate spatial resolution above the native image resolution if required.

3.4.4 Monitors for image display—clinical setting

3.4.4.1 *Monitors for image display—primary diagnosis (large matrix)*

Display equipment used for the generation of formal radiological reports or for immediate clinical management decisions (e.g. in emergency departments or operating theatres) shall meet the requirements defined in Table 2 for ‘primary diagnosis’.

3.4.4.2 *Monitors for image display—secondary diagnosis*

If a radiologist report is available, the images may be displayed on a monitor that meets the requirements for ‘secondary diagnosis’ or clinical Tier 2 (see Table 2).

3.4.4.3 *Monitors for image display—small matrix images*

If high-performance monitors are not available, cross-sectional imaging studies may be viewed satisfactorily on monitors meeting the requirements for a ‘small matrix only’ display (see Table 2).

TABLE 2

MONITOR SPECIFICATIONS CONTRASTING VARIOUS CLINICAL APPLICATIONS (Ref. 7)

	Tier 1: primary diagnosis	Tier 2: clinical review	Tier 2: clinical review (small matrix only)
Image resolution, (pixel pitch, µm)	200–210	250–300	250–300
Brightness (L_{max}, cd/m^2)	> 350	> 250	> 250
Luminance uniformity	≤ ±15% from centre to corners	≤ ±15% from centre to corners	≤ ±15% from centre to corners
Bit depth	10	10	8
Contrast ratio	> 250:1	> 250:1	> 250:1
Calibration	Auto-GSDF	Auto-GSDF	3rd party GSDF
DICOM Part 14 GSDF conformance	At least gamma adjustment, ideally LUT (Look up Tables)	At least gamma adjustment, ideally LUT (Look up Tables)	As per manufacturer's recommendation
Chromaticity	$\Delta (u', v') \leq 0.01$	$\Delta (u', v') \leq 0.01$	$\Delta (u', v') \leq 0.01$
Refresh rate	≥ 60Hz	≥ 60Hz	≥ 60Hz
Dead pixel tolerance	< 10 per screen (< 15 for screens of 24" or above)	< 10 per screen (< 15 for screens of 24" or above)	< 10 per screen (< 15 for screens of 24" or above)
Viewing angle	≥ 800°Horizontal, 500°Vertical	≥ 800°Horizontal, 500°Vertical	≥ 800°Horizontal, 500°Vertical
Typical matrix	2048 by 1536 (53 cm / 21") 3 MP	1600 × 1200 (53 cm / 21") 2 MP	1280 × 1024 (43 cm / 17") 1.3 MP
Calibration ability*	External or internal, with option to upgrade to network management by installation of appropriate video card	As per manufacturer's recommendation	As per manufacturer's recommendation
Input/output signal	DVI-D, HDMI or Display Port	DVI-D, HDMI or Display Port	DVI-D, HDMI or Display Port
Minimum screen size	As specified by radiological provider policy	**Office/clinic**—at least one 21" screen (or equivalent) per examination station **Operating theatre**—two 24" screens (or equivalent) with access to additional mobile monitors	**Office/clinic**—at least one 21" screen (or equivalent) per examination station

* The monitor shall have the capability to be calibrated. However, this Technical Specification does not define exactly how this is to be achieved, how frequently it should be done, or who should perform such ongoing calibration.

3.4.5 Viewing conditions

3.4.5.1 *Reflections*

Lighting around display equipment shall be positioned to eliminate reflections from the monitor screen towards the viewer.

3.4.5.2 *Ambient light*

Ambient lighting level of 20–40 lx is recommended, but higher levels may be acceptable if the display is sufficiently bright.

3.4.5.3 *Transparent film display*

A light box comprising at least one 35 cm × 43 cm panel with light diffusing screen at 2000 cd/m^2 luminance (Ref. 1) should be used for viewing diagnostic quality images. Multiple panels should be colour and luminance matched.

3.5 IMAGE DATA MANIPULATION AND MEASUREMENT

3.5.1 General

Imaging studies are regularly used to plan treatments. Complex reconstructive procedures, in particular arthroplasty, generally require pre-operative planning to achieve an optimal outcome. For these purposes it is critical to know accurately the sizes of certain anatomical parts. The ability to provide image data suitable for manipulation in the form of measurement or templating is a standard requirement for the majority of image distribution systems, and where such systems are deployed, they should—

(a) integrate with surgical templating software to facilitate efficient workflow;

(b) provide appropriate scout images and measurement, particularly for the spine; and

(c) provide additional measuring functionality, as part of primary image viewing software tools.

The basic requirement of measurement and planning could be adequately provided for within the functionality of the basic viewing software. If this is the case, no special software or functionality may be needed in this respect.

This Technical Specification requires a DICOM viewer for general review of diagnostic quality images. However, more specialized software may be required by specific groups. These include—

(i) orthopaedic surgeons for joint templating and 3D multiplanar reconstruction;

(ii) radiation oncologists for CT-MR overlay and treatment field planning;

(iii) spinal surgeons for 2D multi-planar reconstruction; and

(iv) interventional cardiologists and vascular surgeons.

3.5.2 Measurement and manipulation options

The following are the recommended options for image measurement and manipulation:

(a) Templating (measuring) software linked to DICOM viewing interface (including magnification reference marker).

(b) Templating software which is not linked to DICOM viewing interface, but can independently retrieve DICOM image data.

(c) Transparent acetate or clear polyester templating sheets overlaid on a digital display screen with manual magnification and size calibration.

NOTE: The clinician shall have been trained in the use of this technique, as it involves manual calibration of image size on screen against a ruler.

(d) Transparent acetate or clear polyester templating sheets overlaid onto known size laser printed digital copies with or without size marker.

3.6 IMAGE DATA STORAGE

3.6.1 General

The increasing volume of digital images poses challenges in terms of reliable archiving, archive management, image retrieval, and display and manipulation to all clinicians who use diagnostic imaging.

Archiving requirements are affected by patient and clinician needs, regulatory requirements, and infrastructure constraints. The future institutional management of archives will evolve as technology options develop, but will likely involve a combination of registries and secure data repositories. Ownership, resourcing and management of data storage resources are outside the scope of this Technical Specification.

3.6.2 Storage options

The options at time of publication for the storage of diagnostic quality images are the following:

(a) Long-term storage on secure data storage devices or systems, available in DICOM format, with appropriate offsite or alternate site backup.

(b) Hard copy, stored in a secure and environmentally protected repository.

NOTE: Storage on portable devices in IHE PDI format is not recommended for long-term storage; however, it may be used for short-term storage when images are already backed up by other methods.

If image data is stored in electronic form, archiving systems should ensure interoperability and compliance with IHE XDS-I (cross-enterprise document sharing) profile. Proprietary compression algorithms are acceptable, but the data shall be accessible in a DICOM standard vendor neutral format.

SECTION 4 SUMMARY OF REQUIREMENTS FOR DIAGNOSTIC QUALITY IMAGES

Figure 1 provides an outline of the various steps in the production, viewing and management of diagnostic images. When the provision of diagnostic quality images is required, one of the options in the blue boxes in the figure shall be used for each distinct step.

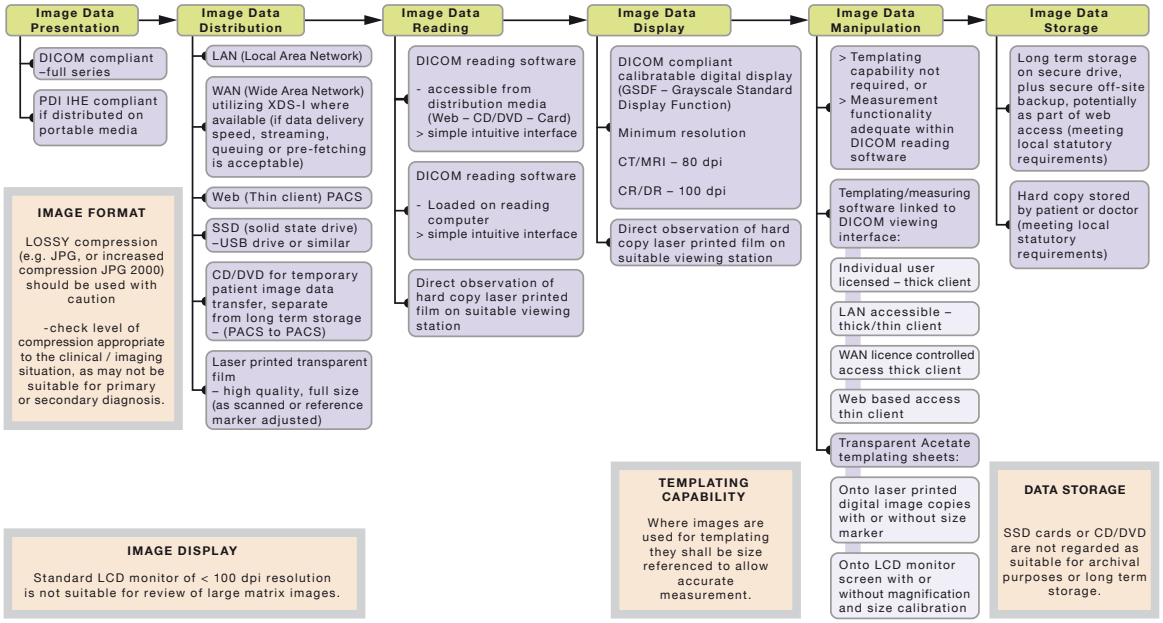

FIGURE 1 STEPS IN THE PRODUCTION, VIEWING AND MANAGEMENT OF DIAGNOSTIC IMAGES

APPENDIX A

TRANSITION TO DIGITAL DIAGNOSTIC IMAGING

(Informative)

A1 GENERAL

The availability of and access to appropriate diagnostic imaging is a crucial component of the information required for providing optimal patient care. Clinicians use such images to confirm or make diagnoses and plan treatment.

Radiological images may be required for the following (not necessarily mutually exclusive) broad purposes—

(a) as diagnostic images requested by a treating clinician—these may be for confirmation of a diagnosis, staging of disease, monitoring of treatment, detection of complications, narrowing of the differential diagnoses, exclusion of unlikely but important diagnoses, or screening;

(b) as images generated in the course of an interventional procedure for guidance and documentation purposes, typically obtained by an imaging provider; and

(c) as images for teaching and research purposes.

The move from analogue screen and film to digital image capture and distribution can deliver many advantages. However, difficulties could occur in the transmission or display of such digital images. Equally, there could be problems with accessing film based images, such as the loss of films, leading to repeat imaging, or an inability to display volumetric studies adequately.

Diagnostic medical images were traditionally obtained by exposing photographic film to X-rays, or later to light emitted from an X-ray detector.

Almost all medical imaging now uses digital detectors, which create electronic signals when struck by an X-ray beam. These signals are digitized and processed to produce medical images that can be displayed on a screen, stored in a digital memory device, or transmitted over a network.

While it is possible to print these images to film (now done by using laser technology and film coated with toner rather than photographic emulsion), this has a number of disadvantages, such as the following:

(i) Each diagnostic imaging event produces a single hard copy, which may be needed by several clinicians simultaneously. It may subsequently be lost, sequestered or damaged.

(ii) The film needs to be physically stored and tracked, which are both expensive activities.

(iii) Film has limited capacity to physically display large numbers of images.

(iv) Film has limited ability to display three dimensional representations, colour and video.

(v) Once printed an image on film has a fixed grayscale and cannot easily be further manipulated.

These factors have led to the rapid decline of film as the medium on which medical images are presented, despite the following residual advantages of film:

(A) Better spatial resolution.

(B) Minimal equipment required for viewing.

Specific advantages of the digital delivery of diagnostic quality images include the following:

(1) The large number of images (particularly in volumetric data capture such as CT and MR) frequently cannot be satisfactorily viewed on film, whereas digital delivery can facilitate this.

(2) Digital presentation has major advantages for image viewing and manipulation (e.g. the ability to scroll through the images and change presentation states).

(3) Image manipulation and 3D image viewing by the treating doctor may be required in certain situations where this is only achievable via digital distribution and display techniques.

Utilizing the technical specifications contained within this document will improve clinical accessing and viewing of digital diagnostic images in the health environment. It is ultimately the responsibility of the treating practitioner to decide what is appropriate for ensuring optimal patient care, while keeping in mind what is technically and economically feasible. However, a major purpose of this document is to inform practitioners of the relevant technical details of digital imaging so they can more effectively request, access and interpret diagnostic images, particularly those captured and transmitted in digital format.

The move to digital imaging may require important changes in patient care and the way images are accessed. However, the move should be made in a way that ensures the maintenance of access by clinicians to relevant patient data. From the surgeon's perspective diagnostic quality images will often be required for surgical management and should be appropriately available for this purpose (RACS Position statement, RACS Standards Committee, Royal Australasian College of Surgeons, February 2007).

The RACS Position statement referred to in the above paragraph specifically addresses situations where diagnostic quality imaging is required, such as in the course of a therapeutic procedure. If non-diagnostic review or educational image access is required, these recommended benchmarks do not necessarily apply. The viewing clinician needs to be aware that such images, although useful for review purposes, may not be of a sufficient standard to allow optimal diagnostic analysis.

A key issue relates to the definition of what constitutes diagnostic quality imaging.

The image characteristics will vary according to the clinical situation, the patient's status and the technique used to capture the images. However, for the purpose of this document the definition of a diagnostic quality image is in line with that provided by the RANZCR/ADIA: '... an image that is comparable in quality and presentation to that used by radiologists in reporting' (Ref. 6).

For those clinicians who require images of sufficient quality for optimal patient care, it is necessary that diagnostic quality images be provided to the treating practitioner that are of high resolution, permit measurement, and are supplied on a medium (whether film or digital) in a form that is accessible and clinically appropriate.

Because of limitations in image storage capacity or transmission time, images of lesser or reduced quality may also be produced. These images may still be of clinical use and helpful for clinical review and patient education, but may not be suitable for primary or secondary diagnosis. The fact that these images are not of the same quality as those used for primary or secondary diagnosis needs to be clearly evident to the viewing clinician. This includes images viewed on digital tablets and viewing platforms that do not achieve the required resolution and display specifications detailed in this Technical Specification.

A2 DIAGNOSTIC IMAGING ACCESS

Access to diagnostic quality images is needed for patients seeking treatment in different parts of the health system, and the most appropriate presentation format for these images can vary between clinical settings. The guidelines in this Technical Specification enable both referrers and providers to work together to develop solutions in each setting, in order to facilitate the transition to digital imaging.

The means of distribution and viewing of diagnostic images produced in digital format should be consistent with the technological capabilities, and their reasonable limitations, of both the diagnostic imaging service and the referring practitioner, and should also consider the needs of any clinician involved in the subsequent management of the particular disease process in question.

Factors that should be considered when distributing images and image sets through a computer network include—

(a) the size and number of images that are required to be distributed within a given time period;

(b) the transmission time for these images through the computer network;

(c) the time taken to read and write these images on network data storage;

(d) the extent to which images can be pre-fetched from a remote image store in order to permit speedier local display;

(e) the security and privacy of the images;

(f) the physical accessibility of computing devices and networks; and

(g) the interoperability of computer systems and applications.

When patient care decisions depend upon the review of the diagnostic images, all parties need to be constructively involved in any decision to adopt a material change in the way images are provided. The transition to digital imaging should not compromise the quality of diagnostic information available to the clinician, and should facilitate—not hinder—appropriate access to images while caring for patients.

A process should be provided to prevent delays in care delivery. This will also prevent unnecessary reimaging of the patient that results in significant inconvenience, radiation exposure and cost, and will obviate the need to provide full size measurable film when only a small percentage of patients are on-referred to specialists who require such images for templating or other measurement techniques.

Similarly, it is important that referrers have realistic expectations in requesting ‘film’ in all cases. Multi-slice CT studies often create over 1000 images per patient study, and the principle of selection appropriate to the clinical setting needs to be applied when key images are provided on film media. However, provision of any subset on a limited number of films will necessarily entail some loss of detail.

The time taken to display an image, set of images or multiple patient studies should be acceptable in relation to the reasonable workflow requirements of the referring doctor and the diagnostic imaging provider. When a computer network is used for distributing diagnostic quality images, the following factors affect the display time for images requiring assessment:

(i) The time taken to read the image from a network data storage device.

(ii) The transmission rate of the wide area network.

(iii) The transmission rate of the local area network.

(iv) Propagation delay on the network.

(v) Waiting times for acknowledgements built into the computer network protocols.

(vi) Server and end user computer processor clock frequency.

(vii) Graphical display processors and devices performance.

(viii) Design and type of application used by end users.

The security and privacy of the images is governed by legislation and is facilitated by the appropriate behaviour of users and the controls built into computer networks and applications. Network transmission should comply with legislative requirements and the general principles of computer network security.

Computer systems and applications use many different access pathways to download an image to an end user computer. Two principal pathways that are available are listed below:

(A) Access to a dedicated image store—known as a picture archiving and communication system (PACS)—for which the user has a computer account using a dedicated client application, or a web browser on the end user computer.

(B) Access via a highlighted link in an electronic radiology report. A DICOM viewing application or a web browser can be used to view the image. The use of uniform resource locators (URLs) should include appropriate authentication mechanisms. This method is similar to the first method; however, access to the image store is pre-authorized by a token contained in the link or some other security process consistent with local regulatory requirements.

The ability to pre-fetch and pre-load the images can assist in image data access, but this may have limited applicability in many clinical situations due to the workflow characteristics, such as the frequent inability to identify before the consultation which images are available and which images could be required.

Factors that should be considered when distributing images and image sets through portable devices (either disc or solid state card) include—

(1) the size and number of images that are required to be distributed on a single storage device;

(2) the time taken to write these images from network data storage to the storage device;

(3) the time taken to read these images from the storage device to an end user computer;

(4) the security and privacy of the images;

(5) the physical accessibility of computing devices; and

(6) the interoperability of computer systems and applications.

The time taken to display an image, set of images and multiple patient studies should be acceptable for the reasonable workflow requirements of the referring doctor and the diagnostic imaging provider. When portable devices are used to distribute diagnostic quality images, the following factors affect the display time for images requiring assessment:

(aa) The time taken to read an image from a network data storage device to portable devices.

(bb) The time taken to write an image from a portable device to an end user computer.

(cc) The end user computer processor clock frequency.

(dd) The performance of graphical display processors and devices.

(ee) The design and type of application used by end users.

(ff) The feasibility of pre-fetching or pre-loading image data off the portable device.

The IHE (Integrating the Healthcare Enterprise) XDS-I profile potentially provides a framework to interlink image archives and repositories, as network access becomes faster and easier. Consideration will need to be given to the balance between centralized image archiving and a more distributed system supported by a network of registries.

Given the likely progressive development of XDS-I capability in the community as an option for accessing patient diagnostic imaging data from studies performed by different imaging providers, XDS-I capability should be a part of the functionality of future PACSs.

A3 BROAD CATEGORIES OF MEDICAL IMAGING STUDIES AND THEIR FILE SIZES

A3.1 Diagnostic imaging modalities

The file size of an examination depends partly on the number of individual images it comprises, and partly on the size of each image.

When considering contemporary imaging, it is useful to differentiate between images such as plain radiographs and those generated by other modalities, including computer tomography (CT) scanning, magnetic resonance (MR) and ultrasound. CT scanning, MR and ultrasound each capture 3D volumetric data that can be displayed as variable numbers of two dimensional images with different matrix sizes (as defined by the number of pixels in each (x,y) direction) as well as 3D representations. The diverse matrix sizes and the variable numbers of images generated by the various modalities pose different challenges in image display. There are two broad groups of modality image data sets (with some overlap between these):

(a) Plain radiography—Represented by plain X-rays where the matrix size is large (up to 2000 pixels by 3000 pixels), but there are few images in each study. When 10 or more bits are used to represent each pixel, the file size may be between 12 MB and 40 MB. In the case of mammography the images are of a far higher resolution—typically described as line pairs per mm (lp/mm)—and a series of studies may exceed 150 MB. Images obtained with high spatial resolution and bit depth—such as mammograms and, to a lesser extent, general radiographic studies—have large image sizes (10–40 MB), but the complete study has only a few (typically fewer than five) images.

(b) Cross-sectional imaging (of a defined volume) such as CT, MR, SPECT/CT (single photon emission computed tomography/computed tomography) or PET/CT (positive emission tomography/computed tomography)—using small matrix sizes, but with many images. Cross-sectional images are typically small matrix (e.g. 512 pixels by 512 pixels) using 12 to 14 bits per pixel. The file size of each individual image is generally less than 1 MB. The major challenges presented by these modalities are the large numbers of images often obtained (from 100 to 3000 images) and the collective size of the entire data set. These modalities can frequently display data in a 3-D, 4-D (time-resolved), or video representation.

Cross-sectional imaging (e.g. CT, MR, SPECT/CT and PET/CT) requires large amounts of cross-sectional data to be recorded and manipulated, and the radiologist's assessment and diagnosis are important. Images are typically of relatively small size (often < 1 MB), but there may be hundreds or even thousands of images per study.

However, adequate assessment of the case by the clinician may require correlation of the clinical features with detailed assessment of the imaging findings, and hence access by the treating clinician to the complete image data in electronic form is frequently required to facilitate radiological consultation and surgical management. This is especially important in urgent situations when treatment is required before the formal radiological report is available.

In the delivery of cross-sectional images (either digitally or by hard copy) a spatial location guide indicating the relationship of each cross-sectional image to standard anatomical landmarks is required (these may be known as scout images or pilot views, topograms, etc.).

A3.2 Advantages of film for medical image presentation

Traditional analogue film was well suited to the recording of radiographic images, as it was capable of quite high spatial resolution, and only a few sheets of film were required to capture all the images at high resolution. Relatively simple equipment was required for viewing.

A3.3 Advantages of digital formats for medical image presentation

Images acquired by digital methods are open to a wide range of image manipulation techniques that can greatly increase their diagnostic value. They can also be stored relatively cheaply on optical or electronic media.

A4 TEMPLATING AND MEASUREMENT

A4.1 General

Some imaging studies are used to plan treatments such as the insertion of a joint prosthesis. For these purposes it is critical to know accurately the sizes of certain anatomical parts.

Plain radiography images are required for diagnostic and linear measurement and templating. The treating clinician may need to use these images for critical decisions regarding prosthesis positioning or loosening, fracture patterns, sequential comparison of suspicious pulmonary lesions, and multiple other clinical requirements.

A4.2 Inherent magnification of radiographic images

A4.2.1 *General*

Because radiographic images are generated by an X-ray beam emanating from a point source and diverging as it moves further away from that source, the 'projected size' of the image generated on the detector (whether film, screen or electronic) is always larger than the true 'anatomical size' of the object in question.

Due to the divergent nature of the imaging beam, radiographs always magnify the imaged anatomy. With analogue methods, standardized techniques are employed (i.e. fixed focus-film distance and minimum object-film distance) so that the degree of magnification is fairly reproducible for a particular examination and patient. An experienced observer can then fairly reliably estimate real size from image size. Traditionally, adjustments to templating and direct measurements have been estimated by competent clinicians who are aware of the predictable magnification inherently caused by the divergent X-ray beam.

With digital imaging there may be difficulty in identifying the relationship between the size of the displayed image and the actual size of the imaged part due to discretionary magnification (or minification) after acquisition. This means that the actual size of the image on the exported hardcopy image can be varied, sometimes to correct for the inherent magnification.

The clinician needs to know whether the image size is as captured and displayed (as would be the case with analogue film) or whether there has been some adjustment, typically based on the co-registration of a marker of a known size.

Terms such as ‘true size’, ‘real size’, ‘anatomical size’ or similar may be unclear if these terms indicate that the displayed image matches the size that was actually captured onto the imaging plate, or if the capture image size has been adjusted using a reference marker. These terms can be confusing and ambiguous, and hence should only be used if clearly and unambiguously defined.

In recent years there has been a trend towards replacing full size film images with reduced size films, particularly where referring clinicians are not likely to be making independent diagnostic decisions based on their interpretation, and are relying on the radiologist’s report. This becomes an issue when these same images are taken by the patient to a subsequent consultation with a clinician who needs to view the images, and is expecting to review images that are in the traditional ‘full size’.

A4.2.2 *Compensating for inherent magnification in analogue radiographic images*

In the era of analogue film it was difficult to produce anything other than a ‘projected size’ image. Surgical practice evolved to compensate for this by using various rules of thumb, or on occasion by requesting studies in which a marker of known size—positioned at the same distance from the film as the anatomical part of interest—was included in the image.

A4.2.3 *Compensating for inherent magnification in digital images*

In the digital era it is a simple matter to vary the size of the displayed image, either to display true anatomical size or to accommodate the images within the constraints of digital film printing.

A5 IMAGE COMPRESSION

A5.1 General

For transmission purposes it may be useful to reduce the amount of data that needs to be sent. This can be done either by reducing the number of images sent (e.g. by sending only every second image of a large set of images) or reducing (‘compressing’) the data for each individual image. Compressed images have the additional advantage of requiring smaller amounts of storage per study.

The DICOM format includes provision for the ‘lossless’ compression of images, where the volume of transferred image data is reduced (typically by a factor of two times) without affecting the appearance of the displayed image.

Higher degrees of data compression are usually ‘lossy’; that is, the displayed image is of lower quality than the uncompressed original. Depending on the nature of the examination, and the nature and degree of compression employed, lossy compression may or may not affect the diagnostic value of an image.

Use of lossy compression can be considered where it has been shown that the degree of lossy compression employed has no effect on diagnostic quality.

There are a number of mathematical algorithms available for compressing image data.

A5.2 Lossless compression

For some of these algorithms it is possible to reconstruct the whole of the original image from the compressed data—these are described as ‘lossless’ compression algorithms. These typically do not reduce the file size of an image by more than a factor of two to three.

A5.3 Lossy compression

Algorithms that do not permit the complete reconstruction of the original image are described as providing ‘lossy’ compression. They may reduce the file size by much more than a factor of two to three, at the cost of reducing the quality of the reconstructed image.

A5.4 Diagnostically acceptable image compression

It has been shown that relatively mild degrees of lossy compression (often by a factor of six to ten) allow reconstruction of images that can be interpreted with the same accuracy as the uncompressed originals. This is known as diagnostically acceptable image compression (DAIC). Unfortunately the level of compression that is acceptable in this sense varies with the imaging modality and even with the anatomical region being studied, so it is not possible to provide simple general rules for the amount of compression that is diagnostically acceptable. More information on acceptable levels of compression for various examination types can be found in the references listed in the Bibliography.

A6 DIGITAL IMAGES THAT MAY NOT BE IN STANDARD DICOM FORMAT

A6.1 Images from legacy equipment

Some images produced by older equipment (particularly in nuclear medicine) may be stored in formats other than those described by the Digital Imaging and Communications in Medicine (DICOM) standard. Not all PACSs are able to distribute such image data; where PACS transmission is not feasible, alternative distribution options will need to be utilized. Given the difficulties of integrating such data into a contemporary data sharing environment, appropriate distribution and data sharing options should be considered and agreed on by the clinicians involved. The priority, however, should be to identify solutions that are consistent with optimum patient care.

A6.2 Images for which a DICOM object definition is not yet widely implemented

Very new modalities may produce images for which a DICOM standard description has not yet been agreed, or where the DICOM ‘object definition’ is not yet widely supported by devices other than those that produced it. This may limit the ability to display these images with standard DICOM conformant hardware and software. The options for image data distribution should follow the principles detailed in Clause 3.2.

The requirements that interoperability should meet image distribution and access benchmarks will ensure that vendors see conformance with IHE profiles as a critical functionality to increase their attractiveness in the market place.

Vendors should be encouraged to ensure that wherever possible images produced are conformant with DICOM image object specifications, and that when necessary new object specifications are promptly developed.

A7 DIAGNOSTIC IMAGING INDUSTRY STANDARDS

Almost all diagnostic images produced in digital format use the DICOM standard for digital image files.

NOTE: The National Electrical Manufacturers Association (NEMA) holds the copyright to the DICOM standard. It was developed by the various DICOM Standards Committees, whose members are also partly members of NEMA.

DICOM is a large set of standards for handling, storing, printing and transmitting information in the field of medical imaging. It includes a file format definition and a network communications protocol. The communications protocol is an application protocol that uses Transmission Control Protocol/Internet Protocol to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.

DICOM enables the integration of scanners, servers, workstations, printers and network hardware from multiple manufacturers into a picture archiving and communication system (PACS).

IHE fills the gap between the creation of e-health standards and their implementation. IHE supports vendors and implementers in effectively building compliant healthcare computing systems and interfaces based on global standards such as HL7 (Health Level Seven) and DICOM.

IHE develops and maintains the IHE profiles which provide precise implementation specifications, based on established international standards for specific health IT interoperability needs.

Vendors of PACS systems, portable data creation systems and image viewing software are able to test their products against the IHE profile, and publish conformance statements for functions such as portable device creator, image display and image print. IHE conformance is becoming a more frequent requirement by buyers in the acquisition of such equipment.

APPENDIX B

VIEWING MONITOR SPECIFICATIONS

(Informative)

B1 GENERAL

When considering viewing monitors for radiology applications it is necessary also to consider the imaging modality. These can be defined as—

(a) *small matrix,* where the image pixel array is less than or equal to 1000 px × 1000 px [e.g. CT (computed tomography), MR (magnetic resonance) and ultrasound]; or

(b) *large matrix,* where the image pixel array is greater than 1000 px × 1000 px [e.g. plain images CR (computed radiography), DR (digital radiography)].

The performance of a monitor in a radiological viewing application can be characterized by a small number of quantitative metrics that are often used to describe image quality. These metrics frequently fall into the categories of spatial resolution (see Paragraph B2) and luminance response (see Paragraph B3).

B2 SPATIAL RESOLUTION

The spatial resolution characteristic involves more than simply specifying minimum monitor matrix sizes [e.g. 2 MP (megapixel) or 3 MP] for each modality. The physical size of the monitor is also an important consideration. (For example, there are notebook screens in excess of 1600 px × 1200 px that have a small pixel pitch that will display a chest X-ray at an inappropriate image size. Pixel pitch determines the smallest sized object that can be resolved when the image is displayed in a 1:1 spatial map from image pixel data to image display data.)

It is more appropriate to define the screen size (e.g. 53 cm or 21" diagonal) as well as the required matrix size. This will determine the pixel pitch.

NOTE: Magnification features of the display application software on the workstation will determine achievable displayed spatial resolution.

The monitor should be capable of displaying the complete image at close to life size (not necessarily at full spatial resolution), and should be capable of displaying the entirety of a region of interest (e.g. pathology) and its relationship with its surroundings in a 1:1 spatial map from image pixel data to image display data (i.e. maximum achievable spatial resolution). It is not necessarily a requirement to display the complete image in the same 1:1 relationship.

B3 LUMINANCE RESPONSE

Monitors applied to radiographic interpretation or the clinical review of medical images should be capable of—

(a) a luminance ratio of greater than or equal to 250:1;

(b) maximum luminance of not less than 350 cd/m^2 for radiological interpretation and 250 cd/m^2 for clinical review. In practice these values are readily achieved;

(c) luminance uniformity of less than ±15% deviation from the central measured luminance value across the area of the screen [high quality LCD (liquid crystal display) panels should be capable of better];

(d) having the luminance transfer characteristic conforming to the DICOM (digital imaging and communications in medicine) Part 14 grayscale display function (GSDF) (Ref. 5);

(e) minimum 10 bit greyscale output from the look up table (LUT); and

(f) automatic luminance calibration.

The maximum luminance output (white level or L_{max}), minimum luminance output (black level or L_{min}) and luminance uniformity determines the ratio L_{max}/L_{min}, which is the dynamic range of the monitor. The range L_{max} to L_{min} on the GSDF will define the maximum achievable number of just noticeable (contrast) difference indices (JNDs) for the display (ignoring any contrast reduction effects of ambient light reflected from the screen).

The American College of Radiology recommends a value of 350 cd/m^2 as the minimum value of L_{max} for a monitor for application in radiological diagnosis (Ref. 1).

The parameter L_{min} is important, as a higher value of L_{min} will have a similar effect to a higher level of ambient light. That is, both circumstances will reduce the effective dynamic range of the display and reduce achievable display contrast.

Higher luminance capable monitors can achieve higher numbers of JND indices per luminance interval and deliver increased image contrast. Currently available monitors can readily achieve the luminance values recommended above.

A 10 bit greyscale output (remembering that the presentation values on the input side are generally only 8 bit) can be mapped to wider separations on the output greyscale, thereby achieving a smoother approximation to the GSDF curve and improved use of available JND indices.

The various Tiers of Monitor Specification with respect to clinical use are defined in summary as follows:

(i) The manufacturer's dead pixel policy should be reviewed as part of the purchase.

(ii) A graphics card recommended by the monitor manufacturer should be used.

(iii) For image viewing in operating theatres a clinical review monitor should be used, taking into account screen size, viewing distance, ingress and sterility issues.

(iv) To achieve the contrast ratio the monitor needs to be able to render very low luminance blacks.

NOTE: Environmental conditions, such as ambient lighting, need to be taken into account as they will affect the performance of the monitor.

Table B1 supplies a summary of the various Tiers of Monitor Specification with respect to clinical use.

TABLE B1

SUMMARY OF MONITOR SPECIFICATION TIERS RELATING TO CLINICAL USE

Type	Tier 1: primary diagnostic	Tier 2: clinical review	Tier 3: remote diagnostic	Tier 4: basic image viewing
Purpose	Used for the interpretation of non-mammography medical images, i.e. in a radiologist's workstation or instances where the primary treatment decision is made in the absence of a interpretative report (e.g. an emergency department, ICU or an orthopaedic clinic).	Used for the viewing of non-mammography medical images for non-interpretative purposes, where a higher standard of image quality is required [e.g. standard operating environment (SOE)]. Typically used by medical staff and consultants (non-radiologists) when an interpretative report is available.	Not ideal, but used for the interpretation of small matrix medical images (e.g. CT, MR and ultrasound) when a primary diagnostic monitor is not available.	Used for basic viewing of medical images, e.g. patient consultation and chart review.
Size (diagonal)	53 cm (21 inches)	53 cm (21 inches)	43 cm (17 inches)	Existing SOE monitors can be used for the basic viewing of medical images. However, caution should be exercised, as the image quality will be inferior to that of Tier 1 and Tier 2 monitors.
Matrix size	3 MP: 1536 by 2048	2 MP: 1600 × 1200	1.3 MP: 1280 by 1024	
Max luminance	≥ 350 cd/m^2 (1)	≥ 250 cd/m^2	≥ 170 cd/m^2 (3)	
Contrast ratio	≥ 250:1	≥ 250:1	≥ 250:1	
Luminance uniformity	≤ 15% variation from centre	≤ 15% variation from centre	≤ 15% variation from centre	
Calibration	Auto-GSDF	Auto-GSDF	Ability to accept 3rd party GSDF calibration	
Bit depth	10 bits	10 bits	8 bit	
Brightness/contrast controls	Locked out	Locked out	Manual	
Colour/monochrome	Monochrome (2)	Either	Either	
Backlight saving	Yes	Yes	N/A	

NOTES:

1 This minimum standard should be easily achieved, as primary diagnostic monitors are generally manufactured with higher luminance (up to 1000 cd/m^2).

2 In general, monochrome monitors are recommended, in preference to colour systems, because of their greater expected backlight life. However, where there is, or is expected to be, a substantial workload in hybrid imaging modalities, colour monitors will be required.

3 Rationale for this minimum standard is discussed in Sim et al (Ref. 7). This is not fully consistent with the normative requirements in this Technical Specification, but has been used as a basis for the development of this Technical Specification, and its usefulness is acknowledged.

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NOTE: Many of these references are websites or online documents which are subject to redirection, updating, address changes and deletion. Using a standard internet search process with the specific terms used in the reference could assist in locating the required material.

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