

Digital Diagnostic Imaging

Recommendations on the Delivery of, Access to and Viewing of Diagnostic Quality Digital Images for Clinicians (RACS DDIR)

developed by the

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

In consultation with the Royal Australian and New Zealand College of Radiologists and the Australian Diagnostic Imaging Association

DIRWP RACS DDIR 15 September 2009

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Foreword

Having both provided and requested diagnostic images for many years I have witnessed first hand the benefits and challenges of the transition to digital technology for the capture and distribution of diagnostic images. It was not so long ago that the sight of Maxwell Smart reaching into the heel of his shoe for a mobile phone was a source of great amusement. But now that is a reality. Not so long ago, many of us would have dismissed as fanciful the possibility of being able to click up an image of say an aorta or a shoulder joint in real time while it is being captured at a remote location. The ability to scroll through multiple images in a multitude of planes, to be able to see three-dimensional reconstructions and to be able to manipulate and measure from these images has undoubtedly revolutionised our ability to rapidly and efficiently diagnose pathology and plan therapeutic measures.

The transition to digital imaging does, however, pose many challenges not the least of which is the difficulty coordinating "who needs what". Not all referrers need all the images, but a clinician to whom the patient is "on referred" may need certain images or certain views or certain measurements in order to plan and execute therapy. However if particular views which subsequent clinicians require were not archived or not captured on appropriate transport media or, as is sometimes the case, cannot be viewed because of computer or software incompatibility, the study will need to be repeated at great inconvenience to patient and clinician alike and at greater expense. Templating, for example, for joint replacements may need hard copy on film if appropriate software is not available or applicable. Further, for example, use of images without correct scout view identification could potentially harm a patient in such areas as spinal surgery whereby the wrong anatomical level for surgery is chosen.

It was for these reasons that a large multi-disciplinary forum was convened at the Royal Australasian College of Surgeons on 12 June 2008. The forum was in response to a discussion paper from the Commonwealth Department of Health and Ageing which in turn arose in response to a letter from the then Chair of the College's Professional Development and Standards Board (Dr Ian Dickinson) to the Federal Minister of Health. As a result of that forum, a consensus statement agreed to by all participants was released and is referred to in this document. Another key recommendation of the forum was the formation of a multi-disciplinary working party led by the Royal Australasian College of Surgeons (RACS) – Digital Imaging RACS Working Party (DIRWP).

Via two face to face meetings at the College of Surgeons and a number of teleconferences, the Working Party has:

- 1. Developed a web-based issues resolution process hosted on the Royal Australian and New Zealand College of Radiologists (RANZCR) website.
- 2. Developed "sister" digital imaging web pages on the RACS and RANZCR websites.
- Recommended that the RACS become of a member of Integrating the Health Enterprise (IHE) to therefore join RANZCR and the Australian Diagnostic Imaging Association (ADIA) in order to progress digital imaging issues at a vendor level. The RACS is now a member of IHE.
- 4. Contributed to the development of the ADIA Code of Practice for the Provision of Digital Diagnostic Images.
- 5. Developed a "scout view" document in consultation with the RANZCR and the Spine Society of Australia, that document to be eventually incorporated into the RANZCR Standards and to be cobadged as a document from both Colleges.
- 6. Modified and developed recommendations on the delivery of, access to and viewing of diagnostic quality digital images for clinicians, which is the subject of this document.

The Working Party is hopeful and confident that this document will be an important resource for the medical profession through the transition to diagnostic digital imaging. Being a multi-disciplinary effort, the document will also provide a powerful signal to health administrators that the transition is a major issue for the medical profession and will signify that government will have to help facilitate this transition to a system which ensures efficient high quality patient care in all scenarios (i.e. the consulting rooms, hospital clinics, operating theatres, etc).

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The Working Party's Terms of Reference have been now fulfilled but much more work is required. If the adoption of secure standardised communications across the health sector can become a reality there will then be a capacity to efficiently capture, transport and archive digital diagnostic images to greatly enhance cost effective health care delivery. The cost and benefits of this delivery should be fairly apportioned across all stakeholders including government.

The Working Party acknowledges existing standards from which it has drawn guidance for the development of this document viz: American Association of Physicists in Medicine¹, American College of Radiology², Digital Imaging and Communication in Medicine³, Deutsches Institut für Normung (German Institute for Standardisation)⁴, Integrating the Healthcare Enterprise^{5,6}, International Organisation for Standardisation⁷ and German Radiological Society⁸.

The Royal Australasian College of Surgeons thanks all members for their contributions to both the proceedings of the Working Party and the development of this document and in particular acknowledges the time and effort expended by the non-surgical members.

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Terminology Abbreviations:

AAPM American Association of Physicists in Medicine (*www.aapm.org*)⁽¹⁾ **ACR** American College of Radiology⁽²⁾

ADIA Australian Diagnostic Imaging Association

BIR IHE Basic Image Review profile

CD Compact Disc

CR Computed Radiography

CT Computed Axial Tomography

DDI Digital Diagnostic Imaging

DI Diagnostic Imaging

DICOM Digital Imaging and Communications in Medicine ⁽³⁾

DIN Deutsches Institut für Normung (German Institute for Standardization)⁽⁴⁾

DIRWP Digital Imaging RACS Working Party

dpi dots per inch

DR Digital Radiography

DVD Digital Versatile Disc

GB Gigabyte

Gb Gigabit

GSDF Grey Scale Display Function

HTML Hypertext Markup Language

IHE Integrating the Healthcare Enterprise ^(5,6)

IOD Information Object Definition (DICOM)

ISO International Organization for Standardization (*www.iso.org*)⁽⁷⁾

JPEG Joint Photographic Experts Group

LAN Local area network

LCD Liquid Crystal Display

LUT Look Up Tables. Relates to DICOM greyscale calibration

MB Megabyte

Mb Megabit

MDCT Multi-Detector (row) Computed Tomography ("multi-slice CT")

MP Mega pixel

MPEG Moving Picture Experts Group

MRI Magnetic Resonance Imaging

OFFIS "Oldenburger Forschungs- und Entwicklungsinstitut für Informatik-Werkzeuge und -Systeme" Media Exchange Certification Project of the German Radiological Society (Deutsche Röntgengesellschaft e. V.)⁽⁸⁾

PACS Picture Archiving and Communication System

PDI Portable Data for Imaging (IHE Profile)

PNG Portable Network Graphics

RACS Royal Australasian College of Surgeons

RAID Redundant Array of Inexpensive Disks, or Redundant Array of Independent Disks

RANZCR Royal Australian and New Zealand College of Radiologists

RIS Radiology Information System

SMPTE Society of Motion Picture and Television Engineers standard

SPECT/CT Single Photon Emission Computed Tomography/CT – a fusion of nuclear medicine imaging and CT

SSD Solid State Drive

USB Universal Serial Bus

USB SSD Solid State Drive memory that connects with a computer via a USB interface

WAN Wide Area Network (BAN – Broad Area Network)

XDS-I Cross Enterprise Document Sharing (from IHE to facilitate clinical documents sharing)

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Definitions:

Diagnostic Imaging Provider - the person(s) who performs or supervises the performance of the diagnostic imaging service, and who usually provides the primary analysis and opinion on the obtained images. This 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.

Diagnostic Quality Image - an image that is comparable in quality and presentation to that used by radiologists in reporting.

In some cases it is important that a diagnostic quality image is **measurable**, and thus capable of being analysed to produce linear dimensions that the clinician will unambiguously understand. Any technique may be used as long as the end user is able to obtain an accurate, reproducible linear measurement within the particular clinical environment

Film - transparent polyester sheets, by which diagnostic images are distributed in hard copy as continuous tone shades of grey. 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.

Lossless - data which when decompressed produces images identical to the original

Lossy - data which when decompressed produces images of different (usually reduced) quality than the original

Reduced Quality Image – Any image that is not a Diagnostic Quality Image

Scout images (also known as "scout films", "pilot images", "topograms", "surviews") - images on which the location of cross-sectional image(s) relative to key anatomical landmarks may be displayed. The scout image may be a digital projection radiograph (like a traditional 'X-ray'), a cross-sectional image in another plane, or a projection image of a 3-dimensional model. For spine studies, the scout images will typically be either a lateral projection radiograph (CT), or a mid-sagital cross-sectional image (CT or MRI).

Scout images are used:

(1) to aid the technologist in planning the location(s) at which cross-sectional images are to be obtained, and choosing their orientation;

(2) to enable the viewer of a cross-sectional image to define its relationship to the overall anatomy of the patient.

Source image / Source data – CT or MR imaging "source data" are generally the spatially localised signal intensity data obtained during the cross sectional image capture and are an intermediate stage between the image acquisition and the processed image data usually used for diagnostic interpretation. Source data may be reconstructed at minimum section thickness of under 1mm - sometimes referred to as "thins" in CT parlance. More complicated post-processing can convert these images into 3D representations of some or all of the anatomy included in the original part of he patient that was imaged – this is useful for unobstructed display of, e.g., bones, or arteries.

Although they may or may not be utilised during the reporting process, the source data are available to reporting radiologists from the imaging modality itself for further processing or re-processing if required. Almost all are in DICOM format, and can be exported on PDI-compliant media if desired, however the data sets may be very large (e.g. >1000 512 x 512 matrix images), and can exceed the storage capacity of a single CD (or even a single DVD). Some specialised applications (e.g. some MR spectroscopy, 3D angiography, 3D ultrasound, some scintigraphy) use non-DICOM data formats, though many of these are moving towards DICOM representations.

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Executive Summary:

The move to digital diagnostic imaging capture, distribution and access is inevitable.

Distribution of images on film will become progressively obsolete and unavailable.

To successfully achieve the transition to digital imaging, clinicians will need to modify image access and viewing technology in the clinic, wards and operating theatre, and this may require equipment upgrades and some changes to workflow practices.

There are a number of aspects to digital imaging distribution, access and archiving, and these can be divided into 6 process steps:

The format of the imaging data (Image Data Format) The way the image data is distributed (Image Data Distribution) The means of reading the images (Image Data Reading) The means of displaying the images (Image Data Display) The options to measure and template the image data (Image Data Manipulation) The means of storage of the data in the longer term (Image Data Archiving)

This document aims to provide the technical details that will enable a clinician as well as their technical advisors to identify the software and hardware capabilities that will assist them to make a successful transition to the digital diagnostic imaging environment.

The particular details within this document that relate to these technology specifications are:

1.	Image Data Format –	<u>page 16</u>
2.	Image Data Distribution –	page 18
3.	Image Data Viewing –	<u>page 22</u>
4.	Image Data Display –	<u>page 25</u>
5.	Image Data Manipulation –	<u>page 27</u>
6.	Image Data Storage –	<u>page 29</u>

It is recognised that most clinicians may not have had sufficient exposure to appreciate the complex technical specifications within this document. The intention is to provide a reference and background for those wishing to embrace such information to ensure that the transition to digital imaging facilitates optimal patient care consistent with the capabilities and resources of local clinicians and imaging providers.

The options provided here specifically address the situation where diagnostic quality imaging is required. Where non-diagnostic review or educational image access is required, these recommended benchmarks do not necessarily apply. The viewing clinician however must be aware that such images, while useful for review purposes, may not of a sufficient standard to allow optimal diagnostic analysis.

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1. Introduction

To provide optimal patient care, clinicians frequently need access to high quality diagnostic imaging to confirm or make diagnoses, and to plan treatment. The move from analogue screen / film to digital image capture and distribution can deliver many advantages. However, clinicians in several countries report that they experience difficulties accessing such images. Equally there are many problems with film based solutions – e.g. loss of images, as high rate of repeat studies, inability to adequately portray volumetric studies.

This document was developed by a group of imaging specialists, clinicians and IT professionals, working through a number of professional associations. The options detailed provide general suggestions and recommendations to facilitate the viewing of diagnostic images in the health environment. It is ultimately the responsibility of the treating practitioner to decide what is appropriate to ensure optimal patient care. 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 will involve some important changes in patient care and the way images are accessed. However, the move must be made in a way that ensures the maintenance of access by clinicians to relevant patient data. From the surgeon's perspective, in the situation where a clinician requires diagnostic quality images, the key elements of this principle are embodied in the RACS Position statement: Position Statement on Diagnostic Images – RACS ⁽⁹⁾

Surgeons recognise imaging techniques as vitally important in the diagnosis, treatment and monitoring of surgical conditions. Whilst surgeons value the experience, knowledge and skills of Radiologists and others in reporting on such images, it remains imperative that the treating surgeon is able to view, interpret and/or corroborate such information where appropriate.

Diagnostic quality imaging is required for the planning and execution of operative approaches and delineation of the extent of pathological changes. It is dangerous, unsafe and unacceptable to plan or commence surgical procedures without access to images either in digital or hardcopy forms. Images must also be available in the operating room as part of Correct Patient, Correct Procedure and Correct Site Surgery protocols.

The Royal Australasian College of Surgeons affirms that for proper patient care and safety, images which are in an accessible form, of sufficient quality and appropriate to the clinical situation generated by X-Ray, MR, CT Scanning, PET scanning, Ultrasound or other modalities must be made available to the referring doctor and the treating doctor in addition to the formal report.

RACS Standards Committee Royal Australasian College of Surgeons February 2007

Note that this comment specifically addresses situations where diagnostic quality imaging is required, such as in the course of a therapeutic procedure. Where non-diagnostic review or educational image access is required, these recommended benchmarks do not necessarily apply. The viewing clinician however must be aware that such images, while useful for review purposes, may not of a sufficient standard to allow optimal diagnostic analysis.

Access to Diagnostic Imaging (DI) is needed as patients seek treatment in different parts of the health system, and the most appropriate presentation format may vary between clinical settings. Both referrers and providers should work together to develop solutions in each setting to facilitate the transition to digital imaging in accordance with appropriate guidelines such as set out in this document.

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A key issue relates to the definition of what constitutes "diagnostic quality imaging". Recognizing that image characteristics will vary according to the clinical situation, the patient's status and the technique used to capture the images, for the purpose of this document, the definition provided by the RANZCR / ADIA is useful:

A diagnostic quality image is defined as "An image that is comparable in quality and presentation to that used by radiologists in reporting". ^(10, 11, 12)

For optimal patient care, it is necessary that the images provided to the treating practitioner be of diagnostic quality (high resolution and, where relevant, measurable) and supplied on a medium (whether film or digital) in a form that is accessible, convenient and clinically appropriate.

Because of limitations in image storage capacity or transmission time, images of lesser quality may also be produced. These "reduced quality" images may still be of great clinical use and helpful for clinical review and patient education, but may not be suitable for primary or secondary diagnosis.

It has to be recognised that the requesting and generation of digital images, and the distribution of these (along with the associated reports) is a complex process with many actors, each of which needs to interoperate and collaborate.

While the whole process of adapting to this change may seem to be daunting, the change is inevitable as film is no longer an integral part of the process of production of diagnostic images and will only realistically be provided for a limited further time. Many of the new imaging modalities, e.g. multi-slice CT scans and MRI are difficult to record and view adequately on film and many clinicians report that viewing these images on the computer monitor is more satisfactory.

This document should be reviewed in conjunction with related documents:

- 1. RACS sponsored Multidisciplinary Digital Imaging Consensus Statement⁽⁹⁾
- 2. RANZCR Principles for the Provision of Digital Diagnostic Images (10,
- 3. RANZCR Standards of Practice for Diagnostic and Interventional Radiology, Version 9.0⁽¹¹⁾
- 4. ADIA Code of Practice for the Provision of Digital Diagnostic Images ⁽¹²⁾
- 5. *Relevant legislative documents* relating to conduct and reimbursement for diagnostic imaging services specific to the locality of practice.

Imaging can be divided into three (not necessarily mutually exclusive) broad categories:

- 1. Diagnostic imaging
- 2. Interventional imaging
- 3. Imaging for teaching and research

This document predominantly addresses category 1, and more specifically, the process and form in which such images are made available to the clinician looking after the patient. It aims to provide guidance to clinicians who have a need to review diagnostic quality images in the course of patient care. A number of specific imaging needs related to certain medical specialties (e.g. cardiology, radiation oncology) are not specifically covered at this stage, however the common utilisation of the DICOM format does mean that the image data can be distributed and accessed using the same principles.

It is also recognised that significant technological advances in diagnostic imaging have led to a variety of image formats and functionality requiring innovative solutions to maximize the effectiveness of delivery, access, manipulation and archiving. Variations in display matrices and bit depth, three-dimensional display methods, multi planar reconstruction, Image fusion, dynamic imaging and colour rendering can all be better supported in digital formats than on film.

However, when patient care decisions depend upon the review of the diagnostic images, those responsible for the ultimate clinical management of the patient must be involved in any decision to adopt a material change in

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the way images are provided. The transition to digital imaging must not compromise the diagnostic and treatment capabilities of the clinician, and should facilitate, not hinder, appropriate image access at the patient care interface.

Similarly, it is important that referrers have realistic expectations in requesting "film" in all cases. Multislice CT studies often create over 1,000 images per patient study, and an element of selection must be applied judiciously when key images are filmed. When selected images are supplied on film (or other hard copy) they must be appropriate to the clinical setting.

Equally, it is not always possible to anticipate at the outset all the possible uses of, and requirements for, a diagnostic imaging examination. While precise communication between the referrer and the provider can minimise difficulties concerning examination type, processing and delivery, there should also be a mechanism whereby additional appropriate requirements (e.g. those arising from on-referral) can be met expeditiously provided such requests are made within a reasonable time period after the performance of the imaging study.

2. Data Content of Diagnostic Imaging Examinations

2.1 Data content

In considering contemporary imaging, it is useful to differentiate between images such as plain radiographs (large matrix) and those generated by other modalities, including CT, MRI and ultrasound (small matrix). The diverse matrix sizes, and the variable numbers of images generated by the various modalities, pose different challenges in image display.

Plain (digital) radiography typically utilizes large matrix (e.g. 2000 x 3000) resolution images. The recommended minimum resolution for diagnostic quality is 2.5lp/mm. This equates to approximately 127ppi, and at 10 or more bits per pixel, the major challenges are the size of the image and the need for a large high quality monitor to allow full size display, and adequate network or transfer capacity as images range from 12 – 40MB in size.

Cross-sectional images obtained from CT and MRI are typically small matrix (e.g. 512×512) at 12 - 14 bit images, and are more easily shared digitally. They are captured digitally, and individual image size is generally less than 1MB. The major challenges from these modalities are the large numbers of images often obtained (~ 100 - 3000) and the collective size of the entire data set whether digital or analogue.

2.2 Imaging modalities classed by data content

Within Diagnostic Imaging there are three broad groups of image data sets (with some overlap between these):

1. Plain Radiography

(e.g. Plain x-rays, Mammography)

- typically large matrix with relatively few images

2. Dynamic and Complex Diagnostic Imaging

(e.g. scintigraphy, angiography, ultrasound, fluoroscopy)

- typically small matrix with relatively few images retained, and / or dynamic image series (though some evolving applications generate large numbers of images)

3. Cross-sectional imaging (of a defined volume)

(e.g. CT, MRI, SPECT/CT, PET/CT)

- typically small matrix, but with many images

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2.3 Requirements for different imaging modalities / types of data content

1. Plain Radiography (e.g. Plain x-rays, mammography)

Full size, diagnostic quality (high resolution and measurable#) images are required for diagnostic and therapeutic measurement and templating, as 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 so on.

- Referring and treating doctors require access to the full set of images in diagnostic quality when in their judgment these are needed.
- Digital images should be of comparable diagnostic quality to analogue (screen) film.
- Computed Radiography (CR) / Digital Radiography (DR) have lower image spatial resolution than analogue film but advantages with respect to contrast resolution, magnification and distribution. However, the following quality issues have to be addressed depending on the means of image display:
- 1. Film printing must be to a "diagnostic quality" standard:
 - a. High resolution (not < 300dpi);
 - b. Full size- (image displayed at same size as captured);
 - c. Measurable (# see below)
- 2. Digital Display::
 - a. Image data in IHE DICOM compliant format (therefore will be lossless)
 - b. Convenient and rapid data loading;
 - c. Viewed on an adequate monitor high resolution and Grey Scale Display function GSDF DICOM (Part 14) compliant;
 - d. Presenting Lossless image resolution (DICOM protocol);
 - e. Display software to provide a suitable interface for the clinician.

Note: Radiographs always magnify the imaged anatomy. With analogue methods, standardised techniques are employed (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 estimate real size from image size fairly reliably. Digital imaging allows arbitrary re-sizing of the displayed image after it has been recorded. Unless re-sizing is avoided (images are displayed "full size"), or there is an unambiguous description of the extent of any re-sizing, measurement estimates can be critically compromised.

In recent years there has been a trend towards replacing full size film images with reduced size films, particularly where the referring clinician is 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 these images, and is expecting to find that they are of full size (for which magnification can be estimated). Unless a process for making available appropriate diagnostic quality images exists, this may result in a delay in care delivery, or unnecessary re-imaging of the patient with significant inconvenience, radiation exposure and cost. It is not practical to provide full size measurable film in all patient studies having radiographs when only a small percentage of patients are on referred to specialists who require analogue images for templating or other measurement techniques. Where possible, referrers should specify the need for measurable images when indicated and providers should then provide appropriate hard copy.

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2. Dynamic and Complex diagnostic Imaging (e.g. scintigraphy, angiography, fluoroscopy, ultrasonography)

These image types may require direct imaging specialist involvement, vascular access, real time dynamic analysis, complicated quantitative analysis, and often time sensitive image capture. This document does not specifically address the transfer of these types of images, although, if the recorded data complies with the DICOM protocol, as will usually be the case for at least the static component, the images may be handled as for other small matrix examinations.

3. Cross-sectional Imaging (e.g. CT, MRI, SPECT/CT, and PET/CT)

Large amounts of cross-sectional data are recorded and manipulated, and the radiologist's assessment and diagnosis are important. However, adequate assessment of the case by the clinician may require correlation of the clinical features with detailed assessment of the imaging findings, and thus access by the treating clinician to the complete image data in electronic form is frequently required. This is especially important in urgent situations when treatment is required before the formal radiological report is available.

Specific issues that promote a move to digital delivery include:

- The large number of source images (in CT typically thin-section transverse ("axial") crosssectional images) sometimes cannot be satisfactorily viewed on film.
- Digital presentation has major advantages for image viewing and manipulation, for example the ability to scroll through the images and change presentation states.
- Image manipulation and 3D Image viewing by the treating doctor are required in certain situations, again only achievable with digital distribution and display techniques.

Where used, non-network digital media should be:

- 1. Fast loading Loads quickly (on an appropriate end-user platform*);
- 2. Reliable, non-volatile and with robust data storage;
- 3. Displayed on a simple intuitive software interface;
- 4. Un-editable;
- 5. Externally labelled for content
- * Provision of this platform is not generally the responsibility of the imaging provider.

The quality of the images supplied to treating doctors, where diagnostic information is required, should be equivalent to those viewed by the radiologist at the time of reporting.

Anatomical Reference Images for Cross-sectional imaging

In the delivery of cross-sectional images, either digitally or by hard copy, it is critical that a spatial location guide, indicating the relationship of each cross-sectional image to standard anatomical landmarks, be provided (these may be known as 'scout images' or 'pilot' views, topograms, etc.) This applies whether the images are delivered on film or on digital media, however for digital media this should be part of the functionality of the DICOM reading software.

2.4 Industry-standard format for digital image data

Diagnostic-quality images distributed in digital format must comply with DICOM standards and IHE PDI profiles if distributed on portable media. For both small and large-matrix digital image data, the data set should provide full resolution data for processing, manipulation and subsequent display if required depending on the clinical situation.

2.5 Compression

The DICOM format includes provision for "lossless" compression of images, where the volume of

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transferred image data is reduced (typically by a factor of 2 times), without affecting the appearance of the displayed image.

Higher degrees of data compression are usually "lossy", i.e. 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 may be considered where it has been shown that the degree of lossy compression employed has no effect on diagnostic quality. However, in most situations, primary or secondary diagnosis should be on lossless images.

3. Digital Diagnostic Imaging Clinician Access Options

There are a number of aspects to digital imaging distribution, access and archiving, and these can be divided into 6 process steps:

The format of the imaging data (Image Data Format) The way the image data is distributed (Image Data Distribution) The means of reading the images (Image Data Reading) The means of displaying the images (Image Data Display) The options to measure and template the image data (Image Data Manipulation) The means of storage of the data in the longer term (Image Data Storage)

Each of these 6 stages relating to provision of digital images to the clinician needs to be adequately addressed to optimally support patient care.

The Stages of Digital Image Delivery and Management can be summarised as:

- 1. Image Data Format
- 2. Image Data Distribution
- 3. Image Data Viewing
- 4. Image Data Display
- 5. Image Data Manipulation
- 6. Image Data Storage

The following provides an overview of the above stages. Each stage is described along with options grouped according to their suitability to achieve diagnostic quality access. Each option is classified as "optimal" or "acceptable" in terms of its ability to deliver clinically relevant imaging data in the course of the care of the patient. All recipients of image sets from diagnostic imaging providers are responsible for the purchase and upkeep of all equipment systems, telecommunication connections, interface and related infrastructure to satisfy compliance with relevant standards and the guidelines in this document.

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3.1 Digital Imaging Access - Stage 1: Image Data Format

Digital diagnostic images can be distributed in one of three formats which relate to requirements of image data size for transfer and storage:

1. DICOM lossless compliant formats achieve "lossless" compression of images, where the volume of image data is reduced (typically by a factor of 2 times), without affecting the appearance of the displayed image. Image data and quality is not lost during the compression and restoration of the image.

2. **DICOM lossy format** allow for a higher degree of data compression however this is at the cost of losing some of the image detail; hence these methods are called "lossy". 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.

3. Non DICOM formats such as JPEG. These lower resolution images (similar to those used in digital photography) are usually intended to provide illustrative images to augment the report or provide patient education. They are lossy images, however have the advantage of being able to be rendered by a wide range of software including basic internet browsers and their small size lends itself to electronic transfer.

	Optimum	Acceptable (qualified)
	IHE compliant DICOM ^(3, 5, 6) images	
Stage 1 Image Data Format	PDI Compliant if distributed on portable media– full image set Note: source data (e.g. "thin" images from MDCT) may be included if requested, but will require higher performance display hardware and software	IHE PDI compliant DICOM – reduced image set

Images reviewed for diagnostic purposes should ideally be in DICOM compliant format (full image data set, depending on the clinical situation), or IHE PDI Compliant if distributed on portable media. While the DICOM Committee sets standards, it does not provide enforcement or possess an ability to review or monitor compliance.

Integrating the Healthcare Enterprise (IHE) is an organization that brings together IT standards to support solutions to practical interoperability problems such as digital image transfer. The IHE profile for this is Portable Data for Imaging. IHE Guidelines (www.ihe.net)^(3, 5, 6) for PDI compliant DICOM data format and delivery are developed. CD is currently the only profile accepted.

IHE PDI Extensions (current and under consideration)^(5, 13) – CD, DVD, USB SSD, Compression, Encryption, Viewer and Sending Software - hyperlinks available from:

http://wiki.ihe.net/index.php?title=Radiology_Technical_Committee http://wiki.ihe.net/index.php?title=PDI_Extensions__Detailed_Proposal http://www.ihe.net/Technical_Framework/public_comment.cfm

Specific relevant documents within these links:

• IHE Radiology Technical Framework (Supplement 2009) IHE PDI Extensions ⁽¹⁴⁾

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- Solid State Proposal for PDI input from IHE Australia (accessed 7th December 2008)⁽¹³⁾
- Preliminary Results of DVD Evaluation as of 3-Feb-08 (accessed 7th December 2008) ⁽¹⁴⁾
- OFFIS Requirements Specification for Exchange Media Containing Patient Information Edition 2006⁽⁸⁾

Vendors of PACS systems, portable data creation systems and image viewing software are able to test their products against the profile and publish conformance statements for functions such as portable media creator, image display, and image print.

An IHE conformance statement should be considered as part of any equipment purchase decision.

While images in compressed or lossy format such as JPEG images accessed via web browser on line or via portable media may be useful for educational, non-diagnostic triage or clinical meeting review, such images may not be suitable or reliable for primary or secondary diagnostic purposes (see 2.5 above).

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3.2 Digital Imaging Access - Stage 2: Image Data Distribution (Digitally or Hard Copy)

Distribution of digital images by network or electronic media has considerable advantages.

However, the infrastructure must be is in place to ensure that appropriate quality digital images can be viewed by the treating practitioner at all stages and in all locations where the viewing of images needs to occur for optimal patient care.

Where such access is not possible, digital image printed on hard copy remains the preferred means of image delivery, because of its ease of access (once physically received).

The currently available "Optimum" and "Acceptable" means of diagnostic image distribution are listed below:

	Optimum	Acceptable (qualified)
	 WAN / LAN speed as high as practical typically 10-100 MB per second, LAN with at least 1 Gb/second speed PACS access. 	 WAN / LAN with less than 1 Gb per second speed: Online access to diagnostic quality images linked with report Thin client PACS
		 Only suitable if data delivery speed is acceptable due to pre- fetching, pre-loading or queuing.
Stage 2 Image Data Distribution	2. Secure server online DICOM data with selectable data quality download for remote and fallback access (note - server access is appropriate where the treating doctor is a regular user of a particular service)	 SSD (solid state drive) – USB SSD or similar data card for patient carried records. SSD are not yet approved devices and cannot be endorsed until issues of identity, privacy, security, data integrity and compliance with IHE profiles and relevant standards and regulations have been achieved. Note Diagnostic: Industry standard and production model not yet defined.
	 CD for patient image data transfer, separate from main long term storage only if accessible by end-user usable systems and workflow (i.e. PACS to PACS) 	 Laser printed transparent film - high quality images. However not often relevant for the majority of CT, MRI, Ultrasound or Nuclear Medicine studies.
		 High quality paper copy (limited application)

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Digital diagnostic imaging distribution:

To achieve a suitable transition to the digital delivery of image data and reduce the reliance on film, specific criteria are required:

- 1. Digital images of an appropriate quality should be captured and distributed at an appropriate quality, including scout images for cross-sectional studies
- 2. The means of distribution should not only be consistent with the technological capabilities of the diagnostic imaging service and the referring practitioner, but also should consider the needs of any clinician involved in the subsequent management of the particular disease process in question. This relates to factors including speed of image data loading, the ability to access multiple studies simultaneously and the availability of suitable image data loading and display technology, with avoidance of propriety formats and systems that may not be compatible with cross vendor platforms.
- 3. Network of sufficient capacity for the clinical workload (1 Gbps network capacity is common in hospitals and large clinics).
- 4. Image distribution must comply with DICOM standards and IHE profiles;
- 5. The means of delivery must enable access to images within an acceptable time frame and must be compatible with the workflow requirements of the treating doctor. Equally, referring doctors must consider how their workflow and systems could reasonably be modified and upgraded to make best use of newer digital means of delivery.
- 6. Clinicians must have access to, and training in the use of, a DICOM image viewer, and preferably one version of the viewer software, to enable them to gain familiarity with the user interface. Some specialties require additional software such as orthopaedic templating and/ or multi-planar reconstruction.
- 7. Images need to be accessible in other clinical locations, with particular emphasis on operating theatres, clinics, wards and clinical meetings.

Digital Data Distribution Options:

1. Network access – WebPACS or WebLink download

Network access may be significantly limited by transmission speed, particularly for large data sets. Although Network and Web access is seen as the principal means of image access in the long term, network speed and capacity, security issues and the multitude of individual data storage and repository systems are currently limiting applicability in many situations:.

WebPACS: This provides access to the images held on the radiology service PACS and allows them to be accessed through a local or wide area network, or via the internet.

The user is granted log in and password access to the PACS of a specific imaging provider to view images using either a web browser (Thin Client) or a local viewing application provided by the radiology provider (Thick Client). There are no standards for WebPACS with each PACS vendor implementing their own version with a unique user interface and functionality.

WebLink – image download: Images can be downloaded in as lossy quality (JPEG) or lossless (DICOM) depending on the preference and needs of the treating practitioner. DICOM images can then be reviewed using a DICOM viewer, and lossy images can be viewed using a web browser. The link is often embedded in the electronic radiology report.

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2. Portable media

The image data are copied to the portable medium (eg CD) and transported (usually by the patient, a courier or post) to the treating health practitioner. The standard for portable media is IHE Portable Data for Imaging (PDI). Only certain portable media types have been approved (CDs prior to May 2009).

Extensions to the Portable Data for Imaging (PDI) Integration Profile - DVD and USB SSD ⁽¹⁴⁾ (http://www.ihe.net/Technical_Framework/upload/IHE-RAD_TF_Suppl_PDI_Extensions_2009-06-21.pdf)

Where used, non-network digital media should be:

- 1. Fast loading Loads quickly (on an appropriate end-user platform);
- 2. Reliable, non-volatile and with robust data storage;
- 3. Displayed on a simple intuitive software interface.
- 4. Un-editable
- 5. Externally labeled for content

3. Hard Copy Distribution (film or paper)

Where distributed on hard copy (film or paper), the printed images should be:

- 1. High resolution (not < 300dpi) printing.
- 2. Printed on High quality print medium (paper or film).
- 3. All images provided and printed at full size (as capture size), unless otherwise agreed by the referring doctor, and annotated on the image. Where measurable radiographic images are required they will be provided and printed at full size (as capture size).
- 4. Printed from a DICOM PRINT compliant and certified printer.
- 5. For Cross-sectional imaging (e.g. CT / MRI):
 - a) Must 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, and/or with additional image display windows, should also be included, where clinically appropriate.
 - b) At least one representative scout images in at least one orthogonal plane, with clearly identifiable anatomical landmarks, in a series must be printed on at least the first film sheet of that series. It is preferable to have a Scout images view printed on each film in the series.
 - c) Where scout images contain multiple lines to represent cross-sections in an orthogonal plane, the density of the lines should not obscure the underlying anatomical detail.
 - d) Where scout images contain multiple lines with numeric labels that reference a slice number in an orthogonal plane, the density of the numeric labels lines must be such that the labels remain legible. The image number on an individual image that corresponds to a scout image line must be clearly stated and not obscured by other numerical information.

Information on the printed images (transparent sheet film or paper) should include:

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- 1. Patient demographics, date and imaging provider details
- 2. Means of capture (CR/ DR)
- 3. Compression if used:
 - i. Compression ratio and whether lossy or lossless
 - ii. If no compression (default setting) no annotation on film
- 4. Magnification and scale (Applicable where measurable images are required)
 - "SC" (as scanned), FC (from capture), Full size or ADJ (Adjusted) to sized reference marker. (Magnification relative to "Full size" should not generally be used unless requested. Images should be printed at the size they were captured onto the incident (CR/DR) plate).
 - Reference ruler to allow calculation of magnification optional.

"Fit to film" specifically not allowable

Magnification or size adjustment if used:

- 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. Previously, analogue film could only display at the size the "x-ray shadow" created. There was always a magnification factor due to beam divergence and the distance of the imaged part from the x-ray plate. Traditionally, adjustments to templating and direct measurements could be estimated by competent clinicians aware of the predictable and obligate magnification inherently caused by the divergent x-ray beam during image capture.
- The advent of digital imaging and discretionary magnification (or minimisation) means that the actual size of the image on the exported hardcopy image can be varied, and an allowance made for the inherent magnification.
- Terms such as "True Size", "Real size", "Anatomical size" or similar are now used by some providers. It 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 thus should only be used if clearly and unambiguously defined.
- The clinician needs to know whether the image size is as captured and displayed, as would be the case with analogue film, or if there has been some adjustment, typically based on the coregistration of a marker of a known size.
- Clear and consistent designations might include:
 - "FC100" (From capture), "SC100% (As scanned), "Full size"- indicates images are displayed at the actual size they were captured or,
 - "ADJ100" displayed image size adjusted, based on a known reference marker size.

The hard copy should therefore contain information regarding the magnification or otherwise of the image in a prominent position on the printed image in an unambiguous format.

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3.3 Digital Imaging Viewing - Stage 3: Image Viewing Software

Unless using digitally printed film, software or an application is needed to view diagnostic digital images.

	Optimum	Acceptable (qualified)
Stage 3	 DICOM reading software with simple intuitive interface and certified by local regulatory 	 Direct observation of hard copy film (however there can be significant problems with large volume cross- sectional studies (e.g. isotropic CT)due to the number of images to be read)
Stage 3 Image Data Viewing	authority as suitable for clinical use and compliant with IHE BIR profile for image display. Ideally each user should have resident software to support familiarity of use	 DICOM reading software on export or transfer media. ** Should have simple intuitive interface and require no set-up or installation on viewing computer. Designed for occasional or emergency use.
		 Direct observation of high quality transparent laser printed images on suitable light box

1. Hard-copy film

No software requirements Light box of adequate luminance (at least 2 000 Cd/m²) in viewing area, with adequate control of ambient light.

2. Electronic (Network or portable digital media) distribution

- WebPACS (Diagnostic Images viewed over the web) viewing software

If using WebPACS, then either a web browser (e.g. Internet Explorer, Firefox or Safari) or local application (client) provided by the radiology service associated with each WebPACS will be needed. Note that each WebPACS product has its own user interface, which can create training issues.

- Portable media viewing software

The DICOM content files can only be accessed using a DICOM reader application. There are three ways of gaining access to a DICOM reader:

- 1. Download a freeware reader
- 2. Purchase and download a commercial DICOM viewer.
- 3. Use a viewer provided on the portable media along with the images.

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The viewer should be certified as able to display images for diagnostic and direct patient care purposes, and be compliant with the requirements of the local statutory regulatory authority.

It is recommended that any viewer to be used for diagnostic purposes be consistent with profiles under development by IHE:

IHE Basic Image Review (BIR) – Implementation version (accessed 10 September 2009)

and the American Medical Association:

<u>AMA Background and Initial Requirements for Simple DICOM Viewer with Universal Icons</u> (http://wiki.ihe.net/images/b/ba/Final_statement_9_26_07_.doc) ⁽¹⁵⁾

It is appropriate that the interface has the following denotation:

"Suitable for clinical use or diagnostic purposes if displayed on appropriate monitor" (or similar)

Summary of functionality recommended – all with standard "pictorial" icons:

- Thumbnails of available studies
- Load
- Clear indicator of active window
- Tile
- Window including automated preset "Window levels"
- Pan
- Measure linear, angle, density
- Zoom
- Scroll
- Save image
- Print image
- Relevant DICOM header details
- Close
- Simple Help menu
- Abort allow operator to terminate current action, and return to previous function
- Refresh return viewer (i.e. windowing and zoom) to default settings
- Cross-sectional images scout image display
 - Scout image display:
 - Minimum requirement At least one representative scout image in at least one orthogonal plane, with clearly identifiable landmarks, that relates to a selected image set, is available to display on the same screen as the image set.
 - Preferred 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. At least one image set must have a clearly identifiable anatomical landmark.
 - Where scout images contain multiple lines to represent sections in an orthogonal plane, the density of the lines must not obscure the underlying anatomical detail.
 - Where scout images contain multiple lines with numeric labels that reference a slice number in an orthogonal plane, the density of the numeric labels lines must be such that the labels remain legible.
 - The image number on an individual image that corresponds to a scout image line must be clearly indicated and not obscured by other numerical information.
 - All images must have an associated scout image.
 - If more than one window is open, there should be an option allowing images obtained in the same plane to be synchronised to the same section position. If images in separate windows

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- are orthogonal then scout image lines should be visible with a simple show scout image line command. (Some have requested mini scouts in the same frame perhaps this could be a separate icon that can be toggled on/off.)
- Ability to display and play DICOM compliant animations MPG2
 Capacity for "screen capture" of animation.
 - o Standard animation controls of play, pause, reverse, fast forward and stop.

Minimum on screen display to include:

- Demographic details name, date of birth, study number
- Study details basic details of study, region and type of study
- CR/DR, LOSSY/LOSSLESS & Magnification
- Relative radiation dose of image to be confirmed and under consideration.
 - This scale is a general measure of the radiation dose of the examination.
 - Does not directly measure actual patient absorbed dose.
 - Provides an overview of total radiation exposure for the study.

Interface should provide the ability to hide or unhide "on screen" details

Ideally all of the above Icons/ Designs should be implemented such that all "simple" viewers look and work in a similar fashion. The advanced viewer capabilities can then be added in any manner deemed desirable by individual manufacturers. In this way, the simple menu option will be the default viewer and an expanded menu option can be accessed if desired by the users.

Computer Specification:

The hardware requirements for the computer will vary with the software system installed, and depends on the manipulation capabilities, and image data caching requirements desired. The video card must be suitable for the display characteristics, however other specifications relate to the particular recommendation of the software supplier. Diagnostic image data should ideally be partitioned, backed up and secured separate from the primary practice management system.

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3.4 Digital Imaging Access - Stage 4 – Display Hardware

The quality of the monitor is a major factor in achieving diagnostic quality imaging.

Critical issues relate to spatial resolution, contrast, refresh rate and ability to calibrate the digital display.

While the <u>LCD</u> monitor has largely taken over from the <u>CRT</u>, alternative digital displays may be suitable depending on their functionality.

	Optimum	Acceptable (qualified)
Stage 4 Image Data Display	Greyscale Standard Display Function) DICOM Format (GSDF) ⁽¹⁶⁾ and DICOM compliant LCD which is Calibratable. Minimum resolution: • CT/MR – 80 ppi • CR/DR – 100 ppi • Mammogram – 127ppi Minimum luminescence of 175 Candela ⁽¹⁷⁾ (See later specifications - 3.4.1b Diagnostic Quality Digital Display)	Appropriate sized 100 ppi non GSDF-compliant LCD at clinician's discretion. Lower resolution (i.e. lower resolution than specified under Optimal specifications) monitors may allow the viewing of images for non-diagnostic purposes. Direct observation of printed transparent film on view box of suitable intensity and with low ambient light.

Suitable display requires an adequate monitor (ideally GSDF Part 14 compliant), with minimum luminance of 175 Cd/m², minimum contrast ratio of 1:500, and spatial resolution of 100dpi or greater (e.g. 20" 1800 x 1200 2MP), and Calibratable with Society of *Motion Picture* and Television Engineers standard (SMPTE), depending on modality:

Modality	Minimum Spatial Resolution	Typical Monitor Resolution
CR / DR	100dpi	1800x1200 Monochrome/Colour (approx 100 dpi on 20" Monitor)
СТ	80 dpi	1024x768 Colour/Monochrome
US	80 dpi	1024x768 Colour/Monochrome
Mammography	127dpi	Minimum: 5MP Monochrome Recommended: 5MP Monochrome
MRI	80 dpi	1024x768 Colour/Monochrome

For optimal review, the spatial resolution of the digital display should match the native resolution of the displayed image.

Diagnostic review of Mammography requires higher resolution digital display screens ⁽¹⁸⁾.

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Where general diagnostic digital image review is anticipated, the monitor resolution should be at a level suitable for viewing CR images. Where larger screens are required such as in an operating theatre, this should be supplemented by a monitor as specified below to allow more accurate review. Although the spatial resolution of CR may exceed 100dpi, the utilisation of the zoom function in the viewing software will allow adequate spatial resolution where required.

3.4.1 Specific Options - Stage 4 – Viewing Hardware

a. View box for hard copy film

At least one 35 x 43 cm panel with light-diffusing screen at 2,000Cd/m² luminance⁽¹⁹⁾ (or 3,500 Cd/m² for mammography) ⁽¹⁸⁾. Multiple panels should be colour and luminance matched.

b. Diagnostic Quality Digital Display (ACR Class 2⁽²⁾)

Image resolution ^(1, 2, 17)	\ge 100 dpi (ppi) (\ge 80 ppi if limited to small matrix - CT / MRI etc)
Minimum Screen size	Office / Clinic – at least one 20" per examination station Operating Theatre – two 24" screens (or equivalent) with access to additional mobile monitors
Brightness ⁽¹⁷⁾	≥ 175 Cd/m ²
Contrast Ratio ^(1, 2)	≥ 1:500
Luminance Uniformity	≤ +/- 15% from centre to corners
DICOM Part 14 GSDF conformance	at least gamma adjustment, ideally LUT (<u>L</u> ook <u>U</u> p <u>T</u> ables)
Chromaticity $\Delta (u', v') \le 0.01$	
Refresh rate	≥ 60Hz
Dead pixel tolerance	< 10 per screen (<15 for screens of 24" or above)
Viewing Angle	$\geq 80^{\circ}$ Horizontal, 50° Vertical
Pixel Depth	≥ 8 bit
Calibration ability	External or internal, with option to upgrade to network management by installation of appropriate video card
Input/Output signal	DVI

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3.5 Digital Imaging Access - Stage 5 – Planning and Measurement

While all users of diagnostic quality images require a standard DICOM viewer, specialised software will be required by specific groups. These include:

Orthopaedic Surgeons	Joint templating and 3 D multi-planar reconstruction
Radiation Oncology	CT-MRI overlay and treatment field planning
Spinal Surgeons	2D multi-planar reconstruction.

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

However, complex reconstructive procedures, and in particular arthroplasties, frequently require careful and specialised pre-operative planning to achieve an optimal outcome.

	Optimum	Acceptable (qualified)
	Templating (measuring) software linked to DICOM viewing interface (ideally with magnification reference marker)	 Templating software, not linked to DICOM Viewing interface, but that can independently retrieve DICOM image data.
Stage 5 Image Data Manipulation	 thick client thin client - web accessible 	 Transparent templating sheets onto known size laser printed digital copies without size marker.
e.g. Templating and Planning	**This software may be required at multiple locations, and therefore may be provided by the prosthesis vendors or by a hospital as part of the usual digital image delivery over a sufficient capacity network. Such software can run on a local machine (thick client), over a LAN or WAN.	 Transparent templating sheets onto digital display screen with manual magnification and size calibration **Some caution is needed - the surgeon must be trained in the use of this technique as it involves manual calibration of image size on screen against a ruler

Image data manipulation in the form of measurement or templating is a standard requirement for the majority of image distribution systems which surgeons will use. The basic requirements include:

- Integration with surgical templating software to facilitate efficient workflow.
- Provision of appropriate scout images and measurement, particularly for spine.
- Other measuring functionality, as part of primary image viewing software tools.
- If integrated templating software is not available, images to be supplied on hard copy transparent film.

Access to such measurement and templating software may be required at multiple locations (clinic, wards and operating theatre), and therefore may be provided by the prosthesis vendors or by a hospital as part of the usual digital image delivery over a sufficient capacity network. Such software can run on a local machine (thick client), or as web based application over a LAN or WAN.

Such capabilities may be provided within the actual DICOM viewing software; however the specific requirement will vary with the clinical needs and circumstances.

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To utilize digital templating, computer specifications should be at least those recommended by vendor for the particular application.

While it is the responsibility of imaging providers to recognise the needs of treating clinicians, the provision and maintenance of these software applications systems, workflow requirements and interfaces with the diagnostic imaging provider should not be considered the responsibility of the diagnostic imaging provider. Appropriate funding, quality assurance and access should be the responsibility of the relevant institution or individual responsible for the management of the patient with collaborative multidisciplinary government lobbying instituted when deficiencies exist.

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3.6 Specific Options - Stage 6 – Image Data Storage and Archiving

While the process of archiving was well defined in public and private radiology practice in the film era, this is still an uncertain and contested area in the transition to digital imaging.

The specific details of long term storage or archiving relate to local patient care needs, available infrastructure, and local statutory requirements.

	Optimum	Acceptable (qualified)
Stage 6 Image Data Storage	Long term storage - should be compliant with local statutory requirements, on secure data storage drive in DICOM format, plus offsite backup and archive - potentially as part of web access	Hard copy - meeting statutory requirements Portable media in IHE format for short term when backed up by other methods

The specific details of long term storage or archiving are beyond the scope of this document, and relate to local patient care needs, available infrastructure, and statutory requirements.

Unresolved issues include:

- 1. The type(s) of image data to be stored, in particular whether it is necessary or feasible to store all source data, video data, and/or all post-processed images.
- 2. Who is responsible for storing and maintaining the data; in the past, private patients have often stored their own images on film, but many digital media are not regarded as adequate for long-term storage How archived data are to be located and retrieved.
- 3. How archived data are to be located and how it will be retrieved.
- 4. Appropriate periods of storage in different clinical and legal scenarios.
- 5. How the acquisition of digital storage systems and their maintenance will be funded in both the private and public sector.
- 6. Interoperability: A national register as part of the electronic health record with links to archives in both private and public settings and between jurisdictions to form part of the solution for image sharing between providers, referrers and treating clinicians.

Particular clinical issues include those relating to:

- 1. Tumour follow-up
- 2. Radiotherapy planning
- 3. Arthroplasty follow-up
- 4. Progression of lung disease
- 5. Notifiable diseases
- 6. Paediatrics

As archiving moves from patient (or clinician) held film to electronic media, there will need to be discussion between relevant stakeholders as to the appropriate length and extent of archiving, which will, as a minimum, need to be in line with local statutory authority requirements.

Details of storage and archiving are also addressed n the following publications and should be reviewed in conjunction with this document:

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- 1. RACS sponsored Multidisciplinary Digital Imaging Consensus Statement⁽⁹⁾
- 2. RANZCR Principles for the Provision of Digital Diagnostic Images (11)
- 3. ADIA Code of Practice for the Provision of Digital Diagnostic Images (12)
- 4. *Relevant local regulatory documents* relating to conduct and reimbursement for diagnostic imaging services specific to the locality of practice, and to local legal requirements for document retention.

4. References:

- 1. AAPM Imaging Informatics Subcommittee Task Group #18 Assessment of Display Performance for Medical Imaging Systems. <u>http://www.aapm.org/pubs/reports/OR_03.pdf</u> (accessed 20 December 2008)
- American College of Radiology (ACR). ACR Standard for Electronic Practice of Medical Imaging. Reston, VA: American College of Radiology, 2007. <u>http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/electronic_practice.a</u> <u>spx</u> (accessed 19 December2008)
- 3. DICOM http://en.wikipedia.org/wiki/DICOM (accessed 20 December 2008)
- DIN Deutsches Institut f
 ür Normung e.V. (German Institute for Standardization) -<u>http://www.din.de/cmd?lang=en&level=tpl- home&contextid=din&languageid=en</u> (accessed 20 December 2008)
- 5. IHE Radiology Technical Committee http://wiki.ihe.net/index.php?title=Radiology_Technical_Committee (accessed 20 December 2008)
- 6. IHE <u>www.ihe.net</u> (accessed 20 December 2008)
- 7. ISO International Organization for Standardization http://www.iso.org/ (accessed 20 December 2008)
- 8. OFFIS Requirements Specification for Exchange Media Containing Patient Information Edition 2006 <u>http://www.dicom-cd.de/docs/DRG-Guidelines-2006.pdf</u> (accessed 11 May 2009)
- RACS (Royal Australasian College of Surgeons) DIRWP minutes and Proceedings, Consensus Statement – <u>www.surgeons.org/dirwp</u> (accessed 20 December 2008)
- 10. RANZCR (2008) Principles for the Provision of Digital Diagnostic Images (<u>http://www.ranzcr.edu.au/digitalimaging/index.cfm</u>) (accessed 13 February 2009)
- 11. RANZCR (2008) Standards of Practice for Diagnostic and Interventional Radiology, Version 9.0) http://www.ranzcr.edu.au/qualityprograms/accreditation/standards2008.cfm (accessed 11 May 2009)
- 12. ADIA Code of Practice for the Provision of Digital Diagnostic Images ADIA Website http://www.adia.asn.au
- 13. Solid State Proposal for PDI input from IHE Australia <u>ftp://iheyr2:interop@ftp.ihe.net/Radiology/iheyr11-</u> 2009/Tech <u>Cmte/TF</u> <u>Supplement</u> <u>Development/Draft</u> <u>Supplements/Media</u> <u>Supporting</u> <u>Documents/SSD%2</u> <u>Oproposal%20for%20PDI%20v1.doc</u>
- 14. IHE Radiology Technical Framework (Supplement 2009) IHE PDI Extensions (accessed 10 September 2009) http://www.ihe.net/Technical_Framework/upload/IHE-RAD_TF_Suppl_PDI_Extensions_2009-06-21.pdf
- 15. AMA Background and Initial Requirements -<u>http://wiki.ihe.net/images/b/ba/Final_statement_9_26_07_.doc</u> (accessed 20 December 2008)

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- NEMA PS 3.14-2000. Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Display Standard Function. Rosslyn, VA: National Electrical Manufacturers Association (NEMA), 2000. <u>http://www.nema.org/</u>. (accessed 20 December 2008)
- Sim L.H., Manthey K., 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.
- 18. RANZCR Breast Imaging Reference Group (BIRG) http://www.ranzcr.edu.au/collegegroups/reference/BIRG/index.cfm (accessed 20 December 2008)
- Viewing conditions in Diagnostic Imaging: A Survey of Selected Malaysian Hospitals: Journal Hong Kong Coll Radiolog 2001 1(4): 264-267 <u>www.hkcr.org/publ/Journal/counter.php?ref=vol4no4/full/264-</u> <u>267%20Viewing.pdf</u> - (accessed 17 March 2009)

N.B: Many of these references are to web sites and online documents, which are subject to redirection, updating, address changes and deletion. Where a link or reference appears incorrect, please advise us at <u>digital.imaging@surgeons.org</u>

Using a standard web search process with the specific terms used in the reference may assist in locating the required material.

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Appendix 1: Summary – Digital Imaging Clinician Access Recommendations – Implementation Strategy and Workflow Planning

Patient Digital Image Delivery, Access, Viewing and Archiving: Recommended minimum standards for DIAGNOSTIC PURPOSES (PRIMARY or SECONDARY) (© RACS DDI Recommendations – www.surgeons.org/dirwp)

Image Data Image Data Image Data Image Data Image Data Image Data Manipulation Format Distribution Reading Display Storage LAN > 1Gb DICOM complaint > Templating capability DICOM reading software DICOM compliant calibratable Long term storage on – full series not required, or - accessible from distribution digital display (GSDF - Grayscale secure drive, plus >Measurement media (Web - CD/DVD -Standard Display Function) secure offsite backup WAN/LAN < 1Gb (if data functionality adequate PDI IHE compliant Card) Minimum resolution and long term archive delivery speed, queuing or if distributed on within DICOM reading > simple intuitive interface CT/MRI – 80 dpi potentially as part of web pre-fetching is acceptable): portable media software >certifiable by local authority as CR/DR - 100 dpi access (meeting local >XDS-I suitable for clinical use if Mammogram – 127 dpi statutory requirements) >Web (thin client) PACS displayed on appropriate Templating/measuring monitor Hard copy stored by Note: IMAGE FORMAT SSD (solid state drive) – USB software linked to DICOM Direct observation of hard copy patient or doctor (meeting drive or similar viewing interface: laser printed film on suitable local statutory LOSSY compression (e.g. DICOM reading software viewing station. requirements) JPG, or increased - Loaded on reading computer compression JPG 2000) CD/DVD for temporary > simple intuitive interface 1. Individual user should be used with caution SSD card or CD/DVD patient image data transfer, >certifiable by local authority as Note: TEMPLATING licensed – thick client -check level of compression separate from long term storage if combined with suitable for clinical use if CAPABILITY appropriate to the clinical / storage - (PACS to PACS) separate secure displayed on appropriate 2. LAN accessible imaging situation, as may not archiving (meeting local monitor Image should be size referenced be suitable for primary or thick/thin client statutory requirements) to allow accurate measurement. secondary diagnosis. Laser printed transparent film 3. WAN licence - high quality, full size (as Direct observation of hard copy Access to templating program Note: DATA STORAGE laser printed film on suitable controlled access thick scanned or reference marker must be compatible with clinical client adiusted viewing station work flow requirements. SSD cards or CD/DVD are 4. Web based access not regarded as suitable for thin client archival purposes or long Note: IMAGE DISPLAY term storage. Transparent Acetate Standard LCD monitor of < 100 dpi templating sheets: Storage must be in IHE resolution is not suitable for review compliant format. of large matrix images. 1. onto laser printed digital image copies with or without size marker The (green) boxes across the top of the page represent process steps for the digital image distribution and access. The (purple) boxes below represent current potential solution to address each process step. 2. onto LCD monitor

To be a standard suitable for diagnostic purposes, every green box must have a purple box solution. Any green box that does not have a purple box solution, appropriate to the particular clinical situation, potentially renders the images provided as not suitable for diagnostic use.

screen with or without

magnification and size

calibration