



Report of QUDI Project QR01.iii
Diagnostic Imaging Standards for Portable Media, phase 2

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The initial draft of these Australian guidelines was prepared following Australian workshop on IHE and portable data for imaging (December 13th 2007) and extensive consultation with health professionals, various professional organisations and the radiology IT industry. This initial draft was authored by:

Dr. Peter MacIsaac
MacIsaac Informatics
Project manager for the Diagnostic Imaging standards for Portable Media Project
peter@macisaacinformatics.org

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Dr. Nick Ferris, Radiologist and member of QUDI Technical Advisory Committee
Ms. Jane Grimm, Program Manager QUDI
Mr. Bernie Crowe, Bernard Crowe and Associates
Mr. Paul Clarke, Jam Pac Consulting.
Ms. Caroline Reid, Department of Health and Ageing
Mr. Thomas Watson, Department of Health and Ageing
Mr. Michael Sandow, Orthopaedic Surgeon, Australian Orthopaedic Association
Dr. Philip Dubois, Radiologist, Australian Diagnostic Imaging Association.
Ms. Lisa Penlington, RANZCR.

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1. INTRODUCTION

This document is a technical report intended to support Diagnostic Imaging services and vendors of radiology systems to understand and implement appropriate standards to the production of digital imaging on portable media such as CDs, DVDs, and solid state drives (SSDs) and the transmission of electronic messaging for diagnostic imaging reports and requests.

In 2008 neither Standards Australia nor the National e-Health Transition Authority (NEHTA) have investigated or published recommendations regarding standards for digital delivery of images. There are no current Australian standards, and hence in keeping with current practice the most suitable international standards are identified and evaluated for their appropriateness for Australian use. In this case the integration profile from Integrating the Healthcare Enterprise (IHE) on Portable Data for Imaging (PDI) was selected after wide consultation with users, Australian standards developers and the IT industry.

The RANZCR approach is to support uptake of information systems that comply with Australian and international standards and implementation profiles for e-health applications.

Further background can be obtained by reference to the following documents:

- Report of RANZCR CD Challenge

<http://www.ranzcr.edu.au/qualityprograms/qudi/projects.cfm>

- DRAFT RANZCR Principles for the Provision of Digital Diagnostic Images

Contact:

QUDI Program Manger
Royal Australian and New Zealand College of Radiologists
Level 9,
51 Drutt St, SYDNEY NSW
+61 2 92689777

1.1 Scope

This document will support the implementation of portable media and electronic messaging used by the Australian e-health industry to transmit and receive electronic formats of digital images to other practitioners as an alternative or supplement to the traditional use of film, and to accept and transmit electronic messages as an alternative to paper based referrals and reports.

The Australian radiology and e-health sectors are in agreement that the management of a change process to introduce digital images into external clinical practice needs to start with a reliable process for transfer of images in a form that is accessible to commonly used IT systems.

This document is intended to identify all relevant standards, provide clarifying and supporting information and to support an industry managed conformance testing process.

This document may be considered as a guide to inform minimum standards of practice to support high quality electronic communication in radiology practices.

The underlying intention is to promote the reliable exchange of image:

1. for use by the originating or another diagnostic imaging service to provide a relevant history of prior images;
2. between diagnostic imaging services, referring or treating doctors, and consumers to support the use of images for both illustrative/educational purposes and diagnostic purposes;
3. to support the transport of diagnostic quality images for other purposes such as case conferences, education and research.

This document describes recommendations for the specifications for the presentation, labelling and internal structure of exchange media containing diagnostic images. The most commonly used media is the Compact Disc, CD – R. Other media such as DVDs and USB interfaced media such as flash drives or SD cards can be expected to be included in the future, as the underlying technical standards, which are referenced in this document, are reviewed to include these media types.

This report is directed at the diagnostic imaging sector in general in Australia and New Zealand and applies to the imaging or communication products that are produced on portable media and transmitted electronically. In doing so, this report will also be of guidance to the e-health industry; and systems vendors supplying technology to the DI sector.

While focusing on the radiology sector (businesses or services that engage radiologists to provide professional services) this report provides guidance to image and electronic communication by other health sectors for example dentists, chiropractors and so on.

This document does not address the delivery of all images, for example it does not include standards for video or cine images used in cardiology, pathology, clinical photography or ultrasound examinations. As these standards are included in portable media profiles, they will inform the RANZCR Standards of Practice. An update to the IHE PDI profile to cover these usecases is due for release in 2009 IHE profile release cycle.

1.2 Normative References

This document references several standards and integration profiles. These are not reproduced in this document for purposes of brevity and also respecting that standards are living documents and should generally be sourced from their custodians.

The key standards referenced in this document are the IHE profiles for portable data imaging (IHE- PDI) and the Australian Standards for Healthcare messaging covering radiology (AS4700.2 & AS4700 .7).

DICOM 2006	NEMA Standards Publication PS3.1-18 Digital Imaging and Communications in Medicine (DICOM), National Electrical Manufacturers Association, Rosslyn VA, 1992-2006
IHE Technical Framework Vol.1	IHE International: IHE Technical Framework, Revision 8 August 2007 Section 15 Portable Data for Imaging (PDI) Integration Profile p161-168 http://www.ihe.net/Technical_Framework/upload/ihe_tf_rev8.pdf
IHE Technical Framework vol. III Transactions (continued)	IHE International: IHE Technical Framework, Revision 8 August 2007 Section 4.47. Page 80 http://www.ihe.net/Technical_Framework/upload/ihe_tf_rev8-3.pdf
ISO 9660 - Level 1	ISO 9660:1988(E): Information Processing – volume and file structure of CD ROM for information exchange, 1988
ISO/IEC 10149	Information Technology-data exchange on readable optical disks
Orange Book, Part III	Phillips/Sony: Technical Specification for rewritable compact disk 1996)
AS 4700.7-2005	Implementation of Health Level Seven (HL7) Version 2.3.1 - Diagnostic imaging orders and results http://www.e-healthstandards.org.au/drafts.asp?area=publications
AS 4700.2-2007	Implementation of Health Level Seven (HL7) Version 2.4 - Pathology and medical imaging (diagnostics) http://www.e-healthstandards.org.au/drafts.asp?area=publications

Table 1: Normative Standards

1.3 Other references

The German Radiological Society assisted by OFFIS has produced similar professional standards adapting the IHE profile for use within Germany. This document draws on their experience and documentation with their permission and grateful acknowledgement.

German Radiological Society (DRG)	Requirements Specification for Exchange medica containing patient information 2006 http://www.dicom-cd.de/specs.php.en
German Radiological Society (DRG)	Guidelines for handling media containing patient information 2006 http://www.dicom-cd.de/handling.php.en

Table 2: Other references

1.4 Abbreviations and Acronyms

The following abbreviations and acronyms are used in this document

ADIA	Australian Diagnostic Imaging Association
CD	Compact Disc
CD-R	Compact Disc Recordable
DICOM	Digital Imaging and Communication in Medicine
DVD	Digital Versatile Disc
HTML	Hypertext Markup Language
IHE	Integrating the Healthcare Enterprise
JPEG	Joint Photographic Expert Group
PACS	Picture Archive Communication System
PDI	IHE Portable Data for Imaging
QUDI	Quality Use of Diagnostic Imaging Program
RANZCR	Royal Australian and New Zealand College of Radiologists
SDD	Secure Digital Drive
USB	Universal Serial Bus

Table 3: Abbreviations

1.5 Document History

Version	Description, Author and Changes	Date
1.0	First draft – Peter MacIsaac	6/2/2008
2.4	Second draft – Peter MacIsaac	2/3/2008
3.0	Third draft - Peter MacIsaac, incorporating editorial changes and input from IHE radiology technical committee.	2/4/2008
4	Proof read & edits prior to publication – Jane Grimm	3/06/2008

Table 4: document history

2.0 GENERAL REQUIREMENTS

This section describes the general requirements for exchange media for images. A number of comments and recommendations have arisen from the experience of the Diagnostic Imaging Standards for Portable Media project, which was conducted as part of the Quality Use of Diagnostic Imaging Program (QUDI).

2.1 Exchange Media and File Systems

2.1.1 Exchange Media

While there are a large range of media which can be potentially used to exchange diagnostic images only media approved by IHE within the Portable Data for Imaging profile are accepted. Current the following media are supported:

- CD-R [ISO/IEC 10149]

As the IHE profile is designed for transport of a single image set, the use of rewritable media is not supported currently.

DVDs and USB related media are in the process of being considered for inclusion in the next IHE revision. The need for DVDs occurs because of the increasing size of images which can require images to be stored on several CDs. Other digital media such as USB and SD drives support specific user requirements. Essentially the same file format and other standards apply to these new media, however there are issues relating to labelling (due to the small form of these media), ability to automate the production of images on these media, and fragility of media (a problem reported with DVDs).

2.1.2 File Systems and extensions

As per the IHE technical framework for PDI (IHE TF Rev 8.0 4.47.4.1.2.1), CD media must be compliant with ISO 9660: 988(E) – level 1, at a minimum even if other file systems are also supported. The use of file system extensions to ISO 9660 level 1 such as Joliet or Rock Ridge is permitted. This requirement is essential to support the ability of any of the current operating systems to read the files contained on the portable media.

File systems for DVDs and other media will be specified by IHE at the time of their inclusion in the PDI profile and such changes will be deemed to be within these requirements as this occurs.

2.2 Malicious Software (Malware)

The creator of the medium must take reasonable steps to ensure that no malicious software (viruses, Trojans, spyware etc) is included on the medium. It is recommended that a successful test for malware be undertaken, at the time when no further data is intended to be written to the disk.

It is acknowledged that the responsibility for protection against Malware rests with the receiving application and appropriate products need to be installed to protect against viruses, Trojans, adware etc. Consequently there is no requirement for printed statements regarding protection against malware to be included on the labelling or storage packaging.

2.3 Auto-run/Autostart/Autoload

The use of auto-run is widely adopted in the Australian market, where the CD will usually run a DICOM viewer. This approach is not recommended as it does not meet the needs of all users, image viewing options and there are other ways of supporting unsophisticated end users or those without custom DICOM viewers to load media. **IHE recommends that media auto-running a specific application on insertion is not used.** This is due to the differing needs of various types of referrers. For example many GPs will not need access to DICOM images and are happy to view either the report or illustrative images (if present on the CD as “web content”), hence the practice of auto-starting a DICOM viewer may not be the required action. Newer IT system management approaches often disable or put authorization/administrator requirements prior to auto-run. Auto-run does not run consistently on different operating systems, and can create a non-standard operating environment for the wide range of end users.

To be consistent with IHE PDI, autorun should be discouraged and adequate loading instructions provided on the disc label or packaging. If it is to be used, then vendors may consider consistently opening the index.htm file of PDI Web Content (see section 3.5). If the index.htm page is appropriately configured, it can provide a useful portal to the content of the disk, from where an embedded viewer can be opened, if required, or other content such as non-diagnostic quality images or reports can be viewed.

2.4 Media Labelling, Packaging and Storage

2.4.1 Labelling

The image medium and the packaging within which the medium is delivered and stored should be labelled with human readable information.

There are two levels of labelling. One is on the media itself and the other is on the packaging. This section refers to labelling of the media. Due to problems with CD damage due to chemicals, the use of adhesive CD labels or hand written labels using a marking pen are to be discouraged in favour of CDs which can have labels directly printed onto their surface.

Note: automated media production systems can print on the medium and label without direct user input. Systems that cannot do this should consider using on–screen prompts displaying suggested label fields which are read then printed on the media. However the labelling requirements make production of labels by hand an inefficient and time consuming process.

2.4.2 Content of label

The label should contain in a clear and legible font to support readability at all ages:

- Name of institution creating the CD and contact details.
- Patient Name
- Date of Birth
- Unit Record (or equivalent) Number
- Date of Examination
- Type of examination(s)

- Date of Media Creation
- Media type and identifier in form “media type” instance number” of “total number of media in series”. (eg CD Disc: 1 of 2). As many media have a similar form (120mm disc), a statement of the type of media will assist in troubleshooting if the media does not load.
- Statement about media content eg. “DICOM Only, DICOM plus Web Content, DICOM Viewer for Windows and Macintosh”
- Statement about sole archive status or retention policy of the DI service. If the media contains the only long term digital record. For example “ARCHIVE COPY- Please take care” or “TRANSPORT COPY – replacement available if required”. Note advice in section 2.5 regarding image archive.
- A confidentiality statement

The content of the label on the media, on the storage package and represented on the media itself will be internally consistent.

These requirements exceed the current IHE profile requirements for labelling. Further consultation will be required with manufacturers of CD printing systems to determine whether there any technical or other factors which make this recommendation too onerous or not sufficient to describe current practice.

2.5 Media Selection, Storage, Packaging and Presentation

Media are subject to accidental damage and being lost or misplaced and mixed up with other media used for data, programs or entertainment, hence media must be of appropriate quality and packaged adequately.

Note: IHE does not recommend that portable media are used for archive purposes. Imaging services are advised to discuss this with their IT systems vendor, read any product disclaimers and seek independent advice about recommendations for media type suitability and storage advice.

2.5.1 Media selection

Media should be selected to be fit for the purpose, use and expected storage requirements of the radiology practice as well as the expected range of end users and consumers. The selection of media is determined by technical factors involving the media printer and can not be pre-determined. Media comes in different qualities based on factors such as dyes used and manufacturing tolerances. Media selection may be based on the advice of the CD production system or subject to a trial and error testing process. As a general rule media intended for long term use should be of high quality.

2.5.2 Media storage

Media should be stored in cool environment and in a light free, environmentally neutral package which is known not to contain chemicals that can degrade the media.

There are a vast range of storage options from paper or soft plastic pouches, through different designs of hard plastic case, and storage envelopes (which may be post office approved) or media folders. As diagnostic imaging media are important clinical documents, they should be packaged and stored in a way that clearly differentiates them from other computer or entertainment media, and supports the requirements for instructions and labelling.

Options for recommendation in this standard regarding media storage include:

- No standard requirements
- Standard paper or plastic pouches
- Hard plastic "jewel cases"
- Sealable envelopes of A5 or A4 size
- Folders containing CD/media pouches or process for fixing the CD.

It is recommended that media are stored universally in an **A4 size envelope or folder**, which is opaque to light, and contains suitable internal storage for the media (eg. CD pouch(s) to avoid accidental loss. This will provide consumers with a consistently sized storage unit, (akin to the standard film bag), which also has storage capacity for more than one media and accompanying reports, paper or film images.

An A4 storage folder or envelop also has ample room for a readable patient label, loading instruction and appropriate quality/compliance statements and logo.

This requirement also exceeds the IHE profile specification. It is proposed that the the benefit of a standard size storage environment outweighs the additional cost and limiting options of individual practices to make their own decisions. Other options may not support the intention of identification of the media as an imaging examination record, or support the provision of labelling and instructions and provide room for other inclusions eg reports, printed images.

2.5.3 External Labelling

The storage envelope or folder should have printed in size 11 or greater font:

- Patient details (as per the media label) – This shall be placed under a flap in the event that the package is to be sent by post in order to protect patient privacy
- Contents of envelop (eg. This envelope contains diagnostic images on CDs, a report and sample printed images)
- Practice identification and contact details
- Detailed instructions for common operating systems on how to load the CD and access the electronic help files or further instructions, or the placement of written instructions within the package
- A phone number the user can call if help is required
- The disk package should contain a statement that the contents are confidential medical records, and if located should have a clear return address

The issue of detailed labelling of media storage is not covered in the IHE PDI profile as this goes beyond the responsibilities of the IT vendor.

2.6 Link between referrals and image media

Patients, referrers or treating health professionals are able to request images in form that allows them to access or view diagnostic quality images. How this request will be conveyed will most likely be managed through local policies within a diagnostic imaging service relating to the type of referrer or clinical situation, or through an indication in the special requirements on the radiology referral form. Vendors of systems managing

radiology workflow may need to give consideration to how to manage this functionality within their applications as supporting end user preference for imaging media.

3. Media Content Requirements

3.1 Media content

This section references the IHE Portable Data for Imaging profile. While some guidance is given here, the requirements of the PDI profile as published take precedence (in the case of ambiguity) and should be consulted. Only a small amount of detail and key principles is included in this section.

The IHE PDI profile generally supports the storage and transport of images relevant to one patient and covering one imaging event or examination (which may include several studies or study components). Once uploaded the images can be integrated into an imaging environment, viewed, printed or forwarded.

While PDI does allow for images for more than one patient to be included on a single media, this is to support other transport use-cases where the media is not given to the patient such as collection of images for clinical research, or grouping of images to be used in an operating session or clinical meeting.

The IHE PDI profile covers the medical content of the medium covering diagnostic quality images (DICOM), non diagnostic content and instructions (Web Content) and other content (DICOM viewers, non DICOM reports).

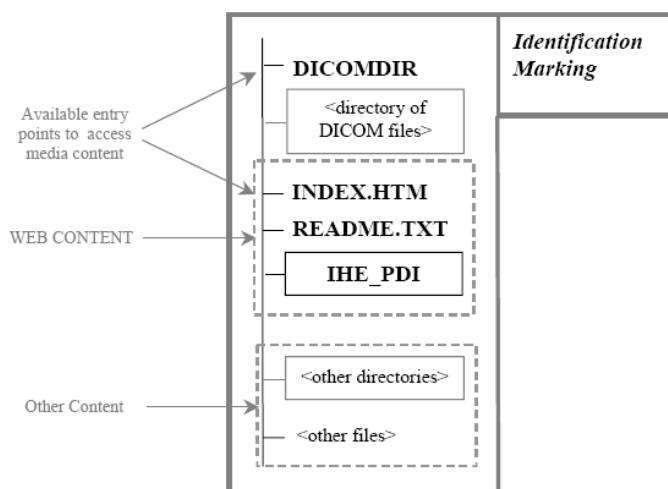


Figure 1: Description of the content of the media file system (IHE TF – Vol 111 p

82)

The following notes are intended to draw attention to issues covered in the DICOM standard and Portable Data for Imaging profile.

3.2 DICOM Content

Media must contain DICOM content which consists of a DICOM Directory (DICOMDIR) located in the media’s root directory and DICOM files which contain DICOM objects. Compliance with the DICOM standard is essential to support interoperability and allow media readers to correctly import and process the diagnostic quality images.

While the nature of the DICOM content on the disk can be determined by the media creator application or radiologist preferences, it is recommended that all DICOM images relating to an examination are included on the portable media. This provides the end user with as much imaging information as possible to support their interpretation and clinical decision making.

The following areas of the IHE profiles describe the requirements:

- IHE Technical Framework Volume II – Portable Data for Imaging (PDI) Integration Profile Page 160.
- IHE Technical Framework Volume III – Section 4-47 Distribute Imaging Information on Media Page 79
- IHE Technical Framework Volume III - Appendix E. DICOM Media Interchange – Critical DICOM Compatibility Tips. Pages 171-173

3.2.1 IHE PDI Actors

PDI profiles cover all systems involved in the creation and use of the portable media.

There are seven actors covering media producers and consumers:

- Portable Media Creator - produce portable media
- Report Creator – able to add reports to the media
- Portable Media Importer – able to import media content
- Display – able to display web content
- Image Display - able to display DICOM images
- Report reader – able to read and display DICOM report format
- Print Composer – able to print images sourced from the media

Not all applications need to do all actors. For systems producing images on media the key actor is Portable Media Creator.

3.2.2 Other relevant IHE profiles

There are a range of other relevant IHE profiles which support image transfer. These include:

- Import reconciliation workflow
- Consistent presentation of images
- Key image note
- Cross Enterprise Document Sharing – Imaging

These largely support the media consumer application in processing the DICOM objects. While not required in this standard vendors are encouraged to implement other appropriate IHE profiles and to issue conformance statements.

3.3 Instruction files (Readme.txt):

The file "readme.txt" must be present and placed in the root directory, even if web content is not supported. It should contain a copy of the static (non patient, non examination) information provided on the label and external packaging. Other content is specified in the PDI profile (PDI TF vol III, section 4.47.4.1.2.2.2 page 83). In addition to information about DICOM viewer software, information about the requirements for HTML viewers required to read web content should also be included.

3.4 Reports

Diagnostic Imaging services tend to have local policies regarding the inclusion of reports with images that are actually handed to the patient. Some hold that the report should be presented to the patient by the referring doctor and do not include these currently with the film images. Others take a contrary view and feel that the report should be stored with the images so that it can be of use to other health professionals who need to refer to either the report or images.

The IHE profile supports both options. If a report is stored then the process is covered at (PDI TF vol III, section 4.47.4.1.2.3.1.3 - page 87) for reports in a basic text DICOM structured report format. Other non-DICOM report formats such as HL7 version 2, or HL7 Clinical Document Architecture (CDA) or generic formats such as PDF may be included on the media as additional content, however uploading these formats is not required by the portable media importer actor of the IHE PDI profile.

The management of reports on media for use in Australia is an issue which should be further reviewed by the College.

This guide would recommend that if a report is stored electronically then at least one copy should be in a human readable format, and one stored in accordance with the Australian Standards (AS4700.2 (2007) or AS4700.7 (2004) to facilitate import into Australian clinical information systems. The advantage of using a CDA format is that the data is able to be human read, and machine processed (if such data is provided).

Note: This recommendation is not covered in the PDI profile. Given that reports and images are often managed in different applications it may be difficult to coordinate reports on the portable media.

HL7 CDA reports will eventually support both human and machine readability requirements. Electronic reports are discussed at section 4.0

If desired a paper copy of the report can be included in the storage envelope/folder (as is the current practice in some centres with film bags).

3.5 Web Content

The IHE PDI profile refers to web content. This is content that can be rendered or viewed using standard web browsers such as Internet Explorer or Firefox or Safari. The purpose of Web Content is to provide images and reports in a form that are viewable without needing access to specialised viewers. The images that can be viewed using web content are usually of lower resolution than the diagnostic DICOM images (eg lossy JPEG) and may be subject to compression and some data loss. This does not imply that these images are of low quality. In some situations using these formats presents the images

in a form that is more appropriate for users who wish to use images for illustrative or educational purposes. In general these types of images are not regarded as suitable as the sole basis of making clinical decision due to the lower resolution and inability to use specialised viewing and measuring software

Information on the Web Content option is at IHE Technical Framework, vol. III: Transactions section 4.47.4.1.2.3.2 page 87

The default web page (index.htm) can be a useful portal or front end application for end users. The web pages would contain key information akin to that used on the media and package, appropriately formatted images eg JPEG and links to help files and software for accessing DICOM file content, if provided. The content and layout of the web content is of course a matter for each vendor, however it is expected that a consistent user interface will support end users who have to accept media from multiple different imaging services. If web content were used consistently then users would have a common pathway to follow: i.e. choosing to navigate the web content, or alternatively to have their existing DICOM viewer upload the diagnostic image content. All vendors have an interest in supporting common workflow and usability of image media.

Where Web Content is used to display non-diagnostic images, the fact that these are non diagnostic should be clearly conveyed to the user either in the instructions or by annotation of individual images image.

The RANZCR Standards of Practice recognises that Web Content is a key component to achieve a common user interface to image media.

Application vendors should note that there are restrictions on HTML features currently in force to limit the complexity of the web content formats, in the interests of maintaining an output that could be viewed by the "common denominator" web browser. Consideration of the addition of more complex web elements is underway in the 2008 revision of IHE profile. Vendors are encouraged to make change requests known to the IHE radiology technical committee, either directly or through IHE Australia.

3.6 DICOM Viewer

A DICOM viewer is a computer application or program which allows the visualisation of DICOM objects, such as diagnostic quality images, which are stored as files on the media.

While not clearly stated in the current IHE technical profile for PDI, the radiology technical committee has restated a firm view that embedded viewers are designed for occasional and emergency use only. Regular users of DICOM images should acquire a suitable viewer to load on their viewing hardware.

The media may contain more than one DICOM viewer such as where an effort is being made to support viewing on different operating system platforms (eg. to support both Apple and Windows platforms)

Regular users of the DICOM content of portable media (such as orthopaedic surgeons) are not likely to appreciate having to use many (perhaps up to 15) different viewers as patient present with images from different DI services (note: the same caveat applies to the use of multiple web access viewers) Each viewer has a different interface and

functionality. Loading the viewer, if images are used on a just in time basis, would extend the loading time. Where images are preloaded prior to the patient consultation, which is an option to improve response times, it will not be possible to use the viewer in any case. Consequently "embedded viewers" are best considered to be a service for occasional use where access to a regular viewer is not possible such as when a surgeon is visiting external rooms or emergency department. This being said there are a number of issues with viewers on the media that can be prevented with appropriate design and usage.

3.6.1 Viewer Instructions

Instructions for starting the viewer need to be present on the media label, media folder and readme.txt file. An online manual should be available. Usability would be supported where the viewer could be loaded from the index.htm page, if that option were desired by the user.

3.6.2 Starting the software (auto-start)

As recommended in section 2.3, auto-start should be avoided. It should be clear to the user which folder the DICOM viewer is placed and what is the executable file. This could be handled in readme.txt or on the label. Alternatively it would be simpler to launch the viewer and help files from the index.htm page.

3.6.3 Execution without installation and without system administrator privileges

Many corporate systems do not allow uploading of executable files or require administrator privileges. It is recommended that applications consider this and avoid this problem and provide a user friendly approach to dealing with such instances if they occur.

3.6.4 Attempted execution on inappropriate systems

Where the software does not load, e.g. incorrect operating systems, the viewer should terminate with an intelligible error message

3.6.5 Use of other operating system objects

Loading the browser should not be dependent on pre-existing components eg Java, MS components. If these are needed they should load from the disk.

3.6.6 Functionality

There are currently no standard specifications or user interface for DICOM viewers. Given that end users will be encouraged to use a consistent product some guidance on desirable features would be useful in assisting users in the management of the change from film to filmless viewing of images by referring and treating doctors.

Not all viewers are able to display certain types of images (DICOM SOP classes). Where a viewer cannot display an image PDI requires that a message is provided to the user to prevent confusion occurring about whether the system is working or the disc corrupted.

Note: It is likely that this guidance should be provided by the radiology profession working with representatives of the groups of practitioners who are using digital imaging. The requirements of each professional or craft group may be different. The Australian Medical Association has published a list of high level user requirements which could be used as a basis for starting this consideration.

3.6.7 Local viewer disclaimer

Developers or suppliers of DICOM viewers may wish to provide advice to end users or limit their exposure to litigation by including various warnings and restrictions on the use of DICOM viewers provided on the portable media. This approach is creating confusion, potential legal issues and is a barrier to adoption. Some products classify their products as “not for diagnostic use”. It is believed that these warnings are motivated by uncertainty about the quality of the viewing environment such as use of non-diagnostic quality monitors rather than concerns about the performance of the software or images contained on the media.

Vendors are encouraged to either put more appropriate and specific advice on the rest of the hardware setup required by end users. For example:

“DICOM files on this disk are suitable to provide diagnostic quality images where this viewer is run on appropriately specified computer equipment and displayed on an appropriate monitor. It is the responsibility of the user to ensure that reliance on the images and DICOM viewer on this media for diagnostic purposes complies with this recommendation.”

4 Electronic Diagnostic Imaging reports

The major use case for electronic management of communications in the diagnostic imaging domain in Australia is messaging for the delivery of radiology reports. In time it can be expected that electronic referrals will become more common place. Using the HL7 message allows the report to be received and processed in a standard workflow across multiple different result receiver applications. The production of a report is a requirement under Medicare regulation and must be provided to the referring doctor and stored for a minimum of 18 months.

4.1 Messaging Standards and Interoperability

Electronic messages are used to convey reports or referrals and other information between applications. Formal messaging standards are required to support interoperability between a wide range of different applications. The background and principles involved in selection of standards are described in the National E-Health Standards Catalogue¹ and reference the Standards Australia HL7 version 2 messaging:

“AS 4700.7-2005 Implementation of Health Level Seven (HL7) Version 2.3.1, Part 7: Diagnostic imaging orders and results is currently in use in a number of different sites in the Australian Healthcare environment and is consistent with the direction recommended in the Standards for E-Health Interoperability v1.0, 08/05/2007.

NEHTA’s recommendation for the use of this standard is on an interim basis, as the future direction recommended by

¹ NEHTA, National E-Health Standards Catalogue Version 4.

NEHTA in the Standards for E-Health Interoperability v1.0 is based on CDA. "

Since the publication of the NEHTA framework a revised standard for diagnostic imaging has been released and this is shared with pathology/laboratory messaging (AS4700.2 2007). There is little substantial difference between the two standards and either is considered acceptable for current usage.

Where a user guide (eg HB262) to the Australian messaging standard is published, this report recommends that implementation of the messaging as per the user guide. Australian standards, technical documents and user guides are available from www.standards.org.au .

As a comparison the pathology industry standards for messaging are similarly focused on Australian standards, a conformance testing process and are specified in guidelines for pathology laboratory accreditation.²

Where the report is delivered to an external referrer or treating practitioner from an independent diagnostic imaging service (that is the report passes between different enterprises) the Australian standard for HL7 messages for radiology is the appropriate standard for the messaging component of the communication solution. There is an alternative standard for messaging radiology reports based on a commonly used legacy message format known as PIT (Pathology Information Transfer). This messaging format was developed in the early 1990s, has significant technical limitations for the transmission of encoded and structured data, and is only used in Australia. **PIT is not an acceptable format for result messaging..**

Certain IHE profiles in radiology structured workflow (SWF) also contain HL7 messages for communication of orders and results. Until such time as an effort to analyse the differences in message structure and usage can be performed, a pragmatic solution recommended in this report is for the standard to reference the Australian standards for HL7 messaging. IHE (Australia) has released a local profile for diagnostic messaging which is to be used for testing compliance with the Australian messaging standards. A copy of this profile is available from IHE Australia (www.ihe.net.au).

For referrals and reports, Standards Australia (www.standards.org.au) describes the local implementation of HL7 version 2 messaging covering referral and requests and the acknowledgement messages indicating both receipt of the message as well as processing by the receiving system.

HL7 standards for radiology reports(ORU) and requests (ORM) and associated acknowledgement messages can be found in Australian Standards AS4700.7 (2005) and AS4700.2 (revised 2007) as implemented using the appropriate user guide. Compliance with the more recent message standard is preferred, however because of "backwards compatibility" of messaging standards compliance with the earlier standard is still very useful. This report recommends that **messages comply with either version of the Australian standard.**

² <http://www.healthconnect.gov.au/internet/main/publishing.nsf/Content/npaac-info-comm-toc~npaac-info-comm-compliance>

HL7 standards also provide for the use of message level acknowledgements to report that the message has been delivered to the recipient's system and a second layer of application level acknowledgement when the user application commits the message data to its database. These two levels are regarded as the minimum necessary for safe practice, as there is a real potential for technical failure to occur on occasion resulting in the loss or failure to process the message. In general applications or systems responsible for message transport will make use of message level acknowledgements. Systems that create the message will be expected to receive and process application level acknowledgements (including failure to receive an acknowledgement).

A third user level acknowledgement can occur when the message requires clinical activity and this occurs as would happen where a clinician received a report and undertook an appropriate action indicating that the result has been viewed and processed. In the case of a radiology referral the third level of acknowledgement would occur when the requested investigation was scheduled.

For the purpose of this standard both message and application level acknowledgements and appropriate application responses to failure to receive these acknowledgements is a requirement.

A third level of acknowledgement is regarded as desirable, however would require significant development to receiver applications and it is recommended that this should be included in product development cycles after appropriate discussion with Standards Australia and HL7 Australia.

It should be noted that the use of acknowledgements places responsibilities on message receivers to respond with the appropriate acknowledgements.

5 Compliance & Conformance Testing

Long experience, both internationally and in Australia, has demonstrated that vendor compliance statements with regard to HL7 messaging or IHE profiles, regardless of how well supported by internal quality management processes, should be supported by independent testing of interoperability in a range of independent laboratory and formal inter-system test environments.

This testing can occur at two levels:

1. Voluntary IT industry based testing of products to support marketing and purchasing processes. An example of this is the Connectathon process used by Integrating the Healthcare Enterprise (IHE). In this model the testing authority is the standards development or integration profile development organisation. There are a range of ancillary individual and group benefits that accrue from this type of process which support an industry environment that is able to support interoperability. The RANZCR and ADIA have strongly encouraged IT vendors to participate in this process.
2. Certification as a requirement by regulation for implementation or receipt of incentives. An example is the requirement that Pathology Laboratory messages are certified to be compliant with AS4700.2 standards as part of mandatory pathology laboratory accreditation. In this model certification is performed by an independent and accredited standards testing service.

In practice the first type of conformance testing is required to support the second. It is important that the DI systems vendors be provided with a reasonable period to implement the relevant standards in their products and make these available to the DI service providers. Consequently conformance testing should occur in a staged process.

5.1 HL7 Messaging Testing

Adherence to these standards can be required or verified by reference to the Australian Health Message Laboratory (AHML). This involves a two layer level of testing. The first involves online using tools provided to assist developers in achieving conformance and debugging problems. The second level is a formal testing of a representative sample of messages and awarding of a compliance statement. The AHML testing process is itself accredited by the International Society for Quality in Healthcare. (ISQua)

HL7 messages can be formally tested and certified in an IHE Australia connectathon, should a message profile be offered for testing. Both AHML certification and an IHE connectathon conformance statement (if available) should be accepted as support for a vendor's compliance statement regarding this group of radiology messages.

Currently AHML processes are only able to test the validity of outbound HL7 messages such as radiology orders, results and their acknowledgements. There is no capacity to test the ability to process incoming messages, the applications response to these, or the capacity of the message to be used in practice by multiple systems. AHML is an example of an "in vitro" (within the glass) testing environment.

The IHE Connectathon Process (which includes pre-testing using the same or similar approach to the AHML level one testing), also tests the message receiver capacity and responsibilities, along with a practical test of interoperability between 3 or more systems. While still removed somewhat from the real implementation environment the IHE Connectathon testing is more of an example of an "in vivo" (in life) testing environment. Further information on the Connectathon process is available in the next section and also at www.ihe.net.au.

5.2 Testing of image media creators

Following from this discussion the testing of an integrated profile of nature of Portable Data for Imaging requires a sophisticated testing process known as a Connectathon. IT vendors are able to test their whole systems for interoperability capacity with a number of other vendors, thereby providing confidence in the end to end solutions. Compliance is signified by vendor conformance statements, backed by an IHE list of those who have successfully passed testing at the connectathon. IHE Australia is being established in 2008 and will conduct connectathon testing for an Australian messaging profile.

Vendors may test at any of the official IHE Connectathons, however where additional local requirements exist for this region, these should be validated by testing within Australia. There is a further advantage of participating in a local/regional connectathon relating to cross testing with other products used in this region and the ability to resolve technical issues in a rapid way through interaction between systems engineers from different organisations.

IHE provide a series of test tools (known as MESA tools) for the pre-connectathon testing of PDI media. These can be downloaded from IHE after registration with the radiology technical committee and used to self test the media.

5.3 Testing of Image Media Importers

The IHE profile specifies a number of actors relating to the import, display and processing of imaging sourced from portable media. Applications such as DICOM viewers, image management (eg. templating, radiotherapy planning) and clinical information systems are able to participate in IHE conformance testing processes. This process is not limited to radiology specific applications.

5.4 Testing of Image Media exports from DI services

It is recommended that media actually produced by DI services be locally tested for conformance with the PDI and message profiles.

While IT systems vendors may be demonstrated to be capable of producing a PDI compliant media format through the above processes, this has to be implemented in practices. There is no guarantee that the system tested is actually used in production or that the compliance applies to all installed systems. Older versions of software can be non-conformant. Variability in actual implementation is possible and does occur.

The desired outcome is image media which when produced by a diagnostic imaging practice is compliant with the PDI profile. Compliant media can only result if produced on a media creator that is implemented in the correct manner at the DI service. In practice, the image media can be produced by a modality (such as a CT scanner), the image manager/archive (PACS) or a separate media creator application (CD printer). Hence the involvement of one IHE compliant component in the image production process does not guarantee that the resulting media will be compliant. There may be local configuration options in some applications which allow an otherwise potentially compliant media to be made non-compliant, for example by disability the burning of DICOM content in favour of only using compressed images such as JPEG. This is not compliant as PDI media must contain DICOM content.

In addition, the specifications recommended in this report add some requirements about labelling and presentation which are not capable of being tested in an IHE Connectathon as these features are rather practice specific and are a function of the media creator configuration at run time. Packaging and labelling are not the responsibility of the media creator.

It is clear that the starting point for practices wishing to produce media consistent with the IHE PDI profile and the RANZCR Standards of Practice should commence with a clear understanding of the process of production of media and identification of the contribution of the modalities, PACS and media creator. Ideally all of these should have a conformance statement against the specific actors in the PDI profile. A verified conformance statement should be a requirement for purchasing or negotiation of service contracts, along with a requirement that local implementations are of themselves able to produce conformant PDI media.

5.4.1 A media testing and support service

Accepting that some form of testing or assessment of the quality of the media output is required, there are several options.

1. No testing at the practice/DI service level – this relies on appropriate implementation and configuration of known compliant systems and waiting until problems are reported to identify issues of concern.
2. Local testing – this would involve individual practices undertaking self-assessment against these standards and technical assessment using the publicly available IHE test tool suite.

Options 1 & 2 do not provide any objectively verified outcomes that could be used for accreditation or other conformance testing process. It is recommended that self testing of image media and messages be made available to DI practices to support quality control and trouble shooting of problems.

3. Remote testing - this would require one or more discs to be provided for independent testing, along the lines of the 2007 CD challenge. This would involve inspection of discs, labelling and storage, bench testing using the IHE tools, and usability testing in a range of machines and perhaps against commonly used PACS systems.

While more intensive this latter method is recommended for the early years of widespread media use as it will provide a baseline to support a good level of industry performance and identify currently unknown issues, and support sharing of expertise and knowledge across the radiology IT community.³

It is proposed that for an initial period of three years (and continuation subject to review) that individual diagnostic services producing image media (whether as their prime method of communication or on request) be offered a service to test their portable media implementations against these requirements and provide preliminary advice about how to correct any problems identified. Such a service would also be in a position to receive reports about potentially inadequate digital media (after a process of local resolution has not succeeded) and assist with analysis of the technical issues and resolution. This service would satisfy accrediting bodies that the testing model was adequate to meet the objectives of this process to support accreditation.

At the same time as offering this testing, a standard test media (CD) could be provided to the diagnostic imaging service, along with a number of example media from other DI services to allow self testing of the media import function of their own system.

The characteristics of this service would include:

- Accountability to an appropriate professional technical committee representing the key stakeholders;
- Using a process which itself is accredited as an independent standards testing service;

³ It should be noted that the author has a potential conflict of interest in this area as this recommendation could result in further consulting or service work.

- Independence of radiology IT vendors and DI service providers
- Possesses the technical knowledge of IHE PDI and its component standards, and has access to appropriate IHE technical committees;
- Has or is able to establish an appropriate testing pro-forma and processes;
- Support of a viable business model

5.4.2 A business model for media testing and support service

There are two business models and one hybrid model.

1. The service is supported by a grant from the Government sector, as this is a “public good” and provides infrastructure which supports the orderly conduct of a key health service. Unless this service is made compulsory by either regulation or linking to payments, then it is likely that a voluntary process could suffer from lack of support due to various factors which lead to recognised “market failure”.

2. The service is supported by charging user fees. As described in the previous section this is most likely to succeed where there are strong incentives. As with any business there are significant set up costs and business risk that have to be reflected in charges.

3. A hybrid model where the establishment costs and some risk are covered by a government grant, with ongoing funding from a user pays model.

Since the appropriate implementation of this electronic communication technology is essential to the proper conduct of DI services and delivery of a safe and convenient service to consumers, this report strongly advocates that compliance with the media and messaging standards be supported by regulation or incentives to support rapid adoption and ongoing compliance. The proposed model supports industry self regulation; however uptake will be supported where there is an underlying requirement to comply.

Options for regulation involve:

1. Referencing these recommendations in the Industry Code of Practice for Management of Digital Imaging
2. Recommendations from this report are used to inform the RANZCR Standards of Practice of use in the RANZCR/NATA voluntary accreditation program
- 3 Referencing these recommendations in the proposed process of accreditation for Medicare payment purposes.

Consultation should occur with professional and industrial associations representing imaging technologist regarding the boundaries of their professional responsibility with regard to suitability of digital images and reports.

5.5 Testing of Messaging exports from DI services

As with media testing a case can be made for testing the messaging output from individual diagnostic imaging services. This could be achieved by provision of sample result messages as part of the media testing service described in the previous section.

At a minimum the testing would involve passing these messages through the AHML on-line testing service. As with PDI, testing against a fully defined messaging profile will provide a more complete assessment of "end to end" interoperability and reliable delivery of report messages.

6 Interoperability Showcase

In the previous section the process of the IHE connectathon was discussed as a suitable process for extending AHML testing and testing end to end connectively and ability of multiple systems to work with each other.

The IHE showcase is a public event held usually at a relevant health informatics or professional conference (after the connectathon) to demonstrate the use of the above recommendations in an environment that simulates actual healthcare practice. Such demonstrations affirm the conclusions that are drawn from successful connectathon participation and demonstrate an end to end working system.

Vendors are strongly encouraged to participate in IHE interoperability showcases and interoperability events sponsored by the RANZCR at its annual scientific meeting.

7. Change Management

The process of supporting change from film to filmless management of images by health professionals outside D.I. services will require a broad process of engagement and change management.

A number of issues are addressed in the attached draft principles for provision of diagnostic digital images. . A range of technical and workflow issues have to be resolved before images on portable media such as CDs can be effectively integrated into the work practices of referring and treating health professionals. Examples of this change include clear statements of the types of IT equipment and monitors needed by treating doctors for display of images and methods for preloading of images to improve speed of loading.

Some of these technical issues are covered in German sourced document, Handling Guidelines for Media Containing Patient Information. <http://www.dicom-cd.de/handling.php.en>

This document provides a guide to those who receive portable media and form an excellent place to start consideration of the issues at the local level.

It would be anticipated that a similar detailed set of guides could be produced to the Australian health sector.

8. Variations from the IHE PDI Integration profile

This section specifies differences between the IHE PDI profile and this recommended specification. As can be seen there are no major departures from the international profile. Where changes and recommendations exist, these are done with the intention of supporting the next phases of change management:

7.1 External labelling

Additional data fields are recommended relating to patient identification and media content and instructions for use.

7.2 Packaging

IHE profile refers to jewel cases as possible storage environments. This specification identifies that an A4 sized folder or envelope is a more appropriate approach for this type of clinical record and to be consistent with current storage practices for film images.

7.3 Readme.txt

This specification recommends the use of a readme.txt file in all cases, whereas this is optional in PDI.

7.4 DICOM Viewers on the Media

This specification recommends that their usefulness is limited to specific use cases and recommends a preferred method for loading or accessing such viewers.

7.5 Web Content

This specification recommends that web content be used in most situations where images are stored to portable media (in addition to the DICOM content).

Non diagnostic images should be clearly indicated to the user.

9. Conclusion

This paper summaries the key aspect of the PDI standards profile which will support data interchange by portable media of DI imaging data and electronic messaging. Further work is required on the details of the conformance testing processes and guidance to end users on the handling and processing of digital imaging media.

In the medium to longer term web based image delivery solutions based on the IHE Cross Enterprise Document Sharing for imaging (XDS – I) profile may address many of the shortcomings of transport by portable media. However regardless of how images are transported there will be a need to have appropriate hardware and software at the receiver end for viewing and processing.

Comments and feedback on this report and standard are welcome.

Please direct them to either:

Jane Grimm, RANZCR Quality Use of Diagnostic Imaging Program –
quid@ranzcr.edu.au

or

Peter MacIsaac - Project Consultant peter@macisaacinformatics.org

Attachment A:

Draft Principles for the Provision of Digital Diagnostic Images

Digital imaging technology is rapidly being introduced with substantial benefits to patients, referring practitioners and diagnostic imaging practices. These benefits cannot be realised unless all those affected are willing and able to adapt and accept that change is necessary.

The current dissatisfaction of some referring and treating practitioners with the quality of the electronic images and the mode of their delivery demonstrates that there needs to be a greater emphasis on standards, professional collaboration and understanding of the impacts of change when new technologies are being introduced.

To address the immediate specific concerns of some referrer practitioners, the RANZCR has developed the following principles, which should guide the practice of radiologists, diagnostic imaging practices and other health services producing digital diagnostic images, whether or not they are members of the RANZCR or ADIA. These guidelines will be offered to other professional bodies for comment, endorsement, and presentation as a joint statement.

❖ Provision of diagnostic images:

Diagnostic imaging examinations should result in a radiologist medical opinion and provision of diagnostic quality images, either on film, online, or by using standard digital media. A referring or subsequent doctor, or the patient him- or her-self, is entitled to request images in a form suitable for viewing in their particular circumstances. Until processes for reading and management of digital images are widely implemented, this may involve printing images on film, if requested, during an agreed transition period.
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Film is becoming obsolete and inadequate for presentation of complex imaging data sets. It is an expensive, inefficient and environmentally poor medium for transmission of diagnostic imaging, now that digital alternatives are available. With the move to digital radiology practice, film is not used routinely in the process of diagnostic imaging, hence the trend to delivery of images by digital methods on portable media, or by the internet. These changes in technology must however be managed to ensure that those affected have the opportunity to adapt, and that there is no adverse impact on patient healthcare or inconvenience for the other health practitioners involved in their care. Clearly this transition period cannot be open-ended, and a reasonable period for the management of change will be agreed to through consultation.

Digital images offer a superior solution for complex imaging data sets, and broader benefits include timeliness of delivery, availability, comparison, ease of transport, and handling. Many practitioners are showing a preference for digital delivery of multi-slice or volumetric images, however the view of several professional societies is that digital plain x-rays are currently better delivered on film, as adequate equipment and software support for templating are not yet widely available. A useful change management strategy for those imaging practices wishing to provide images on portable media (such as CDs) would be to focus on digital delivery of cross-sectional imaging initially, with or without film copies, as required by the referrer.

Regardless of how the image set is delivered, it must be of high quality and specific attention is required to provide:

- documentation or display of magnification (so-called “true size”)
- location or scout views where multi-slice images are provided
- documentation of any image compression used
- indication as to which images are of diagnostic quality, as this is not always apparent to the end user

Imaging services often assess the media requirements of the referring doctor, and may assess whether a downstream referral to a particular specialist type is likely from the referral notes or assessment of image findings. This may result in provision of specific views and image media required for patient care, however, given that the pathway of images cannot be reasonably predicted in all cases, subsequent requests for reproduction of images in digital or film formats may be received from treating doctors. Consequently the practices of routinely requesting or performing investigations where the reason for referral is “unsuitable image format”, without other clinical need, are to be strongly discouraged, as they constitute doubtful ethical practice (as it involves avoidable radiation exposure), and are likely to be in breach of Medicare regulations (if a rebate is requested).

While it can be difficult to define a diagnostic quality image in all situations, a reasonable guide is an image set that is comparable in quality and media presentation to that used by the radiologist in reporting on the examination. For film this means a 100% scale image with sufficient images to cover the intent of the request. For digital imaging, the full DICOM dataset should be provided. Illustrative image sets (which may be in compressed/non diagnostic formats such as JPEG) are useful adjuncts to provide easily accessible images to support a more user friendly interface for some practitioners, and for consumer education. Such illustrative (non diagnostic) image sets could provide key images or a reduced study set based on image reconstructions at conventional thickness (as would have been used for rendering cross sectional studies on film). Many practices are also adopting the useful practice of providing illustrative and/or key image prints on paper which further supports consumer education by referrers.

❖ **Electronic transmission of images and a radiologist medical opinion:**

Where the radiologist medical opinion and image are delivered electronically by portable media, on-line or other means, appropriate Australian implementations of international standards and profiles will be used to enable the efficient and reliable receipt and interpretation of these images.

Compliance with standards is essential to enable image viewing systems to reliably decode and render diagnostic quality images. One practitioner and their local information system may be expected to process images sourced from multiple different imaging services, which in turn will be using many different implementations of a range of imaging hardware and software.

Standards Australia (www.standards.org.au) describes the local implementation of HL7 version 2 messaging, covering electronic referral and requests, and the

acknowledgement messages (indicating both receipt of the message, as well as processing by the receiving system). Adherence to these standards can be required in purchasing specifications and should be verified by reference to a vendor conformance statement supported by testing at the Australian Healthcare Message Laboratory (AHML) or IHE Australia connectathon.

For images on portable media (such as CDs, DVDs or USB drives) the requirements for diagnostic quality imaging are described in the Integrating the Healthcare Enterprise (IHE - www.ihe.net) Portable Data for Imaging (PDI) profile, as localised for use in Australia by reference to RANZCR/ADIA technical experts. Cardiology image management has a specific set of IHE standards and profiles. Radiology services should ensure that their IT vendor has a current IHE compliance statement, and that they have their practice media such as CDs tested for compliance annually as problems do occur at the local implementation level and after software upgrades. Portable media will be adequately labelled, provided with printed and electronic user instructions, and packaged to support appropriate care of the media, and inclusion of other materials such as radiologist medical opinions, sample film or paper printouts. Details of these requirements will be included in the RANZCR Standards of Practice V9, due to be published by June 2008.

The data provided electronically with the report, should enable referring or treating practitioners to view the images at the same level of quality as occurred during the radiologist reporting process, and to support the use of post-processing such as templating and reconstructions.

❖ **Viewing of digital images:**

In order to view diagnostic quality images electronically, referrers and treating practitioners will require computer systems of suitable specification, and will need experience in using digital images. The workflow and patient management may also need to be adjusted to ensure that the images are available to the treating clinician where and when required.

The RANZCR and ADIA will work collaboratively with health professionals and other stakeholders to understand clinician requirements, and provide appropriate technical guidance on issues such as monitors for image display. As an initial guide, a monitor used for display of CT and MRI images needs to be of 300 cd/m² luminescence and 768x1024 resolution (without Grey Scale Calibration). High quality 2 mega-pixel monitors (1200x1600) are now available for business use, and may be suitable for display of plain x-ray images. Higher quality, higher resolution monitors are needed for specialised reporting such as digital mammography. Grey scale calibration, and use of appropriate IHE profiles, will support consistent display of images, and is recommended for systems and monitors used regularly for diagnostic purposes.

Practitioners who regularly use images for diagnosis or planning of treatment are advised to acquire their own DICOM image display software. DICOM viewers provided on media by radiology practices are not often certified by the manufacturer for diagnostic purposes, as the manufacturer cannot vouch for the quality of monitors being used with the viewer. These proprietary embedded viewers do not have a consistent user interface, which creates usability and safety issues for referrers, due to the difficulty of potentially maintaining familiarity with 10-15 different viewers.

The radiology profession is encouraged to work with technical experts from the procedural specialities to provide guidance on functional requirements and identification of products which may be suitable for a specific specialist group. The IT industry is encouraged to provide suitable products at an affordable price to medical practitioners to support image viewing and post-processing. There are a range of excellent freeware or commercial software products which can be downloaded and installed on appropriate hardware for those who wish to create their own solutions. Therapeutic Goods Administration (TGA) listing (Class 1B) is required for a combination of hardware and software used for making measurements from diagnostic images (whether purchased as a commercial product, or constructed locally from hardware and software components).

Practitioners who wish to view images for education or illustrative (non-diagnostic) purposes are encouraged to use their web browser to view standard (non-DICOM) image formats, or alternatively to use the embedded viewer (if they wish to cope with the complexity of this interface). Paper print-outs of images can be very helpful for education or illustrative purposes, however are not suitable for diagnostic use.

Images delivered on portable media, or over the internet (unless streaming technology is used) take a variable amount of time to load. For occasional use this may not be a problem, however when electronic images are used regularly, this time lag is usually unacceptable. One solution is to pre-load the images while the patient is in the waiting room, and the images can then be accessed from the computer disk storage. Alternatively, images can be pre-loaded by the practitioner early in the consultation, and prior to the point of the consultation where images need to be reviewed. Loading time is longest with CDs and DVDs (depending on how much data is required) and is less with solid state drives, such as USB or SD cards, however the latter are not yet widely used for this purpose, and may not be practical for general use for some time to come.

❖ **Digital Image Storage**

<p>Consensus with both referrer and provider craft groups regarding the length of time and content of the data archived needs to be developed during this transition period. Opinions in relation to image archive retention range from 6 months to 2 years depending on the nature of the examination and the needs of the patient. Formal consensus on archive retention will need to be reached but in the meantime imaging providers may need to establish a 6 month archiving period for all examinations, and referrers may need to advise imaging providers of any additional requirements.</p>
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The practice of storing only the radiologist medical opinion with or without illustrative images (on media, or film/paper printout) is not supported as good practice and also conflicts with other parts of this principles document.

There are well known situations in both radiology and specialist practice where review of prior images is a key element of the diagnostic process. The issue of image storage is profoundly affected by the technological changes with digital imaging. User requirements and imaging practice capacity needs to be further clarified. Portable media are currently used for long term storage by some practices that have not yet migrated to the use of image archives. These media are potentially subject to being misplaced or damaged. Good practice in the IT industry would not support the practice of archiving critical data onto a portable media format as the only storage method during the period where the image is needed for immediate patient management. Standards and legal requirements

vary considerably with different locations, diagnostic imaging settings, and patient specific factors. Where images are archived to portable media this should be reflected by appropriate media storage, labelling and instructions. The time period of 18 months has been identified as being consistent with the minimum retention period for radiologist medical opinions for Medicare purposes but this will need to be revised after further consultation with all parties.

❖ **Next Steps:**

The technology for creating and managing digital images is evolving and it is recognised that CDs and portable media are most likely a step in the direction of a standards based web access service, providing open access to images for radiologists and treating doctors with patient consent.

This document will be offered to appropriate specialist colleges and organisations for discussion and revision prior to being adopted jointly with the RANZCR and ADIA and updated as required to address evolving issues and changes in practice. The principles will be reviewed in 2 years (May 2010), particularly with regard to the requirement for ongoing delivery of images by film by request. A reasonable period for implementation of specific elements of the principles will be agreed and appended to the final version.