

Annalise Enterprise

Administration Guide

English

Annalise Enterprise

OPT-PRM-028 v7

This guide is applicable to:

Component	Release
Annalise Enterprise	3.7 which includes: • Annalise Viewer version 3.5 • Annalise Backend version 3.7 • Annalise Integration Adapter version 3.7
Annalise Web Viewer	1.1

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Overview

Introduction

This document provides an overview of the Annalise Enterprise product, including component requirements, supported capabilities, available customisations and configuration backup and security details.

It also shows you how to install and configure the Annalise Viewer and configure your PACS to interface with the Annalise Enterprise product.

Who

This document is for IT administrators and support staff only. It is not intended to be used by clinical users.

For the clinical use of this product, please refer to the *Annalise Enterprise User Guide.*

Intended purpose

Annalise Enterprise is a medical device intended to assist clinicians with the interpretation of radiological imaging studies and provide notification of suspected findings.

Indications for use

Annalise Enterprise identifies suspected findings in:

- digitised (CR) or digital (DX) chest X-ray studies taken in the anterior-posterior (AP) or posterior-anterior (PA) and optionally lateral (LAT) orientations of adult patients
- non-contrast brain CT scans (brain kernel) of adult patients

For chest X-ray (CXR), the device improves the detection of radiological findings visible on chest X-rays. For CT Brain (CTB), the device improves the detection of radiological findings visible on non-contrast CT brain scans.

The device identifies 124 CXR findings and 130 CTB findings (as defined in the *Annalise Enterprise User Guide).*

The device is used on a PC workstation in conjunction with a medical imaging viewer (i.e. PACS).

The device may also be configured to provide input to worklist software to assist with notification and triaging. The device identifies studies with selected findings and communicates these studies to the worklist software which enables triaging of the worklist and notification.

Contraindications

The device:

- is not intended to provide direct diagnosis
- is not to be used on patients under the age of 16 for CXR and under the age of 18 years for CTB
- does not enable an increase in the clinician's scope of practice



WARNING

Qualified clinicians who interpret chest X-rays and/or brain CT scans as part of their scope of practice hold ultimate responsibility for interpreting studies.

The clinician must review the Annalise Enterprise output concurrently with the original chest X-ray images or brain CT scans and all other relevant clinical information before making a clinical decision.

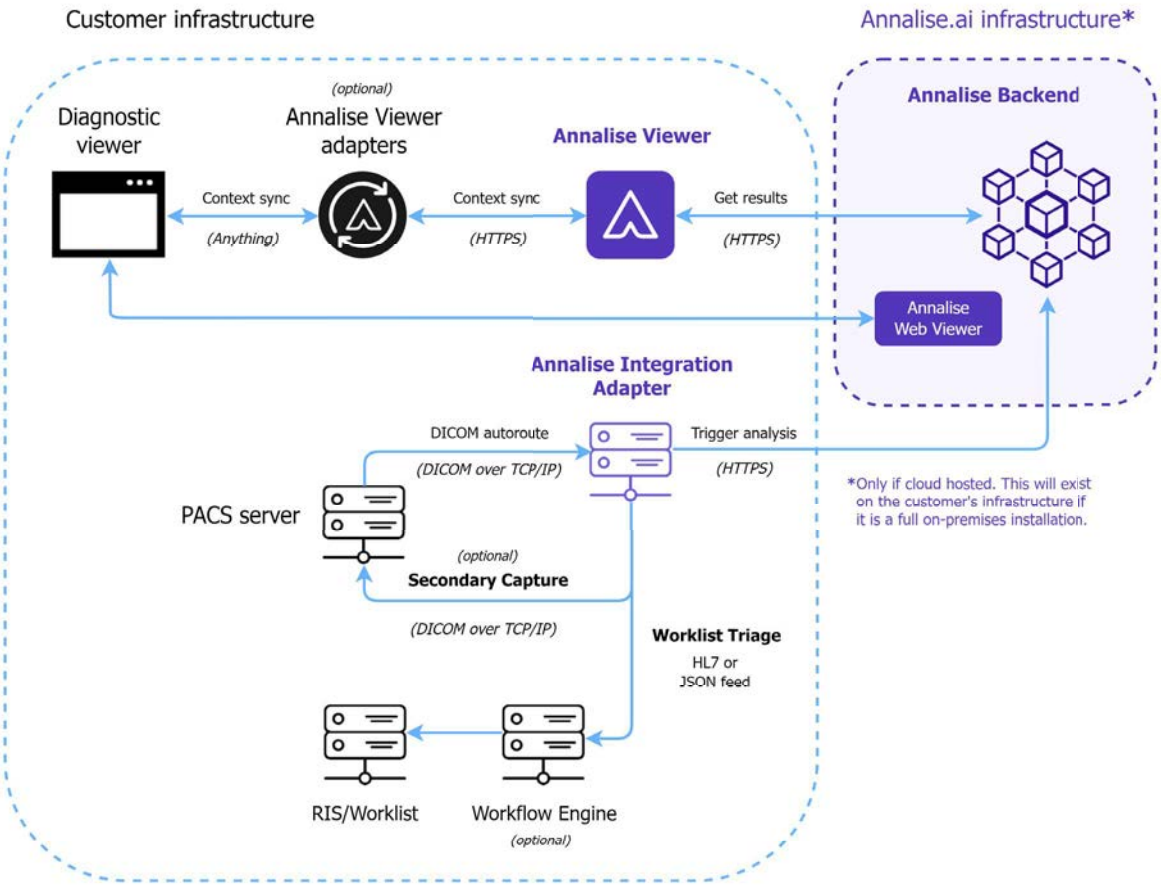
Annalise Enterprise overview

Annalise Enterprise

Annalise Enterprise contains the following three sub-systems:

- Annalise Viewer
- Annalise Integration Adapter
- Annalise Backend

Annalise Web Viewer is an optional accessory.



Annalise Viewer

The Annalise Viewer is a desktop application that receives details about a patient's study from the PACS viewer then retrieves the study's results from the Annalise Backend.

The Annalise Viewer displays the AI results in its own window, enabling the user to review the study's suspected findings and localisation alongside the study's original images.

The Annalise Viewer application is installed on each workstation on the customer's network.

continued

Annalise Web Viewer

The Annalise Web Viewer displays the AI results of adult chest X-ray studies and non-contrast CT brain studies (including findings and localisation information).

The viewer is accessed via an internet browser and includes CXR and CTB modules.

Annalise Integration Adapter

The Annalise Integration Adapter receives images from the PACS server and converts the images and metadata into the appropriate format.

It then sends a trigger to the Backend API services to request AI processing.

The Annalise Integration Adapter can be configured to:

- send information to a worklist software (such as a RIS) to request a change in the study's priority in the worklist
- send AI results in the form of a Secondary Capture DICOM series to the PACS server

The worklist triage output can also be used in other products and/or modules to provide information for the intended users, as specified in the Annalise Enterprise findings list.

The Annalise Integration Adapter also:

- provides a stable interface between the PACS and RIS within the customer's network
- encrypts all data moving between the Annalise Integration Adapter and the Annalise Backend
- acts as a buffer with the Annalise Backend in the event of network outages

Annalise Backend

The Annalise Backend filters images, performs AI processing and stores results. It includes both Backend API services and the AI model.

The Backend API is responsible for performing the business logic of Annalise Enterprise. It manages:

- security for incoming requests from the Annalise Integration Adapter and the Annalise Viewer
- the storage of images and results (including periodic deletion of data as required by the customer)
- requests and responses from the AI Model, Annalise Viewer and Annalise Integration Adapter

The AI model includes AI algorithms (convolutional neural networks) and image pre-processing and post-processing modules. It processes a study's X-ray or CT images and generates suspected radiological findings and localisation information for that study.

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Annalise product compatibility

Annalise Enterprise Backend Services compatibility is as follows:

Release	Component	Version
v3.7	Annalise Integration Adapter	3.7,3.6, 3.4, 3.3, 3.2, 3.1
	Annalise Viewer	3.5, 3.4, 3.2, 3.1
	Annalise Web Viewer	1.1, 1.0

Supported capabilities

The following tables outline the supported DICOM capabilities of Annalise Enterprise.

These include:

- inputs that can be received by Annalise Enterprise, and
- outputs that are available from Annalise Enterprise.

Inputs received by Annalise Enterprise

Supported inputs	Details
Supported body part imaging	• **CXR**: Chest X-ray • **CTB**: Non-contrast brain CT scan
Supported scan types	**CXR**: • minimum one frontal (AP/PA) required for processing • up to three images in total • lateral (LAT) is also supported Note: If a study contains more than three chest X-ray images, the AI model will select a combination of the best three frontal/lateral images. **CTB**: • axial (coronal and sagittal views are generated by the axial view) • slice thickness up to and including 1.5mm • non-contrast CT brain scans • brain reconstruction kernel • up to 1,000 images

continued

<table>
<tr><th>Supported inputs</th><th>Details</th></tr>
<tr><td>Supported DICOM SOP class</td><td>CXR:
Computed Radiography (CR) – 1.2.840.10008.5.1.4.1.1.1
Digital Radiography (DX) – 1.2.840.10008.5.14.1.1.1.1
CTB:
CT Image Storage – 1.2.840.10008.5.1.4.1.1.2
Enhanced CT Image Storage – 1.2.840.10008.5.1.4.1.1.2.1
Legacy Converted Enhanced CT Image Storage – 1.2.840.10008.5.1.4.1.1.2.2</td></tr>
<tr><td>Supported DICOM transfer syntaxes</td><td>The following DICOM transfer syntaxes are supported:<table>
<tr><th>Image format</th><th>8 bit</th><th>16 bit</th></tr>
<tr><td>JPEG 2000 image (lossy) 1.2.840.10008.1.2.4.91</td><td>CXR</td><td>CXR</td></tr>
<tr><td>JPEG 2000 image (lossless) 1.2.840.10008.1.2.4.90</td><td>CXR</td><td>CXR, CTB</td></tr>
<tr><td>Raw uncompressed image (Implicit VR Endian) 1.2.840.10008.1.2</td><td>CXR</td><td>CXR, CTB</td></tr>
<tr><td>Raw uncompressed image (Explicit VR Little Endian) 1.2.840.10008.1.2.1</td><td>CXR</td><td>CXR, CTB</td></tr>
<tr><td>Raw uncompressed image (Explicit VR Big Endian) 1.2.840.10008.1.2.2</td><td>CXR</td><td>CXR, CTB</td></tr>
<tr><td>JPEG lossless, non-hierarchical (Processes 14) 1.2.840.10008.1.2.4.57</td><td>CXR</td><td>CXR, CTB</td></tr>
<tr><td>JPEG lossless, non-hierarchical, first-order prediction (Processes 14 [Selection Value 1]) 1.2.840.10008.1.2.4.70</td><td>CXR</td><td>CXR, CTB</td></tr>
</table></td></tr>
</table>

Outputs available from Annalise Enterprise

Supported outputs	Details
Supported modalities	**Annalise Viewer**: • CXR • CTB **Worklist Triage:** • CXR • CTB **Secondary Capture** • CXR **Annalise Web Viewer**: • CXR • CTB
Supported output formats	**Annalise Viewer** Desktop application installed on a workstation (used in conjunction with the PACS). **Worklist Triage** Priority message forwarded to reporting worklist software (such as a RIS). Available in the following formats: • JSON • HL7 **Secondary Capture** DICOM series: Secondary Capture Image Storage – 1.2.840.10008.5.1.4.1.1.7 **Web Viewer** Web application accessed via a web browser.
Supported DICOM transfer syntaxes	**Secondary Capture** The following DICOM transfer syntaxes are supported (8 bit only): • Raw uncompressed image (Implicit VR Endian) 1.2.840.10008.1.2 • Raw uncompressed image (Explicit VR Little Endian) 1.2.840.10008.1.2.1 • JPEG Baseline (Process 1) 1.2.840.10008.1.2.4.50

Available customisations

Annalise Enterprise and Annalise Web Viewer support multiple configurations that enable your organisation to tailor the application to your specific needs.

As part of the deployment and on-boarding process, Annalise.ai will manage all product configuration in consultation with your IT/infrastructure team.

The following customisations are available:

Configuration item	Variables/controls
Finding visibility	Enable/disable individual findings.
Finding groups	Configure up to eight finding groups.
Allocation of findings to groups	Allocate each finding to defined groups.
Finding order	Select the order in which each finding will appear in the Annalise Viewer and Annalise Web Viewer. Note: By default, the findings display in order of clinical severity (as determined by Annalise.ai expert radiologists), but this order can be configured to meet your requirements.
Finding sensitivity/specificity	Configure sensitivity/specificity for specific findings.
Available languages	The Annalise Viewer supports multiple languages. Note: Additional languages are available on request.
Analytics	Annalise Viewer sends tracking data to our privately hosted server to improve your experience. This feature is optional.
Data retention period	Enable/disable the period for which you want data to be stored in the Annalise Backend.
Worklist Triage	The Worklist Triage can be integrated via HL7 or an API. Depending on the columns available in the worklist, a study's AI priority in the worklist can be displayed in either: • **a single 'Priority' column** Annalise Enterprise will only triage findings with the highest rank. This ensures that it will never decrease a study's existing priority in the worklist. • **a dedicated 'AI priority' column** Annalise Enterprise can triage findings with all ranks in the dedicated AI priority column. This ensures that existing priorities are not changed. The triage priority levels can be configured to suit the worklist configuration.

continued

Configuration item	Variables/controls
Workflow Engine	If implemented into your infrastructure, a message containing both the results and associated priority information will be sent from the Annalise Integration Adapter to the Workflow Engine once the study has been analysed. The priority message may then be forwarded to reporting worklist software (such as a RIS) in the appropriate format.
Annalise Secondary Capture (CXR AI results only)	Enable/disable output of AI results in Secondary Capture DICOM format to a configured PACS destination. Note: This feature may not be available in all regions.
Annalise Web Viewer Results List (AI Findings column)	Your organisation can request to configure the following details in the Web Viewer Results List: • priority group names • priority group order • adding another priority group (there are three default groups), and/or • determining the findings allocated to each group.

For further information or configuration requests, contact the Annalise.ai Professional Services Team.

Configuration backup/restoration of the product

Your IT/infrastructure team will be expected to make regular VM (virtual machine) snapshots to back up the product.

Note: Annalise.ai is not responsible for performing or testing backups, nor do they support any other backup mechanism.

continued

Security and confidentiality

Annalise Enterprise includes security features which protect against unauthorised access and data modification.

These features ensure the secure authentication and encryption of sensitive data when transmitted between:

- the Annalise Integration Adapter and the Annalise Backend
- the Annalise Viewer and the Annalise Backend
- the Annalise Web Viewer and the Annalise Backend
- the PACS Image Viewer and the Annalise Viewer (available only when using the HTTPS interface)

It also includes the encryption of sensitive data stored in the Annalise Backend.

Note: Annalise.ai recommends that you use the most recent version of the Annalise Enterprise product to access the latest features and security improvements.

Multi-tenant backend design

The Annalise product uses a multi-tenant backend design which separates data from different organisations via different organisational accounts.

Users must therefore have the appropriate credentials to access an organisation's internal data.

Annalise Integration Adapter Requirements

Overview

This section outlines the requirements for the installation of the Annalise Integration Adapter.

For further information, see *Annalise Integration Adapter* on page 8.

System requirements

The following components are required to host the Annalise Integration Adapter on your network:

Component	Requirements	
Operating system	Linux (Ubuntu 20.04 LTS) VM image – provided as VMware EXSi or Azure image by Annalise.ai as part of the installation process.	
Hardware *CXR studies only*		**Recommended**
	CPU cores	8 at ~2.2 GHz
	RAM	24 GB
	Storage	SSD for optimal performance: • Disk 1: 100 GB • Disk 2: 100 GB minimum*
CXR and CTB studies		**Recommended**
	CPU cores	16 at ~2.2 GHz Supports AVX, FMA and SSE4.2 instruction sets
	RAM	32 GB
	Storage	SSD for optimal performance: • Disk 1: 100 GB • Disk 2: 100-900 GB minimum*
Internet connection		**Recommended**
	CXR	6 Mbps uplink (cloud-deployed) *Typically supports 3 CXR studies per minute*
	CTB	25 Mbps uplink (cloud-deployed) *Typically supports 3 CTB studies per minute*
Annalise Backend hosted in the cloud	Requires an outbound internet connection via port 443.	

*Storage requirements depend on the number of studies sent per hour and values are based on estimates. Contact the Annalise.ai Professional Services Team if you require amendments to your existing storage specifications.

Annalise Backend Requirements

Overview

The Annalise Backend is hosted on either:

- your network ('on-premises' installation), or
- Annalise.ai's cloud infrastructure.

If you want the Annalise Backend hosted on your network, refer to the system requirements below.

System requirements (on-premises)

The following components are required to host the Annalise Backend on your network ('on-premises').

Component	Requirements
Operating system	Linux (Ubuntu 20.04 LTS) VM image – provided as VMware EXSi image by Annalise.ai as part of the installation process.
Hardware	Contact the Annalise.ai Professional Services Team for details.

System configuration (cloud)

The Annalise Backend can be hosted on Annalise.ai's cloud infrastructure.

To use this infrastructure, you will need to provide the outbound internet IP ranges for each workstation that uses the Annalise Viewer.

The Annalise.ai Professional Services Team will add these details to the Annalise Backend IP allow-list.

Annalise Viewer Requirements

Overview

This section outlines the requirements for the installation of the Annalise Viewer.

For further information, see *Annalise Viewer* on page 7.

System requirements

The following components are required to install the Annalise Viewer:

Component	Requirements
Workstation	The following must be installed and run on your workstation: • 1 GB RAM • 500 MB storage
Operating systems	The following operating systems are supported: • Windows 10 (64-bit) • Windows 11 (64-bit) • MacOS 10.15 (64-bit)
Other	Check the following: • ensure that the nominated network port is not in use on the workstation • if the Annalise Backend is hosted in the cloud, allow outbound HTTPS connection on port 443 to *.annaliseai.io • ensure that the workstation CPU supports the SSE3 instruction set • a PDF reader is required to view the supporting documentation (including the *User Guide*)

Installation and configuration

The Annalise.ai Professional Services Team will work with your IT/infrastructure team to help you install the Annalise Viewer on your required workstations.

Troubleshooting

See *Problems and solutions* on page 32.

Annalise Web Viewer Requirements

Overview	This section outlines the requirements for the installation of the Annalise Web Viewer. For further information, see *Annalise Web Viewer* on page 8.
System requirements	To access Annalise Web Viewer, use a Chrome web browser to open the URL or IP address provided by Annalise.ai during deployment.
Installation and configuration	The Annalise.ai Professional Services Team will work with your IT/infrastructure team to help you install and configure the Annalise Web Viewer.

Install and configure Annalise Viewer

Overview

This section shows you how to install and configure the Annalise Viewer.

You will need to complete the following on each workstation:

- install the Annalise Viewer
- enable Single Sign-On (SSO) via Azure Active Directory (if required)
- install a PDF reader
- configure and test your organisation's credentials

Install Annalise Viewer

Follow these steps to install the Annalise Viewer on each relevant workstation.

You can install the Annalise Viewer via either:

- the user interface, or
- Windows command line or deployment tool.

Before installing, check that you are using the installation file provided by Annalise.ai.

Install via user interface

Follow these steps to install the Annalise Viewer via the user interface.

Note: Annalise.ai will provide the installer file.

1. Double-click the installer file and either:
   - select the installation path required for the PACS/RIS integration, or
   - use the default path C:\Program Files\Annalise.

   See *Configure PACS interface with Annalise Viewer* on page 24.
2. Click **Next** to progress through the installation options until the *Installation Complete* window displays.
3. Determine whether the organisation requires SSO.

If SSO is required	• go to step 4
If SSO is **not** required	• on the *Installation Complete* window, click **Close** • go to step 5

continued

4. On the *Installation Complete* window, click to select **Use SSO login** then enter the following details:

Field	Requirements
Annalise Server URL	The server URL to which the Viewer will connect. This will be provided by Annalise.ai.
App ID	The Application ID created by Azure Active Directory. See *Annalise Viewer: Configure SSO via Azure Active Directory* on page 29.
Tenant ID	The Tenant ID created by Azure Active Directory. See *Annalise Viewer: Configure SSO via Azure Active Directory* on page 29.
OpenId URL	The Open ID URL for your Azure Active Directory (normally *https://login.microsoftonline.com).* Note: There are no trailing slashes after this URL.

5. Once you have finished the installation, check that the Annalise Viewer opens from the shortcut.

   Note: If you have any issues, contact the Annalise.ai Professional Services Team.

Install via Windows command line or deployment tool

Follow these steps to install the Annalise Viewer using the Windows command line or a deployment tool.

1. Change the directory to the folder that contains the installer.
2. Check that the filename matches the version provided by Annalise.ai.
3. Type the following command then replace the angle brackets (<>) and their contents with the credentials provided by Annalise.ai:

   "<Annalise filename 3.x.y.z.exe>" /S /allusers

   Note: The installer version number changes each version.

4. Once you have finished the installation, check that the Annalise Viewer opens from the shortcut.

   Note: If you have any issues, contact the Annalise.ai Professional Services Team.

continued

5. Determine whether the organisation requires SSO and/or the network port needs configuration.

If SSO and/or port configuration is required	• go to step 6
If **neither** is required	• go to step 7

6. Run the script for the relevant operating system using the following command (refer to the table over the page for details).

   Note: All setup details will be provided by Annalise.ai.

Windows

Requirements	Script
SSO only	./SetupConfigurations.ps1 -AppId "<appId>" -TenantId "<tenantId>" -AnnaliseApiUrl "<annaliseApiUrl>" -OpenIdUrl "<openIdUrl> -portNumber "<portNumber>"
Port configuration only	./SetupConfigurations.ps1 -portNumber "<portNumber>"
Both SSO and port configuration	./SetupConfigurations.ps1 -AppId "<appId>" -TenantId "<tenantId>" -AnnaliseApiUrl “<annaliseApiUrl>” -OpenIdUrl “<openIdUrl> -portNumber "<portNumber>"

Mac

Requirements	Script
SSO only	sh setupConfigurations.sh appId="<appId>" -tenantId="<tenantId>" -annaliseApiUrl =”<annaliseApiUrl>” -openIdUrl=”<openIdUrl> -portNumber="<portNumber>"
Port configuration only	sh setupConfigurations.sh portNumber="<portNumber>"
Both SSO and port configuration	sh setupConfigurations.sh appId="<appId>" -tenantId="<tenantId>" -annaliseApiUrl ="<annaliseApiUrl>" -openIdUrl="<openIdUrl>

If the script cannot be run, move a .JSON file containing these parameters into either:

- Windows: C:\ProgramData\Annalise, OR
- Mac: /User/Library/Application Support/Annalise.

Contact Annalise.ai to request a pre-made JSON file.

Field	Requirements
Annalise API URL	The server URL to which the Viewer will connect. This will be provided by Annalise.ai.
App ID	The Application ID created by Azure Active Directory. See *Annalise Viewer: Configure SSO via Azure Active Directory* on page 29.
Tenant ID	The Tenant ID created by Azure Active Directory. See *Annalise Viewer: Configure SSO via Azure Active Directory* on page 29.
OpenId URL	The Open ID URL for your SSO service (normally *https://login.microsoftonline.com).* Note: There are no trailing slashes after this URL.
Port Number	The network port used to call HTTPS requests to the Annalise Viewer. If undefined, the port is 8989. The allowable range is 1024-65535.

8. Once you have finished the installation, check that the Annalise Viewer opens from the shortcut.

   Note: If you have any issues, contact the Annalise.ai Professional Services Team.

Install PDF reader

To enable users to view supporting documentation (including the *User Guide)*:

- install a PDF reader on each relevant workstation
- ensure that the PDF reader is configured as the default application for files with a '.pdf' extension

Configure and test organisation credentials

To ensure system security, Annalise Enterprise uses organisation-level credentials to authenticate both the Annalise Viewer and Annalise Backend.

This applies to log in via Windows Credential Manager only.

The Annalise.ai Professional Services Team will provide both the credentials and the Annalise Backend Server URL during product installation and configuration.

You can either:

- enter these details manually in the application, or
- add this information remotely via a distribution tool.

Note: Ensure that you store the organisation ID and password securely.

Manual configuration

If the Annalise Viewer has not been configured for the user, the *Server Settings* screen will display automatically, prompting you to enter the relevant details.

1. On the *Server Settings* page, type the following:
   - **Organisation ID**
   - **Organisation Password**
   - **Annalise Server URL**
2. Click **Test** to check the settings.

If '*Connected*' displays	The application is ready for testing.
If an error message displays	Check that: • you have entered the correct **Organisation ID**, **Organisation Password** and **Annalise Server URL** • the computer can access the URL: - check that the computer has network connectivity - check whether firewall permissions allow access Note: If you have any issues, contact the Annalise.ai Professional Services Team.

3. Once you have connected successfully, click **Save**.

Configure PACS

Overview

This section explains how to:

- configure the interface between:
  - your PACS and the Annalise Viewer
  - your PACS and the Annalise Integration Adapter, and
- integrate the Annalise Viewer with the Sectra Workstation IDS7.

The Annalise.ai Professional Services Team will give you the information required to liaise with your PACS vendor to integrate these components.

Note: Annalise Enterprise is compatible with any PACS/RIS that conforms with the *Annalise Enterprise HL7 and DICOM Specification*. Contact the Annalise.ai Professional Services Team if you require a copy of this document.

Configure PACS interface with Annalise Viewer

As the Annalise Viewer is intended to be used in conjunction with a PACS viewer, an interface must be established between the Annalise Viewer and either your PACS or RIS.

Depending on the functionality supported by your PACS/RIS, the Annalise Viewer can be configured to:

- automatically launch via the PACS/RIS
- automatically display AI findings after loading a study in the PACS viewer
- display AI findings for a study requested by the PACS viewer (i.e. display a manual synchronise button in the PACS)
- stop showing AI findings after closing a study in the PACS viewer
- quit when requested by the PACS/RIS

The Annalise Viewer supports requests via an HTTPS API (POST or GET) or via a command line interface.

Many PACS and RIS support integration with third-party applications via one of these interfaces. The commands and syntax are specified in the *Annalise Viewer Open API Specifications* and are available on request.

Configure PACS interface with Annalise Integration Adapter

The following details must be set up for the Annalise Integration Adapter to interface with your PACS:

- an Application Entity (AE), and
- auto-routing rules.

If using Secondary Capture, you can also configure your PACS to receive the Secondary Capture series from the Annalise Integration Adapter.

Set up an Application Entity (AE)

Contact your PACS vendor (and/or refer to your PACS reference guide) to set up the Annalise Integration Adapter as an AE in your PACS.

1. Set up the Annalise Integration Adapter AE with the following:
   - the IP address or host name of the Annalise Integration Adapter for your infrastructure
   - a port where the Annalise Integration Adapter listens for DICOM messages

     The default port is '11112'
   - the AE title of the Annalise Integration Adapter

     The default title is 'ANNALISE-AI'
2. Perform a C-ECHO (ping) to the configured Annalise AE title to confirm that the connectivity test has been successful.

Set up auto-routing rules

Refer to your PACS reference guide to set up auto-routing rules to the Annalise Integration Adapter.

Apply your own conventions to these rules. Any rules provided in this document are to be used as a guide only.

1. Configure the rules to forward all studies from the relevant locations to the configured Annalise AE.

   Use the following DICOM tags:
   - Modality (0008,0060)
   - StudyDescription (0008,1030)
   - BodyPart (0018,0015)

continued

For example:

CXR:

- Modality = ‘CR’ AND StudyDescription contains ‘CHEST’
- Modality = ‘DX’ AND StudyDescription contains ‘CHEST’
- Modality = ‘CR’ AND BodyPart contains ‘CHEST’
- Modality = ‘DX’ AND BodyPart contains ‘CHEST’

CTB:

- Modality = ‘CT’ AND Study Description contains ‘STROKE’
- Modality = ‘CT’ AND Study Description contains ‘BRAIN’
- Modality = ‘CT’ AND Study Description contains ‘HEAD’
- Modality = ‘CT’ AND Body Part Examined contains ‘STROKE’
- Modality = ‘CT’ AND Body Part Examined contains ‘BRAIN’
- Modality = ‘CT’ AND Body Part Examined contains ‘HEAD’

Configure Secondary Capture (optional)

A Secondary Capture series is generated by Annalise Enterprise and is presented as AI prediction results. The series contains the same study-level identifiers as the originating images.

The series is intended to be stored in your PACS and be viewable alongside the source images in a DICOM viewer.

The PACS server must be able to receive the Secondary Capture Image Storage SOP class with the appropriate transfer syntax from the Annalise Integration Adapter.

Follow these steps to configure your PACS to receive the Secondary Capture series from the Annalise Integration Adapter.

1. Set up the Annalise Integration Adapter AE in your PACS.

   See *Supported capabilities* on page 9.

2. Annalise requires specific details about your PACS (which must be suitable for receiving C-STORE messages).

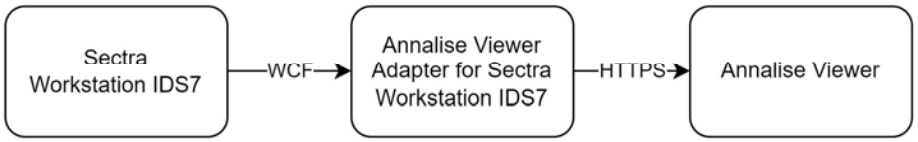
   Provide the following to Annalise:

   - the IP address or host name of the PACS server
   - a port where the PACS server can receive DICOM messages
   - the AE title of the PACS server
   - your required transfer syntax (see *Outputs available from Annalise Enterprise* on page 11)

   Note: The default preferred syntax is JPEG Baseline.

Integrate Annalise Viewer with Sectra Workstation IDS7

The Annalise Viewer Adapter for Sectra Workstation IDS7 (the 'Adapter') is a background application which provides an interface between the Sectra Context Manager and the Annalise Viewer's Open API interface.



To integrate the Annalise Viewer with the Sectra Workstation IDS7, you will need to:

- install the Adapter on each workstation, and
- configure the Sectra IDS7 third-party interface.

Install Adapter

The Annalise.ai Professional Services Team will provide you with the Adapter via a Windows installer. This enables you to perform the installation via a graphical user interface (GUI) or a Windows command line interface (CLI).

Once you have completed the installation, the Adapter will automatically launch each time the user logs on to the workstation.

1. Install the Adapter on each workstation (either per user or system-wide).

   For a silent install, use the following list of CLI commands:

Operation	CLI command
System-wide command	msiexec.exe /i AnnaliseViewerSectraAdapterInstaller.msi WixAppFolder="WixPerMachineFolder" ALLUSERS=1 /qn
User-level install	msiexec.exe /i AnnaliseViewerSectraAdapterInstaller.msi WixAppFolder="WixPerUserFolder" INSTALLFOLDER="%LocalAppData%\ Apps\Annalise\Sectra Adapter" /qn
Uninstall	msiexec.exe /x AnnaliseViewerSectraAdapterInstaller.msi /q

continued

Configure Sectra Workstation IDS7

To configure the Sectra Workstation IDS7 for use with the Annalise Enterprise product, contact your Sectra support team.

Use the following configuration:

Operation	CLI command
Desktop sync	"Desktop sync enabled" = True "Single log on enabled" = True
External application startup	"Close external application" = Do not close "Close workstation" = Do not close "Multiply instance" = Use already running instance "Startup File" = Path for Annalise Viewer installation (i.e. Annalise.exe)
Third party application commands	Configure Sectra ID7 to use the command line interface (as defined in the Annalise Viewer Open API specification) to support the commands listed below: • when starting: Implement STUDY_OPEN request parameters • when changing patient: leave empty • when the user logs off: leave empty

Annalise Viewer: Configure SSO via Azure Active Directory

Overview

This section shows you how to configure Azure Active Directory settings to enable single sign-on (SSO) for the Annalise Viewer desktop application.

This includes:

- create a new app registration
- configure API permissions
- enable automatic log in to the Annalise Viewer

Create new app registration

Create a new app registration for Annalise Enterprise. This will enable you to allocate users or groups specifically for the Annalise Enterprise application.

Follow these steps to create a new registration.

1. Log into your Azure portal and go to **New registration**.
2. Type a name for the registration (for example, 'Annalise Enterprise').
3. Go to the **Redirect URI** field.

   Select 'Public client/native (mobile & desktop)' then add the following callback URL: *https://localhost:8989/auth/oauth/callback.*
4. Ensure that you provide the generated application and directory (tenant) ID during installation of the Annalise Viewer.

   See *Install and configure Annalise Viewer* on page 19.

Configure API permissions

Follow these steps to configure the API permissions.

1. In Azure Active Directory, go to the *API Permissions* page.
2. Check that the API permissions are set to 'User.Read'.

continued

Enable automatic log in to the Annalise Viewer

You can update conditional access settings to enable automatic log in to the Annalise Viewer.

The automatic login period depends on the session expiry time that you set in Azure Active Directory.

Follow these steps to enable automatic log in to the Annalise Viewer.

1. In Azure Active Directory, go to the *Security* page then navigate to the *Conditional Access Policies* section.
2. Under the *Session* options:
   - click to select **Persistent browser session**
   - in the **Persistent browser session** dropdown, select 'Always persistent'
3. Set the persistent session length to 'Always persistent'.
4. Save your changes.

Annalise Web Viewer: Configure authentication via Keycloak

Authentication via Keycloak	To enable user authentication, Annalise Web Viewer can be integrated with various authentication methods and configured through Keycloak. Note: Keycloak supports multiple authentication methods.
Configuration	The Annalise.ai Professional Services Team will work with your IT/infrastructure team to help you configure authentication via Keycloak.

Installation and configuration troubleshooting

Problems and solutions

If you have issues with the setup, installation or configuration of the Annalise Enterprise application, refer to the following tables:

- *Error codes: Annalise Viewer* on page 32
- *Error codes: Annalise Web Viewer* on page 36
- *Troubleshooting: Viewing AI findings* on page 38
- *Troubleshooting: PACS-viewer integration* on page 39
- *Troubleshooting: Secondary Capture* on page 40
- *Troubleshooting: Miscellaneous* on page 42

If you are unable to resolve the issue, contact the Annalise.ai Professional Services Team.

Error codes

The following tables list the error codes that may display for Annalise Enterprise and Annalise Web Viewer and outlines the actions required to resolve these errors.

Error codes: Annalise Viewer

No.	Issue	Solution
001	Invalid ID or password.	Try signing in again using a valid ID and password. For further assistance, contact the Annalise.ai Professional Services Team.
002	Unsupported Annalise Viewer version or licence.	Contact the Annalise.ai Professional Services Team and quote the error code.
003	Annalise servers are currently unavailable.	Contact the Annalise.ai Professional Services Team and quote the error code.
004	Annalise servers are currently offline.	Check your internet connection. If your internet connectivity is OK and the problem continues, contact the Annalise.ai Professional Services Team.
005	Either the study is not supported, or the study may not have reached the Annalise Enterprise Integration Adapter. If the study was recently performed, it may not have been forwarded to Annalise Enterprise.	If the problem continues, contact the Annalise.ai Professional Services Team.

continued

Error codes: Annalise Viewer (cont.)

No.	Issue	Solution
006	Annalise Enterprise only supports studies for patients who are: • 16 years or older (for CXR), or • 18 years or older (for CTB). Annalise Enterprise uses DICOM tags to determine age.	Contact the Annalise.ai Professional Services Team.
007 008	The study does not meet minimum requirements for AI processing: • Annalise Enterprise only supports studies containing chest X-rays or brain CT scans • the study must contain at least one PA or AP image or supported CT views (see *Supported scan types* on page 9) Annalise Enterprise includes an AI feature that determines whether: • the image is a chest X-ray or brain CT, and • if there is a PA or AP image or supported brain image. AI models have an error margin. On rare occasions, Annalise Enterprise will not recognise a chest X-ray or brain CT and this error will display.	For further details, contact the Annalise.ai Professional Services Team and quote the error code.
009 010 011	An unexpected error occurred while analysing the study.	Contact the Annalise.ai Professional Services Team and quote the error code.
014	Annalise servers are currently unavailable.	
015	The study cannot be requested from Annalise servers.	Follow these steps: 1. Restart both the diagnostic viewer and the Annalise Viewer. 2. Confirm that the configuration of the communication interface within the diagnostic viewer is correct. 3. Contact your diagnostic viewer provider for support.
016 020	The study cannot be requested from Annalise servers.	Restart the Annalise Viewer. If the problem persists, contact the Annalise.ai Professional Services Team.
021 022	An unexpected error occurred while analysing the study.	
023	Study exceeds the allowed number of images per CXR study.	Contact the Annalise.ai Professional Services Team.

continued

Error codes: Annalise Viewer (cont.)

No.	Issue	Solution
026	The study cannot be requested from Annalise servers.	Follow these steps: 1. Restart both the diagnostic viewer and the Annalise Viewer. 2. Confirm that the configuration of the communication interface within the diagnostic viewer is correct. 3. Contact your diagnostic viewer provider for support.
027	Cannot connect to your PACS as the port is already in use.	Contact the Annalise.ai Professional Services Team and quote the error code.
029 030	The study has not yet completed AI processing.	Wait for a few moments then try opening the study again. If the problem continues, contact the Annalise.ai Professional Services Team.
031	Unexpected error analysing study.	Contact the Annalise.ai Professional Services Team and quote the error code.
032 033 034 035 036 037 038 039 040 041 042 043 044 045 046 047 048 049 050 051	The study does not meet the minimum requirements for AI processing: • Annalise Enterprise only supports studies containing chest X-rays or brain CT scans • the study must contain at least one PA or AP image or supported CT views Annalise Enterprise includes an AI feature that determines whether: • the image is a chest X-ray or brain CT, and • if there is a PA or AP image or supported brain image. AI models have an error margin. On rare occasions, Annalise Enterprise will not recognise a chest X-ray or brain CT and this error will display.	For further details, contact the Annalise.ai Professional Services Team and quote the error code.
052	The application is currently undergoing maintenance (such as installing upgrades).	Once maintenance is complete, you will be able to use the application as normal.

continued

Error codes: Annalise Viewer (cont.)

No.	Issue	Solution
053	The study does not meet the minimum requirements for AI processing: • Annalise Enterprise only supports studies containing chest X-rays or brain CT scans • the study must contain at least one PA or AP image or supported CT views Annalise Enterprise includes an AI feature that determines whether: • the image is a chest X-ray or brain CT, and • if there is a PA or AP image or supported brain image. AI models have an error margin. On rare occasions, Annalise Enterprise will not recognise a chest X-ray or brain CT and this error will display.	For further details, contact the Annalise.ai Professional Services Team and quote the error code.
099	Unexpected error analysing study	Restart the Annalise Viewer. If the problem persists, contact the Annalise.ai Professional Services Team.

Error codes: Annalise Web Viewer

No.	Issue	Solution
J014	Annalise servers are currently unavailable.	Contact the Annalise.ai Professional Services Team and quote the error code.
J015	The study cannot be requested from Annalise servers.	Restart the Annalise Viewer. If the problem persists, contact the Annalise.ai Professional Services Team and quote the error code.
J016 J017	The study does not meet the minimum requirements for AI processing: • Annalise Enterprise only supports studies containing chest X-rays or brain CT scans • the study must contain at least one PA or AP image or supported CT views Annalise Enterprise includes an AI feature that determines whether: • the image is a chest X-ray or brain CT, and • if there is a PA or AP image or supported brain image. AI models have an error margin. On rare occasions, Annalise Enterprise will not recognise a chest X-ray or brain CT and this error will display.	For further details, contact the Annalise.ai Professional Services Team and quote the error code.
J018 J019 J020 J021 J022	Unexpected error analysing study.	Contact the Annalise.ai Professional Services Team and quote the error code.
J027	Annalise Enterprise only supports studies for patients who are: • 16 years or older (for CXR), or • 18 years or older (for CTB). Annalise Enterprise uses DICOM tags to determine age.	Contact the Annalise.ai Professional Services Team and quote the error code.
J028	Study exceeds the allowed number of images per CXR study.	Contact the Annalise.ai Professional Services Team and quote the error code.
J032 J098 J099	An unexpected error occurred while analysing the study	Contact the Annalise.ai Professional Services Team and quote the error code.

continued

Error codes: Annalise Web Viewer (cont.)

No.	Issue	Solution
J101 J102 J103 J104 J105 J106 J107 J108 J109 J110 J111 J112 J113 J114 J115 J116 J117 J118	The study does not meet the minimum requirements for AI processing: • Annalise Enterprise only supports studies containing chest X-rays or brain CT scans • the study must contain at least one PA or AP image or supported CT views Annalise Enterprise includes an AI feature that determines whether: • the image is a chest X-ray or brain CT, and • if there is a PA or AP image or supported brain image. AI models have an error margin. On rare occasions, Annalise Enterprise will not recognise a chest X-ray or brain CT and this error will display.	For further details, contact the Annalise.ai Professional Services Team and quote the error code.

Troubleshooting: Viewing AI findings

The following table lists potential issues related to viewing the AI findings and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
The following message displays when synchronising: '*No results available*'	The study has not been routed to the Annalise Integration Adapter.	1. Go to your PACS administration page. 2. Check that the auto routing criteria has been met for the relevant study. 3. Check that the image has been sent to the Annalise Integration Adapter through your PACS routing tools.
	The Annalise Integration Adapter has no connectivity to the Annalise Backend.	If you have confirmed that the study has been routed to the Annalise Integration Adapter and the '*No results available*' message still displays, check that there is connectivity between the Annalise Integration Adapter and the Annalise Backend.
Patient details are missing or a hyphen ('-') displays in place of the details. (Includes patient name, gender, age and date of birth).	The Annalise Viewer receives patient details from the PACS or RIS. If the interface is not configured to send all patient details to the Annalise Viewer (and the information is not available in the Annalise Backend) a hyphen ('-') displays in place of the details.	Ensure that the PACS/RIS integration has been configured and enabled according to the vendor's instructions. Note: Some PACS/RIS do not display all patient details on the interface.

Troubleshooting: PACS-viewer integration

The following table lists potential issues related to the PACS-viewer integration and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
Can't see the **Annalise** button or Annalise features in the PACS viewer	The Annalise feature is not enabled for the user currently logged into the PACS/RIS.	Contact the PACS/RIS Admin and request that Annalise be enabled for the user.
Annalise Viewer does not automatically launch when PACS viewer launches	The Annalise Viewer has not been installed on the path required by the PACS/RIS configuration.	Ensure that the install location matches the location configured in the PACS/RIS. Annalise.ai recommends: *C:/Program Files/Annalise/Annalise.exe*
Annalise Viewer does not respond when the user clicks the **Annalise** button in the PACS viewer	The Annalise configuration in the PACS/RIS is incorrect.	Ensure that the PACS/RIS integration has been configured and enabled according to the vendor's instructions. For further help, contact the Annalise.ai Professional Services Team.
	This feature may not be supported by the PACS/RIS.	Ensure that the PACS/RIS is configured as per the vendor's instructions.
AI findings still display after a study has been closed in the PACS viewer.	The Annalise configuration within the PACS/RIS is incorrect.	Ensure that the PACS/RIS integration has been configured and enabled according to the vendor's instructions. For further help, contact the Annalise.ai Professional Services Team.
AI findings still display after the PACS viewer has been closed or locked	This feature may not be supported by the PACS/RIS.	Ensure that the PACS/RIS is configured as per the vendor's instructions. The Annalise Viewer includes a timeout function which stops showing AI findings after a period of inactivity.
AI findings change unexpectedly	PACS viewer shortcut key is mapped incorrectly.	Ensure that any shortcut keys are configured correctly and not shared across multiple applications.
AI findings cease to display	Viewing multiple studies in different windows.	When moving between studies in multiple windows, the PACS viewer may send a request to the Annalise Viewer to display the current in-focus window.
	Annalise Viewer timeout is too short.	Increase the timeout period in the Annalise Viewer.

Troubleshooting: Secondary Capture

The following table lists potential issues related to Secondary Capture and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
There is no Secondary Capture series available	The study is still processing.	Wait a few moments then check whether the Secondary Capture series displays in the PACS. If the series still doesn't display, refer to *The study is out-of-scope*, below.
	The study is out-of-scope.	Check that the study meets all the criteria for processing. See: • *Contraindications* on page 5 • *Supported scan types* on page 9 For further details, contact the Annalise.ai Professional Services Team.
	The study has not been routed to the Annalise Integration Adapter.	1. Go to your PACS administration page. 2. Check that the auto routing criteria has been met for the relevant study. 3. Check that the image has been sent to the Annalise Integration Adapter through your PACS routing tools.
	The Annalise Integration Adapter has no connectivity to the Annalise Backend.	1. Confirm that the study has been routed to the Annalise Integration Adapter. 2. Check that there is connectivity between the Annalise Integration Adapter and the Annalise Backend.
	The system is under maintenance.	Contact the Annalise.ai Professional Services Team
	Technical product error.	Contact the Annalise.ai Professional Services Team

continued

Troubleshooting: Secondary Capture *(cont.)*

Symptom	Root cause	Steps to resolve
One or more images in the Secondary Capture series is missing	The Annalise Integration Adapter has no connectivity to the Annalise Backend.	1. Confirm that the study has been routed to the Annalise Integration Adapter. 2. Check that there is connectivity between the Annalise Integration Adapter and the Annalise Backend.
	The Annalise Integration Adapter failed to send the DICOM series to the PACS server.	1. Check that there is connectivity between the Annalise Integration Adapter and the PACS. 2. Check that the PACS is configured to accept the Secondary Capture SOP class with the appropriate transfer syntax. For further help, contact the Annalise.ai Professional Services Team.
	Technical product error.	Contact the Annalise.ai Professional Services Team.
Not all X-rays in the study are present in the Secondary Capture result	Not all X-ray images in the study have been routed to the Annalise Integration Adapter.	Check that the affected image/s have been sent to the Annalise Integration Adapter through your PACS routing tools.
	Some of the images in the study were received by the Integration Adapter after the first prediction result was completed. Annalise Secondary Capture results will only be sent for the first successfully completed AI result. If further images arrive after the first prediction is triggered, the new Secondary Capture results will not be sent to the PACS.	Confirm that images in the same study are routed to the Annalise Integration Adapter within the configured timeframe for the Annalise Integration Adapter to trigger a prediction. If required, contact the Annalise.ai Professional Services Team to discuss the configuration of your study trigger window.

Troubleshooting: Miscellaneous

The following table lists other potential miscellaneous issues and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
When the Annalise Viewer launches, the following message displays: *'Missing Credentials'*	The **Organisation ID**, **Organisation Password** and **Annalise Server URL** have not been configured for the user.	See *Configure and test organisation credentials* on page 23.
When the user tests the server settings, the following message displays: *'Error – failed to reach server'*	Incorrect server URL.	Check that you have used the URL provided by the Annalise.ai Professional Services Team during the deployment and configuration process.
	Unable to access network.	Check that the computer is connected to the network and has permissions to access the server URL.
	Maintenance in progress.	The application is currently undergoing maintenance. Once maintenance is complete, you will be able to use the application as normal.
When the user tests the server settings, the following message displays: '*Error – invalid credentials'*	The **Organisation ID** or **Organisation Password** is incorrect.	Ensure that the **Organisation ID** and **Organisation Password** match those provided by the Annalise.ai Professional Services Team during the deployment and configuration process.
When the user attempts to open the *User Guide*, the following message displays: *'Guides are available at Annalise.ai/Guides'*	The Annalise Viewer is unable to reach the Annalise Backend.	1. Ensure that the computer is connected to the network. 2. Open the *Settings* page then click **Server Settings**. 3. Click **Test** to check whether the application can reach the Annalise Backend. If the application is connected to the Backend, an error may be present in the Backend. If so, contact the Annalise.ai Professional Services Team.

Support and feedback

Refer to the following table for support and feedback details:

Support type	Details
Professional services, technical support, product feedback and complaints	Email *support@annalise.ai* Any serious incidents related to the device/s should be reported to Annalise.ai, and where applicable, the competent authority or regulatory authority in which the user and/or patient is established.
Product user, performance and administration guides	Check our website: *annalise.ai/guides*

Symbol glossary

Definitions of symbols that may appear on the Annalise Enterprise product or in the related documentation are listed below.

Symbol	Information
CE 2797	CE labelling
	Manufacturer
EC REP	European Authorised Representative
CH REP	Swiss Authorised Representative
	Indicates a warning or caution
	Read the instructions for use
MD	Medical device



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Standards of Practice for Clinical Radiology

The Royal Australian and New Zealand College of Radiologists®

The Faculty of Clinical Radiology

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About the College

The Royal Australian and New Zealand College of Radiologists (RANZCR) is a not-for-profit association of members who deliver skills, knowledge, insight, time and commitments to promote the science and practice of the medical specialties of clinical radiology (diagnostic and interventional) and radiation oncology in Australia and New Zealand.

The Faculty of Clinical Radiology, RANZCR, is the peak bi-national body for setting, promoting and continuously improving the standards of training and practice in diagnostic and interventional radiology, for the betterment of the people of Australia and New Zealand.

Our Vision

RANZCR as the peak group driving best practice in clinical radiology and radiation oncology for the benefit of our patients.

Our Mission

To drive the appropriate, proper and safe use of radiological and radiation oncological medical services for optimum health outcomes by leading, training and sustaining our professionals.

Our Values

Commitment to Best Practice

Exemplified through an evidence-based culture, a focus on patient outcomes and equity of access to high quality care; an attitude of compassion and empathy.

Acting with Integrity

Exemplified through an ethical approach: doing what is right, not what is expedient; a forward-thinking and collaborative attitude, and patient-centric focus.

Accountability

Exemplified through strong leadership that is accountable to members; patient engagement at professional and organisational levels.

Code of Ethics

The Code defines the values and principles that underpin the best practice of clinical radiology and radiation oncology, and makes explicit the standards of ethical conduct the College expects of its members.

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Introduction

Purpose and Scope

The Royal Australian and New Zealand College of Radiologists (RANZCR) is committed to setting, promoting and continuously improving standards of practice for clinical radiology, encompassing diagnostic imaging and interventional radiology, for the betterment of the people of Australia and New Zealand.

RANZCR is the primary organisation in Australia and New Zealand for setting standards of practice for clinical radiology; these are set out in the *Standards of Practice for Clinical Radiology* (the Standards). This document sets minimum standards to support and ensure the delivery of safe, highquality diagnostic imaging and interventional radiology services in both community-based and public hospital settings. These standards also provide a framework for practices to implement and maintain continuous quality improvement.

The Standards are made freely available to all medical imaging stakeholders and are applicable to all clinical radiology services.

Background

The Standards were first developed in 1997. In earlier versions, the ISO/IEC 17025: 2005 Standard provided a quality management framework in which the Standards were applied for the purposes of practice accreditation under the RANZCR/NATA Medical Imaging Accreditation Program. In 2006, RANZCR resolved to include quality management principles specifically designed for medical imaging practice within the Standards.

The Standards are reviewed regularly to reflect progress in clinical practice, technology and quality management systems. Amendments may also be issued between major versions. Standards and documents referenced in the Standards are subject to updates either by RANZCR or external authors whose documents are referenced herein.

How to Interpret and Implement These Standards

Depending on the scope of medical imaging services, a practice is expected to meet the generic requirements (Sections 1 to 9), and any specific modality requirements (Sections 9 to17).

Example 1: A Practice solely providing ultrasound services is expected to comply with the standards relevant to the practice of ultrasound, as described in Section 17 (depending on the scope of ultrasound services provided by the Practice); but also, to comply with all other standards described in Sections 1 to 9.

Example 2: A Practice providing CT, general X-ray, MRI, mammography and ultrasound services is expected to comply with all standards described in Sections 1 to 9, as well as the modality-specific requirements described in Sections 11, 12, 14, 15 and 17 (depending on the scope of modality-based services provided by the Practice).

Government Regulation

Each medical imaging practice is responsible for ensuring that it complies with all relevant jurisdictional legislation (e.g. national, State or Territory). Legislative requirements may take precedence over some standards detailed in this document (e.g. retention times for patient records). References made in this document to legislation are not intended to be exhaustive.

Practices should meet relevant national/State/Territory and local regulations governing Work Health and Safety, discrimination, building, disabled access, equal opportunity of employment, and utilities (water, gas and electricity).

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Australia

The Commonwealth Government of Australia has established legislative requirements to determine eligibility for Medicare benefits under the Health Insurance Act 1973, and associated regulations for the practice of diagnostic imaging. For the purposes of determining eligibility for Medicare Benefits Schedule (MBS) benefits, legislative and regulatory requirements take precedence over the RANZCR Standards. However, to deliver optimal patient care, practices should meet the standard of practice expressed in the Standards where it is set above Commonwealth requirements.

Not all medical imaging services addressed in this document are eligible under the MBS.

RANZCR recognises that the Commonwealth has implemented the Diagnostic Imaging Accreditation Scheme (DIAS), which is underpinned by the *Practice Accreditation Standards* (www.diagnosticimaging.health.gov.au). The standards underpinning the DIAS are not yet as broad in scope as the Standards, and RANZCR encourages the Commonwealth to use the Standards as a reference point when reviewing, updating and extending the *Practice Accreditation Standards*.

New Zealand

In New Zealand, International Accreditation New Zealand (IANZ) administers a radiology practice accreditation program underpinned by the *New Zealand Code of Radiology Management Practice* (2011)(1), which references the Standards.

Acknowledgements

The Faculty of Clinical Radiology Council gratefully acknowledges the extensive work undertaken by the Safety, Quality and Standards Committee in the ongoing review and development of the Standards.

The Safety, Quality and Standards Committee (2017-19) comprised: Prof. Stacy Goergen (Chair), Dr Fiona Bettenay, Dr Fraser Brown, Prof. Graham Buirski, Dr Colin Chong, Dr Kim McAnulty, Dr Katherine O'Connor, Dr Pramod Phadke, Ms Monica Schlesinger (consumer representative), Prof. John Slavotinek, Dr Dean Topham, Dr Bernadette Wong, Dr Felicity Pool, Dr Sophie Thoo and A/Prof Richard Brightwell (consumer representative).

The Faculty of Clinical Radiology Council would also like to acknowledge the dedicated work of the members of each of the modality-based reference groups, the Teleradiology and Artificial Intelligence Working Groups and the Interventional Radiology Committee that contributed to the Standards, and the considered input we received from stakeholders through consultation.

Feedback

RANZCR seeks ongoing feedback from all stakeholders in the medical imaging sector and welcomes suggestions for improvement in the Standards. Stakeholders are encouraged to notify RANZCR with comments particularly relating to any apparent discrepancies or ambiguities.

Please forward feedback to standards@ranzcr.edu.au

Acronyms and Abbreviations

AANMS	Australasian Association of Nuclear Medicine Specialists
AAPM	American Association of Physicists in Medicine
AC	Attenuation Correction
ACPSEM	Australasian College of Physical Scientists & Engineers in Medicine
ACR	American College of Radiology
AED	Automated External Defibrillator
AHPRA	Australian Health Practitioner Regulation Agency
AI	Artificial Intelligence

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ALARA	As Low As Reasonably Achievable
ALS	Advanced Life Support
AnC	Anatomic Correlation
ANZBMS	Australian and New Zealand Bone and Mineral Society
ANZCA	Australian and New Zealand College of Anaesthetists
ANZSNM	Australian and New Zealand Society for Nuclear Medicine
ANZSNR	Australian and New Zealand Society of Neuroradiology
APP	Australian Privacy Principles
ARC	Australian Resuscitation Council
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASA	Australian Sonographers Association
ASAR	Australian Sonographer Accreditation Registry
ASMIRT	Australian Society of Medical Imaging and Radiation Therapy
ASUM	Australasian Society for Ultrasound in Medicine
AVM	Arteriovenous Malformation
BMD	Bone Mineral Densitometry
BMUS	British Medical Ultrasound Society
CCD	Charge-Coupled Device
CPD	Continuing Professional Development
CPR	Cardiopulmonary Resuscitation
CR	Computed Radiography
CRIO	Chief Radiologist Information Officer
CSANZ	The Cardiac Society of Australia and New Zealand
CT	Computed Tomography
CTC	CT Colonography
CTCA	CT Coronary Angiography
CTDI	CT Dose Index
DAP	Dose Area Product
DIAS	Diagnostic Imaging Accreditation Scheme
DICOM	Digital Imaging and Communications in Medicine
DLP	Dose Length Product
DR	Digital Radiography
DRACR	Diploma of Royal Australasian College of Radiologists
DRL	Diagnostic Reference Levels
DXA	Dual-energy X-ray Absorptiometry
ECG	Electrocardiogram
FRL	Facility Reference Levels
FRANZCR	Fellow of the Royal Australian and New Zealand College of Radiologists
FTE	Full Time Equivalent
HL7	Health Level 7
HL7 CDA	HL7 Clinical Document Architecture
IANZ	International Accreditation New Zealand

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IEC	International Electrotechnical Commission
IHE	Integrating the Healthcare Enterprise
IHE-PDI	IHE Portable Data for Imaging
IRSA	Interventional Radiology Society of Australasia
ISO	International Organization for Standardization
IV	Intravenous
MBS	Medicare Benefits Scheme
MIT	Medical Imaging Technologist
ML	Machine Learning
MP	Megapixels
MQAP	Mammography Quality Assurance Program
MRI	Magnetic Resonance Imaging
MRTB	Medical Radiation Technologists Board
NATA	National Association of Testing Authorities, Australia
NEMA	National Electrical Manufacturers Association
NHMRC	National Health and Medical Research Council
NMBA	Nursing and Midwifery Board of Australia
PACS	Picture Archiving and Communication System
PET	Positron Emission Tomography
PRL	Practice Dose Reference Level
QA	Quality Assurance
QC	Quality Control
QCT	Quantitative Computed Tomography
RACP	The Royal Australasian College of Physicians
RANZCR	Royal Australian and New Zealand College of Radiologists
RIS	Radiology Information System
SMPTE	Society of Motion Picture and Television Engineers
TGA	Therapeutic Goods Administration
TIPS	Transjugular Intrahepatic Portosystemic Shunt
TLD	Thermoluminescent Dosimeter
WFUMB	World Federation for Ultrasound in Medicine and Biology

Changes from Version 10

This current version of the Standards of Practice for Clinical Radiology has undergone a significant review and revision. The Faculty of Clinical Radiology would like to extend their thanks to all the individuals, internal bodies and external organisations who have contributed to this review.

In addition to minor amendments, such as application of consistent terminology and updating of content to reflect current practice, the following substantive changes have been made:

1. Version 11 now includes the Teleradiology Standards (Standard 8), which had previously been published as a stand-alone set of standards. The development and inclusion of standards for the practice of teleradiology acknowledges the importance of teleradiology in modern healthcare, and reinforces the standard of care that patients resident in Australia and New Zealand expect.
   By including the teleradiology standard as a new Standard 8, what were Standards 8–15 in Version 10 have now become Standards 9–16 in Version 11.
2. Specific monitor requirements for the various imaging modalities are now provided as a comparative table in the new Appendix D.

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3. The Computed Tomography (CT) Standards (Standard 10) have been modified to reflect and be consistent with the Quality Framework for Diagnostic Imaging (https://www.ranzcr.com/college/document-library/quality-framework-for-diagnostic-imaging).

The Interventional Radiology Standards (Standard 12) have undergone a bridging update. A more thorough, detailed update of standards relating to interventional radiology is planned for 2020.

The Nuclear Medicine Standards were reviewed by a joint AANMS/RANZCR working group and ratified by the AANMS Board on the 27th February 2019.

Changes from Version 11

Version 11.1 has added the teleradiology chapter preamble including the key principles of teleradiology originally published in the standalone teleradiology standards.

Version 11.2 includes the new AI Standards as chapter 9. The previous chapters 9-16 have been renumbered 10-17. Version 11.2 has updated section 15.2.1 (previously 14.2.1) and appendix D to homogenise with other mammography monitor standards.

1 PRACTICE MANAGEMENT SYSTEM

The Practice shall establish, implement, maintain and document a management system that covers all activities performed at the Practice's permanent site and at sites located away from its permanent facilities (e.g. mobile services).

The management system shall be communicated to, understood, adhered to and implemented by all personnel.

The integrity of the management system shall be maintained at all times, including when changes to the service occur, to ensure the quality of all work performed. Where improvements are identified, the staff/personnel are invited to bring suggestions. Where improvements are made to the management system, further training will be undertaken for all staff.

1.1 Practice Management System

The Practice shall implement a practice management system.

INDICATORS

i. The senior management of the Practice ensures that the required operational policies, protocols and practice management system are implemented, applied and are continuously improved.

ii. The Practice ensures that all personnel familiarise themselves with, and commit themselves to, policies and protocols, implementing these in their work.

1.2 Quality Manual

The Practice shall maintain, regularly review and update a quality manual to support the practice management system.

Notes: The quality manual is intended to be appropriate to the scope and size of the Practice. Practices may like to consider designing their manual so that it outlines succinctly who does what, when, where and why in relation to the quality and safety of the services provided, and whether simple tools, such as an organisational chart, can be used to define the levels of responsibility within the Practice.

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INDICATORS

i. The quality manual includes a quality policy defining the quality objectives.

ii. The quality policy is issued under the authority of senior management, and includes management's commitment to:

a. good professional practice and compliance with these RANZCR Standards; and

b. continual improvement of the effectiveness of the management system and to the quality of all services provided.

iii. The quality manual includes policies relating to the management system. iv. The quality manual outlines the structure of the Practice's documentation hierarchy.

v. The quality manual makes reference to supporting documentation.

vi. The quality manual defines the role and responsibilities of management personnel, including the quality manager.

1.3 Quality Manager

The Practice shall appoint a quality manager (however nominated) with direct access to senior management. The quality manager shall have defined responsibility and authority for implementing and maintaining the Practice's management system.

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Notes: The role of a quality manager may be fulfilled differently in different practice settings, and accordingly may be fulfilled in a coordinated manner across more than one position in the Practice.

INDICATORS

i. The Practice personnel records identify:

   a. the quality manager and his/her associated job description; OR

   b. that the role of quality manager is fulfilled within the Practice across more than one position, and that the Practice can identify which position(s) fulfil this role and how this is coordinated.

1.4 Documentation

The Practice shall manage its documents. A master list of controlled documents shall be maintained that identifies the current version and distribution of documents.

Notes: In this context, 'document' refers to any information or instructions, including policy statements, policies, protocols, textbooks, procedures, specifications, calibration tables, charts, posters, notices, memoranda, software, drawings, plans, forms, patient information and instructions; and documents of external origin, such as regulations, standards, guidelines, manuals or examination procedures.

Document management is a system to maintain secure storage, effortless retrieval and access, and eliminate the use of unauthorised, obsolete and/or superseded versions. This system should be appropriate to the scope and size of the Practice, sustainable and practical to maintain.

INDICATORS

i. The Practice has established a documentation system appropriate to the size and scope of the service.

ii. The Practice ensures that all documents are uniquely identified to include the date of issue or revision number, page numbering (including the total number of pages) and the issuing authority.

iii. The Practice has established procedures to define how changes to documents are to be made and controlled including documents maintained in computerised systems. iv. The Practice ensures all documents are periodically reviewed and revised when necessary, and approved or reapproved by authorised personnel prior to issue.

v. The Practice ensures that only current versions of documents are made available.

vi. The Practice ensures that where handwritten amendments to documents are allowed, and pending the re-issue of the documents, the amendments are initialled and dated. However, handwritten amendments are strongly discouraged and, if required in an exceptional circumstance, should be replaced by an electronic amendment as soon as possible. vii. The Practice has retained or archived Master copies of old and/or superseded document versions for legal and knowledge preservation purposes, and are appropriately identified. viii. When its examinations involve remote reporting via teleradiology, the Practice has documentation clearly defining the agreed responsibilities of both the examining and reporting sites. This includes issues of liability, patient safety, transmission arrangements (including personal information and clinical data), report turnaround times and confidentiality.

1.5 Patient Records

Procedures shall be established concerning integrity, identification, collection, storage, protection and disposal of patient records, adhering to relevant jurisdictional legislation.

Retained data should include, at a minimum, the patient referral, all of the images that were made available to the clinical radiologist for interpretation, the radiologist's report and any other correspondence relating to that patient's care.

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Notes: Records kept for children (paediatrics) – in some jurisdictions if the patient was less than 18 years of age at the date of the last record, the records must be kept until the patient attains or would have attained 25 years of age.

INDICATORS

i. The Practice records are legible, identifiable to the responsible personnel, held securely to prevent loss or unauthorised access and retrievable. ii. The Practice retains original data (electronic or hard copy) according to relevant legislation, unless such records are scanned into the RIS.

iii. Where such original records are in hard copy format, these are only disposed of within the retention period after they have been scanned into the RIS and checked for completeness.

iv. Corrections to records ensure that the original recording is not made illegible, and that the correction is initialled and dated. Equivalent measures are taken for records held electronically.

v. The Practice retains all records (including images, billing records and reports) in accordance with the appropriate statutory requirement depending on the jurisdiction, and as per local regulations. Where such a regulatory requirement does not exist, the Practice retains records for a minimum of 36 months.

vi. The Practice has procedures in place that ensure electronic records are protected, backed up and any unauthorised amendment of such records is prevented.

vii. The Practice has a disaster recovery system that addresses the risk of network failure, and also takes into consideration PACS, image failure and teleradiology services.

viii. The Practice ensures that where data is transmitted across a wide area network, such as the Internet, it is encrypted or protected by a username and password.

1.6 Corrective and Preventive Action

The Practice shall have corrective and preventive action processes in case things go wrong. This includes a documented policy and process to identify, investigate, remedy and prevent adverse incidents or near misses.(2, 3)

INDICATORS

i. The Practice has a clear incident reporting process for identifying and investigating nonconforming work and departures from authorised policies and procedures, and for implementing corrective action/s accordingly.

ii. The Practice has documented evidence of policies and procedures outlining the appropriate corrective and preventive actions.

iii. The Practice has a process for identifying and implementing preventive action to eliminate the causes of potential non-conformities, incidents and adverse clinical events.

iv. The Practice records any corrective and preventive action activity. The Practice has a process for ensuring all relevant staff understand incident reporting processes, what constitutes reportable incidents and their responsibilities in this regard.

1.7 Continuous Quality Improvement

The Practice shall establish a program of continuous quality improvement for the key areas of operations. This program of activity will include corrective and preventive action, and be supported by internal audits and assessments conducted by external bodies where applicable.

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INDICATORS

i. The Practice has implemented a continuous quality improvement schedule that establishes a risk register. Plan Do Study Act (PDSA) or similar methodology should be used in QI initiatives.

ii. The Practice ensures that an audit is carried out and reported on annually against these Standards and the Practice's own policies and procedures.

iii. The Practice has procedures in place to ensure the objectivity and impartiality of auditors and the audit process itself. Independent auditors should be guided by ISO standard 19011.

iv. The annual audit includes a review of the Practice's corrective and preventive action processes and activity, as well as the effectiveness of any such action.

v. The Practice has records of participation in and compliance with external quality assurance activities where these are available (including image reviews).

vi. Through this process, the Practice identifies key areas of its operations for quality improvement, including through the use of patient experience(4-6), and implements appropriate training accordingly.

1.8 Feedback and Complaints

The Practice shall have a policy and procedure for obtaining feedback from patients and referrers, and for resolving complaints.

INDICATORS

i. Feedback is actively sought from patients and referrers to ensure appropriate service provisions, patient and referrer satisfaction, and continuous quality improvement.(7)

ii. The Practice has a policy covering the procedure for handling feedback and complaints, which should be made clear to all staff, including staff training in managing and responding to feedback and complaints; is available to the public and referrers; and is adhered to by personnel.

iii. The Practice procedures should be transparent, fair, efficient and timely.

iv. The Practice maintains records of all feedback, complaints, investigations and corrective actions taken, and supports open disclosure of errors and adverse patient outcomes.

1.9 Management Review

Senior management shall regularly review the practice management system to ensure continuing suitability and effectiveness in support of patient care, and introduce any necessary changes for improvements.

INDICATORS

i. The Practice keeps records of management system reviews together with any action plans, outcomes and monitoring activities.

ii. For Practice groups that have a board of directors, senior management should report a summary of this review process regularly to the board.

iii. The Practice maintains a risk register that reflects the actions and mitigations taken in response to various risks.

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1.10 Supplies

The Practice shall establish policies and procedures to ensure that all purchased goods or services comply with defined performance criteria and regulatory requirements, and are obtained only from suppliers that are selected on the basis of their ability to meet specified requirements.

INDICATORS

i. The Practice has implemented a procedure to manage the purchase of services and supplies whereby a listing of all suppliers, contractors and consultants is maintained, and all commitments to purchase are recorded with a description of the product/s being ordered.

ii. The Practice verifies purchased products and services at appropriate intervals.

iii. The Practice stores purchased materials and products in designated storage areas within the facility that are designed to prevent damage and deterioration to the product prior to use. iv. The Practice has procedures in place where special storage conditions are required to prevent deterioration (e.g. refrigeration), to ensure those conditions are adequately controlled and maintained.

v. Contracts with such suppliers specify exactly how the supplier and the Practice will cooperate in the case of an incident; for example, faulty product, breach of service level agreement or breach of data.

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2 FACILITIES

Practice facilities shall support the delivery of safe, quality clinical (diagnostic and interventional) radiology services. These facilities shall be clean and constructed to optimise patients' comfort (including their need for privacy) and to accommodate special needs.

2.1 Facilities for Imaging Procedures

The Practice facilities shall be such as to allow the safe and correct performance of clinical (diagnostic and interventional) radiology services.

INDICATORS

i. The Practice's facilities comply with legislative requirements.(8, 9)

ii. Access to and use of areas affecting the quality of the imaging procedures or safety of patients and personnel are controlled.

iii. There is an effective separation between neighbouring areas in which there are incompatible activities.

iv. The Practice maintains cleanliness of the facilities.

v. The Practice provides appropriate staff amenities.

2.2 Patient Facilities

The Practice has patient facilities suitable for the range of services that are provided.

INDICATORS

i. The Practice has facilities available that optimise the comfort of its patient population and seeks ongoing patient feedback.

ii. The Practice has facilities available for disrobing that ensure the privacy of patients.

iii. Patient facilities are designed to accommodate the special requirements of the patient population of the Practice.

3 EQUIPMENT

The Practice shall ensure that all equipment (including software) is appropriate to its use and that it is appropriately maintained.

3.1 Equipment

The Practice must ensure that all equipment required for all procedural activities carried out at the Practice and any associated software is available, functional, capable, calibrated, compliant with regulatory requirements and has an appropriate program of quality control testing.

Notes: There are modality-specific equipment requirements in these Standards.

INDICATORS

i. Radiology equipment operates within the relevant jurisdiction. Certificates shall be as current as the regulatory environment permits.

ii. The Practice holds records of such compliance testing at each Practice site.

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iii. The Practice carries out quality control, maintenance and calibration of equipment used for all of its imaging services, and maintains records of all such activity.

iv. The Practice keeps records of remedial actions for the operational life of the equipment at each Practice site.

v. Such quality control and maintenance activity is carried out in accordance with both the manufacturer's guidelines and regulatory requirements by appropriately qualified persons.

vi. The Practice complies with legislation concerning the procurement, sale or disposal of any equipment that generates ionising radiation.

vii. Equipment should only be operated by appropriately certified and licensed, where required, staff.

viii. When purchasing or upgrading equipment and software required and used for all procedural activities, the Practice obtains an IHE Integration Statement for the current model or version being purchased or upgraded from the manufacturer, and consults with the vendor regarding the proposed upgrade and retains this advice in writing.

3.2 Equipment Inventory

The Practice shall maintain a current equipment inventory.

Notes: In Australia, under regulation 20A-20C of the Health Insurance Regulations 1975, providers of Medicare-funded diagnostic imaging services must register their equipment with the Department of Human Services and have a Location Specific Practice Number (LSPN).

INDICATORS

i. The Practice maintains a current equipment inventory that includes (but is not limited to):

- Name of item, manufacturer and serial number (or other identifier)
- Notice/certificate of registration or licence, where applicable
- Condition when acquired (i.e. new, reconditioned)
- Date of installation.

ii. The Practice has an equipment inventory, which for each piece of equipment contains:

- The acceptance performance certificate
- The instruction manual
- A statement of the manufacturer's specifications
- A current formal statement of modifications made to the equipment, and/or its operating software and applications, after purchase.

iii. The Practice has a register of all its data, including, but not limited to:

- Software programs
- Data flow diagrams
- Systems the Practice interfaces with • Where patient and clinical data reside
- Where backups reside.

3.3 Equipment – Sedation and Monitoring

In Practices where procedures requiring sedation are performed, equipment for sedation and monitoring of sedated patients shall be available on site, and shall be appropriate for the patient population and the procedure(s) performed.

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Practices shall comply with the requirements set out in the ANZCA PS09 Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures.(10)

INDICATORS

i. Sedation is only performed in a location that is equipped with the resources to deal with a cardiopulmonary emergency according to the ANZCA PS09 Guidelines.(10) ii.

Where sedation of paediatric patients is carried out:

- The monitoring equipment is capable of measuring oxygen saturation, end tidal CO_2 and (non-invasively) blood pressure
- There is separate oxygen saturation monitoring for the recovery area
- There are facilities and equipment for endotracheal intubation of children.

iii. The Practice complies with any regulatory and/or licensing requirements applicable to the use of sedation.

3.4 Equipment – Anaesthesia and Monitoring

Where warranted by the patient population, and/or presentation, and procedure(s) performed; equipment for general anaesthesia and the monitoring of anaesthetised patients shall be available on site.

Practices shall comply with the requirements set out in the ANZCA's PS55 Policy Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations.(11) Practices should also take particular care with paedriatic cases.

INDICATORS

i. Equipment for general anaesthesia and the monitoring of anaesthetised patients is available on site, and meets the requirements set out in the ANZCA PS55 Policy.(11)

ii. Where procedures are carried out on paediatric patients (under 16 years of age or under 18 years of age, depending on local jurisdictional legislation) requiring anaesthetic:

- Anaesthetic monitoring equipment is capable of measuring oxygen saturation, end-tidal CO_2 and (non-invasively) blood pressure
- There is separate oxygen saturation monitoring for the recovery area, and there are facilities and equipment for endotracheal intubation of children
- Procedures on children under one year of age requiring general anaesthesia are not performed in units without specialist paediatric facilities.

iii. The Practice complies with any regulatory or licensing requirements applicable to the use of anaesthesia.

3.5 Equipment – Resuscitation

Resuscitation equipment shall be immediately available for management of adverse events (see notes), including adverse reactions to intravenously administered contrast media, and other specific risks appropriate to the Practice profile.

Notes: Adverse events may include, but are not limited to: vasovagal reaction; post-biopsy haemorrhage (superficial and deep); post-drainage visceral perforation; post-biopsy pneumothorax, including tension pneumothorax; and hypotension following spinal injections.

Paediatric patients require paediatric resuscitation equipment.

INDICATORS

i. The Practice maintains current inventories for resuscitation equipment and associated drugs.

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ii. The Practice carries the minimum resuscitation equipment required to perform Advanced Life Support(12) including an AED.

iii. This equipment is immediately available and maintained so that it is in working order whenever intravenous or other contrast administration takes place.

iv. The Practice has a process for checking that resuscitation drugs are current, and not out of date, and records these checks.

3.6 Computers and Automated Equipment

3.6.1 Computers and Automated Equipment

The Practice shall ensure that when computers or other automated hardware are used for acquisition, processing, recording, reporting, storage retrieval or transmission of data; such equipment, and its operating software, are appropriate for the scope of use.

The Practice shall establish and implement procedures for protecting data, including up-to-date plans and procedures for:

- Securing practice networks and their interfaces with other networks, including the public internet
- Connections from and to individual imaging devices may require particular attention
- Ensuring the integrity, availability, and confidentiality of data collection and entry
- Data storage (on- and off-site)
- Data transmission
- Data processing
- Backup protocols
- Disaster recovery systems with particular consideration of digital imaging and teleradiology services
- Business continuity plan • Data breach notification plan
- Risk management system.

The Practice shall ensure that computer hardware and automated equipment are appropriately serviced, and that software is updated and patched as required.

The Practice shall provide appropriate environmental and operating conditions to ensure the optimal functioning of computer hardware.

The Practice shall ensure that if implementing shared health information software, additional patient identifiers may require additional security provisions.

INDICATORS

i. The Practice has documented procedures for each of the tasks listed

above. ii. The Practice has documented instructions for use of software at the

Practice.

iii. The Practice has service logs of computer and automated equipment, and records of software updates.

iv. The Practice has systems for monitoring the environmental and operating conditions in equipment rooms.

v. The Practice can demonstrate the use of additional security to protect patient information when using shared health information databases.

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3.6.2 Diagnostic Workstations

Monitors and display software used for reporting and diagnosis must meet the requirements for 'Primary (diagnostic) workstations'. There are less stringent requirements for 'Secondary (review) workstations', which may be used for monitoring workflow or case review, but not for primary diagnosis; for example, vendor neutral imaging viewer.

3.6.2.1 Display Software

The Practice's image processing equipment and management procedures shall ensure that the image manipulation performed by medical imaging team members is reflected accurately in the images seen on the primary reporting station used by the clinical radiologist.

INDICATORS

i. The display software used for reporting by the clinical radiologist provide the following minimum functions to support the accurate interpretation of images by the clinical radiologist for all modalities:

- Panning
- Image magnification
- Rotation
- Window level and width adjustment
- Measurement (length at least)
- Signal intensity measurement
- The total number of images in the study.

3.6.2.2 Monitors

The Practice shall ensure that diagnostic imaging monitors are appropriate for the activity for which they are used. In addition to the distinction between primary diagnostic and secondary review uses, the spatial resolution of the images to be reviewed must be considered. In general, cross-sectional modalities do not generate images with the high spatial resolution of CR, DR and mammography.

Notes: There are additional modality-specific monitor requirements in these Standards.

INDICATORS

i. The Practice ensures that initial quality assurance and subsequent reporting of images for PACS or teleradiology is performed on primary monitors.

ii. The Practice's primary monitors for CR and DR meet the requirements set out in Appendix D. Further information may be found in the ACR Practice Parameters and Technical Standards.(13)

iii. The Practice shall give consideration to implementing an anti-reflective coating on the monitor screen to help reduce glare.

iv. Primary monitors used exclusively for lower-resolution modalities may employ a lower matrix size, not less than 1 MP for the typical 53-cm display. CD/DR images reviewed on such a monitor will require frequent zooming and panning for optimal assessment.

v. The Practice ensures that secondary monitors are only used for reviewing medical images, usually in association with the relevant medical imaging report, and are not used to provide a medical interpretation.(14) Secondary monitors should endeavour to meet the following:

- Maximum luminance ≥250 cd/m^2
- Calibration Grayscale Standard Display Function (GSDF) accuracy ≤20%
- Lmin ≥1 cd/m^2.

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vi. Ambient lighting: extraneous room light minimised: 20–40 lux recommended.

3.7 Digital Imaging Data

3.7.1 Digital Image Data Management

The Practice shall ensure that digital image data is managed appropriately in relation to the digital image file format, storage, retention and archiving.

Notes: Government and health sector stakeholders are working to agree on the requirements for image retention and archiving. As such, the requirements in these Standards are of an interim nature.

Guidance on security measures may be obtained from the ACR Practice parameter for electronic medical information privacy and security.(13)

The Practice shall ensure that digital images can readily be made available in a DICOM-compliant format, where one is available for the modality in question.

When storing digital images, the Practice shall use lossless compression where feasible and otherwise shall use compression ratios as recommended in the RANZCR compression guidelines.(15)

The Practice's digital archiving system shall have the capacity to store a record of each examination for the applicable statutory period. The archiving system shall permit retrieval of the images in a DICOM-compliant format.

The Practice shall establish a retention schedule that identifies the studies for which longer-term retention is required. This schedule is reviewed at least annually.

The Practice shall ensure there is sufficient data storage capacity relative to the retention schedule.

INDICATORS

i. The Practice has documented policies on digital image compression.

ii. The Practice has a statement of archive capacity and of typical storage requirement in megabytes.

iii. The Practice can demonstrate the use of a retention schedule.

iv. The digital archiving system shall have the capability and capacity to store radiation dose information for patients.

3.7.2 Privacy and Information Security

The Practice shall maintain the privacy and security of health information it holds, following the legislation of their jurisdiction.

With increasing implementation of electronic communication for the purposes of communicating with patients and other healthcare professionals, policies regarding emails and social media shall be designed and adopted, to protect patient information and the Practice's reputation.

Note: Practices shall comply with the relevant privacy laws and regulations to their jurisdiction. In Australia, this is regulated by the Privacy Act (1988) and the Mandatory Breach Notification Scheme (2018). In New Zealand, this is regulated by the Privacy Act (1993) and the Health Information Privacy Code (1994).

INDICATORS

i. The Practice does not store or leave patient information in areas accessible to members of the public.

ii. The Practice's clinical software can only be accessed using unique individual passwords, and access is determined according to the person's level of authority.

iii. The Practice has policies and procedures for:

- Information recovery and business continuity
- Storage, retention and destruction of patient records

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- The use of email
- The use of social media
- Data breach notification
- Cybersecurity insurance policy.

3.7.3 Exchange of Digital Imaging Data and Reports

3.7.3.1 Exchange Media and File Systems

When providing diagnostic images on portable media, the Practice shall only use media and file systems that are compliant with the IHE Portable Data for Imaging profile.

Notes: Current IHE profiles are available at www.ihe.net (accessed 17 April 2018).

INDICATORS

i. The medium used when exchanging diagnostic images in a digital format on a portable device is either compact disk, compliant with ISO/IEC 10149 (CD-R), or another medium that allows compliance with the IHE-PDI profile.

ii. The file system of such media is compliant with ISO 9660:988(E) – level 1.

iii. The Practice shall be able to provide a complete set of diagnostic quality images, when appropriate to the needs of the patient or the referrer.

3.7.3.2 Malicious Software

The Practice's security procedures must include measures to ensure that no malicious software (viruses e.g. Trojans, spyware) is included on media used in the exchange of diagnostic imaging data.

Media intended to have data recorded on only one occasion must be tested to exclude malicious software, and then be closed to data alteration or addition.

Notes: It is noted that protocols to address malicious software issues are able to be implemented at a network level or at a workstation level.

INDICATORS

i. The Practice has implemented and documented a protocol whereby a check is carried out to confirm that there is no malicious software on disks that record digital imaging data or in systems used in the exchange of diagnostic imaging data. ii. Portable media are 'closed' to data alteration or addition once this check is carried out successfully and no further data is to be written to the disk.

iii. Other media that are only intended to have data added on one occasion are similarly checked and 'closed' to data alteration or addition.

3.7.3.3 Exchange of Digital Imaging Data and Reports Using Portable Media: IHE PDI profile

All portable media used for image data storage and/or transmission by the Practice shall meet appropriate standards, as described in the IHE profile for 'Portable Data for Imaging (PDI)', available at http://wiki.ihe.net/index.php/Portable_Data_for_Imaging (accessed 17 April 2018).

Notes: DICOM viewer requirements are described under Standard 3.7.3.4.

The Practice shall ensure that all such media contain a 'readme.txt' file that is situated in the root directory, even if web content is not supported.

The readme.txt file shall contain a copy of the Practice-specific (but not patient-specific) information provided on the label and external packaging.

This readme.txt file contains information about DICOM viewer software, and information about the requirements for HTML viewers required to read web content.

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When providing diagnostic imaging data as web content, such content is compliant, and:

a. a default web page (index.htm) is used as the loading page for end users, and contains the same key information as that used on the media and package;

b. the web page includes appropriately formatted images (e.g. jpeg), and links to help files and software access DICOM file content, where provided; and

c. where web content is used to display non-diagnostic images, the fact that these are nondiagnostic is clearly conveyed to the user either in the instructions or by annotation of individual images.

If diagnostic imaging reports are included on the portable media, they are:

a. DICOM compliant and stored according to the IHE PDI profile; OR

b. in the HL7 version 2.x or HL7 Clinical Document Architecture formats; OR c. in .pdf format.

INDICATORS

i. The Practice ensures that portable media issued by the Practice are compliant with the IHE PDI profile.

3.7.3.4 Use of Embedded DICOM Viewer on Portable Media

The use of DICOM viewers on portable data image media shall be subject to appropriate protocols.

Notes: The use of DICOM viewers on portable data image media shall be subject to appropriate protocols. In relation to the placement of instructions for running a DICOM viewer, it is recognised that some media (e.g. Universal Serial Bus, or USB) will not be of sufficient size to enable this to be recorded on the media label.

The Practice shall ensure that when a DICOM viewer is provided on such media, that such viewers do not auto-load.

Instructions for starting the viewer shall be present on the media label, media folder and readme.txt file, and an online manual shall be available.

The viewer and help files shall be located in and shall be able to be loaded from the index.htm page.

Where the software does not load (e.g. incompatibility with the operating systems), the viewer will terminate with an intelligible error message.

Loading of the viewer shall not be dependent on pre-existing components (e.g. Java, MS components), and these components shall only load from the disk if they are required.

Minimum specifications in regard to the computer equipment required to run the DICOM viewer software shall be included in the information provided on the media label, media folder, readme.txt file and the online manual. Correspondingly, any limitations of the viewer shall be declared.

INDICATORS

i. Presence of the above instructions and information on portable media, or the media container, produced by the Practice.

3.7.3.5 Electronic Reports

When reports are stored electronically, the Practice shall ensure that they are retrievable in a human readable format, such as the .pdf format. Practices are encouraged to develop the ability to send reports in more structured and interoperable forms, such as HL7 v2.xn (described in AS 4700.2(16)) and/or HL7 CDA messages.

Electronic records should be considered as a part of patient records and should be stored in accordance with the statutory requirements for the jurisdiction.

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Notes: There is a specification developed by the Australian National E-Health Transition Authority, and adapted by the Australian Digital Health Agency(17) for uploading of reports to the Australian My Health Record via an HL7 CDA message. Practical implementation of this is expected to commence in 2018.

Reports in any of the above formats are not 'semantically interoperable' with other software applications (such as clinical decision support); that is, the meaning of their contents is not readily available for processing by a machine.

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

INDICATORS

i. The Practice ensures the availability of reports from the relevant period, and such reports are readable with the appropriate software.

3.8 Portable Media Requirements

3.8.1 Media selection

Media shall be selected to be fit for the purpose, use and long-term storage requirements of the radiology Practice, as well as the expected range of end users and consumers.

Notes: Media come in different qualities based on factors, such as dyes used and manufacturing tolerances. Medium selection may be based on the advice of the CD production system or subject to a trial and error testing process.

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.

The selection of media is determined by technical factors involving the media printer and cannot be predetermined.

INDICATORS

i. Media used for long-term storage or archive shall be appropriate to the planned archive period, with appropriate backup arrangements in place.

ii. Media for portable use meets the requirements set out under Standard 3.7.3.1 Exchange Media and File Systems in these Standards.

3.9 Digital Media Labelling, Packaging and Storage

3.9.1 Portable Media Labelling

Portable media used for image storage and transfer shall be labelled with human readable information. The label shall contain all necessary information relating to the data recorded on the device in a clear and legible font to support readability at all ages. This information shall include the sole archive status or retention policy of the diagnostic imaging service and whether the device contains the only long-term digital record (see notes).

The content of the label on the device, on the storage package and represented on the device itself should be consistent.

The Practice shall ensure that media used for the exchange of diagnostic imaging data have labels directly printed on their surface, where feasible. For smaller-format media, the label shall be included as a file on the device, and shall be printed on the device container.

Labelling information shall include, as a minimum:

- Patient name;
- Patient ID (addition of the Australian Individual Health Identifier is encouraged);
- Patient date of birth;

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- Media creation date;
- Date of examination/s;
- Name of institution creating the media, and contact details;
- Media type and an identifier in the format ‘media type’, ‘instance number’ of ‘total number of media in series’;
- A statement about the sole archive stats or retention policy of the radiology service; and
- A statement that contents are confidential.

Notes: Automated media production systems can print on the device 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 device.

As many devices have a similar form (120-mm disk), a statement of the type of device included in the labelling information will assist in troubleshooting if the device does not load.

For portable media that are too small to support direct labelling as described above, the information should be presented as a readme.txt file on the device (at root level) and printed on the media container.

Storage only on CD is not recommended.

INDICATORS

i. The Practice ensures the presence of the above information on portable media, produced by the Practice, where the size of the media permits.

ii. The Practice ensures the presence of the same information is stored, as an electronic file, on the media.

3.9.2 Portable Media Storage and Packaging

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

These media shall 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.

Labelling of the container shall include recommendations to the recipient for its appropriate storage.

Options for media containers include:

- Standard paper or plastic pouches;
- Hard plastic ‘jewel cases’;
- Sealable envelopes of A5 or A4 size; and
- Folders containing CD/media pouches or other means for physically securing the CD.

INDICATORS

i. The Practice’s storage of blank (unused) portable media is consistent with the media manufacturer’s guidelines.

ii. Portable media are consistently stored in packaging that is suitable for transfer to the patient or referring practitioner, and that is immediately identifiable as a medical record.

iii. Such packaging has suitable internal storage for portable media to avoid accidental loss.

iv. The Practice stores packaged portable media according to the media manufacturer’s guidelines until dispatch.

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3.9.3 External Labelling

The storage envelope or folder for portable digital image media shall be appropriately and consistently labelled.

The Practice shall ensure that all media storage envelopes or folders are affixed with a label printed in size 11 or greater font, containing the same contents as per the media label specifications expressed under Standard 3.9.1.

This label shall be placed under a flap in the event that the package is to be sent by post in order to protect patient privacy

The contents of the envelope or folder shall be clearly defined and expressed.

The Practice name and contact details shall be clearly expressed.

Detailed instructions for common operating systems shall include on the label with clear instructions on how to load the CD and access the electronic help files or further instructions, or advice that written instructions for this are contained within the package.

The label shall include a statement that the contents are confidential medical records, with a clear return address if the package is located.

INDICATORS

i. The Practice ensures compliance of storage envelopes or folders produced by the Practice with the above requirements.

3.10 Online Portals

Practices may choose to make images available to referrers and/or patients via an online portal.

Access to such images shall be restricted to appropriately authorised individuals, who shall be required to authenticate their identity before access is granted.

There shall be provision allowing emergency access to such images by medical staff directly involved in the patient's care, with all such access to be logged, recorded and audited.

Images may be made available by default in DICOM PS 3.10 format, or rendered in other commonly used formats (e.g. jpeg). The Practice shall be able to transfer images in DICOM format if required, either via the online portal or via portable media.

Images transferred to another site online must be transferred with relevant metadata, to ensure that the subject of each image is accurately identified; in practice this requires transfer using the DICOM format.

Where images are made available for viewing online, without transfer of the image data to the viewing site's archive, the viewing software must ensure that the metadata is transferred with the image data and that both are displayed to the remote viewer.

Note: Attention is drawn to the requirements of the Australian Privacy Principles(18) and to the AMA guide to the use of clinical images.(19)

3.11 Reporting Environment

The reporting environment must be organised to ensure optimal reporting conditions for the medical practitioner.

The Practice shall ensure that reporting conditions are confirmed as acceptable for diagnostic image interpretation by each of its medical practitioners providing the reporting services.

The Practice shall provide a reporting environment that has:

- A minimum amount of light reflection on the monitor where interpretation is being made

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- Ambient light intensity of 20–40 lux (recommended),(13) although higher levels may be permissible with bright displays
- Displays placed ergonomically at an approximate reading level for each medical practitioner
- Displays placed away from areas that may cause image degradation, such as magnetic fields and electronic transformers
- Adequate control of temperature, humidity, ventilation and acoustic noise.
- Ergonomic standards are met as set out in Standard 4.1.5.

INDICATORS

i. The Practice has a system for monitoring reporting environments.

3.12 Quality Control Testing

3.12.1 Quality Control Testing

The Practice shall implement, maintain and follow a planned program of QC activity in cooperation with a medical physicist, as appropriate.

The Practice shall implement protocols and procedures for performing QC activities for each modality, and of the primary and secondary workstations, at defined intervals. These shall include appropriate instructions for remedial action.

The Practice shall ensure that measurements and other results of all QC activities are recorded so that trends are detectable.

The Practice shall keep records of remedial actions for the operational life of the equipment at the Practice. If stored centrally, these records shall be accessible to the site housing the relevant equipment.

INDICATORS

i. The Practice has written procedures for QC that are readily accessible to their staff. ii.

The Practice maintains records of the results from QC testing performed.

3.12.2 Quality Control Testing – Diagnostic Workstations and Teleradiology Equipment

The Practice must have a QC program in place relevant to the scope of digital imaging and teleradiology services provided.

The Practice shall implement a QC program for digital imaging and teleradiology services that ensures the monitoring and evaluation of the effective management, safety and proper performance of acquisition, digitization, compression, transmission, archiving and retrieval functions, and backup and recovery of the system.

The Practice's QC program shall also monitor the environmental conditions under which reporting of digital and teleradiology examinations is carried out in accordance with the requirements stated under Standard 3.11.

The Practice's QC program shall include:

- Test images and clinical reference image availability
- Service and maintenance records
- Monitors and image display characteristics in accordance with the visual evaluation techniques as described in Standard 3.6.2.2
- Environmental conditions.

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The Practice's QC program shall include a review of diagnostic image quality by the medical practitioner (in the case of teleradiology services, this includes the reporting medical practitioner).

The Practice shall ensure that:

- Monitor quality assurance testing comprises at minimum monthly SMPTE test pattern assessment, at which the image quality is assessed against agreed criteria for monitor performance, as set out in Standard 3.6.2.2
- Conformance tests of display systems are documented and retained for ongoing quality assurance.

Notes: For monitor quality control testing, the assessment protocol described in Section 4.10.5 (Evaluations Using Anatomical Images) contained in the paper Assessment of Display Performance for Medical Imaging Systems: AAPM TG18 Report(14) is recommended for guidance.

INDICATORS

i. The Practice has written procedures for QC of diagnostic workstations and teleradiology equipment, which are readily accessible to their staff.

ii. The Practice maintains records of the results from QC testing of diagnostic workstations and teleradiology equipment.

4 PERSONNEL

The Practice shall ensure that its personnel arrangements support the delivery of safe, quality clinical (diagnostic and/or interventional) radiology services.

4.1 General

4.1.1 Personnel

All tasks associated with the delivery, supervision, support and management of clinical (diagnostic and/or interventional) radiology services shall be supervised or carried out by personnel who are qualified to perform such tasks in accordance with these Standards. The Practice shall ensure that any statutory requirements in relation to qualifications, registration or licensing of its personnel have been satisfied.

All personnel responsible for the delivery, supervision and support of these services must be free from any conflict of interest that may adversely affect the quality or integrity of the services provided.

INDICATORS

i. The Practice maintains personnel records including details of qualifications, professional and/or regulatory registration, licences and their currency.

ii. The Practice maintains current job descriptions for all positions, which define the responsibilities and authorities of personnel according to their qualifications.

iii. The Practice has a documented policy describing the arrangements for deputisation of key positions.

iv. The Practice has procedures in place to ensure that any potential conflict of interest that it or any of its personnel have in relation to the service's activities activities are identified, reported, recorded and managed.

v. The Practice ensures that each of its personnel is aware of the Practice's policies and procedures in relation to the confidentiality and security of patient personal information, and has agreed to abide by the Practice's privacy policy and other relevant rules.

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4.1.2 Recruitment of Personnel

The Practice shall have a systematic process for the recruitment and selection of new personnel.

INDICATORS

i. The Practice has a process that ensures the systematic recruitment of personnel in a manner appropriate to the size and scope of the service.

ii. The Practice has a documented process for the recruitment and selection of new personnel.

iii. The Practice has a process that ensures formal credentialing is implemented and that selected personnel meet the minimum requirements for the position.

4.1.3 Orientation

The Practice shall have an orientation program that is undertaken by all personnel employed or engaged by the service in the delivery, supervision, support and management of clinical (diagnostic and/or interventional) radiology services.

INDICATORS

i. The Practice undertakes orientation activity for new personnel that is appropriate to the scope and responsibility of each position.

ii. The Practice records such orientation in personnel records.

4.1.4 Training

The Practice shall ensure that its personnel undertake any ongoing training needed to comply with requirements for professional registration and/or licensing, and to gain or retain competence in the application of systems and equipment used in the service and, where necessary, shall ensure that resources are available to allow such training.

INDICATORS

i. The Practice maintains permanent records of internal or external training that its personnel undertake to gain or retain competence in the application of systems and equipment used in the Practice.

ii. It ensures that the personnel involved with the provisions of its digital imaging and/or teleradiology services have undertaken training in the policies and procedures for digital imaging and/or teleradiology, and that such training is recorded in the relevant personnel records.

iii. Medical imaging personnel undergo regular performance reviews to support their professional development and quality improvement.

4.1.5 Ergonomics

The Practice shall ensure that the design of the workplace takes into account the needs of all staff. This should include an analysis of the tasks to be performed and the manner in which they will be undertaken.

INDICATORS

i. The Practice has a documented policy on ergonomics that shall include as a minimum(20):

- The considered arrangement of seating, desk and monitor, together with ancillary equipment, such as dictation devices and task lighting
- Lighting, heating, air quality and sound
- Measures to avoid prolonged computer usage, and ensure operator breaks

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- Minimising adverse static postures through keyboard and pointing device placement.

4.2 Qualifications, Registration and Licensing

4.2.1 Qualifications – Clinical Radiologist

The Practice's clinical (diagnostic and/or interventional) radiology services shall be provided by a clinical radiologist who holds relevant Australian or New Zealand medical registration and meets all applicable radiation and medical registration requirements in the relevant jurisdictions in which he/she is providing these services.

The clinical radiologist must have the credentials and meet any other modality-specific requirements for each modality or procedure he/she performs.

INDICATORS

i. The Practice ensures that evidence of current medical registration is held for each clinical radiologist.

ii. The Practice ensures that each of its clinical radiologists is appropriately licensed to use ionising radiation equipment.

iii. Where remote reporting services are provided by the Practice, the Practice holds copies of the current medical board registration documentation and abides by the jurisdictional requirements for radiation licencing of each of its clinical radiologists providing such services.

iv. The Practice ensures that each clinical radiologist has completed CPR training according to the Australian Resuscitation Council or New Zealand Resuscitation Council's guidelines on Basic Life Support, and the Practice maintains a register of the training completed and training expiry dates for all clinical radiologists.(21)

v. Clinical radiologists who perform sedation shall do so in accordance with the ANZCA PS09 Guidelines.(10)

vi. It is the personal responsibility of the radiologist to ensure regular assessment of visual function be undertaken at the beginning of their career, and at regular intervals; increasing in frequency with age due to visual function deterioration (e.g. macular degeneration and cataracts).

4.2.2 Qualifications – Radiographer

A radiographer must have any licences and current professional registration required for the jurisdiction(s) in which he/she is practising, including any radiation operator's licences required for use of ionising radiation.

INDICATORS

i. The Practice maintains a register of, and holds copies of, current AHPRA, MRPBA or MRTB Medical Radiation Practitioner registration records for each of its radiographers.

ii. The Practice ensures that each of its radiographers providing services requiring the use of ionising radiation holds a current radiation licence, and that this is recorded by the radiation safety officer in a radiographer radiation licence register.

iii. The Practice should ensure that radiographers have completed CPR training according to the Australian Resuscitation Council or New Zealand Resuscitation Council's guidelines on Basic Life Support, and CPR; and the Practice maintains a register of the training completed and training expiry dates for all radiographers.(21)

4.2.3 Qualifications – Sonographer

A sonographer must have recognised qualifications and current professional registration required for the jurisdiction(s) in which he/she is practising.

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INDICATORS

i. The Practice maintains a register of, and holds a copy of, current ASAR or MRTB registration for each of its sonographers.

ii. The Practice should ensure current registration is in line with the scope of practice (i.e. a registered vascular sonographer is not performing obstetric imaging examinations, which would fall outside of scope).

iii. The Practice should ensure that sonographers have completed CPR training according to the Australian Resuscitation Council or New Zealand Resuscitation Council's guidelines on Basic Life Support, and CPR; and the Practice maintains a register of the training completed and training expiry dates for all sonographers.(21)

4.2.4 Qualifications – Medical Physicist

A diagnostic imaging medical physicist must be registered in Radiological Medical Physics.

INDICATORS

i. The Practice ensures that its diagnostic imaging medical physicists are registered on the ACPSEM Register of Qualified Medical Physics Specialists in the Radiology Medical Physics Specialty.

4.2.5 Qualifications – Nurse

Nursing personnel working within the Practice must have current professional registration for the jurisdiction(s) in which they are working.

INDICATORS

i. The Practice holds a copy of the current registration record for each of its nurses.

ii. The Practice should ensure that nurses have completed CPR training according to the Australian Resuscitation Council or New Zealand Resuscitation Council's guidelines on Basic Life Support, and CPR; and the Practice maintains a register of the training completed and training expiry dates for all nurses.(21)

4.2.6 Qualifications – Service Personnel

The Practice shall ensure that all personnel servicing its systems and equipment are suitably qualified.

INDICATORS

i. The Practice has a procedure for obtaining confirmation from the service provider/s that service personnel are appropriately qualified and/or certified for the scope of service activity carried out.

4.2.7 Qualifications – Administrative Staff

Administrative staff shall have undertaken or be undertaking training to perform medical administration tasks.

INDICATORS

i. The Practice holds administrative staff personnel records, which include associated records of training appropriate to the size and scope of the service.

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4.2.8 Qualifications – Radiation Safety Officer

The Practice shall ensure that all radiation safety officers have undertaken training to perform radiation safety checks (e.g. https://www.arpansa.gov.au/our-services/training/radiation-safetytraining).

INDICATORS

i. The Practice holds radiation safety officers personnel records, which include associated records of training and the appropriate radiation safety legislation for the Practice's jurisdiction. ii. The Practice has implemented a policy that its personnel and the Radiation Safety Officer complete tasks against the relevant Radiation Safety Act for it's state, or in New Zealand complies with the International Atomic Energy Agency's (IAEA) Basic Safety Standards (IAEA GSR Part 3).

4.3 Continuing Professional Development (CPD)

4.3.1 CPD

The Practice shall encourage and support personnel participating in continuing professional development (CPD) required for the specific tasks that they perform.

Notes: CPD activity may be undertaken through a staff member's professional body (e.g. RANZCR in the case of clinical radiologists; a radiographer's CPD program, such as or equivalent to the ASMIRT or NZIMRT CPD program).

Some additional CPD requirements are set out in modality-specific requirements.

INDICATORS

i. The Practice has implemented a policy to encourage and support participation by its personnel in their CPD activity. ii. The Practice maintains a register of CPD training attended by its staff or alternatively is able to access this when required.

4.3.2 CPD – Clinical Radiologists

Participation in CPD activity shall be maintained by all clinical radiologists providing clinical (diagnostic imaging and/or interventional) radiology services in order that they may keep abreast of rapidly changing practice in this area of medicine.

Notes: There are specific CPD requirements for practice in certain modalities. These are described in the modality's requirements.

INDICATORS

i. The Practice ensures that each of its clinical radiologists provides it with evidence of ongoing participation in the RANZCR CPD program (or equivalent).

4.3.3 CPD – Radiographers

Radiographers shall participate in a recognised radiographer's CPD program, such as or equivalent to the ASMIRT CPD Program.

INDICATORS

i. The Practice ensures that each of its radiographers provides it with evidence of ongoing participation in a recognised CPD program (e.g. ASMIRT or equivalent).

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4.3.4 CPD – Sonographers

To maintain clinical competence in ultrasound, sonographers shall maintain CPD as per the registration requirements in either Australia and New Zealand as appropriate.

Sonographers practising in Australia shall maintain registration with ASAR including an approved CPD program (e.g. ASAR, ASUM, ASMIRT or ASA).

Sonographers practising in New Zealand shall maintain registration with the MRTB. Participation in CPD is mandatory, but does not require the sonographer to take part in a specified program. For example, CPD can be self-managed or a program may be used to assist.

INDICATORS

i. The Practice ensures that each of its sonographers is registered with an appropriate body.The Practice ensures that each of its sonographers actively participates in CPD to maintain clinical currency and registration.

4.3.5 CPD – Medical Physicists

Medical physicists shall participate in CPD activities and comply with the CPD requirements of the ACPSEM. Medical physicists shall also participate in the ACPSEM CPD audit.

INDICATORS

i. The Practice ensures that each of its medical physicists provides it with evidence of ongoing CPD participation that complies with the ACPSEM CPD requirement, or the CPD Audit.

4.3.6 CPD – Nurses

Nurses shall participate in the NMBA CPD program or the Nursing Council of New Zealand Recertification Audit.

INDICATORS

i. The Practice ensures that each of its nurses provides it with a copy of their current NMBA CPD declaration or the Nursing Council of New Zealand Recertification Audit.

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5 PROFESSIONAL SUPERVISION

The Practice shall meet the professional supervision requirements in these Standards, ensuring at all times the safety and quality of each patient's imaging examination.

5.1 Professional Supervision

A team-based approach works best in clinical radiology, as it ensures that those who provide services to patients do so efficiently, safely and to the ultimate advantage of the patient.

Each component of a diagnostic imaging service shall be carried out under the professional supervision of a clinical radiologist in accordance with jurisdictional requirements.*

Certain tasks may be delegated to team members with the required professional expertise to undertake these tasks independentaly in accordance with established clinical practice, and the risk associated with each service. Delegated tasks remain under the clinical radiologist's professional supervision.

*Notes: *The performance of diagnostic medical imaging services carried out under the leadership of a clinical radiologist is defined as professional supervision.*

Diagnostic imaging services are provided in multidisciplinary teams comprised of members with the required expertise drawn from various professional groups (e.g. clinical radiologists, radiographers, sonographers, medical physicists, nurses and administration staff). The individual professional responsibilities of team members are interdependent, and collectively enable the effective delivery of this service.

The components of professional supervision are:

1. *Professional Competence*
2. *Procedural Justification and Optimisation & Patient Preparation*
3. *Performance of Imaging Examination*
4. *Interpretation & Reporting*
5. *Appropriate and timely communication of critical test results*
6. *Clinical follow-up of procedural results as required*

INDICATORS

i. The Practice has protocols in place to ensure that the clinical radiologist's professional supervision requirements are satisfied through either:

   a. personally conducting all or particular tasks associated with the relevant component of the imaging service; OR

   b. direct (face-to-face) supervision of the other members of the imaging team as the relevant component of the imaging service is undertaken; OR

   c. task delegation through the implementation of and adherence to appropriate written protocols to be followed by members of the imaging team, under the clinical radiologist's direction.

ii. The Practice's professional supervision protocols also provide for different triggers for seeking clinical radiologist input, and are consistent with patient management policies and procedures (refer to Standard 7.1).

iii. The Practice ensures that when teleradiology or remote reporting services are provided in accordance with appropriate written protocols under the direction of its clinical radiologist/s, the professional supervision protocols are clearly written, readily available and implemented at the site at which the examination takes place, as well as at the reporting site (refer to Standard 8).

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5.2 Professional Competence

The Practice shall ensure that where there are specific competencies required for a particular imaging examination, the personnel involved with that imaging examination are suitably qualified and experienced.

INDICATORS

i. The Practice's professional supervision arrangements ensure that all personnel involved in a medical imaging examination are appropriately qualified and experienced according to the specific requirements of the examination.

ii. Where personnel are not considered to be sufficiently experienced, the Practice's professional supervision arrangements ensure that appropriate supervision protocols are in place to support the personnel, and ensure the safety and quality of the patient's examination.

5.2.1 Trainee Clinical Radiologists

A qualified clinical radiologist must be available to provide on-site direct supervision of trainee clinical radiologists for any/all components of the medical imaging service at all times in-hours, and be readily available to provide advice and backup at all times out-of-hours.

INDICATORS

i. Practice rosters ensure that all trainee radiologists have a qualified clinical radiologist (refer to Standard 4.2.1) available to provide direct (on-site) supervision for all components of the medical imaging service in-hours.

ii. The Practice rosters ensure that all trainee clinical radiologists have access to a rostered qualified clinical radiologist (refer to Standard 4.2.1) for all components of the medical imaging service who is available to provide advice and backup at all times out-of-hours.

5.2.2 Trainee Radiographers

All trainee radiographers shall have on-site supervision by a qualified radiographer.

Graduate radiographers must be supervised by a qualified radiographer and follow requirements of the MRPBA or MRTB.

INDICATORS

i. Practice rosters for the past 12 months (including out-of-hours arrangements) demonstrate that:

- Undergraduate trainee radiographers are directly supervised by a qualified radiographer
- Graduate radiographers must be supervised by a qualified radiographer.

ii. Supervision arrangements and rosters for graduate radiographers undertaking the Supervised Practice Program must be consistent with the MRPBA requirements or MRTB guidelines.

5.2.3 Trainee Sonographers

All trainee sonographers shall have on-site supervision by an appropriately qualified sonographer (in line with the course regulations).

All trainee sonographers should be registered with ASAR in Australia or MRTB in New Zealand.

INDICATORS

i. The Practice holds rosters for the past 12 months demonstrating that:

a. trainee sonographers are directly supervised; and

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b. course requirements, such as logbooks, include supervisor acknowledgement and indicate supervision provided for patient examinations.

ii. The Practice has documented evidence of the level of competence for each trainee sonographer, as agreed by the supervising sonographer.

5.2.4 Trainee Medical Physicist

Medical physicists undergoing training must be appropriately supervised.

INDICATORS

i. The Practice ensures that if trainee medical physicists are involved in the delivery of imaging services, they only do so under the supervision of an ACPSEM-registered medical physicist.

5.2.5 Trainee Medical Imaging Nurse

Medical Imaging Nurses undergoing training must be appropriately supervised.

INDICATORS

i. The Practice ensures that if trainee Medical Imaging Nurses are involved in the delivery of imaging services, they only do so under the supervision of a senior nurse or a doctor.

5.3 Review of Appropriateness of Request and Patient Preparation

5.3.1 Requests

A diagnostic imaging procedure may be undertaken upon receipt of a clinically appropriate request made by a medical practitioner.

A request for a diagnostic imaging procedure made by a health practitioner shall be undertaken providing:

- the health practitioner is registered and/or licensed under relevant state or territory laws,
- the requested imaging procedure is;
- directly related to the health practitioner's recognised field of expertise,
- within the scope of practice.

A request may be accepted when it is in a format whereby sufficient clinical information is provided to allow the clinical appropriateness of the requested procedure to be determined.

INDICATORS

i. The Practice ensures that the following information is provided in requests prior to an imaging examination being undertaken:

- Patient name and date of birth
- Study requested
- Clinical indication for the examination
- Date of request
- Signature, electronic signature or another mechanism for requesting health professional authentication, as well as their contact details
- The requestor's Health Provider Number or Health Provider Index. ii. Consultation with the patient to clarify information provided in the request is carried out as necessary and in accordance with professional supervision protocols.

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iii. The Practice has implemented a process by which, when a request is made, the referrer and the Practice have agreed on the format in which the images resulting from the examination need to be provided in order to be clinically useful, and that the Practice has confirmed it is able to provide the images in this format.

5.3.2 Review of the Request

Before undertaking a requested diagnostic imaging procedure, the clinical radiologist shall consider the appropriateness of the procedure requested, based on the clinical information provided for the diagnosis of the of the patient's condition. This task may be delegated to suitably qualified members of the diagnostic imaging team under the supervision, and with the agreement of, the clinical radiologist.

Particular consideration should be given to the paediatric patient population when considering the appropriateness of the procedure requested.

INDICATORS

i. The Practice has documented procedures for reviewing requests, which ensure that the requested examination is appropriate to the needs of the referrer and the patient.

ii. The professional supervision protocols provide for different triggers for seeking clinical radiologist input for the review of requests by delegated medical imaging team members.

iii. The Practice ensures that the clinical radiologist is readily contactable to discuss and, if necessary, alter the conduct of the imaging examination.

iv. Information is recorded relevant to the study being performed on each patient and is obtained by the medical imaging team prior to the examination. Depending on the examination, this information may include the presence of any allergies, pregnancy status and previous studies.

v. When a request contains insufficient information to determine the appropriateness of the request, the practice has documented procedures to ensure that all reasonable attempts are made to obtain the required information as necessary from the referring practitioner, including consultation with the patient to clarify information provided in the request is carried out as necessary.

vi. The Practice obtains and records specific information when patients are undergoing special examinations, such as MRI, angiography, prostate biopsy and examinations requiring the use of contrast.

vii. Practice protocols ensure that prior to an examination being performed, the patient has been informed of the examination to be performed, the associated risks (where applicable, e.g. contrast) and has provided an appropriate form of consent commensurate to these risks.

viii. When reviewing requests and preparing for imaging of paediatric patients, the Practice makes every effort to:

   a. use a non-ionizing radiation modality, providing it will obtain the required imaging data for diagnosis; and

   b. minimise the use of sedation and anaesthesia.(22, 23)

5.3.3 Substituted and Additional Procedures

When it is determined from the clinical information provided in a request that a different diagnostic imaging examination or modality would be more appropriate, or an additional examination is necessary, the appropriate test/s shall be performed and all reasonable steps shall be taken to contact the requesting practitioner before providing the substituted or additional examination or modality.

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INDICATORS

i. Practice records show that when an additional or substituted examination is called for, the imaging report is notated accordingly.

ii. Practice records demonstrate that all reasonable efforts are made to contact the requesting practitioner, and actual communication that is made is recorded.

iii. Practice records show that before proceeding with a substituted or additional examination, the patient is informed of the change of service and has provided consent in a format commensurate with the risks associated with the examination being performed.

5.3.4 Patient Preparation

The Practice shall have processes for ensuring that a patient has complied with any preparation requirements (e.g. fasting) for the procedure that is being performed.

INDICATORS

i. Information on pre-examination preparation required by patients for particular examinations is made available to patients and referrers.

ii. The Practice has implemented procedures to confirm correct patient preparation has been completed prior to an imaging examination, and include provision for patients who are inappropriately prepared.

iii. Where such preparation relates to contrast administration, this conforms with the requirements of the RANZCR Guidelines for Iodinated Contrast Administration.(24)

iv. Where such preparation relates to sedation, this conforms with the requirements of the ANZCA PS09 Guidelines.(10)

5.3.5 Appropriate Use of Medical Imaging

From time to time, the Practice shall provide referrers and consumers with information regarding the merits of the various diagnostic imaging techniques, so that referrers can make informed decisions about the diagnostic information and relative value of the range of studies provided.

Notes: Practices are encouraged to use evidence-based resources, such as www.insideradiology.com.au, www.insideradiology.co.nz and www.choosingwisely.org.au/home and www.choosingwisely.org.nz

Electronic decision support tools may augment the determination of appropriate imaging by the clinical radiologist and other members of the clinical team.

INDICATORS

i. The Practice has representative information sheets and/or documentation of communication to referrers and consumers.

5.4 Performance of the Imaging Examination

5.4.1 Performance of the Imaging Examination

Documented imaging protocols shall be available and include all necessary information for the proper conduct of the examination, taking into account any specifications for the required qualifications, experience and specialisation of the personnel.

Where specific tasks are delegated to members of the medical imaging team, the protocols shall indicate any specific circumstances under which personnel shall seek further guidance from the supervising clinical radiologist.

Notes: The protocols shall specify, for example, that for each specified circumstance/situation, that a clinical radiologist shall be available to either:

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- immediately personally attend the patient;

- personally attend the patient within a specified set timeframe;

- provide immediate verbal advice; or

- provide verbal advice within a specified set timeframe.

INDICATORS

i. The Practice has documented professional supervision protocols for the performance of imaging examinations, and these protocols are developed under the professional supervision of the clinical radiologist.

ii. These protocols ensure that where it is known the clinical radiologist is not available to provide appropriate additional input for particular modalities or examinations, as detailed in the protocols, the medical imaging team members do not proceed with an examination. iii. Examinations that require sedation of the patient are not undertaken unless an appropriately trained clinical radiologist is available to immediately personally attend the patient, and the safety requirements described under Standards 6.6.1 and 6.6.3 are met.

iv. These protocols cover radiographic factors, positioning, sterile tray set-up, and aftercare according to the relevant examinations and/or modalities performed at the service.

v. These protocols also address medical emergencies.

vi. Imaging protocols for paediatric patients are optimised to obtain the required imaging data while delivering the lowest radiation dose possible and with minimal use of sedation and anaesthesia.(22, 23)

5.4.2 Performance of the Imaging Examination – Administration of Contrast

The Practice shall have protocols in place that ensure the appropriate use and administration of contrast.

INDICATORS

i. The Practice has professional supervision protocols in place in relation to the administration of contrast to screen all patients for history of relevant contrast allergy, current medications, risk factors that increase the likelihood of contrast-induced renal impairment and medical conditions that may result in life-threatening complications from contrast administration.

ii. These protocols determine when the clinical radiologist responsible for overseeing the study must be contacted for advice before contrast is administered.

iii. The task of administering contrast is only delegated to personnel who are trained in venepuncture consistent with Appendix A Personnel Administering Intravenous Contrast.

iv. These protocols determine the dose and type of contrast medium that is administered, by whom it is administered and under whose authorisation.

v. The Practice keeps records of contrast administration to a patient, including the batch number of the contrast administered.

vi. These protocols ensure that a registered medical practitioner must be on site, and immediately available to personally attend and treat the patient in case of a complication of intravenous contrast administration or other medical emergencies.

5.5 Interpretation and Reporting

5.5.1 Interpretation and Reporting the Results

A single named clinical radiologist is to be responsible for the supervision, interpretation and reporting of the entire study.

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Where substantial input regarding supervision, interpretation or reporting has been provided by additional clinical radiologists or suitably qualified medical practitioners, this should also be acknowledged in the report. However, a single named clinical radiologist remains responsible for the entire study.

Where a trainee clinical radiologist has reported under supervision, this should be indicated in the report.

Reports must address all information requested by the referrer, required by the procedure and necessary for the interpretation of the results.

Notes: RANZCR recommends the Clinical Radiology Written Report Guidelines(25) as a resource that provides best practice advice to clinical radiologists and trainee clinical radiologists about the clinical radiology written report.

INDICATORS

i. Primary diagnosis is only performed on images that are of an acceptable diagnostic quality to the reporting radiologist.

ii. The imaging reports include at least the following:

- A title (e.g. Imaging Report)
- Name and address of the Practice, and location/site where the imaging procedure(s) was performed (if different to the address on the report)
- Referrer's name
- Date of issue of the report
- Unique identification of the patient (i.e. full name and date of birth, or medical record number)
- Date of imaging procedure(s)
- Identification of the modality used
- Imaging procedure(s) results and, where appropriate, the units of measurement
- Record/s of the administration of any medication and/or contrast
- Opinions and interpretations
- Name of reporting radiologist.

iii. The use of electronic signatures at the Practice complies with relevant legislation.

iv. Practice protocols ensure that if a report is issued jointly, the co-signatory radiologists have all approved its final content.

v. The Practice ensures that where an amendment or addendum to a report is made, this must be identified on the report, and clearly distinguished from the original report. Authorship, time and date of the addendum should be clearly stated.

vi. If preliminary reports are prepared, the Practice has a process for reconciling any differences between preliminary and final reports, and for ensuring that this is communicated to the referrer.

vii. The Practice ensures that when a sonographer is involved in performing an ultrasound examination, the sonographer's initial and surname is included in the record of the examination held by the Practice. viii. The Practice has implemented a policy governing the provision of verbal and written reports to referring medical practitioners.

ix. Comparison with prior studies is included in reports where these prior studies are available and relevant.

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5.5.2 Communication of Imaging Findings and Reports

The Practice shall ensure that reports are made available in a clinically appropriate, timely manner, and shall carry out regular reviews at least once every year on the time between the performance of the study and the issuing of the report.

Notes: Services should refer to the ACR Practice Guideline for Communication of Diagnostic Imaging Findings as a guideline for further detail.(26)

When considering the framework to identify urgent and non-urgent findings, it is recommended that practices refer to the Massachusetts Coalition for the Prevention of Medical Errors Communicating Critical Test Result recommendations for guidance.(27)

INDICATORS

i. The Practice has a documented policy for communication of clinically urgent or critical test results. The policy or report should include at least the following:

- General findings that should be communicated
- How the communication should be documented
- A record of the person communicated to
- A record of what was communicated.

ii. The Practice maintains records of regular reviews of reporting turnaround times in accordance with this policy, and implements and records corrective action should there be any indications that the designated reporting times are not being met.

iii. The Practice has a protocol for urgent and significant unexpected findings that ensures:

a. the reporting radiologist uses all reasonable endeavours to communicate directly with the referrer or an appropriate representative who will be providing clinical follow-up;

b. a record of actual or attempted direct communication is maintained by the Practice; and

c. the reporting radiologist co-ordinates appropriate care for the patient if they are unable to communicate such findings to the referring clinician.

5.5.3 Consultation with Referrers

The Practice shall ensure that there are mechanisms in place to enable the referrer to discuss imaging findings with the reporting radiologist.

INDICATORS

i. The Practice has implemented a policy for consultation with referrers, including the provision of information to referrers regarding imaging strategies that are appropriate for particular clinical problems.

ii. This consultation includes advice on the current transition from film-based to digital image transfer with advice on the advantages of digital techniques and requirements for appropriate viewing equipment.

5.6 Image Review

The Practice develops and implements a fit for purpose and radiologist-led peer review process to regularly monitor the interpretation of imaging studies.

Some modalities have specific image review requirements that are described in the modality-specific requirements.

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INDICATORS

i. Where these are not required elsewhere in these Standards, the Practice participates in or is working towards a peer-based image review for each modality that it provides.

ii. Unless specified differently elsewhere in these Standards, such reviews are carried out at least annually.

6 SAFETY

The Practice shall conduct all clinical (diagnostic and/or interventional) radiology examinations in a manner that ensures the safety of patients, personnel and the environment. As a minimum, all applicable regulatory requirements shall be met.

6.1 Safety of the Practice Environment

The Practice shall monitor accommodation and environmental conditions as required by the relevant imaging specifications (including regulatory requirements), and where they influence the quality and safety of medical imaging services.

INDICATORS

i. Where equipment is found to be defective, it is taken out of service, clearly labelled, and not returned to service until it has been repaired and shown by calibration and/or checks to meet relevant acceptance criteria.

6.2 Infection Control

All applicable regulatory health-related infection control guidelines shall be followed.

INDICATORS

i. The Practice documents all policies and procedures for all infection control issues, including sterilisation/disinfection and hand hygiene.

ii. These policies and procedures comply with the applicable regulatory standards, DIAS Standard(28), the NHMRC Australian Infection Control Guidelines(29) and the Australian Immunisation Handbook(30); and in New Zealand, practices should refer to the Health Quality and Safety Commission's Infection Prevention and Control Program.(31)

6.3 Radiation Safety

6.3.1 ALARA Principle

The Practice shall apply the ALARA principle ('as low as reasonably achievable') to each radiological procedure performed, and must document radiation safety policies and procedures that involve the use of ionising radiation, and aim to minimise radiation exposure and prevent radiation incident, in accordance with the ALARA principle.

INDICATORS

i. The Practice can demonstrate through its radiation safety policies, procedures and imaging protocols that it applies the ALARA principle to each radiological procedure that is performed.

ii. The Practice records patient doses and aggregates these annually in order to establish Facility Reference Levels (FRLs).

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iii. These FRLs are reviewed annually to determine the need for dose optimation activity. iv.

FRLs are also reviewed against national DRLs where these are published.(32)

6.3.2 Compliance with Radiation Safety Legislation

The Practice shall comply with the requirements of all radiation safety legislation.

INDICATORS

i. The Practice retains all records required under relevant radiation safety legislation (including national, state/territory and local government legislation) and under the directions of relevant regulatory authorities or advisory bodies (including: state, territory and New Zealand radiation safety agencies, and ARPANSA).

ii. The Practice retains records of any corrective action notices issued by radiation safety regulatory bodies and the corrective action taken.

iii. The Practice retains records of any corrective action the service itself deems necessary to comply with the requirements of relevant radiation safety legislation and the corrective action that has been taken.

6.3.3 Radiation Safety Officer

Where ionising radiation is used, the Practice shall appoint a radiation safety officer whose responsibility it is to ensure that the Practice adheres to relevant radiation safety legislation at the Practice site/s.

INDICATORS

i. The Practice has appointed a radiation safety officer who maintains the requisite skills to fulfil the position criteria contained in the radiation safety officer job description.

ii. The radiation safety officer monitors changes in the legislation, adjusts policies and activities accordingly, and communicates these to Practice personnel.

iii. The radiation safety officer co-ordinates record keeping in relation to radiation safety at the Practice.

6.4 Waste Management

Practice waste shall be stored and disposed of safely and in a manner that complies with the relevant statutory requirements.

INDICATORS

i. The Practice has implemented procedures addressing the storage and disposal of contaminated medical waste and the use of laundry and linen services, which comply with the relevant statutory requirements.

6.5 Use of Contrast Media

The Practice shall ensure the safe use of contrast media and have a protocol for the management of adverse reactions to contrast media.

Notes: Practices may wish to assign 'the Resuscitation Officer' as the designated CPR training officer in order to efficiently and economically manage CPR training across the Practice.

INDICATORS

i. The Practice has implemented a procedure for the use of contrast media that ensures that the service complies with the current versions of the RANZCR contrast guidelines.(24)

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ii. The Practice has a policy that ensures appropriate storage and use of contrast media in accordance with National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines.(33)

iii. The Practice has designated personnel who hold current CPR certification, and are trained in the appropriate management of contrast reaction and the use of resuscitation equipment to support the management of adverse reactions to contrast.

iv. The Practice has a clearly identified staff member who ensures that resuscitation equipment and drugs etc. are present and in a state of readiness.

v. The Practice maintains a documented plan of management for likely adverse events due to contrast reactions, which includes as a minimum:

a. a prominently displayed documented procedure describing the management of reactions, and reference to 'Emergency management of anaphylaxis in the community'(34);

b. identification of personnel responsible for managing the treatment of contrast reactions;

c. a protocol for transfer of a patient to an acute care facility if required; and

d. the plan of management should be tested by the appropriate staff on an annual basis.

6.6 Sedation and Anaesthesia

6.6.1 Use of Sedation

The Practice shall ensure the safe use of sedation.

Notes: Practices should refer to Standard 7.5 in relation to discharge procedures.

INDICATORS

i. The Practice has implemented policies and procedures that ensure the safe management and use of sedation. The policies and procedures identify personnel who are adequately trained and authorised to select patients for sedation, administer sedation and manage sedated patients.

ii. These policies and procedures are consistent with the ANZCA PS09 Guideline.(10)

iii. The Practice records drugs used for sedation, the person administering the drugs and the management of sedated patients.

6.6.2 Use of Anaesthesia

The Practice shall ensure the safe use of anaesthesia.

Notes: Practices should refer to Standard 7.5 in relation to discharge procedures.

INDICATORS

i. The Practice has implemented policies and procedures that ensure its management of the use of anaesthesia is consistent with ANZCA PS55 Policy(11) and ANZCA PS09 Guideline(10).

ii. The Practice ensures that personnel administering general anaesthesia are trained anaesthetists, with assistance as defined in ANZCA PS55 Policy(11) and ANZCA PS09 Guideline(10).

6.6.3 Use of Medications

The Practice shall ensure that all medications used in imaging procedures are used appropriately, labelled appropriately and are stored according to the manufacturer's guidelines.

Notes: This Standard applies to medications used for sedation and anaesthesia, and all other medications other than contrast media, which are addressed in Standard 6.5.

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INDICATORS

i. The Practice has implemented a medications management process that identifies patients at risk from adverse reactions, and ensures that only appropriately qualified and authorised personnel administer medications.

ii. The Practice has designated personnel who hold current CPR certification, and are trained in the appropriate management of adverse reactions to medication and the use of resuscitation equipment to support the management of these.

iii. The Practice has a clearly identified staff member who is designated as the resuscitation officer to ensure that resuscitation equipment and drugs are present and in a state of readiness in the case of an adverse reaction to medication. iv. Medications are clearly labelled in accordance with the National Recommendations for Userapplied Labelling of Injectable Medicines, Fluids and Lines.(33)

v. The Practice medications inventory demonstrates that all medications are valid, stored and disposed of according to the manufacturer's guidelines.

vi. The Practice has a documented process of auditing expiry dates of unused medication and disposal of expired stock.

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7 PATIENT MANAGEMENT

The Practice shall ensure that patient management procedures address the needs of patients, and support the Practice in its delivery of safe, quality clinical (diagnostic and/or interventional) radiology services.

7.1 Patient Management

The Practice shall have procedures for the management of patients that address all provisions necessary to protect the interests of the patient and the service.

These procedures shall be designed to ensure the safety and well-being of patients, visitors accompanying patients and children in the care of patients while in the Practice.

Notes: Resources to support quality and safety measures for patient management are available from the Australian Commission on Safety and Quality in Healthcare www.safetyandquality.gov.au and from the Health Quality and Safety Commission New Zealand https://www.hqsc.govt.nz

INDICATORS

i. The Practice has implemented patient management policies and procedures that include patient transportation, reception, patient comfort, patient preparation, falls prevention, privacy, clinical handover, and post-procedure observation and discharge; these policies and procedures are consistent with the current Australian Charter of Healthcare Rights(35) and the Code of Health and Disability Services Consumers' Rights.(7)

ii. These patient management policies and procedures address the early identification and management of patients who are at increased risk of being, or who are, seriously or critically ill.

iii. These patient management policies and procedures provide for patients whose examinations involve teleradiology (refer to Standard 8).

7.2 Patient Identification and Records

The Practice shall have a system for uniquely identifying patients and storing records relating to them, which shall occur from the time of the referral, prior to medical records or image data arriving for the patient, to completion and storage of the examination.

Some examinations may require a longer retention period, but agreement on a longer retention period for individual cases will need to be arrived at through consultation between the referring practitioner and the imaging specialist.

INDICATORS

i. The Practice has a patient identification system that uniquely identifies every patient by three approved patient identifiers.

ii. The Practice ensures the correct patient identification is maintained on all records, including reports.

iii. The Practice has implemented a system whereby it can ensure that:

- Diagnostic quality images are recorded for all examinations performed with digital techniques as per Standard 3.7.1 and form part of the patient record
- Where images are not stored on films or portable media held by the patient, digital or film images of diagnostic quality are retained for the applicable statutory period, whichever is the longer, and shall be available to the referring practitioner (or related clinician managing the patient's care, where appropriate) consistent with the requirements stated under Standard 3.9

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- Practices should have regard to the statutory limitation periods for negligence actions in the relevant jurisdiction, and should consider this in relation to the storage of patient records
- The Practice has implemented protocols that identify which studies require an extension to this retention period, and ensure that this occurs.

iv. Examination records include patient identification, the date and, where necessary, time of the study and the Practice name imprinted on them.

v. The identity of the person who performed the study is recorded and stored in accordance with the jurisdictional requirements for medical records, and this identity information may be on the worksheet, request form or radiology information system database entry for the examination.

vi. When images are provided with a report, a record is made of the method of transfer (portable media, film, electronic transmission or other) and of the person to whom the images were provided (i.e. patient or referrer).

7.3 Cultural Competency

The Practice shall ensure to deliver respectful and culturally appropriate care, by advocating cultural awareness and sensitivity. The Practice shall provide patient care that takes into consideration the patients' rights, beliefs (including religious) and cultural background.

Notes: There is different legislation existing in each jurisdiction mandating anti-discrimination and cultural competency. In Australia, there is the Racial Discrimination Act, 1975 (some jurisdictions have additional legislations e.g. Queensland with the Anti-Discrimination Act, 1991). In New Zealand, this includes the recognition of the principles of the Treaty of Waitangi, Health Practitioners Competence Assurance Act, 2003 (section 118(i)) and the Code of Health and Disability Services Consumers' Rights Regulation, 1996.

INDICATORS

i. The Practice has implemented a policy encompassing cultural safety, so that all staff know and understand that the provision of care requires respect for the patient's culture and beliefs, and freedom from discrimination. ii. The Practice should provide appropriate education and/or training for all staff to deliver care that aids patients to feel culturally safe. iii. The Practice should make available resources that are culturally appropriate and tailored for the health literacy of patients.(36)

7.4 Correct Patient, Site and Procedure

The Practice shall ensure that prior to a procedure being performed, it is the correct intended procedure to be performed on the correct patient at the correct site on the patient.

Notes: Existing national, state or territory health department policies may be adopted or used for guidance in developing a practice procedure.

INDICATORS

i. The Practice has implemented a 'time out' protocol, which ensures that prior to a procedure being performed, the medical imaging personnel performing the examination confirm that the correct procedure is being performed on the correct site of the correct patient, and that this process is documented in the patient's record.

ii. This protocol ensures that any discrepancy in patient identification, site and/or procedure prompts corrective action before the imaging procedure, and that this is documented in the patient's record. Any required consent forms are signed and documented. iii. This protocol is consistent with the Australian Commission on Safety and Quality in Health Care's protocols(37) and the Health Quality and Safety Commission(38).

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7.5 Discharge Procedure

The Practice shall have a documented policy for the discharge of sedated patients, those who have been anaesthetised, those who have received iodinated contrast media (in accordance with the RANZCR Iodinated Contrast Media Guidelines(24)) or other medication requiring a postadministration observation period.

INDICATORS

i. The Practice has implemented a procedure that ensures patients who have been sedated or placed under anaesthetic are discharged in the care of a responsible adult after appropriate recovery.

ii. All patients are provided with clear instructions concerning driving, the operation of equipment, making important decisions relating to legal issues and finances or other anticipated sideeffects. For nuclear medicine procedures, this will include information about protecting others from exposure to ionising radiation (refer to Standard 15).

7.6 Patient Consent

The Practice shall ensure that patients have access to appropriate information to make an informed decision prior to an imaging examination being undertaken and to prepare for the examination itself.

Notes: The format of consent will differ according to the level of risk associated with each imaging examination. For example, consent may take the form of 'implied consent' following verbal discussion with patients in the case of general X-ray examinations of extremities. More complex examinations and those involving contrast will require more definitive, written consent.

The RANZCR Medical Imaging Consent Guidelines(39) and ARPANSA's Having a Scan? A Guide for Medical Imaging(40) are recommended as useful resources when approaching patient consent.

InsideRadiology (www.insideradiology.com.au; www.insideradiology.co.nz) is recommended as a useful resource to Practices in providing referrers and patients with information on imaging procedures.

INDICATORS

i. The Practice provides comprehensive information to patients on the imaging procedure to be performed prior to it being undertaken.

ii. The information should be individualised and includes, but is not limited to, the following:

- Pre-treatment preparation and/or instructions
- Post-treatment and/or discharge instructions
- Fee information
- Risks
- Involvement of students/trainees
- The role of the person performing each stage of the examination.

iii. The Practice meets or is developing the capacity to meet the communication needs of nonEnglish speaking patients in providing such information.

iv. The Practice maintains records of patient consent in the patient's record and the information provided during consent. Practices are encouraged to provide standardised information for frequently preformed procedures.

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7.7 Privacy Policy

7.7.1 Privacy Policy

The Practice shall have a privacy policy relating to all practice activities, including those involving teleradiology.

INDICATORS

i. The Practice has implemented a privacy policy that:

   a. governs the use of patient personal information within the service and its disclosure to other parties;

   b. addresses the 13 Australian Privacy Principles (APPs) set out in Schedule 1 of the Privacy Amendment (Enhancing Privacy Protection) Act 2012, which amends the Privacy Act 1988 or the 12 Privacy Principles set out in the Privacy Act 1993 in New Zealand;

   c. complies with other laws and any applicable codes of practice governing personal privacy, confidentiality of clinical information and data protection in the relevant jurisdiction;

   d. is publicly available; and

   e. allows the patient to access their clinical records.

ii. The Practice documents in its Privacy Policy if, where and why its management of patients' personal information varies from the Australian Privacy Act 1988, Privacy Amendment Act 2017 or New Zealand Privacy Act 1993 if this occurs.

iii. The Practice should have processes in place for a mandatory data breach notification plan.

7.7.2 Patient Consent to Use of Information

The Practice shall implement a procedure for seeking the consent of patients to the proposed use of their personal information.

INDICATORS

i. The Practice has implemented a procedure for gaining patients' consent to the use of their personal information.

ii. The method by which consent is sought is consistent with the Practice's privacy policy, and sets out in plain language the proposed uses of personal information (which includes images, reports and requests).

7.7.3 Patient Consent to be Recorded in Information Systems

The Practice shall have information systems that are capable of recording a patient's consent and any restrictions on the use of that patient's personal information.

INDICATORS

i. The Practice has implemented or is working towards the implementation of a process for recording patients' consent in the service's information system.

ii. This information system is or will be capable of flagging any personal information that is subject to restricted consent.

7.8 Open Disclosure

The Practice shall implement an open disclosure program to enable the open disclosure of incidents that result in harm, or could have resulted in harm, to a patient while receiving healthcare.

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INDICATORS

i. The Practice operates an open disclosure program that is consistent with the Australian National Open Disclosure Framework(2) or the Health Disability Commissioners Guidance on Open Disclosure Policies(3).

The open disclosure program involves:

- Processes to detect adverse events through a variety of mechanisms, such as:
  - identification of errors during or immediately after a procedure is performed; and
  - patient/carer/referring clinician communication/complaints after the patient leaves the Practice
- Provision of prompt clinical care to the patient to prevent further harm
- Assessment of the incident for severity of harm and level of response
- Provision of support for staff
- Initiation of a response, ranging from lower to higher levels
- Notification of relevant personnel and authorities
- Ensuring the privacy and confidentiality of patients and clinicians are observed
- Documenting the error and the possible consequences, with copies given to the patient and the referring specialist.

Commencement of the disclosure process, which will include:

- Acknowledgement the adverse event to the patient, their family and carers including an apology or expression of regret (this is not the same as assuming blame or responsibility for the adverse event).
- Some, all or none of the following, depending on the nature and severity of the event, in preparation for formal open disclosure:
  - Negotiate with the patient, their family and carers or nominated contact person:
    - the formality of open disclosure required;
    - the time and place for open disclosure; and
    - who should be there during open disclosure
  - Provide written confirmation and contact details for a Practice staff member for the patient/family
  - Maintain good verbal and written communication throughout the process
  - Consider who will participate in the open disclosure process, and appoint a lead individual
  - Gather necessary information to inform the discussion
  - Consult with professional indemnity insurance providers/other relevant insurers or institutional risk management/medico legal team.

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8 TELERADIOLOGY

Technological advances have seen healthcare services provided remotely. The provision of healthcare remotely through telecommunications technology is referred to as 'telehealth'. The subset of telehealth that relates to the provision of clinical radiology services remotely is 'teleradiology'. Teleradiology can be defined as the electronic transmission of diagnostic radiological images in digital form between locations (Acquisition Site to Reporting Site) for diagnosis and reporting by a clinical radiologist or any other appropriately credentialed medical specialist* using a bi-directional data communication link that keeps all patient data secure.
Teleradiology is an adjunct to conventional on-site radiological service provision. A Teleradiology Service Provider is the entity or person responsible for interpreting the images at the Reporting Site. The primary purpose of a teleradiology service must always be to improve patient care relative to that available in its absence. This can be though provision of:

1. access to specialist diagnostic services for remote and rural centres that cannot support the presence of a full-time diagnostic imaging specialist;
2. after-hours specialist diagnostic services to centres with inability to sustain full specialist cover due to a lack of workforce or inability to provide rostering in keeping with sustainable working practices compliant with local Work Health and Safety principles;
3. support for times of unexpected workforce shortage including personal circumstance of the on-site clinical radiologists;
4. a pool of clinical radiologists within a formalised network arrangement to optimise continuity of the reporting for that group of clinical radiology departments to cover workload variations during the day;
5. subspecialist radiology reporting to cover deficiencies in the combined expertise of a clinical radiology department; and
6. access to clinical radiologist expertise when a clinical radiologist is not available on site.

These Standards have been developed by RANZCR to ensure the provision of hiqh-quality and safe teleradiology services in Australia and New Zealand.

*Notes: *All references to 'clinical radiologist' in this document also apply to any other appropriately credentialed medical specialist, who would be expected to comply with the same requirements.*

Inappropriate use of teleradiology

Any use of teleradiology by management of a site or sites to undermine an on-site clinical radiology service, eliminate the provision of on-site clinical radiologist cover and/or to circumvent compliance with quality processes and governance requirements is contrary to the primary purpose and is considered inappropriate.

Key Principles

a) Teleradiology must be carried out in a manner that is in the best interests of the patient and their medical care.
b) An on-site clinical radiologist is the preferred model of service delivery; teleradiology is supplementary to comprehensive on-site clinical radiology.
c) Image quality and image interpretation must not be compromised by the use of teleradiology reporting.
d) The reporting radiologist must be registered and indemnified in the jurisdiction of image acquisition and appropriately trained, certified and credentialed as necessary for the site of image acquisition such that the patient can pursue litigation, or other complaint resolution processes, in the jurisdiction of image acquisition.
e) The Teleradiology Service Provider having an adequate understanding of the language, cultural differences and specialist vocabulary of the jurisdiction of acquisition is essential.

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f) Communication channels between the reporting radiologist and referring clinician should be established to report on urgent findings.
g) The medical imaging technologist must be licensed and registered in the jurisdiction of image acquisition, adequately trained in the use of teleradiology equipment/software used at that site, and under the overall supervision of an appropriately registered clinical radiologist.
h) A clearly defined service agreement between the Acquisition Site and Teleradiology Service Provider must be in place with a mechanism to deal with urgent or unexpected findings (including their direct communication to the referring clinician and patient).
i) Teleradiology Service Providers should comply with all data protection standards specified in the country or jurisdiction of acquisition with policies for data security to protect patients and compliance with relevant legislation.
j) Robust quality control and audit procedures for clinical radiologists and equipment should be in place and documented and they must comply with local radiation safety requirements.
k) The professional standards applying to both on-site provision and teleradiology are the same or as close to the same as possible.
l) Real time consultation is available between the medical imaging technologist or referring clinical team and the reporting radiologist that includes advice regarding the appropriateness of imaging referrals.
m) A formal documentation system must be in place to record and log the identity of the reporting radiologist and the date and time of reporting.

8.1 Teleradiology (General)

8.1.1 Limitations of Teleradiology

8.1.1.1 Loss of On-site Informal Communication

Partnership with the referring clinicians should be prioritised to ensure appropriate clinical consultation and communication. The process for referral to clinical radiology, discussions between the referrer and clinical radiologist before and after imaging, and communication channels between the patient and clinical radiologist should be well defined, including processes for documentation.

INDICATORS

The Teleradiology Service Provider should show evidence of records of communication, either through RIS or a statement in the report.

8.1.2 Methods of Data Transfer

The reporting radiologist should, wherever possible, have access to the same images and information as an on-site clinical radiologist.

INDICATORS

i. The Acquisition Site ensures that data transferred for off-site reporting is the same as that available for on-site reporting, and the data must not be modified in such a way that the remote reporting site is unable to manipulate the images or post-process the images to the same extent as achieved by the on-site systems. This should also apply to the use of any third party postprocessing software required by the referral request.

ii. The Acquisition Site ensures that data transferred for off-site reporting includes access to prior relevant imaging, the corresponding request forms and reports.

8.2 Qualifications and Registration

8.2.1 Clinical Radiologists

Clinical radiologists supervising and reporting the images remotely must be qualified, credentialed and registered with the appropriate body at the Acquisition Site. The registration status must be either

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the same as would be required of an on-site clinical radiologist or, alternatively, the clinical radiologist must be registered in any specialist registration category, or scope of practice, for teleradiology*.

*Note: *For example, see the Medical Council of New Zealand Policy on Registration Within a Special Purpose Scope of Practice.(41)*

A reporting radiologist must also have adequate medical indemnity insurance in the jurisdiction of the Acquisition Site.

INDICATORS

i. The Teleradiology Service Provider holds a copy of current medical registration for each clinical radiologist reporting for the Acquisition Site.

ii. The Acquisition Site holds a copy of the current medical registrations for all clinical radiologists reporting for the Acquisition Site.

iii. The Teleradiology Service Provider holds a copy of medical indemnity insurance for each clinical radiologist reporting for the Acquisition Site.

iv. The Acquisition Site holds a copy of medical indemnity insurance for all clinical radiologists reporting for the Acquisition Site.

8.3 Clinical Support

8.3.1 Responsibilities of the Specialist

The reporting radiologist or appropriately credentialed specialist may provide clinical support for the components of a diagnostic imaging service under their direct control if requested.

The reporting radiologist is also responsible for other components to the extent that they can directly influence and modify the service for the benefit and protection of the patient.

Clinical support includes timely communication of results in all cases and, in particular, for serious and unexpected findings likely to affect the management and well-being of the patient. This will extend in unusual circumstances to direct communication by the reporting radiologist with the patient where communication with the referring clinician (or another clinician responsible for the management of the patient) cannot be completed and the situation warrants urgent action.

The reporting radiologist or appropriate reporting specialist will provide professional advice and support to the allied health professional and nursing staff directly involved in the components of a diagnostic imaging service. This includes the provision of advice to the technologist regarding imaging in line with protocols and appropriate use of imaging.

INDICATORS

i. The Teleradiology Service Provider ensures that when teleradiology or remote reporting services are provided in accordance with appropriate written protocols under the direction

of its clinical radiologist(s), the protocols are clearly written, approved, readily available and implemented at the site at which the examination takes place, as well as the reporting site (refer to Standard 5.1, Indicator 3).

ii. The service agreement between the Acquisition Site and Teleradiology Service Provider provides a clear framework for clinical support for all components of the diagnostic imaging and reporting process.

8.3.2 Interpretation and Reporting

The teleradiology reporting service must comply with these Standards, including:

- Standard 5.5.1 Interpretation and Reporting the Results, noting that there is a separation between the ‘Practice’ (Acquisition Site) and reporting site, and the ‘single clinical radiologist’ requirement may not be met.

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- Standard 5.5.2 Communication of Imaging Findings and Reports (indicator iii)

INDICATORS

i. The Practice ensures that protocols for transmission of imaging data are available at the transmitting and receiving sites appropriate to the scope of examinations being performed.

ii. These protocols are specific to each examination type being performed, and include references to the following:

- The examination
- Acquisition method including resolution
- Compression type and level for each examination
- Image orientation
- Image sequence selection
- Urgency of examination
- Transmission time
- The number of images in the series
- The personnel responsible for the examination at the examination capture site.

iii. Patient data is identifiable and contains the following information:

- Full name
- Unique identifier
- Date and time of examination
- Diagnostic imaging service name
- Type of examination
- Compression type and level
- Patient notes (including the request for the patient's examination, which is transmitted either by facsimile or electronically) • Annotations including side markers.

8.3.3 Responsibilities of Allied Health Professional and Nursing Staff

Allied health professionals and nursing staff should consult with the supervising clinical radiologist, whether on site or remote, if the circumstances fall outside of normal protocol or there are any clinical concerns.

8.3.4 Responsibilities of the Acquisition Site

The Acquisition Site is responsible for ensuring protocols are in place, stating the responsibilities of:

- Remote reporting radiologist, as agreed with the Acquisition Site (with input from on-site clinical radiologist where available) and with the Teleradiology Service Provider;
- The Teleradiology Service Provider as an entity; and
- The on-site allied health professional and nursing staff are in place, and protocols are followed appropriately.

INDICATORS

i. The Acquisition Site has documented and readily accessible protocols.

ii. The Acquisition Site holds evidence of an agreement between the Acquisition Site and the remote reporting radiologist or the Teleradiology Service Provider.

8.3.5 Appropriateness

There must be a clear statement between the Acquisition Site and any Teleradiology Service Provider as to who has delegated authority for monitoring the appropriateness of requests, including providing clinical support to on-site staff for protocolling and other components, to the extent that the person with delegated authority can influence and modify the service for the benefit and protection of the patient.

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INDICATORS

i. The Acquisition Site has a record of delegated authority.

ii. The Acquisition Site has documented and readily accessible protocols.

8.3.6 Use of Contrast

The appropriate use of contrast shall be stated in the contrast protocol of the Acquisition Site.

The use of contrast outside of on-site protocols shall be approved by an on-site clinical radiologist or appropriately credentialed specialist, or in their absence, by the reporting clinician as per Standard 4.1.1 (Personnel).

The use of iodinated contrast should follow the most current RANZCR Iodinated Contrast Media Guideline(24). In line with those standards, a medical practitioner must be immediately available when contrast is administered.

INDICATORS

i. The Acquisition Site has a documented protocol on contrast usage.

8.4 Reporting Equipment

8.4.1 Specific

As with on-site radiology, Teleradiology Service Providers must meet the same requirements for reporting equipment as per Standard 3 (Equipment).

INDICATORS

i. Refer to Standard 3 (Equipment).

8.4.2 Mammography

As with on-site clinical radiology, Teleradiology Service Providers must meet the same requirements for equipment as per Standard 14.2.1 (Diagnostic Mammography Equipment).

INDICATORS

i. Refer to Standard 14.2.1 (Diagnostic Mammography Equipment).

8.4.3 Fluoroscopy

At present, the standard for fluoroscopy is to have a clinical radiologist on site when performing the examination. There may be exceptions when fluoroscopic images can be transmitted for interpretation via teleradiology. If transmitted, all acquired fluoroscopic images, including video clips and still images, must be sent.

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INDICATORS

i. The Acquisition Site must have a list of limited procedures that can be performed without a clinical radiologist on site.

ii. The Acquisition Site must have documented protocols to determine what images should be taken for any limited procedures that can be performed without a clinical radiologist on site.

8.4.4 Ultrasound

Images must be available for the reporting radiologist as soon as appropriate. There must be the ability to review images with either an on-site or off-site clinical radiologist, preferably during the course of the imaging procedure. The reporting radiologist must also be prepared to follow up queries with the sonographer and call back patients if required.

INDICATORS

i. The Acquisition Site must have documented policies in the use of teleradiology for ultrasound reporting.

ii. The Acquisition Site must have a protocol stating the roles of and limitations upon the sonographer in such a service, in particular on actions to be taken with serious and unexpected findings arising from the ultrasound study.

iii. The equipment should have the ability to save cine loops, and if not, allow some way of real-time review by the reporting radiologist.

8.4.5 Compression

All data compression used must be lossless.

INDICATORS

i. When storing and transmitting digital images, the Acquisition Site uses lossless compression.

8.4.6 Display Capabilities

As with on-site radiology, the reporting environment, displays and computers used by a clinical radiologist to report images performing teleradiology either at home, a reporting hub or within a Teleradiology Service Provider site must meet the same requirements for equipment as per Standard 3.6.2 (Diagnostic Workstations) and Standard 3.6.2.1 (Display Software).

Diagnostic reporting must not be carried out on screens that do not meet Standard 3.6.2.2 (Monitors) of these Standards, in particular on handheld or portable devices and laptop computers, which do not comply.

INDICATORS

i. Refer to Standard 3.6.2 (Diagnostic Workstations).

ii. Refer to Standard 3.6.2.1 (Display Software).

iii. Refer to Standard 3.6.2.2 (Monitors).

8.4.7 Patient information

As with on-site radiology, teleradiology service providers must meet the same requirements for patient identification as per Standard 7.2 (Patient Identification and Records).

i.

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INDICATORS

Refer to Standard 7.2 (Patient Identification and Records).

8.5 Record Keeping and Security

8.5.1 Environment

The Acquisition Site and Teleradiology Service Provider are to take all reasonable measures to ensure health information is securely collected, transferred, stored and accessed. Data protection standards and laws relating to the Acquisition Site will apply to the teleradiology transaction.

The teleradiology reporting service will comply with Standard 3.11 (Reporting Environment).

INDICATORS

i. Refer to Standard 3.11 (Reporting Environment).

8.5.2 Image Management

Both the Acquisition Site and the Teleradiology Service Provider must have adequate systems to maintain records and the service in the event of system failure. This should include internal system redundancy, backup communication links, a disaster recovery plan and documentation of the actions to be carried out in the event of failure available at both the Acquisition Site and the Reporting Site.

INDICATORS

i. All systems must include a mechanism to ensure that all transmitted information from the Acquisition Site is received without corruption, complete and without data loss by the Teleradiology Service Provider.

ii. The Acquisition Site must provide a system to obtain any relevant prior examinations and reports, and make them available to the reporting radiologist at the time of reporting. iii. The Acquisition Site and the Teleradiology Service Provider must provide evidence of system redundancy, backup communication links and a disaster recovery plan.

iv. The Acquisition Site and the Teleradiology Service Provider have documented protocols stating the actions to be carried out in the event of failure of any component of the service that would affect patient care.

8.5.3 Communication and File Sharing

When files are transmitted from the Acquisition Site, individual patient data should include:

a. patient name and date of birth;

b. date and time of radiological examination;

c. location of origin of examination;

d. type of examination;

e. brief clinical history ;

f. details of responsible clinician;

g. number of images acquired;

h. identification of technologist acquiring images;

i. the intended destination of transmitted images; and

i.

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j. time of transmission.

INDICATORS

The Acquisition Site must retain logs of images transmitted.

8.5.4 Archiving and Retrieval

Storage, archiving and retrieval of images, requests and reports are the responsibility of both the persons or entities responsible for operating the Acquisition Site and Reporting Site, to the extent required by local legislation, regulation and any other requirements, including medicolegal obligations.

Maintenance of this storage must be fully compliant with all legislative requirements concerning the duration of image storage. Refer to Standard 3.7 (Digital Imaging Data).

INDICATORS

i. Refer to Standard 3.7 (Digital Imaging Data).

8.5.5 Storage of Records

Teleradiology systems should incorporate image management protocols that ensure the security and confidentiality of patient data.

The persons or entities responsible for operating the Acquisition Site and the Reporting Site are both responsible for ensuring the security and storage of images in accordance with all applicable laws. If a site is not required to store images by law, it must still store images relating to reported cases sufficient to provide the ability to review, to audit and to provide prompt consultation when required.

INDICATORS

i. A Teleradiology Service Provider must store all reports as required by legislation and regulation at the acquisition site.

8.5.6 Security

The persons or entities responsible for operating the Acquisition Site and the Reporting Site must both comply with all data protection standards and privacy legislation applicable to the teleradiology service.

The persons or entities responsible for operating the Acquisition Site and the Reporting Site should both give due consideration to data protection standards and privacy legislation relating to the site of reporting, and document how these requirements have been met.

All appropriate measures to safeguard the system against intentional or unintentional corruption or data security breaches must be in place.

All data security breaches or significant corruption events must be recorded and reported to the other party (either the Teleradiology Service Provider or the Acquisition Site/Healthcare Provider), as well as any other body required to be notified by law.

This requirement applies to all teleradiology services whether a service provided by:

a. an individual employee on call providing formal diagnostic reports remotely for their hospital or healthcare facility;

b. an individual radiologist or group of individual radiologists;

c. a practice group;

d. a network of practices or practice groups;

i.

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e. the local health authority or jurisdiction health department; or

f. a third party provider.

INDICATORS

The persons or entities responsible for operating the Acquisition Site and the Reporting site must both have documented and accessible policies and procedures for security and the maintenance of security of patient identification and image data.

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ii. The persons or entities responsible for operating the Acquisition Site and the Reporting Site must both have current accessible policies and procedures in place and available for reference at the reporting site(s):

   a. to cover actions to be taken to prevent data security breaches or corruption;

   b. to record and notify the appropriate authority of any data security breaches or corruption;

   c. to record actions taken by those involved in handling such event(s);

   d. to document the actions taken by site management in response to the breach to prevent recurrence of the event(s); and

   e. to guide the relevant personnel on the actions needed to be taken both immediately and by way of follow-up after a data breach or corruption.

iii. The persons or entities responsible for operating the Acquisition Site and the Reporting Site must both maintain a log of all data security breaches or significant corruption events, which must be available for inspection by any authority entitled to do so.

iv. The persons or entities responsible for operating the Acquisition Site and the Reporting Site must both have documented guidelines for the use of teleradiology data for education and research that comply with ethics and patient privacy principles and legislation in the jurisdiction of acquisition.

8.6 Teleradiology Service Provision

8.6.1 Teleradiology Service Providers

Teleradiology Service Providers are encouraged to be accredited under the RANZCR/NATA Medical Imaging Accreditation Program, IANZ or other applicable standards.

Teleradiology Service Providers must have clear contractual and procedural arrangements with the items in these standards for all client sites for whom they provide a reporting service.

The Teleradiology Service Provider must ensure that their clinical radiologists are registered as specialists to practise radiology in the jurisdiction that the patient had their images acquired.

The Teleradiology Service Provider must ensure that their clinical radiologists are credentialed as specialists to practice radiology for the site and jurisdiction that the patient had their images acquired.

The Teleradiology Service Provider must demonstrate that their clinical radiologists have undertaken annual continuing professional development (CPD) and an annual appraisal in line with the requirements of the Medical Board of Australia or Medical Council of New Zealand as appropriate.

The Teleradiology Service Provider must ensure that the clinical radiologists have individual medical indemnity cover, as required, to practise radiology in the jurisdiction where the patient had their images acquired. The Teleradiology Service Provider should also have adequate medical indemnity cover to cover, at a minimum, any vicarious liabilities.

The Teleradiology Service Provider should arrange clear communication pathways with the organisations it is supporting such that clinicians and clinical radiologists can discuss reports and cases. They must comply with the requirements for communication on significant and unexpected findings.

INDICATORS

i. The Teleradiology Service Provider must hold certificates indicating accreditation of the service, where applicable.

ii. The Teleradiology Service Provider must hold contracts with each client site.

iii. The Teleradiology Service Provider must hold copies of current registration certificates from the Medical Board of Australia or Medical Council of New Zealand for each reporting radiologist.

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iv. The Teleradiology Service Provider must hold copies of current credentialing certificates from the local/regional credentialing committee for each reporting radiologist.

v. The Teleradiology Service Provider must hold copies of current certificates or equivalent showing CPD compliance for each reporting radiologist.

vi. The Teleradiology Service Provider must hold copies of current insurance certificates or equivalent showing required cover for each reporting radiologist.

vii. Refer to Standard 3.7.3 (Exchange of Digital Imaging Data and Reports).

viii. If there are urgent and significant unexpected findings, the Teleradiology Service Provider has a documented protocol that ensures:

a) the reporting radiologist uses all reasonable endeavours to communicate directly with the referrer or an appropriate representative who will be providing clinical follow-up;

b) a record of actual or attempted direct communication is maintained by the Practice; and

c) the reporting radiologist co-ordinates appropriate care for the patient if they are unable to communicate such findings to the referring clinician.

(As per RANZCR Standards of Practice for Diagnostic and Interventional Radiology, Standard 5.5.3, Indicator 3.)

8.6.2 Healthcare Providers Using Teleradiology

The Healthcare Provider using a Teleradiology Service Provider:

a. must have clear contractual and procedural arrangements with the provider to comply with the items in these standards;

b. should give consideration to regular management meetings with the provider to review the quality of service provision and reporting, at a minimum every six months; and

c. must provide the reporting radiologist with access to the same referral and clinical information as an on-site clinical radiologist.

INDICATORS

i. The Healthcare Provider must hold contracts with the Teleradiology Service Provider.

ii. The Healthcare Provider holds a record of meetings with the Teleradiology Service Provider.

iii. The Healthcare Provider can demonstrate completeness of the information for cases sent to the Teleradiology Service Provider.

8.6.3 Image Viewing at Home for Clinical Radiologists

There must be a secure link between the clincal radiologist's reporting station and the organisation's RIS/PACS to ensure secure transfer of data.

The clinical radiologist's viewing facility should comply with patient data security requirements.

It is essential that the clinical radiologist has a viewing facility(s) that meets or exceeds the standards set out in this document.

It is essential that, wherever possible, the clinical radiologist has access to all previous images and reports.

INDICATORS

i. The Healthcare Provider holds a record of IT and security governance for the home reporting sufficient to comply with the requirements.

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8.7 Quality Assurance for Teleradiology

8.7.1 Quality Assurance for Teleradiology Reporting

Teleradiology does not provide opportunities for regular formal or informal meetings with referring clinicians and colleagues, as may occur with an on-site service. There is a need to closely monitor the quality of teleradiology reporting, and provide feedback and educational opportunities to the reporting radiologist for continuous quality improvement. This is so for all types of teleradiology services, most particularly where the clinical radiologist does not practise a mix of on-site and teleradiology reporting.

INDICATORS

i. The Acquisition Site has a clear, documented framework to monitor and/or audit the Teleradiology Service Provider.

ii. The Acquisition Site has a clear, documented framework to monitor and/or audit the individual radiologists working for those providers, as they would for on-site clinical radiologists. iii. The Acquisition Site regularly undertakes reviews and/or audits of Teleradiology Service Providers and individual radiologists working for those providers, as they would for on-site clinical radiologists.

8.7.2 Monitoring of Performance of Teleradiology Equipment

The Acquisition Site complies with the relevant requirements from Standard 3.

INDICATORS

i. The Teleradiology Service Provider has policies and procedures for monitoring and evaluating the proper performance of equipment used for the transmission, receipt and reporting process in keeping with Standard 3 covering the elements under their direct control, and licensing processes and requirements for jurisdiction radiation safety authorities.

8.7.3 Peer Review

The Teleradiology Service Provider should have a peer review process to ensure and improve the quality of radiology reporting. Such peer review process should be structured:

a. to anonymise the identity of the reporting radiologist during the peer review process to minimise bias;
b. to direct the reviewing radiologist to take into account only the information available to the reporting radiologist at the time of reporting the case; and
c. to keep all patient and clinical radiologist review data confidential and secure within a system strictly limited to those directly involved in the peer review process.

INDICATORS

i. The Teleradiology Service Provider has a documented peer review process and must include processes and policies that provide:

- review of any discrepant reports notified to the Teleradiology Service Provider by an Acquisition Site, and the notification should be recorded and undergo the same review process as the internal review studies;
- for verbal communication with the referring clinician or equivalent person when required following review of a report. and the preparation and authorisation of any addendum to be delivered to the person(s) responsible for the patient's care in a timely manner;
- for a record to be maintained of the peer review cases, the classification of that review and any actions that follow the review;
- feedback to the reporting radiologist with the opportunity for discussion, appeal and/or amendment if necessary;
- the clinical radiologist with a regular report of their peer review results and any data needed to comply with RANZCR CPD requirements; and

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- for peer review feedback to occur on an annual basis if required.

8.7.4 Significant or Unexpected Findings

The Teleradiology Service Provider maintains a record of all Significant or Unexpected Findings and associated actions in compliance with Standard 5.5.2 (Communication of Imaging Findings and Reports).

INDICATORS

Standard 5.5.2 (Communication of Imaging Findings and Reports) – note that text in italics below varies from the wording of the original:

i. The Acquistion Site has a documented policy for report turnaround times that sets out expected turnaround times for defined urgent and non-urgent findings.

ii. The Acquistion Site maintains records of regular reviews of reporting turnaround times in accordance with this policy, and implements and records corrective action should there be any indications that the designated reporting times are not being met.

iii. The Acquisition Site has a protocol for urgent and significant unexpected findings that ensures:

   a. the reporting radiologist uses all reasonable endeavours to communicate directly with the referrer or an appropriate representative who will be providing clinical follow-up;

   b. a record of actual or attempted direct communication is maintained by the *Reporting Site*; and

   c. the reporting radiologist co-ordinates appropriate care for the patient if they are unable to communicate such findings to the referring clinician.

8.7.5 Adverse Patient Outcome Events

The clinical radiologist and/or the Teleradiology Service Provider should have an agreement with the Acquisition Site on processes for handling any adverse events relating to the teleradiology service that meets local incident reporting protocol.

INDICATORS

i. Demonstration that the remote reporting radiologist has access to the same referral and clinical information as an on-site clinical radiologist.

ii. Demonstration of the peer review record including feedback to the clinical radiologist and any actions that followed that feedback.

iii. Demonstration of regular medical management review of the overall peer review process and results. iv. Demonstration of the record of Significant and Unexpected Findings and subsequent actions.

9 Artificial Intelligence

These Standards are guided by RANZCR's Ethical Principles on Use of Artificial Intelligence in Medicine and align with existing standards of practice for clinical radiology.

The Standards are intended to mitigate clinical risks and ensure best clinical care when using artificial intelligence (AI) in radiology. They set out what is expected across a series of domains and what specific evidence would need to be shown to demonstrate compliance with the Standard.

The scope of these AI Standards is to guide the development, deployment and monitoring of AI and machine learning in public and private radiology settings, and guide governance bodies and others

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involved in areas where decisions are made external to the practice or hospital department that have the potential to impact on patient care in radiology.

Introduction

It is important that consistent definitions of artificial intelligence (AI) and machine learning (ML) are used to ensure a common understanding of the technology. RANZCR has adopted the following definitions in advance of an internationally agreed standard being available.

Definitions Relating to AI

Artificial Intelligence

An AI system is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy.(42)

Machine Learning

One particular form of AI, which gives computers the ability to learn from and improve with experience, without being explicitly programmed. When provided with sufficient data, a machine learning algorithm can learn to make predictions or solve problems, such as identifying objects in pictures or winning at particular games, for example.(43) **Algorithm**

A series of instructions for performing a calculation or solving a problem especially with a computer. They form the basis for everything a computer can do and are therefore a fundamental aspect of all AI systems.(43)

Expert System

A computer system that mimics the decision-making ability of a human expert by following preprogrammed rules, such as ‘if this occurs, then do that’. These systems fuelled much of the earlier excitement surrounding AI in the 1980s, but have since become less fashionable, particularly with the rise of neural networks.(44)

Neural Network

Also known as an artificial neural network, this is a type of machine learning loosely inspired by the structure of the human brain. A neural network is composed of simple processing nodes, or ‘artificial neurons’, which are connected to one another in layers. Each node will receive data from several nodes ‘above’ it and give data to several nodes ‘below’ it. Nodes attach a ‘weight’ to the data they receive and attribute a value to that data. If the data does not pass a certain threshold, it is not passed on to another node. The weights and thresholds of the nodes are adjusted when the algorithm is trained until similar data input results in consistent outputs. (44)

Deep Learning

A more recent variation of neural networks, which uses many layers of artificial neurons to solve more difficult problems. Its popularity as a technique increased significantly from the mid-2000s onwards, as it is behind much of the wider interest in AI today. It is often used to classify information from images, text or sound. (44)

Ethical Principles for AI in Medicine

RANZCR has produced a set of Ethical Principles for the use of AI in Medicine (45) that outline the behavioural expectations of clinicians, health executives and AI developers. They are intended to guide all stakeholders involved in research, deployment and use of machine learning systems or artificial intelligence tools in a healthcare setting.

Introduction

The nine ethical principles outlined below guide the development of professional and practice standards regarding the research and deployment of machine learning systems (ML) and artificial intelligence tools (AI) in medicine. These tools should at all times reflect the needs of patients, their care and their safety, and they should respect the clinical teams that care for them.

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These principles are intended to guide all stakeholders involved in research or deployment of ML systems and AI tools, including developers, health service executives and clinicians. They are also designed to complement existing medical ethical frameworks, which do not adequately address the issues likely to emerge from use of ML and AI in medicine.

In order to bridge this gap, RANZCR has developed nine ethical principles specifically to guide the following:

- development of standards of practice for research in AI tools
- regulation of market access for ML and AI
- development of standards of practice for deployment of AI tools in medicine
- upskilling of medical practitioners in ML and AI, and
- ethical use of ML and AI in medicine.

All stakeholders should take heed of all the ethical principles for AI in medicine, noting that some will have greater applicability to them.

PRINCIPLE ONE: SAFETY

Although ML and AI have enormous potential, a range of new risks will emerge from ML and AI or through their implementation.

The first and foremost consideration in the development, deployment or utilisation of ML or AI must be patient safety and quality of care, with the evidence base to support this.

PRINCIPLE TWO: PRIVACY AND PROTECTION OF DATA

Healthcare data is amongst the most sensitive data that can be held about an individual. Patient data must not be transferred from the clinical environment at which care is provided without the patient's consent, approval from an ethics board or where otherwise required or permitted by law. Where data is transferred or otherwise used for AI research, it must be de-identified such that the patient's identity cannot be reconstructed.

A patient's data must be stored securely and in line with relevant laws and best practice.

Note: A clinical environment is any area relating to patient treatment or diagnosis and may include physical or secure virtual environments

PRINCIPLE THREE: AVOIDANCE OF BIAS

ML and AI are limited by their algorithmic design and the data they have access to, making them prone to bias. As a general rule, ML and AI trained on greater volumes and varieties of data should be less biased. Moreover, bias in algorithmic design should be minimised by involving a range of perspectives and skill sets in the design process and by considering how to avoid bias.

The data on which ML and AI is based should be representative of the target patient population on which the system or tool is being used. The characteristics of the training data set and the environment in which it was tested must be clearly stated when marketing an AI tool to provide transparency and facilitate implementation in appropriate clinical settings. Particular care must be taken when applying an AI tool to a population, demographic or ethnic group for which it has not been proven effective.

To minimise bias, the same standard of evidence used for other clinical interventions must be applied when regulating ML and AI, and their limitations must be transparently stated.

PRINCIPLE FOUR: TRANSPARENCY AND EXPLAINABILITY

ML and AI can produce results that are difficult to interpret or replicate. When used in medicine, the doctor must be capable of interpreting the basis on which a result was reached, weighing up the potential for bias and exercising clinical judgement regarding findings.

When designing or implementing ML or AI, consideration must be given to how a result that can impact patient care can be understood and explained by a discerning medical practitioner.

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PRINCIPLE FIVE: APPLICATION OF HUMAN VALUES

The development of ML and AI for medicine should ultimately benefit the patient and society. ML and AI are programmed to operate in line with a specific world view; however, the use of ML and AI should function without unfair discrimination and not exacerbate existing disparities in health outcomes. Any shortcomings or risks of ML or AI should be considered and weighed against the benefits of enhanced decision-making for specific patient groups.

The doctor must apply humanitarian values (from their training and the ethical framework in which they operate) to any circumstances in which ML or AI are used in medicine, but they also must consider the personal values and preferences of their patient in this situation

PRINCIPLE SIX: DECISION-MAKING ON DIAGNOSIS AND TREATMENT

Fundamental to quality healthcare is the relationship between the doctor and the patient. The doctor is the trusted advisor on complex medical conditions, test results, procedures and treatments who then communicates findings to the patient clearly and sensitively, answers questions and provides advice on the next steps.

Whilst ML and AI can enhance decision-making capability, final decisions about care are made after a discussion between the doctor and patient, taking into account the patient's presentation, history, options and preferences.

PRINCIPLE SEVEN: TEAMWORK

ML and AI will necessitate new skill sets and teams forming in research and medicine. It is imperative that all team members get to know each other's strengths, capabilities and integral role in the team.

To deliver the best care for patients, each team member must understand the role and contribution of their colleagues and leverage them through collaboration.

PRINCIPLE EIGHT: RESPONSIBILITY FOR DECISIONS MADE

Responsibility for decisions made about patient care rests principally with the medical practitioner in conjunction with the patient. Medical practitioners need to be aware of the limitations of ML and AI and must exercise solid clinical judgement at all times. However, given the multiple potential applications of ML and AI in the patient journey, there may be instances where responsibility is shared between:

- The medical practitioner caring for the patient;
- The hospital or practice management who took the decision to use the systems or tools; and
- The manufacturer that developed the ML or AI.

The potential for shared responsibility when using ML or AI must be identified, recognised by the relevant party and recorded upfront when researching or implementing ML or AI.

PRINCIPLE NINE: GOVERNANCE

ML and AI are fast moving areas with potential to add great value, but also to do harm. The implementation of ML and AI requires consideration of a broad range of factors, including how the ML or AI will be adopted across a hospital or practice and to which patient groups, and how it might align with patients' goals of care and values.

A hospital or practice using or developing ML or AI for patient care applications must have accountable governance to oversee implementation and monitoring of performance and use, to ensure practice is compliant with ethical principles, standards and legal requirements.

BROADER ETHICAL FRAMEWORKS

Other ethical frameworks cover the expected approach and behaviour of medical practitioners when delivering care to patients, and provide general guidance relating to the development and adoption of new technologies in medicine.

Medical practitioners in Australia are expected to practice in accordance with the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia (46) and the Australian Medical Council's Good Medical Practice (47).

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Medical practitioners in New Zealand are expected to practice in accordance with the New Zealand Medical Council's Good Medical Practice (48) and the Code of Ethics set by the New Zealand Medical Association (49).

RANZCR has also developed a more explicit Code of Ethics for clinical radiologists and radiation oncologists (50).

Artificial Intelligence Standards for Clinical Radiology

The standards outlined below guide the development, deployment, subsequent monitoring and oversight of use of ML systems and AI tools in a clinical radiology setting. They can be applied to manufacturers developing ML systems and AI tools, hospital or practice executives responsible for deployment of ML or AI, professional service organisations advising on the use and acquisition of ML or AI tools, and various clinicians working in a hospital, private practice or other community radiology setting.

Within this set of standards, 'Practice' refers to the clinical setting in which clinical radiology services are delivered, which may be a hospital department, private practice or other community radiology setting.

Within this set of standards, 'developer' refers to the whole team involved in the development of ML systems and AI tools.

Additional Digital Health Guidance

Some practices are required to comply with additional digital standards under their specific funding and contractual arrangements.

The Medical Board of Australia has published Guidelines for Providing Technology-based Patient Consultations(51) that provide advice on the use of technology in delivering safe patient care. RANZCR recommends reviewing the Australian Commission on Safety and Quality in Health Care's (ACSQHC) e-Health Safety Program(52), which provides a series of resources relating to digital health.

Regarding New Zealand-based practice, the Medical Council of New Zealand has published a Statement on Telehealth(53) that outlines the responsibilities of clinicians relating to the use of technology to deliver healthcare. RANZCR further recommends the Ministry of Health's Health Information Standards Organisation (HISO)(54), which supports and promotes the development and adoption of fit-for-purpose health information standards.

Prior to its amalgamation into the Australasian Institute of Digital Health (AIDH)(55), the Health Informatics Society of Australia (HISA)(56) produced a helpful resource in e-safety governance framework and a complementary summary of standards relating to quality management, risk management, IT security and governance in eHealth(57). The AIDH has also published a Professional and Practice Standard with supporting resources aimed at promoting patient safety in relation to e-Health, which includes advice on incorporating patient safety into governance(58).

Notes: Practices should refer to Standard 8 for teleradiology standards.

9.1 Algorithm Development

ML systems and AI tools used in clinical radiology practices must be developed in line with RANZCR's Ethical Principles on the Use of Artificial Intelligence in Medicine. The developer has a responsibility to develop ML and AI ethically, and in particular to minimise bias. A developer may be employed within the practice group or be external (for example, employed by a medical device manufacturer). If the developer is employed by the practice group, they must also meet the standards outlined below. Practices procuring AI tools developed by external vendors should satisfy themselves that Standards 1.1, 1.2 and 1.3 have been met by the developer.

There must be a clear distinction between mature tools that are deemed appropriate (and likely registered) for clinical use, and those that are under development. The latter should not be used to inform clinical management.

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9.1.1 Expert Advice

A team-based approach is imperative to the safe development of ML systems and AI tools for clinical radiology. Each team member will have specific professional expertise, and input from a range of professions is required to ensure optimal patient care outcomes.

INDICATORS

i. The Practice seek assurance that the developer had input from multidisciplinary teams including computer scientists and data scientists.

ii. The Practice must ensure that the developer had input from medical expert(s) relevant to the clinical issue that the AI application is being designed for. This may require generalist and/or subspecialist expertise and involvement of other members of the clinical team where relevant.

iii. Consideration should also be given to the need for advice and other input from non-clinical perspectives, including regulatory, legal and risk management.

9.1.2 Design for Clinical Use

The developer shall review existing technologies and consider how the ML or AI tool will integrate into existing systems.

INDICATORS

i. The Practice must ensure that the developer gave consideration up front to subsequent integration of the tool into clinical workflow.

ii. The Practice must ensure that the developer considered how the algorithm can be generalised and applied to the full range of populations. This should take into account differences in age, gender, ethnicity and clinical risk factors that may differ between the population used to train the algorithm and the population to whom it will be applied in practice.

9.1.3 Transparency and Explainability

The developer shall clearly and transparently advise the Practice of the training and testing data sets and past performance for the algorithm and any limitations of the tool.

Performance of the ML or AI should be clearly documented, along with details of the testing process and conditions under which testing took place. Limitations of application of the ML or AI algorithm should be provided by the developer, clearly documented and considered prior to any decision to implement.

ML or AI used in the Practice must have been tested, reached saturation of learning(59) and met requirements for regulatory approval. The ML or AI can continue to learn, but this must be done in a parallel version of the tool, which cannot be used in patient care until its performance has been tested.

INDICATORS

i. The Practice must ensure that the developer used appropriately independent data sets for each of the training, validation and testing phases of the algorithm development.

ii. The Practice must ensure that the developer demonstrated that an ML or AI tool proposed for clinical use has:

   a) reached ‘saturation’ of learning before being implemented, and be fixed thereafter and not change the model being used in patient care; and

   b) met the requirements for regulatory approval in the various locations where it will be used.

iii. The Practice must ensure that the developer provides clarity on the nature of the training data used in the development of the tool when placing ML or AI on the market. This must include clarity about the way ‘ground truth’ was established in the training data.

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iv. The Practice must ensure that the developer provides clarity on the nature of the testing and patient populations (as for pharmaceutical drugs) to allow users to consider their appropriateness in relation to the patient group in whom it is proposed to be used.

v. The Practice must ensure that the developer provides information about the integrity of training data and how and by whom labelling accuracy has been established.

vi. The Practice must ensure that the developer provides clarity on the nature of the imaging hardware (including all vendors and models), imaging parameters, software settings (e.g. MRI sequence parameters), and post-processing algorithms used in developing and testing the ML and AI tools.

vii. The Practice must ensure that the developer states clearly which vendor equipment the application has been tested on.

9.2 Information Management

Healthcare data are among the most sensitive types of information that can be held about an individual. ML and AI will use data in a new range of ways. These techniques may be most powerful when applied to raw imaging data, before it has been post-processed into pixel data. Specific care must be taken to comply with all relevant laws and best practice in information management when accessing, storing and transferring healthcare data.

Due to the new opportunities and risks that could emerge with the use of ML and AI, developers and Practices will need to consider upfront the robust information management policies that will be required, including those pertaining to the retention or otherwise of raw data. Patients have a right to sensitive health data being used judiciously in ML or AI. These Standards state RANZCR's expectations relating to the information management practices to be followed when AI techniques are being developed or used in AI in clinical radiology.

Notes: Please refer to the following sections for further information. Patient Records (Section 1.5), Privacy and Information Security (Section 3.7.2), Privacy (Section 7.7) and Record Keeping and Security (Section 8.5).

9.2.1 Information Security

The Practice shall ensure appropriate measures are in place to ensure that patient information is safely and securely stored and transmitted.

Notes: Please refer to Section 1.5 for further guidance on patient records.

INDICATORS

i. The Practice must ensure that repositories securely store data and comply with existing laws.

ii. The Practice must comply with existing best practice and regulations relating to privacy and management of healthcare data.

iii. The Practice must demonstrate that is has appropriate security measures to protect patient information.

iv. The Practice must implement a user registry to track access to patient information.

9.2.2 Consent and Privacy

The Practice shall obtain appropriate consent before sharing data and shall have procedures in place to ensure patient privacy is protected.

Notes: Please refer to Sections 3.7.2 and 7.7 for further guidance on privacy and information security.

INDICATORS

i. The Practice must seek the consent of the patient or approval of an appropriate ethics board to waive consent procedures prior to sharing patient data with ML or AI developers, as permitted under relevant regulatory regimes.

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ii. The Practice must take due care to anonymise or pseudonymise data being used to train or test ML and AI.

iii. There must be ongoing consideration of the patient's confidentiality as technology matures, with the Practice keeping up-to-date with best practice and regulatory requirements.

iv. When sharing data from the Practice environment for the purpose of ML or AI development, the Practice will aim to ensure the data shared is: 'as confidential as reasonably achievable'. This means removing all elements that are not essential to the intended use of the data so as not to allow someone's identity to be reconstructed.

9.2.3 Information Sharing

Procedures shall be established concerning secure data transfers, protection and disposal of records, and use of standard terminologies.

Notes: Please refer to Sections 3.6, 3.7, 7.7 and 8.5.6 for related standards on information sharing.

INDICATORS

i. The Practice must ensure that information sharing is performed via secure channels.

ii. The Practice must ensure that data sharing agreements must include provisions for the secure disposal of data at the conclusion of the agreement, consistent with regulatory requirements.

iii. The Practice must implement a mechanism to control the flow of patient information beyond the Practice.

iv. Where possible, the Practice should ensure that recognised standard annotations and terminologies (e.g. SNOMED CT-au, LOINC) are used to express inputs and outputs from ML and AI tools.

9.3 Algorithm Deployment

Algorithms have been in use in certain formats for some time; however, the introduction of more sophisticated neural networks and deep learning in new ML systems and AI tools will have significant impacts on patient care. These are difficult to fully anticipate in the early stages of deployment of ML and AI; therefore, these Standards take a conservative approach to deployment in patient and clinical care. Appropriate governance measures must be in place in a Practice prior to ML systems or AI tools being deployed (see Section 9.6: Governance).

RANZCR recommends that Practices ensure clinical teams are appropriately trained in the use of any new technologies prior to their use in patient care. RANZCR also recommends strong clinical leadership with a designated clinician (referred to here as the Chief Radiologist Information Officer (CRIO) providing oversight for ML, AI and related health informatics considerations.

9.3.1 Clinical Oversight

The Practice shall appoint a designated clinician – a CRIO – to oversee the selection, deployment, and monitoring of ML and AI tools and associated staff training within the Practice. This is a key component of medical oversight, but not expected to be a full-time role. For small practices, the CRIO responsibilities can be designated to a nominated clinical radiologist.

Notes: Please refer to section 3.6.1 for related standards on Computers and Automated Equipment.

INDICATORS

i. The Practice selecting, deploying and subsequently monitoring the ML and AI must designate a medical clinical lead (in the case of clinical radiology, a radiologist) as CRIO to oversee processes relating to ML and AI in the Practice, training of the clinical team (including relevant trainees), and interactions with developers and the broader health informatics team at the Practice.

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ii. The CRIO will guide the proposed ML or AI application process and must be capable of assessing associated benefits and risks, managing software upgrades and overseeing contingency planning.

iii. The CRIO must be trained and current in appropriate skills, knowledge and competencies for their role.

iv. The CRIO must advise the senior management of the Practice and any governance body established by the entity seeking to implement AI or ML.

v. The CRIO must engage with clinical radiologists, technologists, radiographers, sonographers, medical physicists and nurses who will be affected by the deployment of ML or AI.

9.3.2 Suitability and Appropriateness

The CRIO must consider the appropriateness of the use of ML systems and AI tools on specific patient groups.

INDICATORS

i. The CRIO and radiology team will determine the degree of autonomy that the ML system or AI tool has in the specific clinical environment and provide evidence of the impact of clinical service provision.

ii. The Practice must retain a record of the assessment of appropriateness and usability of an ML or AI tool for its different patient groups.

9.3.3 Implementation: Compliance and Records

The Practice shall have in place systems to ensure adequate and contemporaneous record keeping, reporting processes, audit processes and training when introducing ML and AI into a Practice, consistent with legal and other regulatory requirements in that jurisdiction.

INDICATORS

i. An ML system or AI tool must not have the capacity for ongoing learning when implemented at the Practice. Any substantial modifications to the original model (such as changes that could impact clinical diagnosis management) will require authorisation from the regulatory body appropriate to the jurisdiction.

ii. The Practice must maintain a register of risks that have been considered relating to deployment of ML and AI, and outline how those risks are going to be managed.

iii. The Practice must ensure that the general mode of operation of the algorithm, how a conclusion was arrived at and the levels of confidence in the conclusion (in terms of accuracy, sensitivity/specificity, probability, diagnostic weight) can be understood and explained by the medical team.

iv. The Practice must record the exact algorithm/s used within the patient record.

v. All clinicians using ML or AI tools must be trained in its use before the tool is incorporated into their workflow (and thus patient care).

vi. The Practice must ensure there are mechanisms to record traceability of ML or AI tool operations; that is, for each patient for whom the ML or AI tool is applied, there shall be a record of the software and version of the tool in use at the time.

9.3.4 Implementation: Integration

The Practice shall review existing systems and procedures to ensure that ML and AI tools are implemented without negative effect on clinical workflow, and that any ML and AI tools are given appropriate access to data sets.

INDICATORS

i. Workflow considerations must be carefully assessed, including consideration of adverse impact on performance, safety, service output and timeliness, work health and safety, and well-being.

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ii. When deploying the tool, the Practice must consider the specifications and performance characteristics of ML and AI, the training and test data used in its development, and the imaging equipment it can be used with (please refer to Section 9.1: Algorithm Development).

iii. The Practice must assess interoperability of the ML or AI tool with key existing radiology systems, such as RIS and PACS and, where relevant, other data sources in the Practice such as electronic medical records.

iv. The Practice must consider which data sets the ML or AI tool may have access to and the implications of this access; for example, should access be restricted only to image data within the Practice, or include third-party data as well?

v. Appropriate approvals must be sought, and precautions taken, for data outside of the Practice that the ML or AI will have access to.

9.3.5 Risk Management

The Practice shall have procedures in place to ensure that systems continue to function effectively in the instance of ML systems or AI tools being unavailable.

Notes: Please refer to Section 3.6.1 for further guidance on use of equipment and automated equipment.

INDICATORS

i. The Practice must ensure there are systems in place to ensure that Practice production systems, particularly other informatics systems, will continue to function effectively if the AI tool is temporarily unavailable or withdrawn and that delivery of clinical services will not be compromised.

9.3.6 Initial Audit

ML systems and AI tools must undergo a performance audit within a set period of time (no longer than six months for low-risk applications of ML or AI). The CRIO and clinical team will determine the timing, of the initial performance audit, and of regular follow-up, governed by procedural volume and the clinical impact of incorrect diagnosis in the event of performance failure. (see Standard 9.5: Audit).

INDICATORS

i. The Practice must have a schedule in place to ensure that the ML and AI are audited in line with the determined timeframe after being deployed, and periodically thereafter. ii. The audit must include analysis of actual performance of the ML or AI tool.

9.4 Professional Standards

The Practice and all clinical staff employed by it are responsible for both understanding the principles behind ML systems and AI tools, and for relaying relevant information to patients.

The clinical team should play a central role in the deployment and use of ML and AI at the Practice.

9.4.1 Patient Safety

The Practice and medical practitioners shall ensure that patient safety is the top priority in the delivery of care, and that patients have access to information to make informed decisions about their care.

INDICATORS

i. The clinical radiologist retains primary responsibility for all aspects of patient care, including the use of using ML or AI for a particular patient, with input and support from a multidisciplinary team. ii. The CRIO and, where relevant, clinical radiologists at the Practice will take responsibility for ensuring that ML and AI are used ethically and in line with these standards of practice. Primary responsibility, however, rests with the Practice and the associated governance body that chose to deploy the ML or AI.

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iii. The Practice will have access to general information for patients about the use of ML and AI in clinical care.

9.4.2 Training in ML and AI

The Practice shall provide appropriate training to all users of ML and AI tools. The radiology team shall not utilise any ML systems and AI tools that they are not adequately trained to use.

INDICATORS

i. The Practice will ensure that the radiology team completes general training (or related Continuing Professional Development) in ML and AI.

ii. The radiology team will be trained to understand the risks and shortcomings of ML and AI, and when to escalate issues to the CRIO. iii. The Practice will ensure that staff are trained in the specific AI tool being deployed at the Practice (as it would for new RIS/PACS systems).

iv. The clinical radiologist must have the skills to understand the output from the AI or ML tool and how it relates to a particular patient.

9.4.3 Decision-making

The clinical radiologist holds ultimate responsibility for diagnosis and understanding the medical consequences of diagnosis(es). ML systems and AI tools are designed to assist clinicians in reaching a decision; however, the practitioner must apply clinical judgement to integrate ML and AI output with other clinical information.

INDICATORS

i. The clinical radiologist treating the patient will give consideration to the ML and AI output alongside pertinent clinical and other information.

ii. The CRIO or clinical radiologist will be involved in judgements regarding further testing for patients, resources devoted to patient care and timeframes for clinical care. The Practice must not rely on ML or AI to make value judgements; however, ML and AI may inform these considerations.

9.4.4 Responsibilities of the CRIO

The Practice will appoint a CRIO with direct access to senior management. The CRIO will have defined responsibility and authority for implementing and maintaining ML and AI tools within the Practice.

INDICATORS

i. The CRIO will have a broad understanding of standards frameworks relating to digital health, including enterprise IT governance, information security, knowledge and data management, risk management, business analysis, change management and how to resolve issues that may arise through implementation.

ii. The CRIO will work with the implementing governing body to recognise the preferences, cultural values and other values of the Practice's patients, and how they may affect use of ML and AI tools in the Practice.

iii. The CRIO and radiology team at the Practice will identify tasks or decisions that should not be delegated to technology(59).

iv. The CRIO and governance body will consider how to guard against (contain and manage) automation bias(59).

v. The CRIO will oversee ongoing monitoring of ML and AI software to ensure optimal performance.

9.5 Audit

Audit is the official evaluation or inspection of systems in use at the Practice, including ML systems and AI tools.

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Due to the potential impacts on patient well-being if a ML system or AI tool does not function as intended, ongoing audit or monitoring is imperative.

Through this process, the Practice identifies key areas of its operations for quality improvement, and implements appropriate training accordingly.

9.5.1 Audit

The Practice shall commit to ongoing scheduled audits to ensure optimal functioning of ML and AI tools.

INDICATORS

i. The Practice has procedures in place to ensure the objectivity and impartiality of auditors and the audit process itself.

ii. The Practice commits to an ongoing requirement for periodic audit and evaluation.

iii. The Practice ensures that monitoring and/or audit based on these Standards is carried out and reported on annually against these Standards, and in line with the Practice's own policies and procedures. The Practice thereby ensures that ML and AI systems function as intended.

iv. A set of 'benchmark cases' (defined as a technical input with known output), also known as 'test cases', must be used to measure the ongoing validity (and replicability) of the AI tool against a data set developed specifically for this purpose.

v. The audit should consider any feedback from patients or any impact on patient experience.

vi. The annual audit includes a review of the Practice's corrective and preventive action processes and activity, as well as the effectiveness of any such action.

vii. The audit must assess whether the radiology team understands the use of ML systems and AI tools at the Practice and the process to escalate issues to the CRIO or designated medical lead.

viii. The Practice retains records of each audit and participation in or compliance with external quality assurance activities where these are available.

9.5.2 Monitoring and Maintenance

The Practice shall establish a procedure to monitor ML systems and AI tools and associated software updates. This program of activity will include preventative and corrective action to ensure ML systems and AI tools are functioning as intended.

INDICATORS

i. The Practice will ensure all ML and AI systems are kept up-to-date and that applicable standards continue to be met.

ii. Software updates for ML and AI tools will be reviewed by the CRIO and assessed for suitability prior to implementation at the practice, with particular consideration given to changes that affect data management or clinical use.

iii. The Practice will record and act on any discrepancies of performance of ML systems and AI tools, and ensure that these are considered by the CRIO.

9.5.3 Reporting Requirements

The CRIO shall be aware of regulatory reporting requirements and report any adverse events via the correct channels.

INDICATORS

i. In line with existing duties for incident reporting, the CRIO will report to the regulatory authorities (the Therapeutic Goods Administration in Australia or Therapeutic Products Agency in NZ) if

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there is an adverse event arising from the use of an ML system or AI tool that the regulator has authorised for use in that jurisdiction (such as near miss). In this instance, the CRIO will also notify the supplier of the ML system or AI tool(58).

ii. The CRIO will report any adverse event arising from the use of an ML system or AI tool directly to the manufacturer.

iii. The Practice will ensure that any reporting is done via the correct channel(s), to the appropriate authorities.

iv. The Practice will update the risk register for ML and AI following audits and as new risks or management strategies emerge.

9.6 Governance

Appropriate governance measures must be in place in a Practice prior to ML systems or AI tools being deployed.

Special consideration should be given to the interaction of the ML or AI with clinical decision-making, the responsibilities of the different parties, how conflicts of interest are managed and ensuring the completion of due diligence.

9.6.1 Governance

The Practice must establish appropriate governance mechanisms to oversee the deployment and use of ML and AI.

INDICATORS

i. The Practice must establish an appropriate governance body (or bodies) to oversee the deployment and use of ML and AI at the Practice.

ii. Decisions made by the governance body must be recorded.

iii. The Practice's CRIO must be a member of the principal governance body and provide input on behalf of the clinical team.

iv. The Practice must give particular consideration to the potential for conflicts of interest during research, deployment or subsequent monitoring (i.e. where a secondary interest of, perhaps a tool developer or vendor, may influence clinical decisions about a patient)(60).

v. Any conflict of interest held by the Practice or employees of the Practice should be disclosed by the individual or institution to the governance body and be managed appropriately.

vi. Due diligence must be completed on suppliers of ML systems and AI tools and on any parties, who would have access to sensitive patient data. Particular consideration must be given to companies that are new to the Practice or who do not have a proven track record in healthcare.

9.6.2 Responsibility

There is shared responsibility for patient safety when implementing and using ML and AI for patient care that must be assessed by the governance body prior to implementing ML or AI.

INDICATORS

i. The governance body must consider the specific responsibilities of all entities involved in the use of ML and AI in patient care prior to implementing ML system or AI tool. This includes the Practice, CRIO, clinicians and ML or AI supplier.

ii. Ultimate responsibility for the safety and outcome of procedures of selecting, deploying and subsequently monitoring the ML systems and AI tools lies with the Practice or healthcare service.

iii. The clinical radiologist holds ultimate responsibility for patient care and should have the opportunity to input directly if required to the governance body put in place to manage ML systems or AI tools used in clinical care.

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iv. Responsibility for the decision to use ML and AI for an individual patient primarily resides with the clinical radiologist. There may also be responsibilities on referring clinicians (e.g. for provision of all relevant clinical data).

9.6.3 Teamwork

The delivery of healthcare involving ML and AI must involve input from an interdisciplinary team who understand and respect the professional skills and perspective that each team member contributes.

INDICATORS

i. The governance body must ascertain that all members of the care team are working collaboratively when deploying or using ML or AI.

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10 BONE MINERAL DENSITOMETRY (BMD)

10.1 Patient Records

Practices shall comply with the requirements for the retention of non-medical records contained in the Accreditation Guidelines for Bone Densitometry.(61)

INDICATORS

i. The Practice stores raw data from all scans using long-term electronic storage media.

ii. The Practice stores quality control data needed to validate scans.

iii. The Practice stores these records for a minimum of 10 years, or for the minimum applicable statutory requirements (whichever is longer).

10.2 Equipment

10.2.1 BMD – Equipment

Practices performing Bone Mineral Densitometry must comply with the equipment and instrumentation requirements for compliance testing and calibration in the Accreditation Guidelines for Bone Densitometry.(61)

INDICATORS

i. The Practice equipment records demonstrate that acceptance testing has been, and compliance testing of BMD equipment is, carried out according to regulatory requirements.

ii. The Practice has operation manuals for the BMD equipment readily available to personnel operating BMD equipment.

iii. The Practice has implemented a BMD equipment maintenance program and all aspects of the densitometer performance are checked according to the manufacturer's specifications.

iv. The Practice keeps records of all communications with the manufacturer, subsequent to installation of the machine.

v. The Practice implements all software updates as soon as practicable.

vi. The Practice remedies all faults discovered, and the fault and remedial action activity are recorded.

vii. The Practice keeps records of calibration, QC, repair and maintenance of each item of equipment for the life of the equipment.

10.2.2 BMD – Equipment Quality Control

Practices performing BMD must comply with the quality control requirements of the Accreditation Guidelines(61) and the BMD In Vivo Short Term Precision Testing Guideline(62).

INDICATORS

i. In addition to those required by the manufacturer, the Practice's BMD equipment operation manuals include quality control monitoring requirements and quality assurance criteria that are consistent with Appendices 2 and 4 of the Accreditation Guidelines.(61)

ii. If the unit fails any of the quality control procedures, it is evaluated in accordance with the operating manual. With repeated failures, patient measures are suspended until the equipment is thoroughly evaluated by an engineer recognised by the relevant regulatory body.

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iii. If there is a suspicion that previous patient results may be inaccurate, a retrospective reanalysis of the relevant data is performed.

iv. Quality control activity, including corrective and preventive action, is recorded.

v. Subject to any required regulatory approval, the Practice performs In Vivo Short Term Precision Testing(62) on all DXA machines upon installation and after every major service/repair.

10.3 BMD – Personnel

10.3.1 Qualifications – BMD Technologist

A BMD Technologist's qualifications shall meet those specified in the Accreditation Guidelines.(61)

Notes: A BMD technologist who was operating BMD equipment as at 1 November 2000 and who has certification of competence by a clinical radiologist meets these guidelines.

A BMD technologist who commenced operating BMD equipment after 1 November 2000 and before 31 December 2004 who has certification of competence by a clinical radiologist shall also have a tertiary qualification in radiography/nuclear medicine/nursing.

A BMD technologist commencing operation of BMD equipment after 31 December 2004 must have completed the undergraduate and postgraduate training requirements set out in the Accreditation Guidelines(63).

INDICATORS

i. The Practice's BMD technologists have either:

   a. certification by a clinical radiologist that as at 1 November 2000 they were operating BMD equipment and were deemed competent to do so; OR

   b. a tertiary qualification (degree or diploma) in the field of radiography, nuclear medicine, science or nursing and additional post-graduate training in bone densitometry; OR

   c. certification of their BMD training from the ANZBMS.

ii. Only MITs meeting the qualifications described in Standard 4.2.2 perform QCT examinations.

iii. The BMD technologists hold current regulatory radiation licenses or registration (where these are available).

10.3.2 Qualifications – BMD Service Engineers

BMD Service Engineers must comply with the Accreditation Guidelines.(61)

INDICATORS

i. The Practice's BMD equipment is tested for compliance and maintained by a service engineer accredited to do so by the relevant regulatory body/ies, and where appropriate, the ACPSEM.

10.3.3 CPD – BMD Radiologist or Medical Specialist

A clinical radiologist or other medical specialist practising BMD shall comply with the CPD requirements set by the Accreditation Guidelines.(61)

INDICATORS

i. The Practice's clinical radiologist/medical specialist providing the BMD services maintains a BMD reference library that he/she updates annually.

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10.4 BMD – Professional Supervision

10.4.1 BMD Technologist Responsibilities

The responsibilities of the BMD technologist shall comply with those described in the current version of the Accreditation Guidelines.(61)

INDICATORS

i. The scope of responsibilities of the Practice's BMD technologists covers:
   - Personal preparation and positioning of the patient
   - Personal conduct of the scan
   - Personal analysis of the scan, and preparation of the report for checking by the clinical radiologist/medical specialist
   - Quality control, quality assurance and equipment performance activity.

10.4.2 Performance of the BMD Examination

Professional supervision protocols for the performance of BMD examinations shall comply with those described in the current version of the Accreditation Guidelines.(61)

INDICATORS

i. These protocols ensure the maintenance of a BMD procedure manual under the professional supervision of the clinical radiologist/medical specialist.

ii. Only validated methods are used, and these are documented in the BMD procedure manual.

iii. The Practice's BMD reference library is available to support and supplement this BMD procedure manual.

iv. BMD examinations are conducted in accordance with the Practice's BMD procedure manuals.

v. The Practice's professional supervision protocols for BMD examinations ensure that the clinical radiologist/medical specialist is readily contactable to discuss and, if necessary, alter the conduct of the examination.

10.4.3 BMD – Reports

Practices shall comply with requirements for reports contained in the Accreditation Guidelines.(61)

INDICATORS

i. In addition to those items required under Standard 5.5.1, the Practice's BMD reports contain:
   - Type of densitometer, scan mode and software version
   - Type of scan
   - Quantitative result
   - Reference intervals and their source
   - Reference to previous studies, where applicable.

ii. Practice protocols ensure that all reports are checked and approved by the supervising clinical radiologist/medical specialist prior to issue.

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10.4.4 BMD – Interpretation and Consultation

The clinical radiologist/medical specialist providing BMD services shall be readily available to provide a consulting service to referring clinicians in order that they may obtain authoritative advice from the clinical radiologist/medical specialist (or under their delegation, the BMD technologist).

INDICATORS

i. The Practice's professional supervision protocols ensure that a consultation service is available to referring practitioners whereby they can obtain information in relation to a patient's BMD examination, which includes:

- The precision and accuracy of methods used in the unit, including *in vivo* and *in vitro* precision estimates for all scans performed in the unit
- The statistical significance of results and their relation to reference intervals, this includes data on the source of the reference interval used for scan interpretation
- The scientific basis and the clinical significance of the results
- The suitability of the requested procedure to solve the clinical problem in question
- Further procedures that may be helpful.

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11 COMPUTED TOMOGRAPHY (CT)

Including Dental Cone Beam CT

11.1 Equipment

11.1.1 CT – Equipment Quality Control

The Practice shall undertake all quality control requirements as determined by the manufacturer, including maintenance and calibration.

INDICATORS

i. The Practice maintains a fully documented program of quality control for CT with access to the services of a medical physicist as required.

ii. The Practice takes action to remediate any variations from normal that are indicated by such testing, and records are kept of any remedial action taken.

iii. The Practice schedules, performs and records preventative maintenance by a qualified service engineer on a regular basis in accordance with manufacturer specifications. Service performed to correct system deficiency is recorded and the records are maintained at the site where the equipment is located.

11.1.2 CT – Monitors

Monitors for image interpretation must be appropriate to the modality being used and for the scope of examinations performed.

INDICATORS

i. The reporting and interpretation of CT examinations are only carried out using monitors meeting the requirements as specified by the manufacturer to facilitate full resolution display (refer to Appendix D).

11.2 Personnel

11.2.1 CT – Medical Practitioner

The medical practitioner providing CT services shall meet the qualifications requirements set out in Standard 4.2.1.

The medical practitioner providing CTC and specialist providing CTCA must hold the relevant additional qualifications and registration to perform these procedures.

INDICATORS

i. The Practice's CTCA services are provided by a specialist who holds current registration as a CTCA specialist with the Conjoint Committee for the Recognition of Training in CT Coronary Angiography.

ii. The Practice's CTC services are provided by a clinical radiologist who is currently recognised to do so by the RANZCR CT Colonography Accreditation Committee.

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11.3 Professional Supervision

11.3.1 Review of Appropriateness of Request

The Practice shall ensure that the review of the request and patient preparation for CT examinations is carried out under appropriate professional supervision to ensure they are clinically indicated, and to minimise radiation exposure.

INDICATORS

i. The Practice has protocols in place, so that inappropriate studies can be avoided and triaged to non-ionising radiation-based imaging techniques.

ii. The Practice maintains professional supervision protocols for CT that set out criteria regarding indications for patients who should or should not receive contrast agent, the appropriate dose of contrast agents for CT examinations and indicate when consultation with the supervising radiologist is required.

iii. The professional supervision protocols include flags for mandatory clinical radiologist image review prior to the patient leaving the site.

iv. The Practice ensures that the clinical radiologist can consult with the patient to discuss and, if necessary, alter the conduct of the imaging examination.

v. The Practice maintains records of on-site attendance by the clinical radiologist/s.

vi. The Practice meets any regulatory requirements in relation to on-site supervision by the clinical radiologist/s for this component of the service.

11.3.2 CT – Performance of the Examinations

The Practice shall ensure that the clinical radiologist is responsible for the implementation and adherence of appropriate written protocols to be followed by members of the imaging team for this component of the imaging service.

INDICATORS

i. The Practice has protocols for CT examinations that have been developed and implemented collaboratively by the medical imaging team.

ii. These protocols ensure that a clinical radiologist supervises all components of the imaging examination and has ongoing in-person interaction with members of the imaging team.

iii. These protocols ensure that a clinical radiologist reviews images and alters the conduct of the examination or scanning protocols as required.

iv. These protocols ensure that CT examinations, either with or without IV contrast, are performed by a radiographer (refer to Standard 4.2.2), and that the clinical radiologist is readily contactable to discuss and, if necessary, alter the conduct of the imaging examination in- or out-of-hours.

v. These protocols ensure that the task of obtaining IV access for administering intravenous contrast for CT examinations is only performed by a medical practitioner, or delegated to a radiographer, nurse or other person who is adequately trained in venepuncture and the administration of contrast.(24)

vi. These protocols ensure that the clinical radiologist or another medical practitioner who is aware of this responsibility shall be immediately available to personally attend and treat the patient in case of a complication of intravenous contrast administration or other medical emergencies.

vii. The Practice meets any regulatory requirements in relation to on-site supervision by the clinical radiologist for this component of the service.

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11.3.3 CT – Interpretation and Reporting of the Results

A CT examination shall be interpreted and reported by a diagnostic imaging specialist.

The reporting radiologist is responsible for the interpretation of all information on the axial source images obtained from all phases of the examination (e.g. pre-contrast, arterial phase, venous phase and delayed phase), as well as any 2D and 3D reformatted images and cine loops resulting from the study.

INDICATORS

i. CT examinations at the Practice are interpreted and reported by a medical practitioner holding the qualifications described in Standard 4.2.1.

11.3.4 Quality

11.3.4.1 CT – Image Review

The Practice shall complete the RANZCR CT Image Review Self Audit protocol(64) for each CT unit at least annually. The Practice shall take action to remediate any variations from normal that are indicated by the audit and shall maintain a record of actions taken.

INDICATORS

i. The Practice's RANZCR CT Image Review Self Audit records demonstrate that the Practice:
   - Completed this protocol within three (3) months of installation.
   - Completes this protocol at least annually.

ii. The Practice records any variations from normal.

iii. The Practice records any corrective or preventive action required taken as part of the audit process.

11.3.4.2 CT – Dose

The Practice shall maintain and annually review CT scanning protocols to ensure they are optimised to limit patient radiation exposure.

Where the CT unit being used is capable of displaying DLP or CTDI figures, the Practice shall review CT patient dosimetry for specific common scan protocols, and shall document the typical DLP for the specified protocols. Where relevant national DRLs exist, typical patient doses shall be regularly compared with the DRLs. Significant deviation of typical doses above (or below) national DRLs must be investigated with a view to optimisation of doses while maintaining image quality.

INDICATORS

i. The Practice records show that its clinical radiologists maintain and regularly review CT scanning protocols, which are optimised to limit patient radiation exposure. This is ideally achieved collaboratively by the radiographers and other relevant staff.

ii. Where the CT unit being used is capable of displaying DLP or CTDI figures, the Practice reviews CT patient dosimetry at least annually for specific common scan protocols, and documents the typical DLP for the specified protocols.

iii. Through this process, the Practice establishes Facility Reference Levels (FRLs) for CT.

iv. The Practice investigates any significant deviation above (or below) previous FRLs, and a dose optimisation program is conducted that addresses this deviation while maintaining diagnostic image quality.

v. Where national DRLs exist(65), FRLs are regularly compared with these national DRLs.

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vi. The Practice investigates significant deviation of FRLs from established DRLs, and a multidisciplinary dose optimisation program is conducted that addresses this deviation while maintaining diagnostic image quality.

12 GENERAL X-RAY

12.1 Equipment

12.1.1 General X-Ray, CR/DR – Monitors

Monitors for image interpretation must be appropriate to the modality being used and for the scope of examinations performed.

INDICATORS

i. For the interpretation and reporting of general X-ray, CR/DR examinations are carried out on monitors meeting the requirements set out in Appendix D.

12.2 Personnel

12.2.1 Operators of General Radiography Equipment

General X-ray examinations must be performed by personnel who hold the relevant jurisdiction's use licence (however named) and restrict their Practice to the scope of this licence.

Notes: Medicare Australia has criteria for 'rural and remote' status that Practices should meet if the personnel providing general X-ray examinations are other than a radiographer qualified as per Standard 4.2.2.

INDICATORS

i. The particular circumstances of the Practice are such that the personnel operating the general X-ray equipment hold a current relevant jurisdiction/s use or operator's license (however named) and restrict their practice to the scope of that licence.

ii. The Practice meets all regulatory conditions relating to the supervision of such personnel.

12.3 Professional Supervision

12.3.1 Fluoroscopy Examinations

The Practice shall ensure that appropriate professional supervision arrangements are implemented for fluoroscopic examinations depending on the nature of the examination.

INDICATORS

i. The Practice protocols and corresponding rosters ensure that the clinical radiologist responsible for each fluoroscopic examination is available to personally attend the patient.

ii. The Practice ensures the safe use of contrast for fluoroscopic examinations according to Standard 5.4.2.

12.3.2 Quality

12.3.2.1 General X-Ray – Plain Film Image Review

The Practice shall ensure that X-ray repeats are monitored and reviewed in adherence to the ALARA principle.

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INDICATORS

i. The Practice performs repeat analysis for general X-ray examinations, and records results and corrective actions where required.

ii. The Practice uses this repeat analysis to monitor dose usage and image quality in its general X-ray services.

12.3.2.2 CR/DR Performance Testing

The Practice shall maintain a QA program specifically designed to assess the performance of its CR/DR equipment.

INDICATORS

i. The Practice follows the manufacturer's equipment testing guidelines and the RANZCR General X-ray QA and QC Guideline(66) for all its CR/DR equipment, and maintains records of this activity.

ii. The Practice has implemented a process that maintains dose output records (commencing from acceptance testing) and reviews Facility Reference Levels (FRLs) at least six-monthly, ensuring that any general increase in dosage levels is identified, examined, corrected as necessary and recorded.

iii. The Practice maintains records of repeat analysis for CR/DR examinations, and takes and records any required corrective action.

12.3.2.3 Fluoroscopy – Image and Screening Time Review

The Practice shall implement, maintain and follow a documented QA program for fluoroscopy procedures.

INDICATORS

i. The Practice's review of its fluoroscopy services includes a six-monthly review of reference Air Kerma and DAP.

ii. The Practice conducts an internal fluoroscopy image review program that is subject to an annual audit by the medical and non-medical imaging team members.

12.4 Regulatory Safety Requirements

12.4.1 Radiation Safety – Fluoroscopic Examinations

A log must be maintained of screening times and (where the fluoroscopy equipment is capable of this) dose for all fluoroscopic examinations.

Corrective action shall be taken, as necessary, to minimise patient exposure to radiation.

INDICATORS

i. The Practice records screening times for all fluoroscopic examinations.

ii. The Practice records the DAP for all fluoroscopic examinations, or where that is not possible, the average kVp and mAs is recorded.

iii. The Practice takes and records any corrective action that is necessary to minimise patient exposure.

13 INTERVENTIONAL RADIOLOGY

NOTE: Section 13 has been replaced by the Standards of Practice for Interventional Radiology and Interventional Neuroradiology
https://www.ranzcr.com/documents/5591-standards-of-practice-for-interventional-radiology-and-interventional-neuroradiology/file

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NOTE: Section 13 has been replaced by the Standards of Practice for Interventional Radiology and Interventional Neuroradiology
https://www.ranzcr.com/documents/5591-standards-of-practice-for-interventional-radiology-and-interventional-neuroradiology/file
This section has received an interim review for the publication of Version 11 and is currently undergoing comprehensive review. Results of the latter will be published in due course.

RANZCR determines that there are two tiers of interventional radiology: Tier A and Tier B. These are defined in Appendices B and C.

13.1 Facilities

13.1.1 Interventional Radiology Suite – Tier A Procedures

The Interventional Radiology suite used for Tier A procedures must be of sufficient size to allow safe patient transfer from bed to table, to allow room for all the fixed hardware and movable hardware, such as physiological monitors, resuscitation trolleys and any patient support systems, and to allow adequate space for the operating team and support personnel.

INDICATORS

i. The CT and ultrasound rooms have sufficient space to allow safe patient transfer from bed to table.

ii. The interventional radiology suite used for Tier A interventional radiology procedures allows sufficient room for all fixed hardware and movable hardware, such as physiological monitors, resuscitation trolleys and any patient support systems, without compromising either the transfer of the patient or the operating team, and support personnel's ability to manage the patient.

iii. The suite is equipped with ALS(12) equipment.

13.1.2 Interventional Radiology Suite – Tier B Procedures

The interventional radiology (or angiography) suite used for Tier B interventional radiology procedures must be sterile and of sufficient size to allow safe patient transfer from bed to table, to allow room for all the fixed hardware and movable hardware, such as physiological monitors, resuscitation trolleys and any patient support systems, and to allow adequate space for the operating team and support personnel.

INDICATORS

i. The interventional radiology/angiography suite used for Tier B interventional radiology procedures at the Practice is of sufficient size to allow safe patient transfer from bed to table. ii. The angiography suite allows sufficient room for all fixed hardware and movable hardware, such as physiological monitors, resuscitation trolleys and any patient support systems, without compromising either the transfer of the patient or the operating team and support personnel's ability to manage the patient.

iii. The suite is equipped with ALS(12) equipment.

13.1.3 Interventional Neuro-radiology Facilities

Intracranial, spinal and neural axis neuro-interventional procedures shall only be performed in a hospital where appropriate facilities and suitably qualified personnel are available.

INDICATORS

i. The Practice ensures that intracranial, spinal and neural axis neuro-interventional procedures are performed only when/if neurosurgical facilities are available on site and a neurosurgeon or other appropriate clinical specialists are available either on site or on call.

13.2 Equipment

13.2.1 Angiography

The Practice shall ensure that appropriate equipment is used for angiography procedures.

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Mobile image intensifiers are not recommended for diagnostic angiography on a routine basis, as they may have limitations in real-time image quality, stored image data handling, permanent image quality (hard copy), comparative increase in radiation dose to patients and staff, and increased contrast material requirements. Further, as their output is less than 50 kW, their use leads to inferior images in thick body parts. Mobile flat-panel technology can be used for diagnostic angiography on a temporary basis; for example, to cover fixed equipment breakdown.

INDICATORS

i. The Practice ensures that when diagnostic angiography procedures are performed, a fixed high resolution (at least 512 × 512) matrix image intensification system or flat-plate CCD system with at least a 25-cm field of field (and preferably greater than 40 cm) and with digital acquisition and subtraction is used.

ii. The use of image intensifiers should be confined to relatively simple non-vascular interventions or hybrid procedures (combined open surgical/endovascular) performed in an operating room.

13.2.2 Angiographic Injector

The Practice shall use appropriately equipped angiographic injectors.

INDICATORS

i. The Practice ensures that when angiographic injectors are used they are capable of varying injection volumes and rates, and have appropriate safety mechanisms to prevent over injection (e.g. psi monitoring).

13.2.3 Equipment for Non-vascular Procedures

For non-vascular interventional procedures, all necessary imaging modalities required for the successful completion of the case in question must be available on site or the patient shall be referred to another site where these modalities are available.

INDICATORS

i. The Practice ensures that all imaging modalities appropriate to non-vascular interventional procedural requirements are available on site, and when these modalities are not available, patients are referred to another service.

13.2.4 Supplies

The Practice must maintain sufficient supplies of equipment and devices for the range of interventional procedures performed at the site, and for the management of possible complications.

INDICATORS

i. The Practice's supplies records show that it maintains sufficient supplies of equipment and devices required for interventional procedures and the management of possible complications.

13.2.5 Physiological Monitoring

Equipment for physiological monitoring of patients undergoing interventional procedures shall be appropriate to the procedure being performed.

Notes: Direct pressure monitoring is advisable for pulmonary arteriography, and may be required for determining intravascular pressure gradients in peripheral and visceral diagnostic angiography.

INDICATORS

i. For Tier A procedures, ECG and blood pressure monitoring is available when angiography is performed. If patients are ill or receive conscious sedation, a pulse oximeter is also used. ii. For Tier B procedures, and procedures requiring sedation, comprehensive physiological monitoring is available, including ECG, blood pressure and pulse oximetry. For those Tier B procedures that

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NOTE: Section 13 has been replaced by the Standards of Practice for Interventional Radiology and Interventional Neuroradiology
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require general anaesthesia, relevant gas supplies, suction, electrical capability, monitoring and other facilities/supplies required are available.

iii. Where warranted, further/supplementary equipment is used that is appropriate to the risks associated with the procedures being performed. Such additional equipment includes, where warranted, direct pressure monitoring for pulmonary arteriography, and intravascular pressure gradients in peripheral and visceral diagnostic angiography.

13.2.6 Emergency and Resuscitation Equipment

When interventional procedures are performed, there must be ready access to complete emergency resuscitation equipment and drugs (12).

INDICATORS

i. When interventional procedures are performed, the Practice ensures that emergency resuscitation equipment and drugs are readily available and in working order, and that attending personnel are trained in resuscitation techniques (67):

• For Tier A and B procedures, ALS equipment and drugs (12) are available, accessible and ready for use.

13.3 Personnel

Note: There is a range of training pathways that may be considered to recognise appropriate training and experience for Tier B procedures that are not a mandatory requirement for practice. These include, but are not limited to:

- *Conjoint Committee for Recognition of Training in Interventional Neuroradiology (CCINR)*
- *Interventional Radiology Society of Australia (IRSA) Credentialing Guidelines*
- *European Board of Interventional Radiology (EBIR)*
- *Conjoint Committee for the Recognition of Training in Peripheral Endovascular Therapy (CoPET).*

13.3.1 Radiologists – Interventional Radiology – Under Review

The radiologist performing interventional procedures must be trained to perform the procedures and maintain competency specific to the range of interventional procedures he/she is performing.

INDICATORS

i. The Practice ensures that each radiologist performing Tier A procedures complies with the requirements listed under Item 4.2.1 in these Standards.

ii. The Practice ensures that each radiologist performing Tier B procedures has undertaken sufficient additional training, beyond FRANZCR, appropriate to the scope of their interventional practice.

iii. The Practice ensures that when an endovascular or ablating device is to be used, but is not listed on the TGA register, the radiologist performing the associated procedure/s is authorised by the TGA(71).

13.3.2 CPD – Interventional Radiology

Radiologists performing any interventional procedures must demonstrate participation in CPD activities relevant to their scope of practice.

INDICATORS

i. The Practice holds records that demonstrate that its radiologists performing procedures participate in associated CPD activities recognised by their professional body, including a clinical audit of their cases. ii. This CPD activity is consistent with the procedural training requirements listed in Item 13.3.1 in these Standards.

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13.4 Professional Supervision

13.4.1 Review of Appropriateness of Request – Review of the Referral for Interventional Radiology

The radiologist performing an interventional procedure shall personally attend the patient for this component of the imaging service and, where warranted, shall include consultation with the appropriate members of the multidisciplinary team managing the patient's care.

INDICATORS

i. The Practice ensures that the radiologist personally attends each patient undergoing interventional procedures for this component of the medical imaging service, and that this is demonstrated in the Practice records and patient history/notes.

ii. The Practice's professional supervision protocols ensure that, where warranted, the radiologist includes consultation with multidisciplinary team members managing the patient's care for this component of the medical imaging service.

13.4.2 Examination Supervision – Interventional Radiology (Tier A & Tier B) and Interventional Neuroradiology

Interventional procedures must be performed by a suitably qualified radiologist who is credentialed by the Practice where these procedures are performed.

INDICATORS

i. The Practice ensures that its records demonstrate that interventional procedures are personally performed by suitably qualified radiologists who meet the requisite qualifications criteria described in Item 13.3.1.

ii. Neurosurgery facilities and a neurosurgeon are available as per Item 13.1.2 in these standards when an intracranial interventional neuroradiology procedure is being performed.

13.4.3 Interventional Radiology – Availability of Personnel

Appropriately trained personnel shall be available during all phases of the procedure, including the immediate post-procedure period, in the event of a need for emergency resuscitation. There is appropriate access to anaesthetic services and staff as required for Tier B procedures.

INDICATORS

i. The Practice protocols ensure that interventional procedures are performed only when personnel trained in emergency resuscitation techniques (Basic Life Support training as a minimum), and emergency resuscitation equipment and drugs are immediately available at the Practice and in working order.

ii. When Tier A interventional procedures are being performed, appropriately trained personnel are available to respond in a timely fashion in the event of a patient emergency.

iii. When Tier B interventional radiology procedures are being performed, personnel trained in advanced life support are available to respond in an appropriate timeframe in the event of the need for emergency resuscitation.

13.4.4 Interventional Radiology – Pre- and Postoperative Assessment

All interventional radiologists (peripheral and neuro-interventionist) shall personally attend their patients in order to perform the preoperative and postoperative assessment of their patients, including obtaining consent.

INDICATORS

i. The Practice's professional supervision protocols ensure that each radiologist performing interventional procedures personally either:

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NOTE: Section 13 has been replaced by the Standards of Practice for Interventional Radiology and Interventional Neuroradiology
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a. attends their patients to make preoperative and postoperative assessments; OR

b. delegates this activity to an associate medical practitioner who is a member of the multidisciplinary team managing the patient's care.

ii. Each radiologist performing interventional procedures personally either:

a. obtains consent from each of his/her patients prior to a procedure being performed; OR

b. delegates this activity to an associate radiologist who is a member of the multidisciplinary team managing the patient's care.

13.4.5 Interventional Radiology Quality Assurance and Improvement Program

A fully documented quality assurance and improvement program must be established to monitor the Practice's standards of patient care. It must incorporate the full range of procedures that are performed and shall include a clinical audit of outcomes at regular intervals.

Notes: Audit should include, but not be limited to, all cases performed during the period of the audit, review of any morbidities and mortality arising from these cases, and action taken to minimise future complications.

INDICATORS

i. The Practice has a quality assurance and improvement program for interventional radiology covering the full range of procedures that are performed at the Practice.

ii. Indicator thresholds and success rates for all interventional procedures performed by the Practice have been established against external evidence-based criteria and are regularly assessed.

iii. Policies and practices are reviewed at regular intervals, and action is taken to resolve any problems identified to maintain quality assurance.

iv. The quality assurance and improvement program shall include regular mortality and morbidity meetings.

13.5 Safety

13.5.1 Rapid Transport

The Practice shall ensure the availability of and have a formal detailed protocol for rapid transport of patients undergoing Tier A Interventional Radiology procedures to an acute care facility.

INDICATORS

i. The Practice has documented protocols that ensure the availability of emergency care/surgical support, when required, for patients undergoing Tier A interventional radiology procedures. ii. The Practice has protocols in place that ensure the rapid transport of interventional patients to an acute care facility ensuring timely access to appropriate treatment for all patients consistent with the potential risks associated with the interventional procedures being performed.

13.5.2 Surgical Support and/or Rapid Transport

When Tier B Interventional Radiology procedures are performed, the Practice shall ensure the availability of emergency care and/or surgical support, or have a formal detailed protocol for rapid transport of patients to an acute care facility if required.

INDICATORS

i. The Practice has documented protocols that ensure the availability of emergency care/surgical support for interventional patients undergoing Tier B interventional radiology procedures.

ii. The Practice has protocols in place that ensure the rapid transport of interventional patients to an acute care facility ensuring timely access to appropriate treatment for all patients consistent with the risks associated with the interventional procedures being performed.

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iii. Interventional neuroradiology procedures are only performed in Practice settings where neurosurgical support is immediately available on site.

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14 MAGNETIC RESONANCE IMAGING (MRI)

14.1 Equipment

14.1.1 MRI – Equipment Specifications and Acceptance Testing

The Practice shall ensure that its MRI system meets the requirements of the TGA, as contained in the Therapeutic Goods Amendment (Medical Devices) Bill 2002 and the Therapeutic Goods (Medical Devices) Regulations 2002 in Australia, or the Medicines Act 1981 and the Medicines Regulations 1984 in New Zealand.

The Practice shall ensure that acceptance testing is carried out at the completion of the installation of the MRI unit prior to regular patient imaging.

Notes: Some jurisdictions also require testing of the magnetic shielding of the system.

INDICATORS

i. The Practice's equipment inventory shows that the MRI system meets TGA or Medsafe requirements.

ii. The Practice holds acceptance testing records that demonstrate that such acceptance testing follows AAPM(72), NEMA or other RANZCR-approved standards, and includes tests of:

- Magnetic field homogeneity
- RF shield integrity
- RF calibration
- System signal to noise ratio
- Signal uniformity
- Geometrical distortion
- Slice thickness and positioning accuracy or equivalent tests of gradient performance and radiofrequency pulse characteristics.

iii. The minimum resolution of monitors used for interpretation and reporting of MRI is 1024 × 768 colour/monochrome.

14.1.2 MRI-Compatible Equipment (In-room Equipment)

The Practice shall ensure that all in-room equipment used for sedation/anaesthesia monitoring and resuscitation is MRI-compatible, operational and readily available.(73)

INDICATORS

i. Sedation and associated monitoring equipment for MRI procedures are available within the MRI magnet room, operational and certified MRI-compatible by the manufacturer of the equipment.

ii. Resuscitation drugs and equipment for the potential complications of sedation are immediately available, and all such equipment is operational and certified MRI compatible by the manufacturer of the equipment.

iii. When paediatric patients are sedated, sedation and monitoring equipment of an appropriate size for paediatric patients is available in the procedure room before the start of the procedure, operational and certified MRI-compatible by the manufacturer of the equipment. iv. Anaesthesia equipment used in relation to MRI examinations is stationed in the examination room for MRI, operational and certified as MRI-compatible by the manufacturer.

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14.1.3 MRI Quality Control Program

A documented quality control program must be maintained at the MRI site.

*Notes: *Indirect tests of these parameters (e.g. shim checks, tests of gradient and radiofrequency system performance) may be used.*

INDICATORS

i. The Practice maintains a documented MRI quality control program that assesses relative changes in system performance as determined by the MRI radiographer, service engineer, qualified physicists or supervising clinical radiologist(s).

ii. All quality control testing is carried out in accordance with specific procedures and methods, such as those of AAPM(74) or those recommended by the manufacturer. Quality control testing will often require the skills of a multidisciplinary team including medical imaging technologists and medical physicists, and include tests of:

- System signal to noise ratio
- Signal uniformity
- Radiofrequency system stability
- Ghost intensity (for systems with analogue radiofrequency subsystems)
- Geometrical distortion*
- Slice thickness and positioning accuracy*.

Phantoms used for the above tests may include the manufacturer-supplied or other third-party equipment.

iii. The Practice ensures that regular servicing of the MRI system is carried out, and that service reports and corrective action records are held on site.

iv. The Practice schedules, performs and records preventative maintenance by a qualified service engineer on a regular basis in accordance with the manufacturer's specifications.

v. The MRI site maintains records of service performed to correct system deficiencies.

14.2 Personnel

14.2.1 Qualifications – MRI Radiologist

The medical practitioner reporting and interpreting MRI examinations must hold the clinical radiologist qualifications described in Standard 4.2.1, and must have completed an appropriate level of training in MRI demonstrated by registration with the RANZCR as an MRI radiologist.

Notes: As of 1 January 2013, the RANZCR MRI Supervising Radiologist credential was changed to MRI Radiologist. Certification as an MRI Radiologist is required for radiologists who have:

a) been awarded the DRACR or FRANZCR prior to 1 January 1995 who were not registered as an MRI Supervising Radiologist at 1 January 2013; OR

b) are Educational Affiliates or International Medical Graduates who were not registered as an MRI Supervising Radiologist on 1 January 2013.

INDICATORS

i. The Practice ensures that each of its clinical radiologists interpreting and reporting MRI examinations for each MRI system operating at the service is registered with the RANZCR as an MRI Radiologist.

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14.2.2 Qualifications – MRI Radiographer

Radiographers who conduct MRI examinations must have appropriate training, such as the ASMIRT Level 1 Certificate, or equivalent training and experience.

INDICATORS

i. The Practice's MRI radiographers have training and experience that can be demonstrated in one of the following ways:

   a. meeting the requirements for ASMIRT's Level 1 Certificate; OR

   b. training and experience equivalent to that required for the ASMIRT's Level 1 Certificate, including at least 300 supervised clinical MRI examinations during the past two (2) years; OR

   c. meeting the radiographer qualifications as stated in Standard 4.2.2 with an additional minimum three (3) months' FTE MRI experience and performance of at least 300 clinical examinations within the past two (2) years; OR

   d. certificate of equivalency as conferred by ASMIRT.

ii. Radiographers training in MRI are supervised by:

   a. an MRI radiographer who either holds the ASMIRT Level 2 Certificate, or has equivalent qualifications and experience; OR

   b. an MRI radiographer, in conjunction with a supervising radiologist, who has taken into consideration the student's previous MRI experience (including the number and range of studies), the needs of the MRI facility and the guidelines of ASMIRT.

14.2.3 Qualifications – MRI Service Engineers

MRI service engineers must be qualified on the basis of training and experience. Their training must have included the model and manufacturer of the MRI equipment used at the Practice, details of which must be certified by the service organisation.

INDICATORS

i. The Practice ensures that the service organisation providing service engineers for the MRI system confirms certification of the service engineers.

14.2.4 CPD – MRI Radiologist

The clinical radiologist supervising and reporting MRI examinations must complete a minimum of 30 MRI-specific CPD points every three (3) years.

INDICATORS

i. The Practice ensures that each of its clinical radiologists is a current participant in the MRI Quality Program.

14.2.5 CPD – MRI Radiographer

MRI radiographers shall participate in a CPD program, such as ASMIRT's CPD program, and shall include MRI-specific CPD activity.

INDICATORS

i. The Practice ensures that its radiographers performing MRI examinations can provide evidence of MRI-specific CPD activity.

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14.3 Professional Supervision

14.3.1 MRI System Supervision

Each MRI unit must be registered with the RANZCR MRI Quality Program in order to establish a consistent MRI supervision framework. Each unit shall have one designated Liaison MRI Radiologist with overall responsibility for running the unit, supervising the staff and maintaining Practice standards within the unit, including ensuring that examinations are supervised by suitably qualified clinical radiologists and MRI radiographers, and assuring the quality of images and reports.

INDICATORS

i. Each MRI unit holds current RANZCR MRI registration, ensuring the professional supervision of the MRI unit is maintained by its nominated Liaison MRI Radiologist.

ii. The nominated Liaison MRI Radiologist is responsible for designing and periodically reviewing the MRI unit's protocols, including those for safety screening, contrast usage and pulse sequences, and implementing and ensuring adherence to these. iii. The nominated Liaison MRI Radiologist is responsible for ensuring that each MRI radiologist is participating in the RANZCR Quality and Accreditation Program.

iv. The professional supervision protocols for MRI provide for the delegation of duties to MRI radiographers.

14.3.2 MRI – Review of Appropriateness of Request and Patient Preparation

All requests shall be reviewed and protocoled by an MRI radiologist or a delegated and appropriately qualified medical imaging technologist before an examination is undertaken, and, where appropriate, specific triggers for further review by the MRI radiologist shall be defined.

INDICATORS

i. The review of the request for an MRI examination is undertaken and protocolled by one of the Practice's MRI radiologists.

ii. Protocols define a list of examinations that routinely require prompt MRI radiologist review before patient discharge (e.g. suspected cord compression).

iii. There is provision for the imaging protocol to require prompt MRI radiologist review of the images before patient discharge (e.g. where it is unclear from the initial request whether additional pulse sequences or contrast administration will be required).

iv. Safety screening follows RANZCR MRI Safety Guidelines(73) whereby an MRI radiologist is available for telephone consultation within 10 minutes.

14.3.3 MRI – Performance of the Examination

The Practice shall ensure that each MRI examination is carried out under professional supervision arrangements appropriate to both the patient's clinical needs and the specific examination being undertaken.

INDICATORS

i. The Practice's professional supervision protocols for MRI ensure that all MRI examinations requiring contrast are carried out under the supervision requirements stated in Standard 5.4.2. ii. The Practice's professional supervision protocols ensure that MRI examinations requiring sedation or monitoring of an unstable patient are only carried out when an appropriately trained medical practitioner is immediately available to personally attend the patient, and an MRI radiologist is immediately available to review the images.

iii. The Practice's professional supervision protocols ensure that when MRI examinations require image review prior to patient discharge, an MRI radiologist is available to do so within 10 minutes of the completion of image acquisition (either on site or remotely).

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iv. The Practice's professional supervision protocols ensure that when all other MRI examinations are performed, an MRI radiologist is available for telephone consultation within 10 minutes of the completion of image acquisition.

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14.3.4 MRI – Procedures

Technical factors for standard MRI procedures for each anatomic site must be documented.

MRI procedures must be reviewed at least annually by MRI staff, including the nominated Liaison MRI Radiologist.

INDICATORS

i. The Practice documents technical factors for each anatomic site for standard MRI procedures commonly performed by the Practice. ii. The Practice records a review of MRI procedures by MRI staff, including the nominated Liaison MRI Radiologist, at least annually.

14.3.5 Quality

14.3.5.1 MRI – Image Review

The Practice shall register its MRI system with the RANZCR MRI Quality Program and meet all ongoing requirements of this program.

INDICATORS

i. The Practice ensures that each of its MRI units holds current registration with the RANZCR MRI Quality Program.

ii. The Practice ensures that MRI clinical image review is performed in accordance with that Program and at intervals determined under the Program.

iii. The Practice ensures that images of an approved MRI phantom are submitted for review by RANZCR approved consultants, at intervals determined under the Program.

iv. The Practice has protocols to ensure that necessary quality assurance of the MRI system is performed at appropriate intervals.

14.3.5.2 MRI Quality Improvement Program

A documented systematic quality improvement program must be established and implemented under the direction of the Liaison MRI Radiologist to monitor relevant issues in patient care.

INDICATORS

i. The Practice maintains an MRI quality improvement program under the direction of the Liaison MRI Radiologist, which includes the recording of adverse events including, but not limited to, carriage of inappropriate objects into the examination room, failure to complete an examination due to patient distress and system malfunction.

ii. The Practice's MRI quality improvement program includes periodic review of these records to identify opportunities to improve patient care. iii. The Practice's MRI quality improvement program attempts to correlate imaging findings with surgical, pathological and clinical outcomes.

iv. The Practice ensures that regular servicing of the MRI system is carried out, and that service reports and corrective action records are held on site.

14.4 Safety

14.4.1 MRI – Safety

MRI safety practices and policies must be documented, enforced and periodically reviewed by the supervising radiologist(s).

Notes: The main international standard is IEC 60601-2-33:2010+A1:2013+A2:2015, which now includes safety measures for patients and workers (see: https://webstore.iec.ch/publication/22705). The ACR Guidance

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Document for Safe MR Practice guideline(75) and the UK MHRA Safety guidelines for magnetic resonance imaging equipment in clinical use document(76) are also recommended as useful resources.

INDICATORS

i. The Practice ensures that MRI safety practices and policies are reviewed at least annually by the Liaison MRI Radiologist.

ii. The Practice's MRI safety practices and policies comply with the RANZCR MRI Safety Guidelines.(73)

iii. The Practice's MRI safety practices and policies take into consideration potential interactions of the magnetic field with ferromagnetic objects in the environment of the scanner, and potential hazards posed by objects implanted within the patient, as well as within personnel in the area.

iv. The Practice's MRI safety policy includes:

   a. exclusion of the general population outside the 5 Gauss line with appropriate warning signs; and

   b. procedures to screen patients and all other personnel entering the MRI examination room for intracranial aneurysm clips, cardiac pacemakers, intra-ocular foreign bodies and other contraindicated devices (e.g. cochlear implants).

v. The Practice provides an MRI safety education session for all staff accessing the MRI area.

vi. The Practice's MRI safety practices ensure that an appropriately equipped emergency cart is immediately available to treat serious adverse reactions and for resuscitation in case of respiratory or cardiac arrest within the MRI suite.

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15 MAMMOGRAPHY (INCLUDING TOMOSYNTHESIS)

15.1 Practice Management System

15.1.1 Mammography – Labelling of Images

The labelling of mammography images must be sufficiently comprehensive to ensure that they can be unequivocally traced to the patient and to enable their interpretation.

Notes: It is recommended that images be labelled with the technical factors used including mAs, kV, compression force, compressed breast thickness and the degree of obliquity for MLO views.

INDICATORS

i. The Practice ensures that its mammography images are labelled with the following:

a. A permanent identification label, that details:

- Facility name
- Patient's full name
- Patient identification (e.g. unique Medical Record Number or patient date of birth)
- Examination date.

b. Radiopaque markers (or electronic markers with CR/DR units) indicating laterality (R/L) and projection/view (MLO/CC)

- Placed near the aspect of the breast closest to the axilla
- Placed on the cassette, so they can be read from overhead (in the case of film screen and CR units)
- Large enough to be clearly readable without being distracting
- Utilising standard abbreviations.

c. Radiographer's name, initials or unique radiographer identifier code either on the identification label or in radiopaque letters on the cassette holder; or in the case of CR/DR units, cassette identification (to enable tracking of artefacts or defects).

d. Cassette/screen identification by Arabic number written or pressed on the screen to identify screens with artefacts or defects.

e. A radiopaque (or electronic in the case of CR/DR units) dedicated mammographic unit identifier (e.g. MQAP number).

ii. With the exception of the markers indicating laterality and view, all labels are placed as far from the breast as possible. iii. Where initials are used on labels; for example, radiographers' initials, a log of names and identifying initials are maintained.

iv. Collimation is to the edge of the image, so that as much of the image as possible will be exposed.

v. Image labelling does not obscure breast tissue.

15.2 Equipment

15.2.1 Diagnostic Mammography – Equipment

Mammography must only be performed on dedicated mammographic equipment that has the ability to prevent scattered radiation from contaminating the image, and has devices for compression (whole

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breast and spot) and geometric magnification. Digital mammography requires dedicated equipment for image acquisition, evaluation and interpretation.

INDICATORS

i. The Practice only performs mammography examinations on dedicated mammography equipment that complies with the equipment requirements of the MQAP.(77)

ii. The Practice ensures that acquisition monitors used for mammography have a minimum resolution of 3MP and a minimum brightness of 250cd/m^2

iii. The reporting of digital mammography examinations is carried out on paired monitors, or appropriate single monitor of correct specification, each meeting the requirements set out in Appendix D; the mammographic image being displayed in monochrome.

15.2.2 Diagnostic Mammography – Quality Control

There must be documented procedures for quality control checks as specified in the RANZCR Guidelines for Quality Control Testing for Digital (CR DR) Mammography(78) or the ACPSEM recommendations for a digital mammography quality assurance program.(79)

INDICATORS

i. The Practice's MQAP records confirm that it carries out mammography quality control procedures according to the RANZCR Guidelines for Quality Control Testing for Digital (CR DR) Mammography.(78)

15.2.3 Diagnostic Mammography – Annual Equipment Testing

Mammography equipment must be tested annually in accordance with the manufacturer's guidelines, and the RANZCR Guidelines for Quality Control Testing for Digital (CR DR) Mammography.(78)

INDICATORS

i. The Practice records demonstrate that its mammography equipment meets the manufacturer's equipment testing guidelines, where applicable. ii. MQAP records demonstrate that the equipment also complies with the Guidelines for Quality Control Testing for Digital (CR DR) Mammography.(78)

15.3 Personnel

15.3.1 Qualifications – Equipment Assessors for Mammography Equipment

Equipment checks required by MQAP must be performed by an appropriately certified mammography equipment assessor.

Notes: As of 1 January 2012, ACPSEM certification of Equipment Assessors is awarded for one of the following:

a) Review of CR Mammography Machines; or

b) Review of DR Mammography Machines; or

c) Review of CR and DR Mammography Machines.

MQAP sites need to choose the assessor with the correct qualification to assess the type of equipment operated by the site.

INDICATORS

i. The Practice's MQAP records show that annual mammography equipment testing is carried out by an equipment assessor who has been certified as such by the ACPSEM, and who has

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certification for undertaking assessments of the type of mammography equipment operated by the Practice.

15.3.2 CPD – Clinical Radiologist

The Practice must ensure that the clinical radiologist interpreting mammograms meets RANZCR's mammography CPD requirements.

INDICATORS

i. The Practice can demonstrate that each of its clinical radiologists who interpret mammograms for the service has accumulated 15 mammography-specific CPD points in the past three (3) years in mammography CPD activities recognised by the RANZCR CPD program.

15.3.3 CPD – Radiographer

The Practice must ensure that each of its radiographers performing mammography examinations shall participate in a CPD program, such as ASMIRT's CPD program, and shall include mammography-specific CPD activity.

INDICATORS

i. The Practice ensures that its radiographers who perform mammography examinations participate in at least 15 hours of mammography-specific CPD every three (3) years.

15.4 Professional Supervision

15.4.1 Professional Competence

The Practice ensures that high-quality diagnostic mammography is achieved by qualified radiographic and radiological staff who are able to tailor the examination to each patient's specific needs in accordance with the Guidelines for Quality Control Testing for Digital (CR DR) Mammography.(78)

Notes: Radiographers in Australia wishing to gain advanced training in mammography are encouraged to seek recognition through the ASMIRT Certificate of Clinical Proficiency in Mammography or Advanced Breast Imaging Certificate or equivalent.

INDICATORS

i. The Practice ensures that its personnel providing mammography services are appropriately qualified and experienced according to the requirements of these standards.

ii. The Practice's MQAP clinical image review records demonstrate that the Practice consistently strives to achieve a consistent, quality mammography service.

15.4.2 Mammography – Review of Appropriateness of Request

The clinical radiologist shall be readily contactable to discuss and, if necessary, alter the conduct of the imaging examination.

INDICATORS

i. The Practice's records show that the clinical radiologist rostered for its mammography services is available to discuss the request and, when necessary, alter the conduct of the mammography examination.

15.4.3 Mammography – Reporting the Results

The clinical radiologist reporting mammograms must do so on a regular basis.

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INDICATORS

i. The Practice ensures that only clinical radiologists meeting the requirements set out in Standards 4.2.1 and 15.3.1 report mammography examinations.

ii. The Practice ensures that these clinical radiologists are rostered on a regular basis at a service performing mammography.

15.4.4 Mammography – Performance of the Examination

The clinical radiologist shall be responsible for ensuring the implementation and adherence of appropriate written protocols to be followed by members of the imaging team.

The clinical radiologist shall be available to personally attend the patient in order to alter the conduct of the examination. Screening mammography performed as part of an organised population screening program is excluded from 15.4.4.

INDICATORS

i. The Practice's records show that the clinical radiologist rostered for mammography services is able to communicate with the patient and/or direct the radiographer in relation to positioning that is consistent with the Guidelines for Quality Control Testing for Digital (CR DR) Mammography(78) protocols.

ii. The Practice's professional supervision arrangements for mammography provide for the rostered clinical radiologist being able to request repeat or additional projections (e.g. magnification views) when these are required to achieve a diagnostic quality examination.

15.4.5 Diagnostic Mammography – Image Review

Each diagnostic mammography unit must participate in the RANZCR MQAP to ensure systematic peer-based clinical image audit and ongoing supporting quality assurance activity.

INDICATORS

i. The Practice holds current MQAP records for each of its diagnostic mammography units.

15.5 Safety

15.5.1 Mammography – Radiation Dose

The Practice must not exceed the mammography radiation dose limit requirements of the ACPSEM Recommendations for a digital mammography quality assurance program.(79)

INDICATORS

i. The Practice's mammography records show that the mean glandular dose, as determined by the equipment assessor, does not exceed 2 mGy per view, using the RMI-156, Nuclear Associates (18-220), CIRS 015 or the Gammex Mammo FFDM phantoms.

16 NUCLEAR MEDICINE

16.1 Definition

For the purposes of these Standards, the term 'nuclear medicine' encompasses general nuclear medicine services, PET services, nuclear medicine therapy and theranostics.

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16.2 Nuclear Medicine Facilities

Nuclear medicine facilities shall be designed to enable the delivery of safe, high-quality nuclear medicine services, to assure the comfort of patients (including their need for privacy) and to accommodate special needs.

INDICATORS

i. The Facility complies with specific legislative requirements for the provision of nuclear medicine services.

ii. Access to and use of areas affecting the quality of the nuclear medicine services or safety of patients and personnel is controlled. iii. There is an effective separation between areas where nuclear medicine services are performed and other areas of the Facility.

iv. The Facility maintains safety practices appropriate to the handling of radioactive substances.

v. The Facility demonstrates compliance with workplace safety and other regulatory requirements concerning employment.

vi. The Facility maintains cleanliness of the facilities.

vii. The Facility assures patient privacy. viii. The Facility provides appropriate staff amenities.

16.3 Equipment

16.3.1 Nuclear Medicine – Equipment

A Facility performing nuclear medicine services must have equipment suitable for the performance of any nuclear medicine service provided at the facility.

INDICATORS

i. The Facility's equipment inventory demonstrates that appropriate equipment for nuclear medicine services is available.

ii. The Facility's equipment inventory demonstrates that all equipment is serviced according to the manufacturers' specifications and does not exceed the recommended life of the item of equipment.

iii. Where cardiac stress testing is performed, the Facility must have equipment available for advanced life support that complies with the requirements of Item 16.6.6.

16.4 Personnel

16.4.1 Qualifications – Nuclear Medicine Specialist

In order to practise nuclear medicine, a nuclear medicine specialist must comply with the requirements for training in nuclear medicine, maintaining professional development requirements, licencing to use radioactive substances and credentialing, as described in the current AANMS Standards.

INDICATORS

i. The Facility's nuclear medicine services are provided by nuclear medicine specialists who:

a. are recognised as a specialist in nuclear medicine by AHPRA or the equivalent authority in New Zealand; and

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b. are credentialled as nuclear medicine specialists and additionally, if reporting PET are credentialled in PET, by the Joint Nuclear Medicine Specialist Credentialing Program.

ii. Each nuclear medicine specialist holds a current radiation licence applicable to the provision of nuclear medicine services in the Facility's state/territory jurisdiction. iii. Each nuclear medicine specialist maintains a record of CPD activity (which may include RANZCR/RACP program records) with specific details of nuclear medicine activities.

iv. Where cardiac stress testing is performed, the conduct of such testing is in compliance with the CSANZ Safety and Performance Guidelines for Clinical Exercise Stress Testing (reference). *https://www.csanz.edu.au/wp-content/uploads/2014/08/Clinical_Exercise_Stress_Testing_2014-August.pdf*

16.4.2 Qualifications – Nuclear Medicine Technologist

A nuclear medicine technologist must be registered by AHPRA and hold a radiation operator's licence with the relevant jurisdiction in which the technologist is practising, where these are available.

INDICATORS

i. The Facility ensures that its nuclear medicine technologists hold current registration with AHPRA.
ii. Where these are available, each nuclear medicine technologist holds a current radiation operator's licence applicable to nuclear medicine services with the applicable regulator in the Facility's state/territory jurisdiction. iii. Each nuclear medicine technologist can demonstrate participation in nuclear medicine continuing professional development activity
iv. If a technologist operates a gamma CT unit for AC and AnC, appropriate training in the operation of the CT component is demonstrated.

16.4.3 Trainee Nuclear Medicine Technologists

All trainees must have on-site supervision by a registered nuclear medicine technologist at all times. Nuclear medicine facilities that provide nuclear medicine technologist training must be accredited by the ANZSNM for technologist training.

INDICATORS

i. The Facility holds an ANZSNM accreditation certificate in relation to any trainee nuclear medicine technologists working at the facility.

ii. The Facility's rosters demonstrate that such trainees are supervised by a registered nuclear medicine technologist at all times

16.4.4 Qualifications – Nuclear Medicine Medical Physicist

The nuclear medicine medical physicists hold current regulatory licenses to use sealed and unsealed sources, where applicable in the Facility's state/territory jurisdiction.

INDICATORS

i. The medical physicists providing support to the Facility's nuclear medicine services are accredited in nuclear medicine physics by the ACPSEM, or the relevant jurisdiction authority.

ii. The nuclear medicine medical physicists hold current regulatory licenses to use sealed and unsealed sources, where applicable, in the Facility's state/territory jurisdiction.

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16.5 Professional Supervision of Nuclear Medicine Services

16.5.1 Responsibility of the Nuclear Medicine Specialist

The specialist in nuclear medicine shall comply with the Responsibility of the Specialist requirements in the AANMS Standards.

INDICATORS

i. Nuclear medicine specialists at the Facility are responsible for the quality and safety of all nuclear medicine services provided by personnel at the Facility, and assuring the nuclear medicine service provided is appropriate for the presenting condition of the patient.

ii. This responsibility includes ensuring that such personnel are properly trained, qualified and competent to perform each service that they are directed to perform.

iii. The Facility ensures that only the responsible nuclear medicine specialist is able to delegate responsibility to other persons to perform patient care tasks.

iv. Nuclear medicine specialists participate in multidisciplinary team meetings and interact with referring doctors as required. Nuclear medicine specialists address medicolegal requirements by formal preparation for review, portrayal and discussion of pertinent findings. Nuclear medicine specialists may delegate these duties to advanced trainees in nuclear medicine, as appropriate.

v. Where therapeutic nuclear medicine services are provided at a Facility, the nuclear medicine specialists are responsible for ensuring that patients and carers are appropriately counselled in relation to the benefits and potential risks of radiation exposure and organ damage.

16.5.2 Responsibility of the Nuclear Medicine Technologist

A nuclear medicine technologist's responsibilities shall comply with the AANMS Standards.

INDICATORS

i. The Facility's records demonstrate that the nuclear medicine technologist's responsibilities include radiopharmaceutical preparation and administration, imaging and data processing, and the full range of nuclear medicine services that are carried out under the supervision of the nuclear medicine specialist.

16.5.3 Nuclear Medicine – Supervision of Service

Supervision in the practice of nuclear medicine shall comply with AANMS Standards.

INDICATORS

i. The Facility's professional supervision policies ensure that the nuclear medicine specialist is available to personally attend the patient during the conduct of the nuclear medicine service.

ii. The Facility's professional supervision policies ensure that the nuclear medicine specialist determines the appropriateness of and monitors the quality of the service.

iii. The Facility's professional supervision policies ensure that the nuclear medicine specialist is able to assess and influence the outcome of the nuclear medicine service.

iv. The Facility's professional supervision policy extends to out-of-hours arrangements.

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16.5.4 Nuclear Medicine – Technical Service Manual

The Facility shall prepare and maintain a technical service manual as set out in the AANMS Standards.

INDICATORS

i. The Facility maintains a nuclear medicine service manual that has been established and is maintained by the nuclear medicine specialist/s.

ii. The Facility's nuclear medicine service manual includes for each service performed by the Facility:

- A summary of patient conditions that may affect the nuclear medicine specialist's interpretation of the nuclear medicine service
- A description of instruments used and the control settings, and the technical and analytic steps followed in performing the service that complies with the requirements of the AANMS Standards
- Reagents or other materials used in the test, including a listing of any special precautions for the use of such substances and any restrictions on the source of supply
- Medical literature citations when appropriate for a more thorough understanding of the service
- A description of any special quality assurance measures specific to a service
- A definition of quality control limits if appropriate
- Instructions on any preliminary actions to be taken in case of deviation from acceptable limits before referring the problem to the nuclear medicine specialist • Examples of typical indications for performing service
- Details of required quality control services.

iii. The Facility's nuclear medicine service manual is reviewed biennially by the nuclear medicine specialist.

iv. Superseded services are clearly identified and the reports retained by the Facility until such time as the retention period for reports relating to such services has expired.

16.5.5 Modification to Services

Where modifications to services are required and can be clinically justified, these modifications shall be noted in the patient records and in the consultation report, as determined by the reporting nuclear medicine specialist.

INDICATORS

i. The Facility notates both the patient records and the consultation report (as determined by the nuclear medicine specialist's directions) for any nuclear medicine services where services are modified.

16.5.6 Nuclear Medicine – Interpretation and Timeliness of Reporting of Results

Facilities shall comply with the reporting standards contained in the AANMS Standards.

The nuclear medicine report shall comply with the requirements described in the AANMS Standards.

INDICATORS

i. The nuclear medicine specialist shall ensure that the provision of nuclear medicine reports to requesting medical practitioners meets the requirements of the AANMS Standards.

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ii. The Facility rosters demonstrate that the nuclear medicine specialist complies with the reporting requirements applicable to the jurisdiction of the Facility.

iii. Copies of patient reports demonstrate that the contents of reports contain the requirements listed in the AANMS Standards.

iv. The Facility ensures that, generally, nuclear medicine reports are provided to requesting medical practitioners within 24 hours of the service being provided.

v. Where there are clinically significant or urgent unexpected findings, verbal communication of results is undertaken in a timeframe appropriate to allow timely medical intervention where required.

vi. Information about verbal communications is recorded at the Facility, either in the report or in the patient's notes, or in the Facility's record for the patient, including the name of the person with whom the results were discussed, and the date and time of the verbal communication.

16.6 Safety

16.6.1 Nuclear Medicine Facility Safety

Facilities shall comply with the standards for hazardous, toxic or biological materials contained in the AANMS Standards and any current jurisdiction or Commonwealth regulatory requirements.

INDICATORS

i. The Facility ensures that all toxic, irritant or caustic chemicals are appropriately labelled, and personnel are trained in the use of such materials.

ii. The Facility has readily available suitable eye protection devices, impervious aprons and means for flushing materials from the skin or eyes rapidly in the event of accidental splashing.

iii. Materials presenting biological or other hazards are carefully handled and in accordance with a documented protocol to minimise risks to personnel and patients.

iv. The Facility prohibits eating and drinking in patient care and laboratory areas.

v. Noxious, toxic or volatile materials presenting a hazard of airborne transport are handled in fume hoods providing adequate and safe venting to the atmosphere.

vi. Nuclear medicine waste materials are disposed of according to regulatory requirements. vii.

Aseptic technique is used when penetrating patient skin.

16.6.2 Nuclear Medicine – Radiation Safety

The Facility shall comply with all applicable radiation safety regulations

INDICATORS

i. The Facility retains at the site all applicable radiation licenses pertaining to nuclear medicine and refers to them for confirmation of ongoing compliance.

ii. Radiation safety policies and services contained in the Facility's radiation safety manual specific to the Facility's nuclear medicine services comply with all relevant radiation safety regulations, including notification of maladministration.

iii. Personnel are trained in radiation safety techniques according to the manual and have periodic in-service reviews. iv. The Facility records confirm that personnel are monitored by TLD badges (or other regulatory compliant dosimeters).

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v. The Facility records demonstrate that a comprehensive program of radiation monitoring is followed, and that radiation monitoring equipment is maintained and available for the detection of contamination and radiation exposure levels. vi. Services and resources have been implemented that ensure the correct handling of accidents involving radioactive materials and subsequent decontamination that complies with the relevant jurisdiction regulations.

vii. A CTDI (mGy) and DLP (dose length product – mGy/cm) value for each CT component of a gamma CT study is recorded and is available with the patient's images.

viii. The Facility observes precautions for children, and pregnant and breastfeeding patients, including posting warning signs, a verbal enquiry by facility personnel at the time the patient attends for the service and the provision of special instructions to a patient as required.

ix. The Facility undertakes dose calibration surveys with regular assessment of prescribed radiopharmaceutical doses.

x. The Facility ensures that administered activity for diagnostic and therapeutic procedures complies (generally within +/– 10%) with what has been prescribed.

16.6.3 Radioisotopes – Preparation, Handling, Administration

Facilities performing nuclear medicine services shall comply with the safety standards contained in the AANMS Standards.

INDICATORS

i. One month of the Facility's records of radiopharmaceutical receipt, preparation and disposition demonstrating that appropriate measures are maintained for identification of radiation areas, and the receipt, storage and disposal of radioactive substances.

ii. The Facility ensures that radioactive material dispensed for administration to patients is calculated according to established protocols.

iii. The Facility ensures the radiopharmaceutical activity is measured and recorded either in the patient's record or within the Facility's own reporting system.

16.6.4 Blood Products

The Facility performing nuclear medicine services shall comply with the standards regarding blood products contained in the AANMS Standards.

INDICATORS

i. The Facility performs labelling of blood or blood products in-house, and has established a blood-labelling protocol that is adhered to by all applicable personnel under the professional supervision of the nuclear medicine specialist.

ii. The services ensure the correct re-administration of the blood products to the correct patient. iii. Blood products are prepared in aseptic conditions using at least a Class II enclosed system.

iv. Externally supplied blood and/or blood products are verified for:

a. patient identification upon receipt, and again immediately prior to administration; and

b. radioactivity, with any discrepancy of more than 50% from the prescribed activity for diagnostic procedures, shall be confirmed with the nuclear medicine specialist prior to administration.

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16.6.5 Handling of Biological Materials

The Facility shall follow the requirements contained in the handling of biological materials by the Facility to meet the requirements of the AANMS Standards.

INDICATORS

i. The Facility ensures that glassware contaminated with toxic or biologic materials is made safe as soon as practicable after use.

ii. Bench-tops and area surfaces subject to substantial contamination risk should be covered with disposable protective materials when feasible, which are discarded in a safe manner according to waste management protocols.

iii. The Facility has protocols to ensure that appropriate care is exercised in handling sera and other materials.

iv. The Facility's protocols ensure that due care is taken to avoid the uncontrolled release of any potentially infectious material.

16.6.6 Cardiopulmonary Resuscitation and Basic Life Support

All personnel involved in patient care in the provision of nuclear medicine services shall be trained and retain competency in cardiopulmonary resuscitation services appropriate to the level of services provided by the Facility.

INDICATORS

i. The Facility ensures that all personnel involved in the provision of nuclear medicine services can administer basic or advanced life support in accordance with ANZCOR guideline 8 or ARC guideline 11.1.

16.6.7 Risks

All persons who may be exposed to radiation as a result of undergoing a therapeutic nuclear medicine service must be advised of manoeuvres they can take to minimise their own radiation exposure, as well as precautions to be adopted so as to reduce radiation exposure to other persons.

INDICATORS

i. The Facility makes written information and instructions available to patients, and provides advice on precautions that they can take to minimise their radiation dose, in particular for therapeutic services (e.g. radioiodine or strontium therapy).

16.7 Management of Patient Records

16.7.1 Nuclear Medicine – Patient Records

The Facility shall comply with the requirements of the AANMS Administrative Standard.

INDICATORS

i. The Facility ensures that the patient record identifies:

- Patient name, date of birth and unique identifier
- Name of the requesting medical practitioner
- Request date

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- Name of the responsible nuclear medicine specialist
- The nuclear medicine service is performed as it is identified in the facility service manual, with notation and explanation of any special modifications of this service
- Type, activity, route and injection site for any radioactive or non-radioactive substances administered to the patient
- The name of the nuclear medicine technologist performing the service (where applicable)
- The date that the service was performed
- A description of findings of any services performed, with interpretive information including background information on the predictive value of the service or expected values on a reference population to inform referring practitioners.

ii. The Facility ensures that all nuclear medicine patient reports contain:

- Patient name, date of birth and unique identifier
- Name of the requesting medical practitioner
- Name and signature of the responsible nuclear medicine specialist
- The nuclear medicine service performed as it is identified in the facility service manual, with notation and explanation of any special modifications of this service
- The date and description of findings of any services performed, with interpretive information including background information on the predictive value of the service or expected values on a reference population to inform referring practitioners.

17 ULTRASOUND

17.1 Equipment

17.1.1 Ultrasound – Equipment

The Practice shall ensure that all of its ultrasound equipment is appropriate for its intended use, is regularly maintained and is serviced by manufacturer-certified service engineers.

INDICATORS

i. Where the Practice offers comprehensive ultrasound services (including general ultrasound, cardiac ultrasound, vascular ultrasound, urological ultrasound, obstetric and gynaecological ultrasound, and musculoskeletal ultrasound), it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler
- Spectral (pulsed) Doppler
- M-mode scanning
- Linear transducer of frequency 12 MHz or greater
- Linear transducer of frequency 7 MHz or greater • Curved linear array transducer of frequency 2.5–5 MHz
- Transvaginal transducer.

ii. Where the Practice offers general ultrasound services, it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler

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- Spectral (pulsed) Doppler
- Linear transducer of frequency 7 MHz or greater
- Curved linear array transducer of frequency 2.5–5 MHz.

iii. Where the Practice offers cardiac ultrasound services, it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler
- Spectral (pulsed) Doppler
- Continuous and pulsed-wave Doppler
- Linear transducer of frequency 2.5 MHz
- M-mode scanning
- 2D scanning.

iv. Where the Practice offers vascular ultrasound services, it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler
- Spectral (pulsed) Doppler
- Linear transducer of frequency 7 MHz or greater
- Curved linear array transducer of frequency 5 MHz.

v. Where the Practice offers urological ultrasound services it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler
- Spectral (pulsed) Doppler
- Curved linear array transducer of frequency 2.5–5 MHz
- Endorectal transducer.

vi. Where the Practice offers obstetric and gynaecological ultrasound services, it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler
- Spectral (pulsed) Doppler
- M-mode scanning
- Curved linear array transducer of frequency 2.5–5 MHz
- Transvaginal transducer.

vii. Where the Practice provides musculoskeletal ultrasound services, it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler including power Doppler
- Linear transducer of frequency 12 MHz or greater
- Linear transducer of frequency 17 MHz or greater. viii. Where the Practice provides paediatric ultrasound services, it has the appropriate software and, as a minimum, equipment with the following capability:

- Colour Doppler, including power Doppler
- Spectral (pulsed) Doppler
- Linear transducer of frequency 7 MHz or greater
- Curved linear array transducer of frequency 5 MHz

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- C8-5 curved array (tight convex) transducer
- C5-1 curved array transducer • C9-2 curved array transducer
- Small footprint high-frequency linear transducer (hockey stick).

ix. Monitors used for ultrasound examinations have a minimum colour/monochrome resolution of 1024 × 768.

17.1.2 Equipment – Maintenance and Upgrades

All ultrasound equipment is maintained appropriately and meets currently accepted specifications.

INDICATORS

i. The Practice maintains its ultrasound equipment according to the manufacturer's recommended maintenance and servicing guidelines; and only uses manufacturer-certified service engineers. A service history record is maintained.

ii. The Practice regularly reviews the capability of its ultrasound equipment in consideration of available software and hardware upgrades, and meets any requirements of such upgrades when they occur.

iii. The Practice ensures that ultrasound equipment (hardware and software) is not more than 10 years old, or more than 15 years old if the equipment has been significantly upgraded with appropriate software, such that the software is equivalent to that of a machine less than 10 years old.

17.2 Personnel

17.2.1 Qualifications – Sonographer

The Practice shall ensure that its sonographers are appropriately qualified and accredited.

INDICATORS

i. In Australia, the Practice ensures that its sonographers are ASAR accredited and recorded on the ASAR register of accredited sonographers.(84)

ii. In New Zealand, the Practice ensures that its sonographers are registered with the MRTB, hold an Annual Practicing Certificate, and follow the MRTB Code of Ethics for Medical Radiation Technologists.(85)

iii. The Practice holds a copy of the current annual ASAR (Australia)/MRTB (New Zealand) membership receipt for each of its sonographers.

iv. The Practice can demonstrate that each of its sonographers follows the ASA Code of Conduct.(86)

17.2.2 Qualifications – Student Sonographers

The Practice shall ensure that its student sonographers are appropriately qualified and accredited.

INDICATORS

i. In Australia, the Practice ensures that its student sonographers are enrolled in an ASARaccredited course; are themselves ASAR accredited; and are recorded on the ASAR register of accredited sonographers.(84)

ii. In New Zealand, the Practice ensures that its student sonographers hold current MRTB registration and an Annual Practicing Certificate. iii. The Practice holds a copy of the current annual ASAR (Australia)/MRTB (New Zealand) membership receipt for each student sonographer.

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iv. The Practice can demonstrate that each of its student sonographers follows the ASA Code of Conduct(87) (Australia)/MRTB Code of Ethics for Medical Radiation Technologists(65) (New Zealand).

17.2.3 CPD – Clinical Radiologists

The clinical radiologist providing ultrasound services shall participate in ultrasound-specific CPD.

INDICATORS

i. The clinical radiologists providing the Practice's ultrasound services can demonstrate evidence of ongoing continuing professional development activity specific to the range of ultrasound services they provide.

17.2.4 CPD – Sonographers and Student Sonographers

In Australia, the Practice shall ensure that its sonographers and student sonographers comply with the requirements of an ASAR-approved CPD program (Australia).

In New Zealand, the Practice shall ensure that sonographers must be registered with the MRTB and hold an Annual Practicing Certificate.

INDICATORS

i. The Practice ensures that its sonographers and student sonographers hold current ASAR accreditation and are registered on the ASAR register of accredited sonographers(88) (Australia)/MRTB (New Zealand).

17.3 Professional Supervision

17.3.1 Student Sonographers

All student sonographers must have on-site supervision by a clinical radiologist or a sonographer accredited by ASAR/MRTB in the relevant field/s of practice at all times. The student sonographer must make the supervisor and managing radiologist aware of the course regulations for the successful progression.

INDICATORS

i. The Practice ensures that its professional supervision arrangements provide for on-site supervision of student sonographers by either the clinical radiologist or an ASAR-accredited sonographer so delegated by the clinical radiologist. ii. The Practice ensures that supervising sonographers are accredited by the ASAR/MRTB in the fields of practice in which they are supervising.

17.3.2 Sonographers Performing Ultrasound Examinations in Remote Locations

Sonographers performing ultrasound examinations in rural and remote locations shall have appropriate professional supervision and clinical guidance from the reporting radiologist.

Notes: It is recognised that clinical supervision of ultrasound examinations in remote locations will be conducted via different methods depending on the examination setting and the experience of the sonographer conducting the examination. It is important that sonographers are supported clinically in these remote settings, and in particular, that student sonographers are supported by both their sonographer peers and the reporting radiologist/s.

INDICATORS

i. In Australia, the Practice meets the criteria for 'rural and remote' status for Medicare.

ii. The sonographer meets the requirements under Items 17.2.1 and 17.2.4.

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iii. Where a student sonographer is performing ultrasound examinations in remote locations, he/she meets the requirements under Items 17.2.2 and 17.2.4, and has either:

a. completed one year of directly supervised training that has included the full scope of ultrasound examinations that he/she is performing at the Practice; OR

b. the reporting radiologist has determined that the student sonographer has completed sufficient training and obtained sufficient practical experience under direct supervision to perform a defined range of ultrasound examinations under remote supervision protocols as per Indicator v under this Standard.

iv. During the conduct of each ultrasound examination, the clinical radiologist is readily contactable to discuss the procedure with the sonographer or student sonographer and influence the examination.

v. The Practice ensures that this clinical supervision is supported through on-site supervision and/or teleradiology and/or internet access and/or telephone support, as is determined by the reporting radiologist.

vi. The Practice ensures that professional supervision arrangements for student sonographers in remote locations are consistent with those for qualified sonographers, but that it is exercised during the course of an examination, so that appropriate imaging, decision-making and review can be made at the time of the examination.

vii. This supervision of student sonographers is supported by the additional resource of an ASARaccredited sonographer who provides guidance to the student sonographer through on-site supervision and/or teleradiology and/or internet access and/or telephone support, as determined by the reporting radiologist.

viii. The Practice conducts regular (at least annual) reviews of the quality of the remote ultrasound examinations in order to confirm that the supervision arrangements of these services do not compromise patient care.

17.3.3 Ultrasound – Review of Appropriateness of Request

The clinical radiologist shall be readily contactable to discuss and, if necessary, alter the conduct of the imaging examination in consideration of the examination request.

INDICATORS

i. The Practice's professional supervision protocols ensure the provision of clinically directed scanning and appropriate triaging for all ultrasound services.

ii. Within the Practice's professional supervision protocols, the clinical radiologist has implemented and ensures adherence to appropriate written protocols to be followed by members of the imaging team for this component of the imaging service.

iii. The Practice's professional supervision protocols recognise that a clinical radiologist may need to personally attend the patient prior to an ultrasound examination proceeding in order to determine the optimum imaging pathway for the patient.

17.3.4 Ultrasound – Performance of the Examinations

Ultrasound scanning of the patient shall be performed by the clinical radiologist, the sonographer acting on behalf of the clinical radiologist, or the clinical radiologist and sonographer in collaboration. When a sonographer performs the examination, a collaborative, team approach between the sonographer and sonologist maximises the clinical ability of the ultrasound examination. The clinical radiologist shall be available to personally attend the patient to discuss and influence the conduct of the examination. When the ultrasound scan reveals specified significant or unexpected findings, the sonographer will communicate with the clinical radiologist while the patient is on site to facilitate review of the patient and/or the images by the clinical radiologist to ensure patient triage. A subspeciality opinion or reporting may be used with teleradiology if it promotes the standard of the reporting and service to the patient. The radiologist should be contactable by the sonographer when the scan is performed to discuss the case, and influence the conduct of the examination.

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INDICATORS

i. The clinical radiologist has implemented a system for communication with the sonographer. This communication may be verbal and/or by sonographer worksheets and/or annotated images.

ii. The Practice's professional supervision protocols and rostering for ultrasound examinations ensure that the clinical radiologist is available and contactable and, if necessary, is available to personally attend the patient, to influence and/or alter the conduct of the examination. iii. The Practice has protocols in place that set out the criteria for which findings trigger the scan being brought to the attention of the clinical radiologist while the patient is on site.

iv. The Practice ensures that its clinical radiologists providing ultrasound services are responsible for determining:

- How much of an ultrasound examination should be shown and demonstrated to a patient
- What examination information can be independently passed on to a patient by the sonographer.

v. The Practice ensures that its clinical radiologist and sonographer have read, understood and adhere to Standard 8 when providing teleradiology services.

17.3.5 Ultrasound – Interpretation and Reporting of the Results

The responsibility for the conduct of the study and the production of the report lies with the clinical radiologist. The clinical radiologist's report shall draw upon all the available information, which may include communication with the sonographer; reviewing the sonographer's images; attending the patient to talk to, examine or scan the patient; and/or observing the sonographer scan in real time. The sonographer's worksheet is primarily a communication medium between the sonographer and clinical radiologist, and contributes to the final report produced by the sonologist. Part, or all, of the sheet may be incorporated into the clinical radiologist's report at the radiologist's discretion. The worksheet does not constitute a report, and the clinical radiologist's report may differ from the content of the worksheet.

It is expected that all sonographer worksheets will be appropriately stored and filed with the request form.

INDICATORS

i. The report issued to the referring clinician contains relevant clinical details and ultrasound findings, draws conclusions pertinent to the patient and the clinical indicators for the study, and complies with the Clinical Radiology Written Report Guideline.(25)

ii. The Practice can demonstrate that the request form and the sonographer worksheet are appropriately stored in the patient's electronic medical records.

iii. The Practice ensures that when a sonographer is involved in performing an ultrasound examination, the sonographer's initial and surname is included in the record of the examination held by the Practice.

17.4 Safety

17.4.1 Ultrasound – Safety

The Practice shall ensure that it meets all safety requirements for the ultrasound services it provides.

INDICATORS

i. The Practice ensures that sonographers and clinical radiologists working at the site are aware of the potential thermal and mechanical bio-effects of ultrasound, and that they meet the requirements set out in the BMUS Guidelines for the safe use of diagnostic ultrasound equipment.(89)

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ii. The Practice ensures that sonographers and sonologists working at the site meet the safety requirements set out in the WFUMB Policy and Statements on Safety of Ultrasound for the safe use of diagnostic ultrasound equipment.(90) iii. The Practice meets all regulatory requirements in relation to ultrasound safety.

iv. The Practice ensures it provides a safe working environment for sonographers and sonologists, and meets recommendations contained in ASA and ASUM joint guidelines for reducing injuries to sonographers/sonologists.(91)

17.4.2 Ultrasound – Infection Control

The Practice holds a readily accessible copy of the ASUM/ACIPC Guidelines for Reprocessing Ultrasound Transducers and adheres to the protocols outlined.(92)

The Practice adheres to the infection control protocols for the environment in which a patient is being examined.

INDICATORS

i. The Practice ensures that sonographers and radiologists are familiar with the contents of this guideline.(72)

ii. The Practice ensures that the use of solutions for sterilising and cleaning endocavity transducers complies with the relevant jurisdiction's occupational health and safety regulations. iii. The Practice ensures it maintains a record of their Infection Control activity regarding transducers. iv. The Practice meets regulatory requirements in relation to the hygiene of the scanning environment.

Appendices

Appendix A – Personnel Administering Intravenous Contrast

Diagnostic imaging services must ensure that personnel who are involved in IV medication administration are regularly assessed for their competence.

Classes of persons considered to be suitably qualified/trained to administer intravenous medication within their context and scope of practice include the following (may not be all inclusive):

- Medical practitioners
- Dentists
- Registered nurses
- Enrolled nurses
- Ambulance officers
- Medical radiation scientists (Nuclear Medicine)
- Medical radiation scientists (Radiography)
- Anaesthesia technicians who have completed the Australasian Society of Anaesthesia Technicians Diploma Course
- Clinical perfusionists who are certified by the Australasian Board of Cardio-vascular Perfusion as certified clinical perfusionists
- Cardio-pulmonary technicians/technical officers
- Anaesthesia technicians and clinical perfusionists in training, only under the direct supervision of a medical practitioner

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- Medical students, only under the direct supervision of a medical practitioner
- Nursing students, only under the direct supervision of a registered nurse
- Ambulance officers in training, only under the direct supervision of a qualified ambulance officer, medical practitioner or registered nurse.

Appendix B – Tier A Interventional Procedures

- Basic diagnostic angiography and interventional techniques
- Basic diagnostic angiography
- Nephrostomy
- Abscess and cyst drainage and biopsy
- Simple venous access
- Breast localisation
- Image-guided biopsies
- Joint arthrography and injection
- Spinal tap, epidural and spinal nerve root block
- Other non-tier B interventional procedures.

Appendix C – Tier B Interventional Procedures

1. All neuro-interventional procedures, intracranial and extracranial – these are subject to additional specific credentialing requirements determined jointly by the RANZCR, ANZSNR and IRSA
2. All vascular interventional procedures other than basic diagnostic angiography; that is, stents (including carotid stenting with its associated intracranial and extracranial angiography), angioplasty, thrombolysis, thrombectomy, atherectomy, embolisation, retrieval of foreign bodies and laser and mechanical angioplasty
3. Venous and arterio-venous graft interventions other than basic diagnostic venography or fistulography; that is, thrombolysis, angioplasty, stents, atherectomy, pulmonary embolectomy/thrombolysis and caval filter insertion
4. Biliary intervention including TIPS
5. Thoracic intervention; that is, embolisation of AVMs, bronchial stents, occlusion of bronchopleural fistulas and bronchial artery embolisation
6. Gastro-intestinal intervention; that is, oesophageal and duodenal stents, percutaneous gastrostomy, and gastrointestinal vascular procedures other than diagnostic angiography, such as embolisation, chemo-embolisation and transplant intervention
7. Urological intervention; that is, renal artery embolisation, angioplasty or stenting, percutaneous nephrolithotomy
8. Gynaecological – fallopian tube recanalisation, embolisation of fibroids and temporary aortic occlusion
9. Orthopaedic – percutaneous vertebroplasty and percutaneous discectomy.

Appendix D – Monitor Specification Table

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	CR/DR[a]	CT[a]	Mammography[(79)b]	MRI[a]
Matrix size	≥3 megapixels	≥3 megapixels	≥4.2 megapixels per image at full resolution & maximum pixel pitch of 0.2mm	≥3 megapixels
Max luminance	≥350 cd/m^2	≥350 cd/m^2	≥450 cd/m^2	≥350 cd/m^2
Luminance ratio[c]	≥250	≥250	≥250[d]	≥250
Bit depth	≥8 bits	≥8 bits	≥8 bits	≥8 bits
Luminance uniformity[e]	≤30%	≤30%	≤30%	≤30%
Calibration	GSDF ≤10%[d]	GSDF ≤10%[d]	GSDF ≤10%[d]	GSDF ≤10%[d]
L_{min}[f]	≥1 cd/m^2	≥1 cd/m^2	≥1 cd/m^2	≥1 cd/m^2

[a] Australian Technical Specification ATS 5816-2013. Digital images for diagnostic and other clinical purposes: Presentation, communication, display and manipulation. Standards Australia [b] Display Quality Assurance AAPM Report NO. 270; January 2019 [c] L_{max} / L_{min} [c]350 preferable [d]Grayscale standard display function [e] (L_{max} - L_{min}) / L_{centre} (ideally ≤15%) [f] Grayscale standard display function

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