# MEDICAL IMAGING ASSESSMENT WORKSHEET

## Self-assessment

The Royal Australian and New Zealand College of Radiologists

NATA

This self assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

| RANZCR | DIAS 2015 | Description of Standard | Evidence Sighted |
|---|---|---|---|
| | **Part 1** | **Organisational Standards** | |
| 1.2 & 1.4 | Std 1.1 | Safety and Quality Governance Standard | |
| 4.1 & 4.2 (11.2; 12.2; 13.3; 14.2; 15.3; 16.4;17.2) | Std 1.2 | Registration and Licensing Standard | |
| 6.3.2 (11.3.4.2; 12.4.1; 16.6) | Std 1.3 | Radiation Safety Standard | |
| 3.2 | Std 1.4 | Equipment Inventory Standard | |
| 3.1; 4.2.4; 6.1 | Std 1.5 | Equipment Servicing Standard | |
| 6.2 (13.4; 16.6.1; 17.4.2) | Std 1.6 | Healthcare Associated Infection Standard | |
| | **Part 2** | **Pre-Procedure Standards** | |
| 5.3.1 & 5.3.2 (11.3.1; 13.4.1; 14.3.2; 15.4.2; 17.3.3) | Std 2.1 | Provision of Service Standard | |
| 5.3.4; 7.3; 7.6; 7.7 | Std 2.2 | Consumer Consent and Information Standard | |
| 7.1; 7.2; 7.4 | Std 2.3 | Patient Identification & Procedure Matching Standard | |

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|---|---|---|---|
| 1.10; 5.4.2; 6.6.3 | Std 2.4 | Medication Management Standard | |
| | **Part 3** | **Procedure Standards** | |
| 5.4 (11.3.2; 14.3.4; 15.4.4; 16.5.4; 17.3.4) | Std 3.1 | Diagnostic Imaging Protocol Standard | |
| 6.3.1 (11.3.4; 12.3.2; 15.5.1;16.6.2) | Std 3.2 | Optimised Radiation Technique Charts Standard | |
| | **Part 4** | **Post Procedure Standards** | |
| 5.5; 8.3.2; 8.7.4 | Std 4.1 | Communicating Results and Reports Standard | |
| NA | Std 4.2 | Findings of Self-Determined Services Standard | |
| 1.8 | Std 4.3 | Consumer and Stakeholder Feedback and Complaints Management Standard | |

| Clause | Standard | QM cross reference | Comments |
|---|---|---|---|
| **1 PRACTICE MANAGEMENT SYSTEM** | | | |
| **1** | **Practice Management System** | | |
| **1.1** | **Practice Management System** | | |
| Indicator i | The senior management of the practice ensures that the required operational policies, procedures and practice management system are implemented, applied and are continuously improved. | | |
| Indicator ii | The practice ensures that all personnel familiarise themselves with and commit themselves to policies and procedures and implement these in their work. | | |
| **1.2** | **Quality Manual** | | |
| Indicator i | The quality manual includes a quality policy defining the quality objectives. | | |
| Indicator ii | The quality policy is issued under the authority of senior management, and includes managements commitment to:<br>a) good professional practice and compliance with these RANZCR Standards; and<br>b) continual improvement of the effectiveness of the management system and to the quality of all services provided. | | |
| Indicator iii | It includes policies relating to the management system. | | |
| Indicator iv | It outlines the structure of the practice's documentation hierarchy. | | |
| Indicator v | It makes reference to supporting documentation. | | |

| Clause | Standard | QM cross reference | Comments |
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| Indicator vi | It defines the role and responsibilities of management personnel, including the Quality Manager. | | |
| **1.3** | **Quality Manager** | | |
| Indicator i | The practice personnel records identify:<br>a) the quality manager and his/her associated job description; OR<br>b) that if the role of quality manager is fulfilled within the practice across more than one position, and the practice can identify which personnel members fulfil this role and how this is co-ordinated. | | |
| **1.4** | **Documentation**<br>*A master list of controlled documents shall be maintained which identifies the current version and distribution of documents.* | | |
| Indicator i | The practice has established a documentation system | | |
| Indicator ii | All documents are uniquely identified to include the date of issue or revision number, page numbering (including total number of pages) and the issuing authority. | | |
| Indicator iii | Procedures are established to define how changes to documents are to be made and controlled | | |
| Indicator iv | All documents are periodically reviewed and revised when necessary, and approved or reapproved by authorised personnel prior to issue. | | |
| Indicator v | Only current versions of documents are available. | | |
| Indicator vi | Where handwritten amendments are allowed, they are initialled and dated. | | |

| Clause | Standard | QM cross reference | Comments |
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| Indicator vii | Master copies of old and/or superseded document versions are retained or archived for legal and knowledge preservation purposes and are appropriately identified. | | |
| Indicator 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, report turnaround times and confidentiality. | | |
| **1.5** | **Records** | | |
| Indicator i | The practice records are legible, identifiable to the responsible personnel, held secure to prevent loss or unauthorised access, and retrievable. | | |
| Indicator ii | Original data (electronic or hard copy) are retained according to relevant legislation, unless such records are scanned into the Radiology Information System (RIS). | | |
| Indicator 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. | | |
| Indicator 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. | | |
| Indicator v | All records (including billing records and reports, but excluding images) are retained in accordance with the appropriate statutory requirement depending on the state/territory. Where such a regulatory requirement does not exist, the practice retains records for a minimum of 36 months. | | |
| Indicator vi | There are procedures in place which ensure that electronic records are protected, backed up and unauthorised amendment of such records is prevented. | | |

| Clause | Standard | QM cross reference | Comments |
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| Indicator vii | There is a disaster recovery system that addresses the risk of network failure and also takes into consideration PACS, image failure and teleradiology services. | | |
| Indicator viii | Where data is transmitted across a wide area network it is encrypted or protected by a username and password. | | |
| **1.6** | **Corrective and Preventive Action** | | |
| Indicator i | Process for identifying and investigating non-conforming work and departures from authorised policies and procedures, and for implementing corrective action/s accordingly. | | |
| Indicator ii | Documented policies and procedures outlining the appropriate corrective and preventive actions | | |
| Indicator iii | It has a process for identifying and implementing preventive action to eliminate the causes of potential non-conformities, incidents and adverse clinical events. | | |
| Indicator iv | Corrective and preventive action activity is recorded.<br>Staff understand incident reporting processes, what constitutes reportable incidents and their responsibilities in this regard. | | |
| **1.7** | **Continuous Quality Improvement** | | |
| Indicator i | The practice has implemented a continuous quality improvement schedule which establishes a risk register. | | |
| Indicator ii | An audit against theses Standards and the Practices own policies and procedures occur at least annually. | | |
| Indicator iii | Procedures are in place to ensure the objectivity and impartiality of auditors and the audit process itself. Independent auditors should be guided by ISO standard 19011 | | |

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| Indicator iv | This audit includes review of the practice's corrective and preventive action processes and activity, and the effectiveness of any such action taken. | | |
| Indicator v | It has records of participation in and compliance with external quality assurance activities where these are available (including image reviews). | | |
| Indicator vi | The practice identifies key areas of its operations for quality improvement, including through the use of patient experience, and implements appropriate training accordingly. | | |
| **1.8** | **Feedback and Complaints** | | |
| Indicator i | Feedback is actively sought from patients and referrers | | |
| Indicator 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. | | |
| Indicator iii | Procedures should be transparent, fair, efficient and timely. | | |
| Indicator iv | Records are maintained of all feedback, complaints, investigations and corrective actions taken, and support open disclosure of errors and adverse patient outcomes. | | |
| **1.9** | **Management Review** | | |
| Indicator i | Records of management system reviews are kept together with any action plans, outcomes and monitoring activities. | | |
| Indicator ii | For Practice groups that have a board of directors, senior management should report a summary of this review process regularly to the board. | | |

| Clause | Standard | QM cross reference | Comments |
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| Indicator iii | A risk register is maintained that reflects the actions and mitigations taken in response to various risks. | | |
| **1.10** | **Supplies** | | |
| Indicator i | Procedures to manage purchasing of services and supplies.<br>List of all suppliers, contractors and consultants is maintained, | | |
| Indicator ii | Purchased products and services are verified at appropriate intervals. | | |
| Indicator iii | Purchased materials and products are stored in designated storage areas within the facility which is designed to prevent damage and deterioration to the product prior to use. | | |
| Indicator iv | Where special storage conditions are required to prevent deterioration (e.g. Refrigeration), procedures are in place to ensure those conditions are adequately controlled and maintained. | | |
| Indicator 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. | | |

| 2 FACILITIES | | | |
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| **2 Facilities** | Practice facilities shall support the delivery of safe, quality clinical (diagnostic and/or 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** | | |
| Indicator i | The practice's facilities comply with legislative requirements. | | |
| Indicator ii | Access to and use of areas affecting the quality of the imaging procedures and/or safety of patients and personnel is controlled. | | |
| Indicator iii | There is effective separation between neighbouring areas in which there are incompatible activities. | | |
| Indicator iv | The cleanliness of the facilities is maintained. | | |
| Indicator v | Appropriate staff amenities are provided | | |
| **2.2** | **Patient Facilities** | | |
| Indicator i | The practice has facilities available which optimise the comfort of its patient population and seeks ongoing feedback. | | |
| Indicator ii | Facilities are available for disrobing which ensure the privacy of patients. | | |
| Indicator iii | Patient facilities are designed to accommodate special needs required by the patient population of the practice. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3 EQUIPMENT** | | | |
| **3.1** | **General** | | |
| Indicator i | The practice holds state/territory regulatory compliance certificates for each piece of diagnostic and/or interventional radiology equipment it operates within the relevant jurisdiction. Such certificates shall be as current as the regulatory environment permits. | | |
| Indicator ii | Records of such compliance testing are held at the practice site. | | |
| Indicator iii | It carries out quality control, maintenance and calibration of equipment used for all of its imaging services and maintains records of all such activity. | | |
| Indicator iv | Records of remedial actions are kept for the operational life of the equipment at the practice. | | |
| Indicator v | Such quality control and maintenance activity is carried out in accordance with both manufacturers' guidelines and regulatory requirements by appropriately qualified persons. | | |
| Indicator vi | The practice complies with legislation concerning the procurement, sale or disposal of any equipment which generates ionising radiation | | |
| Indicator vii | Equipment should only be operated by appropriately certified and licensed, where required, staff. | | |
| Indicator viii | When purchasing or upgrading equipment and software 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.2** | **Equipment Inventory** | | |
| Indicator i | The practice maintains a current equipment inventory which includes (but is not limited to):<br>• Name of item, manufacturer, serial number (or other identifier<br>• Notice/certificate of registration or licence, where applicable.<br>• Condition when acquired (i.e. new, re-conditioned<br>• Date of Installation | | |
| Indicator ii | The equipment inventory, for each piece of equipment, contains:<br>• The acceptance performance certificate<br>• The instruction manual<br>• A statement of the manufacturer's specifications<br>• Current formal statement of modifications made to the equipment, and/or its operating software and applications, after purchase. | | |
| Indicator iii | The Practice has a register of all its data, including, but not limited to:<br>• Software programs<br>• Data flow diagrams<br>• Systems the Practice interfaces with<br>• Where patient and clinical data reside<br>• Where backups reside. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.3** | **Equipment Sedation and Monitoring** | | |
| Indicator i | Sedation is only performed in a location which is equipped with the resources to deal with a cardiopulmonary emergency according to the ANZCA PS09 Guidelines[ | | |
| Indicator ii | Where sedation of paediatric patients is carried out:<br>• The monitoring equipment is capable of measuring oxygen saturation, end tidal CO2 and (non-invasively) blood pressure<br>• There is separate oxygen saturation monitoring for the recovery area<br>• There are facilities and equipment for endotracheal intubation of children. | | |
| Indicator iii | The practice complies with any regulatory and/or licensing requirements applicable to the use of sedation. | | |
| **3.4** | **Equipment – Anaesthesia and Monitoring** | | |
| Indicator 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 [3]. | | |
| Indicator ii | Where procedures are carried out on paediatric patients requiring anaesthetic:<br>• Anaesthetic monitoring equipment is capable of measuring oxygen saturation, end-tidal CO2, and (non-invasively) blood pressure.<br>• There is separate oxygen saturation monitoring for the recovery area and there are facilities and equipment for endotracheal intubation of children.<br>• Procedures on children under one year of age requiring general anaesthesia are not performed in units without specialist paediatric facilities. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator iii | The practice complies with any regulatory and/or licensing requirements applicable to the use of anaesthesia. | | |
| **3.5** | **Equipment – Resuscitation** | | |
| Indicator i | The practice maintains current inventories for resuscitation equipment and associated drugs. | | |
| Indicator ii | The practice carries the minimum resuscitation equipment required to perform Advanced Life Support including an Automated External Defibrillator (AED). | | |
| Indicator iii | This equipment is immediately available and maintained so that it is in working order whenever intravenous or other contrast administration takes place. | | |
| Indicator iv | The practice has a process for checking that resuscitation drugs are current, and not out of date, and records these checks. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.6.1** | **Computers and Automated Equipment – General** | | |
| Indicator i | The Practice has documented procedures for<br>• Securing practice networks and their interfaces with other networks, including the public internet<br>• Connections from and to individual imaging devices may require particular attention<br>• Ensuring the integrity, availability, and confidentiality of data collection and entry<br>• Data storage (on- and off-site)<br>• Data transmission<br>• Data processing<br>• Backup protocols<br>• Disaster recovery systems with particular consideration of digital imaging and Teleradiology services<br>• Business continuity plan<br>• Data breach notification plan<br>• Risk management system.<br>The Practice shall ensure that computer hardware and automated equipment are appropriately serviced, and that software is updated and patched as required.<br>The Practice shall provide appropriate environmental and operating conditions to ensure the optimal functioning of computer hardware | | |
| Indicator ii | The Practice has documented instructions for use of software at the Practice | | |
| Indicator iii | The Practice has service logs of computer and automated equipment, and records of software updates. | | |
| Indicator iv | The Practice has systems for monitoring the environmental and operating conditions in equipment rooms. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator v | The Practice can demonstrate the use of additional security to protect patient information when using shared health information databases | | |
| **3.6.2** | **Diagnostic Workstations**<br>Monitors and display software used for reporting and diagnosis must meet the requirements for 'Primary (diagnostic) workstations'.<br>There are less stringent requirements for "Secondary (review) workstations", which may be used for monitoring workflow or case review, but not for primary diagnosis. | | |
| **3.6.2.1** | **Display Software** | | |
| Indicator i | The display systems used for reporting by the radiologist provide the following minimum functions to support accurate interpretation of images by the radiologist for all modalities:<br>• Panning<br>• Image Magnification<br>• Rotation<br>• Window level and width adjustment<br>• Measurement (length at least)<br>• Signal intensity Measurement<br>• Total number of images in study. | | |
| **3.6.2.2** | **Monitors**<br>The practice shall ensure that diagnostic imaging monitors are appropriate for the activity for which they are used. | | |
| Indicator i | The practice ensures that initial quality assurance and subsequent reporting of images for PACS or teleradiology is performed on primary monitors. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | The Practice's primary monitors for CR and DR meet the requirements set out in Appendix D.<br>Further information may be found in the ACR Practice Parameters and Technical Standards: | | |
| Indicator iii | Consideration to implementing anti-reflective coating to monitors | | |
| Indicator 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. | | |
| Indicator 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.<br>Secondary monitors should endeavour to met the following:<br>• Maximum luminescence ≥250 cd/m$^2$<br>• Calibration Grayscale Standard Display Function (GSDF) accuracy ≤20%<br>• Lmin ≥1 cd/m$^2$ | | |
| Indicator vi | Ambient lighting: extraneous room light minimised: 20-40 lux recommended | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| 3.7.1 | **Digital Image Data Management**<br>The practice shall ensure that digital image data is managed appropriately in relation to digital image file format, storage, retention and archiving.<br>The Practice shall ensure that digital images can be readily be made available in a DICOM-compliant format, where one is available for the modality in question.<br>When storing images, the Practice shall use lossless compression where feasible and otherwise shall use compression ratios as recommended in the RANZCR compression guidelines<br>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.<br>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. | | |
| Indicator i | The Practice has documented policies on digital image compression. | | |
| Indicator ii | The Practice has a statement of archive capacity and of typical storage requirement in Megabytes. | | |
| Indicator iii | The Practice can demonstrate the use of a retention schedule. | | |
| Indicator iv | The digital archiving system shall have the capability and capacity to store radiation dose information for patients. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.7.2** | **Privacy and Information Security**<br>The Practice shall maintain the privacy and security of health information it holds, following the legislation in its jurisdiction.<br>Policies regarding emails and social media shall be designed and adopted, to protect patient information and the Practice's reputation. | | |
| Indicator i | The Practice does not store or leave patient information in areas accessible to members of the public. | | |
| Indicator 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. | | |
| Indicator iii | The Practice has policies and procedures for:<br>• Information recovery and business continuity<br>• Storage, retention and destruction of patient records<br>• The use of email<br>• The use of social media<br>• Data breach notification<br>• Cybersecurity insurance policy. | | |
| **3.7.3** | **Exchange of Digital Imaging Data and Reports – General Requirements** | | |
| **3.7.3.1** | **Exchange Media and File Systems** | | |
| Indicator i | When exchanging diagnostic images in a digital format on a portable device, the medium used is either compact disk, compliant with ISO/IEC 10149 (CD-R), or another medium which allows compliance with the IHE-PDI profile. | | |
| Indicator ii | The file system of such media is compliant with ISO 9660:988(E) – level 1. | | |
| Indicator iii | The practice shall be able to provide a complete set of diagnostic quality images, when appropriate to the needs of the patient and/or the referrer. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.7.3.2** | **Malicious Software** | | |
| Indicator 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 which record digital imaging data, or in systems used in the exchange of diagnostic imaging data. | | |
| Indicator ii | For portable media, once this check is carried out successfully and no further data is to be written to the disk, such media are ‘closed’ to data alteration or addition. | | |
| Indicator iii | Media which are only intended to have data added on one occasion are similarly checked and 'closed' to data alteration or addition. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.7.3.3** | **Exchange of Digital Imaging Data and Reports Using Portable Media : IHE PDI profile** | | |
| | The practice has implemented systems that ensure that all portable media issued by the practice are compliant with the IHE PDI profile. | | |
| | The practice ensures that all such media contain a “readme.txt” file which is situated in the root directory, even if web content is not supported.<br>This readme.txt file contains a copy of the generic facility (not patient-specific) information provided on the label and external packaging.<br>This readme.txt file contains information about DICOM viewer software, and information about the requirements for HTML viewers required to read web content.<br>When providing diagnostic imaging data as web content, such content is compliant, and<br>a) a default web page (index.htm) is used as a the landing page for end users, and contains the same key information as that used on the media and package;<br>b) the web page includes appropriately formatted images (e.g. JPEG) and links to help files and software for accessing DICOM file content if this is provided; and<br>c) where web content is used to display non-diagnostic images, the fact that these are non-diagnostic is clearly conveyed to the user either in the instructions or by annotation of individual images.<br>If diagnostic imaging reports are included on the portable media, they are:<br>a) DICOM compliant and stored according to the IHE PDI profile; OR<br>b) in the HL7 version 2 or HL7 Clinical Document Architecture formats; OR<br>c) in PDF file format. | | |
| Indicator i | The Practice ensures that portable media issued by the Practice are compliant with the IHE PDI profile | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.7.3.4** | **Use of Embedded DICOM Viewer on Portable Media** | | |
| | The practice ensures that when a DICOM viewer is provided on such media that such viewers do not auto-load.<br>Instructions for starting the viewer are present on the media label, media folder and readme.txt file, and an online manual is available<br>The viewer and help files are located in and can be loaded from the index.htm page.<br>Where the software does not load (e.g. incorrect operating systems), the viewer will terminate with an intelligible error message.<br>Loading the viewer is not dependent on pre-existing components (e.g. Java, MS components), and these components only load from the disk if they are required<br>Minimum specifications in regard to the computer equipment required to run the DICOM viewer software are included in the information provided on the media label, media folder, readme.txt file, and the online manual. Correspondingly, any limitations of the viewer are declared. | | |
| Indicator 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** | | |
| Indicator 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** | | |
| Indicator i | Media used for long term storage or archive shall be appropriate to the planned period of archive, with appropriate back-up arrangements in place. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | Media used for portable use meets the requirements set out under item 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**<br>The content on the label on the device, on the storage package and represented on the device itself should be consistent.<br>Media used for the exchange of diagnostic imaging data shall have labels printed directly 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. | | |
| Indicator i | The Practice ensures the following information on portable media, (where the size of the media permits).<br>• Patient name;<br>• Patient ID (addition of the Australian Individual Health Identifier is encouraged);<br>• Patient date of birth<br>• Media creation date<br>• Date of examination/s<br>• Name of institution creating the media, and contact details<br>• Media type and an identifier in the format 'media type', 'instance number' of 'total number of media in series'.<br>• A statement about the sole archive status or retention policy of the radiology service<br>• A statement that contents are confidential. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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** | | |
| Indicator i | The practice ensures that storage of blank (unused) portable media is consistent with the media manufacturer's guidelines. | | |
| Indicator ii | Portable media are consistently stored in packaging which is suitable for transfer to the patient or referring practitioner and that is immediately identifiable as a medical record. | | |
| Indicator iii | Such packaging has suitable internal storage for the portable media to avoid accidental loss. | | |
| Indicator iv | This packaged portable media is stored according to the media manufacturer's guidelines until dispatch. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **3.9.3** | **External Labelling** | | |
| Indicator i | The practice ensures compliance of the following for the storage envelopes and folder produced by the Practice<br>• 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 clause 3.9.1.<br>• This label is placed under a flap in the event that the package is to be sent by post in order to protect patient privacy<br>• The contents of envelope are clearly defined and expressed.<br>• The Practice name and contact details are clearly expressed.<br>• Detailed instructions for common operating systems are included 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<br>• The label includes a statement that the contents are confidential medical records, with a clear return address if the package is located. | | |

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| **3.10** | **Online Portals** | | |
| | Access to such images via on-line portals shall be restricted to appropriately authorised individuals, who shall be required to authenticate their identity before access is granted.<br><br>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.<br><br>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.<br><br>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<br><br>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 | | |

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| **3.11** | **Reporting Environment** | | |
| | The reporting environment must be organised to ensure optimal reporting conditions for the medical practitioner.<br>The practice ensures that reporting conditions are confirmed as acceptable for diagnostic image interpretation by each of its medical practitioners providing the reporting services<br>The reporting environment ensures that the reporting environment has<br>• A minimum amount of light reflection on the monitor where interpretation is being made<br>• Ambient light intensity of 20–40 lux (recommended), although higher levels may be<br>• permissible with bright displays<br>• Displays placed ergonomically at an approximate reading level for each medical practitioner<br>• Displays placed away from areas that may cause image degradation, such as magnetic fields<br>• and electronic transformers<br>• Adequate control of temperature, humidity, ventilation and acoustic noise.<br>• Ergonomic standards are met as set out in Standard 4.1.5. | | |
| Indicator i | The Practice has a system for monitoring reporting environments | | |

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| **3.12.1** | **Quality Control Testing**<br>The Practice shall implement, maintain and follow a planned program of QC activity in cooperation with a Medical Physicist, as appropriate.<br>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.<br>The Practice shall ensure that measurements and other results of all QC activities are recorded so that trends are detectable.<br>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. | | |
| Indicator i | The Practice has written procedures for QC that are readily accessible to their staff. | | |
| Indicator ii | The Practice maintains records of the results from QC testing performed | | |

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| **3.12.2** | **Quality Control Testing – Diagnostic Workstations and Teleradiology Equipment**<br>The Practice must have a QC program in place relevant to the scope of digital imaging and teleradiology services provided. | | |
| Indicator i | The Practice has written procedures for QC of diagnostic workstations and teleradiology equipment, which are readily accessible to their staff.<br>The QC program includes:<br>• Test images and clinical reference image availability<br>• Service and maintenance records<br>• Monitors and image display characteristics in accordance with the visual evaluation techniques as described in standard 3.6.2.2<br>• Environmental conditions.<br>The practice ensures that:<br>• Monitor quality assurance testing comprises as a 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.<br>• Conformance tests of display systems are documented and retained for ongoing quality assurance. | | |
| Indicator ii | The Practice maintains records of the results from QC testing of diagnostic workstations and teleradiology equipment. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **4 PERSONNEL** | | | |
| **4 Personnel** | The practice shall ensure that its personnel arrangements support the delivery of safe, quality diagnostic and/or interventional radiology services. | | |
| **4.1.1** | **Personnel – General** | | |
| | All tasks associated with the delivery, supervision, support and management of 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. | | |
| Indicator i | The practice maintains personnel records including details of qualifications, professional and/or regulatory registration, licenses and their currency. | | |
| Indicator ii | Current job descriptions are maintained for all positions, which define the responsibilities and authorities of personnel according to their qualifications. | | |
| Indicator iii | The practice has a documented policy describing the deputisation arrangements for key positions. | | |
| Indicator iv | There are 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 are identified, reported, recorded and managed. | | |
| Indicator v | The practice ensures that each of its personnel are 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. | | |
| **4.1.2** | **Recruitment of Personnel** | | |
| Indicator i | The practice has a process which ensures the systematic recruitment of personnel in a manner appropriate to the size and scope of the service. | | |
| Indicator ii | The process for the recruitment and selection of new personnel is documented. | | |
| Indicator iii | This process ensures that a formal credentialing process is implemented that ensures that personnel selected meet the minimum requirements for the position. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **4.1.3** | **Orientation**<br>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 radiology services. | | |
| Indicator i | The practice undertakes orientation activity for new personnel that is appropriate to the scope and responsibility of each position. | | |
| Indicator ii | Such orientation is recorded in personnel records. | | |
| **4.1.4** | **Training**<br>The practice shall ensure that its personnel undertake any ongoing training needed to comply with requirements for professional registration and/or licensing. | | |
| Indicator 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. | | |
| Indicator 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. | | |
| Indicator iii | Medical imaging personnel undergo regular performance reviews to support their professional development and quality improvement. | | |
| **4.1.5** | **Ergonomics** | | |
| Indicator i | The Practice has a documented policy on ergonomics that shall include as a minimum:<br>• The considered arrangement of seating, desk and monitor, together with ancillary<br>• equipment, such as dictation devices and task lighting<br>• Lighting, heating, air quality and sound<br>• Measures to avoid prolonged computer usage, and ensure operator breaks<br>• Minimising adverse static postures through keyboard and pointing device placement. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **4.2.1** | **Qualifications, Registration and Licensing – Clinical Radiologist** | | |
| Indicator i | Evidence of current medical registration is held for each clinical radiologist. | | |
| Indicator ii | Each clinical radiologists is appropriately licenced to use ionising radiation equipment | | |
| Indicator 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. | | |
| Indicator iv | The Practice ensures that each clinical radiologist has completed CPR training according to the Australian Resuscitation Council guidelines on Basic Life Support, and the Practice maintains a register of the CPR training completed for each clinical Radiologist which includes expiry dates. | | |
| Indicator v | Radiologists who perform sedation shall do so in accordance with the ANZCA PS09 Guidelines. | | |
| Indicator vi | Regular assessment of visual function is the personal responsibility of the radiologist. | | |
| **4.2.2** | **Qualifications, Radiographer**<br>A radiographer must have any licenses and current professional registration required for the jurisdiction in which he/she is practising, including any radiation operator's licences required for use of ionising radiation. | | |
| Indicator 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. | | |
| Indicator ii | Radiographers providing services requiring the use of ionising radiation must have a current radiation licence, which is recorded by the radiation safety officer in a radiographer radiation licence register. | | |
| Indicator iii | Radiographers have completed CPR training according to the Australian Resuscitation Council guidelines on Basic Life Support and the Practice maintains a register of completed CPR training ( includes expiry dates) for Radiographers | | |

| Clause | Standard | QM Cross reference | Comments |
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| **4.2.3** | **Qualifications Sonographer** | | |
| Indicator i | The Practice maintains a register of, and holds a copy of, current ASAR for each of its sonographers. | | |
| Indicator 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) | | |
| Indicator iii | Sonographers have completed CPR training according to the Australian Resuscitation Council guidelines on Basic Life Support and the Practice maintains a register of completed CPR is maintained which includes expiry dates for all sonographers | | |
| **4.2.4** | **Qualifications- Medical Physicist** | | |
| Indicator 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**<br>Nursing personnel working within the Practice must have current professional registration for the jurisdiction/s in which they are working. | | |
| Indicator i | The practice holds a copy of the current registration record for each of its nurses. | | |
| Indicator ii | Nurses have completed CPR training according to the Australian Resuscitation Council guidelines on Basic Life Support and the Practice maintains a register of completed CPR is maintained which includes expiry dates for all nurses. | | |
| | **Qualifications– Service Personnel**<br>The practice shall ensure that all personnel servicing its systems and equipment are suitably qualified. | | |
| Indicator i | The Practice has a procedure for obtaining information from the service provider/s that service personnel are appropriately qualified and/or certified for the scope of service activity carried out. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **4.2.7** | **Qualifications – Administrative Staff** | | |
| Indicator i | The practice holds administrative staff personnel record/s, including training records which are appropriate to the size and scope of the Practice. | | |
| **4.2.8** | **Qualifications - Radiation Safety Officer** | | |
| Indicator i | The Practice holds radiation safety officers personnel records, including records of training and the appropriate radiation safety legislation for the Practice's jurisdiction. | | |
| Indicator 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 | | |
| **4.3.1** | **CPD** | | |
| Indicator i | There is a policy to encourage and support participation by staff in CPD activities. | | |
| Indicator ii | A register (or able to access the records) of staff CPD training. | | |
| **4.3.2** | **CPD – Clinical Radiologists** | | |
| Indicator i | Radiologists to provide facility evidence of ongoing participation in the RANZCR CPD program (or equivalent). | | |
| **4.3.3** | **CPD – Radiographers** | | |
| Indicator i | Radiographers to provide facility evidence of ongoing participation in either the ASMIRT's CPD program, or an equivalent program of CPD. | | |
| **4.3.4** | **CPD – Sonographers** | | |
| Indicator i | The Practice ensures that each of its sonographers is registered and actively participates in CPD to maintain clinical currency and registration<br>*(Sonographers practising in Australia shall maintain registration with ASAR including an approved CPD program (e.g. ASAR, ASUM, ASMIRT or ASA).* | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **4.3.5** | **CPD- Medical Physicists** | | |
| Indicator i | Medical physicists to provided facility with evidence of ongoing CPD participation that complies with the ACPSEM CPD requirement, or the CPD audit. | | |
| **4.3.6** | **CPD – Nurses** | | |
| Indicator i | Nurses to provide a facility with a copy of their current NMBA CPD declaration. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **5 PROFESSIONAL SUPERVISION** | | | |
| **5.1** | **General Professional Supervision**<br>Each component of a diagnostic imaging service shall be carried out under the professional supervision of a clinical radiologist in accordance with jurisdictional requirements. *The performance of diagnostic imaging services carried out under the leadership of a clinical radiologist is definaed as professional supervision.* | | |
| Indicator i | The practice has protocols in place to ensure that the radiologist's professional supervision requirements are satisfied through either:<br>a) personally conducting all or particular tasks associated with the relevant component of the imaging service; OR<br>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<br>c) task delegation through the implementation of and adherence to appropriate written protocols to be followed by members of the imaging team, under the radiologist's direction. | | |
| Indicator ii | Protocols also provide for different triggers for seeking radiologist input, and are consistent with patient management policies and procedures (as per 7.1). | | |
| Indicator iii | The practice ensures that when teleradiology or remote reporting services are provided in accordance with appropriate written protocols under the direction of its 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) | | |
| **5.2** | **Professional Competence** | | |
| Indicator i | All personnel involved in a medical imaging examination are appropriately qualified and experienced according to the specific requirements of the examination. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| Indicator 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 Radiologist** | | |
| Indicator i | Rosters ensure that all trainee radiologists have a qualified radiologist (as per 4.2.1) available to provide direct (face-to-face) supervision | | |
| Indicator ii | An after hour's roster is available for access to a qualified radiologist to provide advice and backup at all times out of hours. | | |
| **5.2.2** | **Trainee Radiographers** | | |
| Indicator i | Practice rosters for the past twelve months (including out of hours arrangements) demonstrate that :<br>• Undergraduate trainee (student) radiographers are directly supervised by a qualified radiographer.<br>• Graduate radiographers undertaking their PDY program have on site supervision by a qualified radiographer. | | |
| Indicator 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**<br>All trainee sonographers should be registered with ASAR. | | |
| Indicator i | The Practice holds rosters for the past 12 months demonstrating that:<br>a) trainee sonographers are directly supervised; and<br>b) course requirements, such as logbooks, include supervisor acknowledgement and indicate supervision provided for patient examinations. | | |
| Indicator 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** | | |
| Indicator i | Where trainee medical physicists are involved in the delivery of imaging services, they only do so under the supervision of an ACPSEM registered medical physicist. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **5.2.5** | **Trainee Medical Imaging Nurse** | | |
| Indicator i | Trainee Medical Imaging Nurses involved in the delivery of imaging services, are supervised by 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.<br>A request for a diagnostic imaging procedure made by a health practitioner shall be undertaken providing:<br>• the health practitioner is registered and/or licensed under relevant state or territory laws;<br>• the requested imaging procedure is;<br>o directly related to the health practitioner's recognised field of expertise<br>o within the scope of practice.<br>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. | | |
| Indicator i | The practice ensures that the following information is provided in requests prior to an imaging examination being undertaken:<br>• Patient name, date of birth<br>• Study requested<br>• Clinical indication for the examination<br>• Date of request<br>• Signature, electronic signature or another mechanism for requesting health professional authentication and their contact details<br>• Requestor's Health Provider Number or Health Provider Index | | |
| Indicator ii | Consultation with the patient to clarify information provided in the request is carried out as necessary and in accordance with professional supervision protocols. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **5.3.2** | **Review of the Request** | | |
| Indicator i | Documented procedures for reviewing requests which ensure that the requested examination is appropriate to the needs of the referrer and the patient. | | |
| Indicator ii | Protocols are in place to provide for different triggers for seeking radiologist input for the review of requests by delegated medical imaging team members. | | |
| Indicator iii | The practice ensures that the radiologist is readily contactable to discuss and, if necessary, alter the conduct of the imaging examination. | | |
| Indicator iv | Information is recorded relevant to the study/ies 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. | | |
| Indicator v | When a request contains insufficient information to determine the appropriateness of the request, the practice has documented procedures which ensure that all reasonable attempts are made to obtain the required information as necessary from the referring practitioner, and/or consultation with the patient to clarify information provided in the request is carried out as necessary. | | |
| Indicator vi | When patients are undergoing special examinations such as MRI, angiography, prostate biopsy and examinations requiring the use of contrast, additional specific information is obtained and recorded. | | |
| Indicator 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. | | |
| Indicator viii | When reviewing requests and preparing for imaging of paediatric patients, every effort is made to:<br>a) use a non-ionizing radiation modality, providing it will obtain the required imaging data for diagnosis; and<br>b) make minimal use of sedation and anaesthesia | | |
| **5.3.3** | **Substituted and Additional Procedures** | | |
| Indicator i | Practice records show that when an additional or substituted examination is called for the imaging report is notated accordingly. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | These records demonstrate that all reasonable efforts are made to contact the requesting practitioner, and actual communication that is made is recorded. | | |
| Indicator iii | The 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** | | |
| Indicator i | Information on pre-examination preparation is made available to patients and referrers. | | |
| Indicator ii | Procedures to confirm correct patient preparation has been completed which includes include provision for patients who are inappropriately prepared. | | |
| Indicator iii | Where such preparation relates to contrast administration, this conforms to the requirements of the RANZCR Guidelines for Iodinated Contrast Administration. | | |
| Indicator iv | Where such preparation relates to sedation, this conforms to the requirements of the ANZCA PS09 Guidelines. | | |
| **5.3.5** | **Appropriate Use of Medical Imaging** | | |
| Indicator i | The practice has representative information sheets and/or documentation of communication to referrers and consumers. | | |
| **5.4.1** | **Performance of the Imaging Examination** | | |
| Indicator i | Documented protocols for the performance of imaging examinations, and these protocols are developed under the professional supervision of the radiologist. | | |
| Indicator ii | Protocols include when not to proceed with an examination if the radiologist is not available. | | |
| Indicator iii | Examinations which require sedation of the patient are not undertaken unless an appropriately trained radiologist is available to immediately personally attend the patient and the safety requirements under 6.6.1 & 6.6.3 are met. | | |
| Indicator iv | The protocols cover radiographic factors, positioning, sterile tray set-up, and after care according to the relevant examinations and/or modalities performed at the service. | | |
| Indicator v | These protocols also address medical emergencies. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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. | | |
| **5.4.2** | **Performance of the Imaging Examination – Administration of Contrast** | | |
| Indicator i | Protocols for the administration of contrast which 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. | | |
| Indicator ii | These protocols determine when the radiologist responsible for overseeing the study must be contacted for advice before contrast is administered. | | |
| Indicator iii | The task of administering contrast is only delegated to personnel who are trained in venepuncture consistent with Appendix A Personnel Administering Intravenous Contrast. | | |
| Indicator iv | The protocols determine the dose and type of contrast medium that is administered, by whom it is administered, and under whose authorisation. | | |
| Indicator v | The administration of contrast to a patient is recorded, including the batch number of the contrast administered. | | |
| Indicator 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. | | |
| **5.5.1** | **Interpretation and Reporting the Results**<br>A single named clinical radiologist is to be responsible for the supervision, interpretation and reporting of the entire study.<br>Where substantial input regarding supervision, interpretation or reporting has been provided by additional clinical radiologists or suitably qualified medical practitioners, this should be also be acknowledged in the report. A single named radiologist however, remains responsible for the entire study.<br>Where a trainee clinical radiologist has reported under supervision, this should be indicated in the report.<br>Reports must address all information requested by the referrer, required by the procedure and necessary for the interpretation of the results | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator i | Primary diagnosis is only performed on images which are of acceptable diagnostic quality to the reporting radiologist. | | |
| Indicator ii | The imaging reports include at least the following:<br>• A title<br>• Name and address of the practice, and location/site where the imaging procedure(s) was performed if different to the address on the report<br>• Referrer's name<br>• Date of issue of the report<br>• Unique identification of the patient<br>• Date of imaging procedure(s)<br>• Identification of the modality used<br>• Imaging procedure(s) results and, where appropriate, the units of measurement<br>• Record/s of the administration of any medication and/or contrast<br>• Opinions and interpretations<br>• Name of reporting radiologist. | | |
| Indicator iii | The use of electronic signatures complies with relevant legislation. | | |
| Indicator iv | If a report is issued jointly, the co-signatory radiologists have all approved its final content. | | |
| Indicator 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. | | |
| Indicator 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. | | |
| Indicator 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. | | |
| Indicator viii | Policy for the provision of verbal and written reports to referring medical practitioners. | | |
| Indicator ix | Comparison with prior studies is included in reports where these prior studies are available and relevant. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **5.5.2** | **Communication of Imaging Findings and Reports**<br>The Practice shall ensure that reports are made available in a clinically appropriate, timely manner, and shall carry out regular reviews at least once a year on the time between the performance of the study and the issuing of the report. | | |
| Indicator i | Documented policy for communication of clinically urgent or critical test results.<br>It should include at least the following:<br>• General findings that should be communicated<br>• How the communication should be documented<br>• A record of the person communicated to<br>• A record of what was communicated | | |
| Indicator ii | The practice maintains records of regular reviews of reporting turnaround times, and implements and records corrective action should there be any indications that the designated reporting times are not being met. | | |
| Indicator iii | If there are urgent and significant unexpected findings, there is a protocol which ensures that<br>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;<br>b) a record of actual or attempted direct communication is maintained by the practice; and<br>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** | | |
| Indicator i | Policy for consultation with referrers, including the provision of information to referrers regarding imaging strategies which are appropriate for particular clinical problems. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **5.6** | **Image Review**<br>The Practice develops and implements a fit for purpose and radiologist-led peer review process to regularly monitor the interpretation of imaging studies. | | |
| Indicator 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. | | |
| Indicator ii | Unless specified differently elsewhere in these standards, such reviews are carried out at least annually. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **6 SAFETY** | | | |
| **6 Safety** | The practice shall conduct all diagnostic and/or interventional radiology examinations in a manner which 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**<br>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. | | |
| Indicator 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 – General**<br>All applicable regulatory health-related infection control guidelines shall be followed. | | |
| Indicator i | Documents all policies and procedures for all infection control issues, including sterilisation/disinfection and hand hygiene. | | |
| Indicator ii | These policies and procedures comply with the applicable regulatory standards, DIAS Standard, the NHMRC Australian Infection Control Guidelines and the Australian Immunisation Handbook. | | |
| **6.3.1** | Radiation Safety - ALARA Principle | | |
| Indicator 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. | | |
| Indicator ii | The practice records patient doses and aggregates these annually in order to establish Facility Reference Levels (FRLs). | | |
| Indicator iii | These FRLs are reviewed annually to determine the need for dose optimisation activity. | | |
| Indicator iv | FRLs are also reviewed against national DRLs where these are published. | | |
| **6.3.2** | **Compliance with Radiation Safety Legislation** | | |
| Indicator i | The Practice retains all records required under relevant radiation safety legislation and under the directions of relevant regulatory authorities or advisory bodies. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | It retains records of any corrective action notices issued by radiation safety regulatory bodies, and the corrective action taken. | | |
| Indicator iii | It 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 taken. | | |
| **6.3.3** | **Radiation Safety Officer** | | |
| Indicator 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. | | |
| Indicator ii | The radiation safety officer monitors changes in the legislation, adjusts policies and activities accordingly and communicates these to practice personnel. | | |
| Indicator iii | The radiation safety officer co-ordinates record keeping in relation to radiation safety at the practice. | | |
| **6.4** | **Waste Management** | | |
| Indicator 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** | | |
| Indicator i | The practice has implemented a procedure for the use of contrast media which ensures that the service complies with the current versions of the RANZCR contrast guidelines. | | |
| Indicator ii | It has a policy which ensures appropriate storage and use of contrast media in accordance with National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines. | | |
| Indicator iii | It 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. | | |
| Indicator iv | It has a clearly identified staff member who ensures that resuscitation equipment and drugs etc. are present and in a state of readiness. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator v | It maintains a documented plan of management for likely adverse events due to contrast reactions, which includes as a minimum:<br>a) a prominently displayed documented procedure describing the management of reactions, and reference to 'Emergency management of anaphylaxis in the community'<br>b) identification of personnel responsible for managing the treatment of contrast reactions;<br>c) a protocol for transfer of a patient to an acute care facility if required, and<br>d) the plan of management should be tested by the appropriate staff on an annual basis. | | |
| **6.6.1** | **Use of Sedation** | | |
| Indicator i | Policies and procedures which 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 to and manage sedated patients. | | |
| Indicator ii | These policies and procedures are consistent with the ANZCA PS09 Guideline. | | |
| Indicator iii | It records drugs used for sedation, the person administering the drugs and the management of sedated patients. | | |
| **6.6.2** | **Use of Anaesthesia** | | |
| Indicator i | The practice has implemented policies and procedures which ensure its management of the use of anaesthesia is consistent with ANZCA PS55 Policy and ANZCA PS09 Guideline. | | |
| Indicator ii | It ensures that personnel administering general anaesthesia are trained anaesthetists with assistance as defined in ANZCA PS55 and ANZCA PS09 Guideline. | | |
| **6.6.3** | **Use of Medications** | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | It 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. | | |
| Indicator iii | It 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. | | |
| Indicator iv | Medications are clearly labelled in accordance with the National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines. | | |
| Indicator v | The practice medications inventory demonstrates that all medications are stored and disposed of according to manufacturer's guidelines. | | |
| Indicator vi | The Practice has a documented process of auditing expiry dates of unused medication and disposal of expired stock | | |

| Clause | Standard | QM Cross reference | Comments |
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| **7 PATIENT MANAGEMENT** | | | |
| **7** | **Patient Management** | | |
| **7.1** | General | | |
| Indicator i | Patient Management policies and procedures which 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. | | |
| Indicator ii | These policies and procedures address the early identification and management of patients at increased risk of being, or who are seriously or critically ill. | | |
| Indicator iii | These patient management policies and procedures provide for patients those examinations involve teleradiology. | | |
| **7.2** | **Patient Identification and Records** | | |
| Indicator i | Patient identification system that uniquely identifies every patient by three approved patient identifiers | | |
| Indicator ii | It ensures the correct patient identification is maintained on all records, including reports. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator iii | The practice has implemented a system whereby it can ensure that:<br>• Diagnostic quality images are recorded of all examinations performed with digital techniques as per item 3.7.1, and form part of the patient record..<br>• 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.<br>• 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.<br>• The practice has implemented protocols that identify which studies require an extension to this retention period, and ensure that this occurs. | | |
| Indicator iv | Examination records include patient identification, the date and, where necessary, time of the study and the practice name imprinted on them. | | |
| Indicator v | The identity of the person who performed the study is recorded and stored in accordance with jurisdictional requirements for medical records.<br>This may be on the worksheet, request form or RIS | | |
| Indicator 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** | | |
| Indicator i | Policy encompassing cultural safety. | | |
| Indicator ii | The Practice should provide appropriate education and/or training for all staff to deliver care that aids patients to feel culturally safe. | | |
| Indicator iii | The Practice should make available resources that are culturally appropriate and tailored for the health literacy of patients. | | |
| **7.4** | **Correct Patient, Site and Procedure** | | |
| Indicator i | The practice has implemented a 'time out' protocol to 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | This protocol ensures that and discrepancy in patient identification, site, and/or procedure prompts corrective action before the imaging procedure in undertaken, and that this is documented in the patient's record. Any required consent forms are signed and documented | | |
| Indicator iii | This protocol is consistent with the Australian Commission on Safety and Quality in Health Care's protocols and the Health Quality and Safety Commission. | | |
| **7.5** | **Discharge Procedure (sedated/anaesthetised patients)** | | |
| Indicator i | Procedure which ensures that patients who have been sedated or placed under anaesthetic are discharged in the care of a responsible adult after appropriate recovery. | | |
| Indicator 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 side-effects.<br>For nuclear medicine procedures, this will include information about protecting others from exposure to ionising radiation. | | |
| **7.6** | **Patient Consent** | | |
| Indicator i | The practice provides comprehensive information to patients on the imaging procedure to be performed prior to it being undertaken. | | |
| Indicator ii | The information includes:<br>• Pre-treatment preparation and/or instructions<br>• Post-treatment and/or discharge instructions<br>• Fee information<br>• Risks<br>• Involvement of students/trainees<br>• The role of the person performing each stage of the examination. | | |
| Indicator iii | The practice meets or is developing capacity to meet the communication needs of non-English speaking patients in providing such information. | | |
| Indicator iv | 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 performed procedures. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **7.7.1** | **Privacy Policy** | | |
| Indicator i | The practice has implemented a privacy policy which:<br>a) governs the use of patient personal information within the service and its disclosure to other parties;<br>b) addresses the 13 Australian Privacy Principles (APPs) set out in Schedule 1 of the Privacy Amendment (Enhancing Privacy Protection) Act 2012<br>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;<br>d) is publicly available; and<br>e) allows the patient to access their clinical records. | | |
| Indicator ii | The Practice documents any variation (where and why) from the Privacy Act. | | |
| Indicator iii | The Practice should have processes in place for a mandatory data breach notification plan | | |
| **7.7.2** | **Patient Consent to Use of Information** | | |
| Indicator i | Procedure for gaining patients' consent to the use of their personal information. | | |
| Indicator 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** | | |
| Indicator i | The practice has implemented, or is working towards implementation of a process for recording patients' consent in the service's information system. | | |
| Indicator ii | This information system is or will be capable of flagging any personal information that is subject to restricted consent. | | |
| **7.8** | **Open Disclosure** | | |
| Indicator i | The practice operates an open disclosure program which is consistent with the Australian National Open Disclosure Framework. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8 TELERADIOLOGY** | | | |
| **8.1.1.1** | **Loss of on-site Informal communication** | | |
| Indicator i | The Teleradiology Service Provider should show evidence of records of communication with the referrer, either through RIS or a statement in the report. | | |
| **8.1.2** | **Methods of Data transfer** | | |
| Indicator 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 post- processing software required by the referral request | | |
| Indicator ii | The Acquisition Site ensures that data transferred for off-site reporting includes access to prior relevant imaging, the corresponding request forms and reports. | | |
| **8.2.1** | **Qualifications and Registration - Clinical Radiologists** | | |
| Indicator i | The Teleradiology Service Provider holds a copy of current medical registration for each clinical radiologist reporting for the Acquisition Site. | | |
| Indicator ii | The Acquisition Site holds a copy of the current medical registrations for all clinical radiologists reporting for the Acquisition Site | | |
| Indicator iii | The Teleradiology Service Provider holds a copy of medical indemnity insurance for each clinical radiologist reporting for the Acquisition Site | | |
| Indicator iv | The Acquisition Site holds a copy of medical indemnity insurance for all clinical radiologists reporting for the Acquisition Site. | | |
| **8.3.1** | **Responsibilities of the Specialist** | | |
| Indicator 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 iii). | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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**<br>The teleradiology reporting service must comply with these Standards, including:<br>• **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.<br>• **Standard 5.5.2** Communication of Imaging Findings and Reports (indicator iii) | | |
| Indicator 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. | | |
| Indicator ii | These protocols are specific to each examination type being performed, and include references to the following:<br>• The examination<br>• Acquisition method including resolution<br>• Compression type and level for each examination<br>• Image orientation<br>• Image sequence selection<br>• Urgency of examination<br>• Transmission time<br>• The number of images in the series<br>• The personnel responsible for the examination at the examination capture site. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| Indicator iii | Patient data is identifiable and contains the following information:<br>• Full name<br>• Unique identifier<br>• Date and time of examination<br>• Diagnostic imaging service name<br>• Type of examination<br>• Compression type and level<br>• Patient notes (including the request for the patient's examination, which is transmitted either by facsimile or electronically)<br>• Annotations including side markers | | |
| **8.3.3** | **Responsibilities of the Allied Health Professionals and Nursing Staff**<br>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** | | |
| Indicators i | The Acquisition Site has documented and readily accessible protocols stating responsibilities of<br>• Remote reporting radiologist, as agreed with the Acquisition Site (with input from on-site clinical radiologist where available) and with the Teleradiology Service Provider;<br>• The Teleradiology Service Provider as an entity; and<br>• The on-site allied health professional and nursing staff are in place, and protocols are followed appropriately. | | |
| Indicator 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**<br>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. | | |
| Indicator i | The Acquisition Site has a record of delegated authority. | | |
| Indicator ii | The Acquisition Site has documented and readily accessible protocols. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8.3.6** | **Use of Contrast**<br>The use of contrast outside of on-site protocols shall be approved by an on-site clinical radiologist or appropriately credentailled specialists, or in their absence, by the reporting clinician as per Standard 4.1.1. | | |
| Indicator i | The Acquisition Site has a documented protocol on contrast usage. | | |
| **8.4.1** | **Reporting Environment - Specific**<br>As with on-site radiology, Teleradiology Service Providers must meet the same requirements for reporting equipment as per Standard 3 (Equipment). | | |
| Indicator i | Refer to Standard 3 (Equipment). | | |
| **8.4.2** | **Reporting - Mammography**<br>As with on-site clinical radiology, Teleradiology Service Providers must meet the same requirements for equipment as per Standard 15.2.1 (Diagnostic Mammography Equipment). | | |
| Indicator i | Refer to Standard 15.2.1 (Diagnostic Mammography Equipment). | | |
| **8.4.3** | **Reporting - Fluoroscopy**<br>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. | | |
| Indicator i | The Acquisition Site must have a list of limited procedures that can be performed without a clinical radiologist on site. | | |
| Indicator 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** | **Reporting - Ultrasound** | | |
| Indicator i | The Acquisition Site must have documented policies in the use of teleradiology for ultrasound reporting. | | |
| Indicator 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. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **8.4.5** | **Compression** | | |
| Indicator i | When storing and transmitting digital images, the Acquisition Site uses lossless compression. | | |
| **8.4.6** | **Display Capabilities** | | |
| Indicator i | Refer to Standard 3.6.2 (Diagnostic Workstations). | | |
| Indicator ii | Refer to Standard 3.6.2.1 (Display Software). | | |
| Indicator iii | Refer to Standard 3.6.2.2 (Monitors) | | |
| **8.4.7** | **Patient Information** | | |
| Indicator i | Refer to Standard 7.2 (Patient Identification and Records). | | |
| **8.5.1** | **Environment** | | |
| | Refer to Standard 3.11 (Reporting Environment). | | |
| **8.5.2** | **Image Management** | | |
| Indicator 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. | | |
| Indicator 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 | | |
| Indicator iii | The Acquisition Site and the Teleradiology Service Provider must provide evidence of system redundancy, backup communication links and a disaster recovery plan. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8.5.3** | **Communication and File Sharing**<br>When files are transmitted from the Acquisition Site, individual patient data should include:<br>a. patient name and date of birth;<br>b. date and time of radiological examination;<br>c. location of origin of examination;<br>d. type of examination;<br>e. brief clinical history ;<br>f. details of responsible clinician;<br>g. number of images acquired;<br>h. identification of technologist acquiring images;<br>i. the intended destination of transmitted images; and<br>j. time of transmission | | |
| Indicator i | The Acquisition Site must retain logs of images transmitted. | | |
| **8.5.4** | .**Archiving and Retrieval**<br>Storage, archiving and retrieval of images, request and report are the responsibility of the persons or entities responsible for operating both the Acquisition Site and Reporting site, to the extent required by local legislation, regulation and any other requirements, including medico-legal obligations. | | |
| Indicator i | Refer to Standard 3.7 (Digital Imaging Data). | | |
| **8.5.5** | **Storage of Records**<br>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. | | |
| Indicator i | A Teleradiology Service Provider must store all reports as required by legislation and regulation at the acquisition site. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8.5.6** | **Security**<br>Requirement applies to all teleradiology services whether a service provided by:<br>a. an individual employee on call providing formal diagnostic reports remotely for their hospital or healthcare facility;<br>b. an individual radiologist or group of individual radiologists;<br>c. a practice group;<br>d. a network of practices or practice groups;<br>e. the local health authority or jurisdiction health department; or<br>f. a third party provider. | | |
| Indicators i | 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. | | |
| Indicator 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):<br>a. to cover actions to be taken to prevent data security breaches or corruption;<br>b. to record and notify the appropriate authority of any data security breaches or corruption;<br>c. to record actions taken by those involved in handling such event(s);<br>d. to document the actions taken by site management in response to the breach to prevent recurrence of the event(s); and<br>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 | | |
| Indicator 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. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8.6.1** | **Teleradiology Service Providers** | | |
| Indicator i | The Teleradiology Service Provider must hold certificates indicating accreditation of the service, where applicable. | | |
| Indicator ii | The Teleradiology Service Provider must hold contracts with each client site. | | |
| Indicator iii | The Teleradiology Service Provider must hold copies of current registration certificates from the Medical Board of Australia for each reporting Radiologist. | | |
| Indicator iv | The Teleradiology Service Provider must hold copies of current credentialing certificates from the local/regional credentialing committee for each reporting radiologist. | | |
| Indicator v | The Teleradiology Service Provider must hold copies of current certificates or equivalent showing CPD compliance for each reporting radiologist | | |
| Indicator vi | The Teleradiology Service Provider must hold copies of current insurance certificates or equivalent showing required cover for each reporting radiologist. | | |
| Indicator vii | Refer to Standard 3.7.3 (Exchange of Digital Imaging Data and Reports). | | |
| Indicator viii | If there are urgent and significant unexpected findings, the Teleradiology Service Provider has a documented protocol that ensures:<br>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;<br>b) a record of actual or attempted direct communication is maintained by the Practice; and<br>c) the reporting radiologist co-ordinates appropriate care for the patient if they are unable to communicate such findings to the referring clinician.<br>(As per Standard 5.5.3, Indicator iii) | | |
| **8.6.2** | **Healthcare Providers Using Teleradiology** | | |
| Indicator i | The Healthcare Provider must hold contracts with the Teleradiology Service Provider. | | |
| Indicator ii | The Healthcare Provider holds a record of meetings with the Teleradiology Service Provider. | | |
| Indicator iii | The Healthcare Provider can demonstrate completeness of the information for cases sent to the Teleradiology Service Provider. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8.6.3** | **Image Viewing at Home for Clinical Radiologists** | | |
| Indicator i | The Healthcare Provider holds a record of IT and security governance for the home reporting sufficient to comply with the requirements | | |
| **8.7.1** | **Quality Assurance for Teleradiology Reporting** | | |
| Indicator i | The Acquisition Site has a clear, documented framework to monitor and/or audit the Teleradiology Service Provider. | | |
| Indicator 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. | | |
| Indicator 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** | | |
| Indicator 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**. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| Indicator i | The Teleradiology Service Provider has a documented peer review process and must include processes and policies that provide:<br>• 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;<br>• 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;<br>• for a record to be maintained of the peer review cases, the classification of that review and any actions that follow the review;<br>• feedback to the reporting radiologist with the opportunity for discussion, appeal and/or amendment if necessary;<br>• the clinical radiologist with a regular report of their peer review results and any data needed to comply with RANZCR CPD requirements; and<br>• for peer review feedback to occur on an annual basis if required. | | |
| **8.7.4** | **Significant or Unexpected Findings** | | |
| Indicator i | The Acquisition Site has a documented policy for report turnaround times that sets out expected turnaround times for defined urgent and non-urgent findings | | |
| Indicator ii | The Acquisition 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 | | |
| Indicator iii | The Acquisition Site has a protocol for urgent and significant unexpected findings that ensures:<br>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;<br>b. a record of actual or attempted direct communication is maintained by the *Reporting Site*; and<br>c. the reporting radiologist co-ordinates appropriate care for the patient if they are unable to communicate such findings to the referring clinician. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **8.7.5** | **Adverse Patient Outcome Events**<br>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. | | |
| Indicator i | Demonstration that the remote reporting radiologist has access to the same referral and clinical information as an on-site clinical radiologist. | | |
| Indicator ii | Demonstration of the peer review record including feedback to the clinical radiologist and any actions that followed that feedback. | | |
| Indicator iii | Demonstration of regular medical management review of the overall peer review process and results. | | |
| Indicator iv | Demonstration of the record of Significant and Unexpected Findings and subsequent actions. | | |

## 9 ARTIFICIAL INTELLIGENCE

The scope of these AI Standards is to guide the development, deployment and monitoring of AI and machine learning in radiology settings. They set out what is expected across a series of domains and are intended to mitigate clinical risks and ensure best clinical care when using AI in radiology.

**The Standards for Artificial Intelligence that are contained within this section (Section 9) will not be assessed at this time,** however, Practices utilising AI or machine learning are still expected to comply with this section of the Standards.

During the assessment process, a discussion will be held with the Practice to better understand how/whether AI and machine learning is used within your practice.

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **10 BMD** | | | |
| **10.1** | **BMD Records**<br>Practices shall comply with the requirements for the retention of non-medical records contained in the Accreditation Guidelines for Bone Densitometry. | | |
| Indicator i | Raw data from scans is stored using long-term electronic storage mediums. | | |
| Indicator ii | The Practice stores quality control data needed to validate scans. | | |
| Indicator iii | Records are stored for a minimum of 10 years, or for the minimum applicable statutory requirements (whichever is longer). | | |
| **10.2.1** | **BMD – Equipment** | | |
| Indicator i | Equipment records demonstrate that acceptance testing and compliance testing has been carried out according to regulatory requirements. | | |
| Indicator ii | Operation manuals for the BMD equipment are readily available | | |
| Indicator iii | A BMD equipment maintenance program has been implemented and all aspects of the densitometer performance are checked according to the manufacturer's specifications. | | |
| Indicator iv | Records are kept of all communications with the manufacturer, subsequent to installation of the machine. | | |
| Indicator v | All software updates are implemented as soon as practicable. | | |
| Indicator vi | All faults discovered are remedied and the fault and remedial action activity are recorded. | | |
| Indicator vii | Records of calibration, QC, repair and maintenance of each item of equipment are kept for the life of the equipment. | | |
| **10.2.2** | **BMD Equipment Quality Control** | | |
| Indicator i | The practice's BMD equipment operation manuals include quality control monitoring requirements and quality assurance criteria which are consistent with Appendices 2 and 4 of the Accreditation Guidelines. | | |
| Indicator 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 to do so by the relevant regulatory body. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator iii | If there is a suspicion that previous patient results may be inaccurate, a retrospective reanalysis of the relevant data is performed. | | |
| Indicator iv | Quality control activity, including corrective and preventive action, is recorded. | | |
| Indicator v | Subject to any required regulatory approval the practice performs *In Vivo Short Term Precision Testing* on all DXA machines upon installation and after every major service/repair. | | |
| **10.3.1** | **BMD Technologist Qualifications** | | |
| Indicator i | The practice's BMD technologists have either:<br>a) certification by a radiologist that as at 1 November 2000 they were operating BMD equipment and were deemed competent to do so; OR<br>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<br>c) certification of their BMD training from the ANZBMS. | | |
| Indicator ii | Only MITs meeting the qualifications described in 4.2.2 perform quantitative computed tomography (QCT) examinations. | | |
| Indicator iii | The BMD technologists hold current regulatory radiation licenses or registration where these are available. | | |
| **10.3.2** | **BMD Service Engineers - Qualifications** | | |
| Indicator i | The practice's BMD equipment is tested for compliance and maintained by an accredited service engineer | | |
| **10.3.3** | **BMD - Radiologist or Medical Specialist CPD** | | |
| Indicator i | The BMD radiologist/medical specialist maintains a BMD reference library which he/she updates annually. | | |
| **10.4.1** | **BMD Technologist Responsibilities** | | |
| Indicator i | The scope of responsibilities of the practice's BMD technologists covers:<br>• Personal preparation and positioning of the patient<br>• Personal conduct of the scan<br>• Personal analysis of the scan, and preparation of the report for checking by the radiologist or reporting medical specialist<br>• Quality control, quality assurance and equipment performance activity. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **10.4.2** | **Performance of the BMD Examination** | | |
| Indicator i | The BMD procedure manual is maintained under the professional supervision of the radiologist/medical specialist. | | |
| Indicator ii | Only validated methods are used and these are documented in the BMD procedure manual. | | |
| Indicator iii | BMD reference library is available to support and supplement this BMD procedure manual. | | |
| Indicator iv | BMD examinations are conducted in accordance with the practice's BMD procedure manuals. | | |
| Indicator v | The practice's protocols for BMD examinations ensure that the radiologist/medical specialist is readily contactable to discuss and, if necessary, alter the conduct of the examination. | | |
| **10.4.3** | **BMD – Reports** | | |
| Indicator i | In addition to those items required under 5.5.1, the practice's BMD reports contain:<br>• Type of densitometer, scan mode, software version<br>• Type of scan<br>• Quantitative result<br>• Reference intervals and their source<br>• Reference to previous studies, where applicable. | | |
| Indicator ii | All reports are checked and approved by the supervising radiologist/medical specialist prior to issue. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **10.4.4** | **BMD – Interpretation and Consultation** | | |
| Indicator i | 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:<br>• 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<br>• 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<br>• The scientific basis and the clinical significance of the results<br>• The suitability of the requested procedure to solve the clinical problem in question<br>• Further procedures which may be helpful. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **11 CT** | | | |
| **11.1.1** | **CT - Equipment Quality Control** | | |
| Indicator i | Documented program of quality control for CT with access to services of a medical physicist as required. | | |
| Indicator 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. | | |
| Indicator iii | Preventative maintenance is scheduled, performed and recorded by a qualified service engineer in accordance with manufacturer specifications.<br>Service performed to correct system deficiency is recorded and the records are maintained at the site where the equipment is located. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **11.1.2** | **CT -Monitors** | | |
| Indicator 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). | | |
| **11.2.1** | **CT -Medical Practitioner** (**see 4.2.1** in these standards). | | |
| Indicator i | CT Coronary Angiography (CTCA) services are provided by a registered specialist (CTCA specialist with the Conjoint Committee for the Recognition of Training in CT Coronary Angiography). | | |
| Indicator ii | CT Colonography (CTC) services are provided by a registered radiologist (RANZCR CT Colonography Accreditation Committee). | | |
| **11.3.1** | **Review of Appropriateness of Request** | | |
| Indicator i | Protocols are in place so that inappropriate studies can be avoided and triaged to non-ionizing radiation based imaging techniques. | | |
| Indicator ii | Protocols for CT which 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. | | |
| Indicator iii | The protocols include flags for mandatory radiologist image review prior to the patient leaving the site. | | |
| Indicator iv | The practice ensures that the radiologist is readily contactable to discuss and, if necessary, alter the conduct of the imaging examination. | | |
| Indicator v | Maintains records of on-site attendance by the clinical radiologist/s. | | |
| Indicator vi | Any regulatory requirements in relation to on-site supervision by the radiologist/s for this component of the service are also met. | | |
| **11.3.2 CT** | **Performance of Examinations** | | |
| Indicator i | Protocols for CT examinations which have been developed and implemented collaboratively by the medical imaging team. | | |
| Indicator ii | 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. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| Indicator iii | Protocols ensure that a clinical radiologist reviews images and alters the conduct of the examination or scanning protocols as required. | | |
| Indicator iv | Protocols ensure that CT examinations, either with or without IV contrast, are performed by a radiographer (as per 4.2.2), and that the radiologist is readily contactable to discuss and, if necessary, alter the conduct of the imaging examination in or out of hours. | | |
| Indicator v | Protocols ensure that the task of obtaining intravenous access for administering intravenous contrast for CT examinations is only performed by staff trained in venepuncture and the administration of contrast. | | |
| Indicator vi | Protocols ensure that the 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 emergency. | | |
| Indicator vii | Any regulatory requirements in relation to on-site supervision by the radiologist for this component of the service are also met. | | |
| **11.3.3** | **CT Interpretation and Reporting of Examinations** | | |
| Indicator i | CT examinations are interpreted and reported by a clinical radiologist holding the qualifications described in 4.2.1 these standards. | | |
| **11.3.4.1** | **CT- Image Quality** | | |
| Indicator i | The practice's RANZCR CT Image Review Self Audit records demonstrate that the practice:<br>• Completed this protocol within 3 months of installation<br>• Completes this protocol at least annually | | |
| Indicator ii | Any variations from normal are recorded. | | |
| Indicator iii | Any corrective or preventive action required is taken and is recorded as part of the audit process. | | |
| **11.3.4.2** | CT Dose | | |
| Indicator i | Records show that its radiologists maintain and regularly review CT scanning protocols, which are optimised to limit patient radiation exposure. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| Indicator 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. | | |
| Indicator iii | Through this process, the practice establishes Facility Dose Reference Levels (FRLs) for CT. | | |
| Indicator iv | Any significant deviation above (or below) previous FRLs are investigated and a dose optimisation program is conducted that addresses this deviation while maintaining diagnostic image quality. | | |
| Indicator v | Where national DRLs exist, FRLs are regularly compared with these national DRLs. | | |
| Indicator vi | Significant deviation of FRLs above (or below) DRL's are investigated and a dose optimisation program is conducted that addresses this deviation while maintaining diagnostic image quality. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **12 GENERAL X-RAY** | | | |
| **12.1.1** | **Monitors – General X-Ray, CR/DR** | | |
| Indicator i | The interpretation and reporting of general x-ray, CR/DR examinations are carried out on monitors meeting the requirements set out in Appendix D. | | |
| **12.2.1** | **Operators of General Radiography Equipment** | | |
| Indicator i | 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. | | |
| Indicator ii | The practice meets all regulatory conditions relating to supervision of such personnel. | | |
| **12.3.1** | **Fluoroscopy Examinations** | | |
| Indicator i | Protocols and rosters ensure that the radiologist responsible for each fluoroscopic examination is available to personally attend the patient. | | |
| Indicator ii | The practice ensures the safe use of contrast for fluoroscopic examinations according to item 5.4.2 in these standards. | | |
| **12.3.2.1** | **General X-Ray– Plain Film Image Review** | | |
| Indicator i | Repeat analysis is performed<br>Results and any corrective actions are recorded | | |
| Indicator ii | Repeat analysis to monitor dose usage and image quality | | |
| **12.3.2.2** | **CR/DR Performance Testing** | | |
| Indicator i | The Practice follows the manufacturer's equipment testing guidelines and the RANZCR General X-ray QA & QC Guideline for all its CR.DR equipment.<br>Records are maintained for all CR/DR performance testing activities | | |
| Indicator ii | The practice has implemented a process which 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. | | |
| Indicator ii | Repeat analysis is performed (CR/DR examinations).<br>Results and any corrective actions are recorded. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **12.3.2.3** | **Fluoroscopy – Image and Screening Time Review**<br>The practice shall implement, maintain and follow a documented QA program for fluoroscopy procedures. | | |
| Indicator i | The review of its fluoroscopy services includes a six-monthly review of reference Air Kerma and DAP. | | |
| Indicator ii | The practice conducts an internal fluoroscopy image review program which is subject to an annual audit by the medical and non-medical imaging team members. | | |
| **12.4.1** | **Radiation Safety – Fluoroscopic Examinations** | | |
| Indicator i | The practice records screening times for all fluoroscopic examinations. | | |
| Indicator ii | The practice records the Dose Area Product (DAP) for all fluoroscopic examinations or where that is not possible, the average kVp and mAs is recorded. | | |
| Indicator iii | The practice takes and records any corrective action that is necessary to minimise patient exposure. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **13 INTERVENTIONAL RADIOLOGY** | | | |
| RANZCR determines that there are two tiers of interventional radiology: Tier A and Tier B. These are defined in Appendices B and C. | | | |
| **13.1.1** | **Interventional Radiology Suite – Tier A Procedures** | | |
| Indicator i | The CT and ultrasound rooms have sufficient space to allow safe patient transfer from bed to table. | | |
| Indicator ii | There is sufficient room for all fixed hardware and movable hardware without compromising either the transfer of the patient or the operating team and support personnel's ability to manage the patient. | | |
| Indicator iii | The suite is equipped with Advanced Life Support (ALS) equipment. | | |
| **13.1.2** | **Interventional Radiology Suite – Tier B Procedures** | | |
| Indicator i | The suite is of sufficient size to allow safe patient transfer from bed to table. | | |
| Indicator ii | The angiography suite allows sufficient room for all fixed hardware and movable hardware without compromising either the transfer of the patient or the operating team and support personnel's ability to manage the patient. | | |
| Indicator iii | The suite is equipped with ALS equipment. | | |
| **13.1.3** | **Interventional Neuro-radiology Facilities** | | |
| Indicator 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. | | |
| **13.2.1** | **Angiography**<br>*The practice shall ensure that appropriate equipment is used for angiography procedures.* | | |
| Indicator i | The practice ensures that when diagnostic angiography procedures are performed, a fixed high resolution (at least 512x512) matrix image intensification system or flat plate CCD system with at least a 25cm field and with digital acquisition and subtraction is used. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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.<br>*Mobile image intensifiers are not recommended for diagnostic angiography on a routine basis* | | |
| **13.2.2** | **Angiographic Injector** | | |
| Indicator i | 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** | | |
| Indicator i | The practice ensures that all imaging modalities appropriate to non-vascular interventional procedural requirements are available on site and that patients are referred to another service when these modalities are not available. | | |
| **13.2.4** | **Supplies** | | |
| Indicator i | The practice's supplies records show that it maintains sufficient supplies of devices for interventional procedures and the management of possible complications. | | |
| **13.2.5** | **Physiological Monitoring** | | |
| Indicator i | For Tier A procedures<br>Angiography : ECG and blood pressure monitoring<br>Sedated or ill patient : include pulse oximeter | | |
| Indicator ii | For Tier B procedures and procedures requiring sedation, comprehensive physiological monitoring, including ECG, blood pressure and pulse oximetry.<br>Anaesthetised patients - relevant gas supplies, suction, electrical capability, monitoring and other facilities/supplies are required | | |
| Indicator iii | Where warranted, further/supplementary equipment is used which is appropriate to risks associated with the procedures being performed. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **13.2.6** | **Emergency and Resuscitation Equipment** | | |
| Indicator i | • For Tier A and B procedures, ALS equipment and drugs are readily available, accessible and ready for use.<br>• Attending personnel are trained in resuscitation techniques. | | |
| **13.3.1** | **Radiologists – Interventional Radiology – Under Review** | | |
| Indicator i | Each radiologist performing Tier A procedures complies with the requirements listed under Item 4.2.1 in these standards. | | |
| Indicator ii | Each radiologist performing Tier B procedures has undertaken sufficient additional training, beyond FRANZCR, appropriate to the scope of their interventional practice. | | |
| Indicator 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. | | |
| **13.3.2** | **CPD – Interventional Radiology** | | |
| Indicator i | Records demonstrating performance in appropriate CPD activities for the radiologists, including a clinical audit of their cases. | | |
| Indicator ii | This CPD activity is consistent with training requirements listed in Item 13.3.1 in these standards. | | |
| **13.4.1** | **Review of Appropriateness of Request – Review of the Referral for Interventional Radiology** | | |
| Indicator i | The practice ensures that the radiologist personally attends each patient undergoing interventional procedures<br>Attendance is demonstrated in the practice records and patient history/notes. | | |
| Indicator ii | 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** | | |
| Indicator i | Records to indicate interventional procedures are personally performed by suitably qualified radiologists (see 13.3.1) | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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** | | |
| Indicator i | Protocols ensure that interventional procedures are performed only when personnel trained in emergency resuscitation and emergency resuscitation equipment and drugs are immediately available at the practice and in working order. | | |
| Indicator ii | When Tier A interventional procedures are being performed, appropriately trained personnel are available to respond in a timely fashion in the event of an emergency. | | |
| Indicator 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 Post-operative Assessment** | | |
| Indicator i | Protocols ensure that each radiologist performing interventional procedures personally either:<br>a. attends their patients to make pre-operative and post-operative assessments; OR<br>b. delegates this activity to an associate medical practitioner who is a member of the multidisciplinary team managing the patient's care. | | |
| Indicator ii | Each radiologist performing interventional procedures personally either:<br>a) obtains consent from each of his/her patients prior to a procedure being performed; OR<br>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**<br>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. | | . |
| Indicator i | There is a quality assurance and improvement program for interventional radiology covering the procedures performed at the practice. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | Indicator thresholds and success rates for procedures performed have been established against external evidence-based criteria and are regularly assessed. | | |
| Indicator iii | Policies and practices are reviewed at regular intervals, and action is taken to resolve any problems identified. | | |
| Indicator iv | The quality assurance and improvement program shall include regular mortality and morbidity meetings. | | |
| **13.5.1** | **Rapid Transport** | | |
| Indicator i | Documented protocols for the availability of emergency care/surgical support for patients undergoing Tier A procedures. | | |
| Indicator ii | Protocols for 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. | | |
| **13.5.2** | **Surgical Support and/or Rapid Transport** | | |
| | When Tier B Interventional Radiology procedures are performed, the practice shall ensure the availability of surgical support or have a formal detailed protocol for rapid transport of patients to an acute care facility. | | |
| Indicator i | Documented protocols that ensure the availability of emergency care/surgical support for interventional patients undergoing Tier B interventional procedures. | | |
| Indicator ii | Protocol for rapid transport of 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. | | |
| Indicator iii | Interventional neuroradiology procedures are only performed in practice settings where neurosurgical support is immediately available on site. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **14 MRI** | | | |
| **14.1.1** | **MRI Equipment Specifications and Acceptance Testing**<br>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. | | |
| Indicator i | The practice's equipment inventory shows that the MRI system meets TGA requirements. | | |
| Indicator ii | The practice holds acceptance testing records which demonstrate that such acceptance testing follows AAPM, NEMA or other RANZCR-approved standards and includes tests of:<br>• Magnetic field homogeneity<br>• RF shield integrity<br>• RF calibration<br>• System signal to noise ratio<br>• Signal uniformity<br>• Geometrical distortion<br>• Slice thickness and positioning accuracy or equivalent tests of gradient performance and RF pulse characteristics. | | |
| Indicator iii | The minimum resolution of monitors used for interpretation and reporting of MRI is 1024 x 768 Colour/Monochrome. | | |
| **14.1.2** | **MRI Compatible Equipment (In-room Equipment)** | | |
| Indicator i | Sedation and associated monitoring equipment for MRI procedures is available within the MRI magnet room, operational, and certified MRI-compatible by the manufacturer of the equipment. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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. | | |
| Indicator iv | Anaesthesia equipment used in relation to MRI examinations is stationed in the magnet room for MRI, is operational and is certified as MRI compatible by the manufacturer. | | |
| **14.1.3** | **MRI Quality Control Program** | | |
| Indicator i | The practice maintains a documented MRI quality control program. | | |
| Indicator ii | All quality control testing is carried out in accordance with specific procedures and methods such as those of AAPM or those recommended by the manufacturer, and include tests of:<br>• System signal to noise ratio<br>• Signal uniformity<br>• RF system stability<br>• Ghost intensity (for systems with analogue RF subsystems)<br>• Geometrical distortion<br>• Slice thickness and positioning accuracy.<br>Phantoms used for the above tests may include manufacturer-supplied phantoms, or other third-party equipment. | | |
| Indicator 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. | | |
| Indicator v | Preventative maintenance is scheduled, performed and recorded by a qualified service engineer on a regular basis in accordance with manufacturers' specifications. | | |
| Indicator vi | Service performed to correct system deficiency is recorded and the records are maintained at the MRI site. | | |
| **14.2.1** | **Qualifications – MRI Radiologist** | | |
| Indicator i | The practice ensures that each of its radiologists interpreting and reporting MRI examinations for each MRI system operating at the service is registered with the RANZCR as an MRI Radiologist. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **14.2.2** | **Qualifications – MRI Radiographer** | | |
| Indicator i | The practice's MRI radiographers have training and experience that can be demonstrated in one of the following ways:<br>a. meeting the requirements for the ASMIRT's Level 1 Certificate; OR<br>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 2 years; OR<br>c. meeting the radiographer qualifications as stated in 4.2.2 with an additional minimum 3 months' FTE MRI experience and performance of at least 300 clinical examinations within the past 2 years; OR<br>d. certificate of equivalency as conferred by the ASMIRT. | | |
| Indicator ii | Radiographers training in MRI are supervised by:<br>a. an MRI radiographer who either holds the ASMIRT Level 2 Certificate, or has equivalent qualifications and experience; OR<br>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 the ASMIRT. | | |
| **14.2.3** | **Qualifications – MRI Service Engineers**<br>MRI service engineers must be qualified on the basis of training and experience and must have included the model and manufacturer of the MRI equipment used at the practice. | | |
| Indicator i | The practice ensures that the service organisation providing service engineers for the MRI system confirm certification of the service engineers. | | |
| **14.2.4** | **CPD - MRI Radiologist**<br>The radiologists supervising and reporting MRI examinations must complete a minimum of 30 MRI specific CPD points every 3 years. | | |
| Indicator i | Each of its radiologists is a current participant in the MRI Quality Program. | | |
| **14.2.5** | **CPD – MRI Radiographer** | | |
| Indicator i | Radiographers performing MRI examinations can provide evidence of MRI-specific CPD activity. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **14.3.1** | **MRI System Supervision** | | |
| Indicator i | Each MRI unit holds current RANZCR MRI registration<br>Professional supervision of the MRI unit is maintained by its nominated Liaison MRI Radiologist. | | |
| Indicator 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. | | |
| Indicator iii | The nominated Liaison MRI Radiologist is responsible for ensuring that each MRI radiologist is participating in the RANZCR QAP. | | |
| Indicator iv | Protocols for MRI provide for delegation of duties to MRI radiographers. | | |
| **14.3.2** | **MRI Review of Appropriateness of Request and Patient Preparation** | | |
| Indicator i | The review of the request is undertaken and protocolled by one of the practice's MRI radiologists, or a delegated and appropriately qualified MIT. | | |
| Indicator ii | Protocols define a list of examinations that routinely require prompt MRI Radiologist review before patient discharge. | | |
| Indicator iii | There is provision for the imaging protocol to require prompt MRI radiologist review of the images before patient discharge. | | |
| Indicator iv | Safety screening follows RANZCR MRI Safety Guidelines whereby an MRI Radiologist is available for telephone consultation within 10 minutes. | | |
| **14.3.3 –** | **MRI Performance of the Examination**<br>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. | | |
| Indicator i | Protocols ensure that all MRI examinations requiring contrast are carried out under the supervision requirements stated in 5.4.2. | | |
| Indicator ii | 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator iii | 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). | | |
| Indicator iv | The 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. | | |
| **14.3.4** | **MRI Procedures** | | |
| Indicator i | The technical factors are documented for each anatomic site for standard MRI procedures commonly performed by the practice. | | |
| Indicator ii | The practice records a review of MRI procedures by MRI staff, including the nominated Liaison MRI Radiologist, at least annually. | | |
| **14.3.5.1** | **MRI Image Review** | | |
| Indicator i | Each MRI units holds current registration with the RANZCR MRI Quality Program. | | |
| Indicator ii | MRI clinical image review is performed in accordance with that Program and at intervals determined under the Program. | | |
| Indicator iii | Images of an approved MRI phantom are submitted for review by RANZCR approved consultants, at intervals determined under the Program. | | |
| Indicator iv | Quality assurance of the MRI system is performed at appropriate intervals. | | |
| **14.3.5.2** | **MRI Quality Improvement Program** | | |
| Indicator 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. | | |
| Indicator ii | The MRI quality improvement program includes periodic review of these records to identify opportunities to improve patient care. | | |
| Indicator iii | The MRI quality improvement program attempts to correlate imaging findings with surgical, pathological and clinical outcomes. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **14.4.1** | **MRI Safety** | | |
| Indicator i | MRI safety practices and policies are enforced and reviewed at least annually by the Liaison MRI Radiologist. | | |
| Indicator ii | MRI safety practices and policies comply with the RANZCR MRI Safety Guidelines. | | |
| Indicator iii | 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. | | |
| Indicator iv | The MRI safety policy includes:<br>a. exclusion of the general population outside the 5 Gauss line with appropriate warning signs; and<br>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). | | |
| Indicator v | An MRI safety education session is provided for all staff accessing the MRI area. | | |
| Indicator vi | The 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **15 MAMMOGRAPHY (Including tomosynthesis)** | | | |
| **15.1.1** | **Mammography Labelling of Images**<br>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 | | |
| Indicator i | The practice ensures that its mammography images are labelled with the following:<br>a. A permanent identification label, that details:<br>○ Facility name<br>○ Patient's full name<br>○ Patient identification (e.g. unique Medical Record Number or patient date of birth)<br>○ Examination date.<br>b. Radiopaque markers (or electronic markers with CR/DR units) indicating laterality (R/L) and projection/view (MLO/CC.)<br>○ Placed near the aspect of the breast closest to the axilla<br>○ Placed on the cassette so they can be read from overhead (In the case of film screen and CR units)<br>○ Large enough to be clearly readable without being distracting<br>○ Utilising standard abbreviations.<br>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).<br>d. Cassette/screen identification by Arabic number written or pressed on the screen to identify screens with artefacts or defects.<br>e. A radiopaque (or electronic in the case of CR/DR units) dedicated mammographic unit identifier, e.g. MQAP number. | | |
| Indicator ii | With the exception of the markers indicating laterality and view, all labels are placed as far from the breast as possible. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator iii | Where initials are used on labels, a log of names and identifying initials are maintained. | | |
| Indicator iv | Collimation is to the edge of the image so that as much of the image as possible will be exposed. | | |
| Indicator v | Image labelling does not obscure breast tissue. | | |
| **15.2.1** | **Diagnostic Mammography Equipment** | | |
| Indicator i | The practice only performs mammography examinations on dedicated mammography equipment which complies with the equipment requirements of the RANZCR Mammography Quality Assurance Program (MQAP). | | |
| Indicator ii | Acquisition monitors used for mammography have a minimum resolution of 3MP and a minimum brightness of 250cd/$m^2$ . | | |
| Indicator 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**<br>There must be documented procedures for QC checks as specified in the RANZCR Guidelines for QC Testing for Digital (CR DR) Mammography or the ACPSEM recommendations for a digital mammography QA program. | | |
| Indicator i | The 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. | | |
| **15.2.3** | **Diagnostic Mammography Annual Equipment Testing**<br>Mammography equipment must be tested annually. | | |
| Indicator i | Records demonstrate that its mammography equipment meets the manufacturer's equipment testing guidelines, where applicable. | | |
| Indicator ii | MQAP records demonstrate that the equipment also complies with the Guidelines for Quality Control Testing for Digital (CR DR) Mammography. | | |
| **15.3.1** | **Qualifications – Equipment Assessors for Mammography Equipment** | | |
| Indicator i | The Practice's MQAP records show that annual mammography equipment testing is carried out by a certified equipment assessor. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **15.3.2** | **CPD – Radiologist** | | |
| Indicator i | Each of its radiologists who interpret mammograms has accumulated 15 mammography specific CPD points in the past 3 years in mammography CPD activities recognised by the RANZCR CPD program. | | |
| **15.3.3** | **CPD – Radiographer** | | |
| Indicator i | Radiographers who perform mammography examinations participate in at least 15 hours of mammography specific CPD every 3 years. | | |
| **15.4.1** | **Professional Competence** | | |
| Indicator i | Personnel providing mammography services are appropriately qualified and experienced according to the requirements of these standards. | | |
| Indicator ii | Its 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** | | |
| Indicator i | Practice records show that the 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** | | |
| Indicator i | The practice ensures that only radiologists meeting the requirements set out in items 4.2.1 and 15.3.1 in these standards report mammography examinations | | |
| Indicator ii | It ensures that these radiologists are rostered on a regular basis at a service performing mammography. | | |
| **15.4.4** | **Mammography - Performance of the Examinations**<br>The Radiologist shall be responsible for ensuring the implementation and adherence of appropriate written protocols to be followed by members of the imaging team.<br>The Radiologist shall be available o personally attend the patient in order to alter the conduct of the examination.<br>Screening mammography performed as part of an organized population screening program is excluded from 15.4.4. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator i | Records show that the 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 QC Testing for Digital (CR/DR) Mammography protocols. | | |
| Indicator ii | Its professional supervision arrangements for mammography provide for the rostered 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** | | |
| Indicator i | The practice holds current MQAP records for each of its diagnostic mammography units. | | |
| **15.5.1** | **Mammography - Radiation Dose**<br>The Practice must not exceed the mammography radiation dose limit requirements of the ACPSEM Recommendations for a digital mammography QA program. | | |
| Indicator i | Practice mammography records show that the mean glandular dose as determined by the equipment assessor, does not exceed 2mGy per view, using the RMI-156 phantom or the Gammex Mammo FFDM phantoms. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **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* | | |
| **16.2** | **Nuclear Medicine Facilities** | | |
| Indicator i | The Facility complies with specific legislative requirements for the provision of nuclear medicine services. | | |
| Indicator ii | Access to and use of areas is controlled. | | |
| Indicator iii | There is an effective separation between areas where nuclear medicine services are performed and other areas of the Facility. | | |
| Indicator iv | The Facility maintains safety practices appropriate to the handling of radioactive substances. | | |
| Indicator v | The Facility demonstrates compliance with workplace safety and other regulatory requirements concerning employment. | | |
| Indicator vi | The Facility maintains cleanliness of the facilities. | | |
| Indicator vii | The Facility assures patient privacy. | | |
| Indicator viii | The Facility provides appropriate staff amenities. | | |
| **15.3.1** | **Nuclear Medicine -Equipment** | | |
| Indicator i | The Equipment inventory demonstrates that appropriate equipment used for nuclear medicine services is available. | | |
| Indicator ii | The 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. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **16.4.1** | **Qualifications – Nuclear Medicine Specialist** | | |
| Indicator i | The Facility's nuclear medicine services are provided by nuclear medicine specialists who:<br>a. are recognised as a specialist in nuclear medicine by AHPRA; and<br>b. are credentialled as nuclear medicine specialists and additionally, if reporting PET are credentialled in PET, by the Joint Nuclear Medicine Specialist Credentialing Program. | | |
| Indicator ii | Each nuclear medicine specialist holds a current radiation license applicable to the provision of nuclear medicine services in the Facility's state/territory jurisdiction. | | |
| Indicator iii | Each of these specialists maintains a record of CPD activity (which may include RANZCR/RACP program records) with specific details of nuclear medicine activities. | | |
| Indicator 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). | | |
| **16.4.2** | **Qualifications – Nuclear Medicine Technologist** | | |
| Indicator i | Nuclear medicine technologist's current accreditation with the AHPRA. | | |
| Indicator ii | Where these are available, each nuclear medicine technologist holds current registration and a current radiation operator's licence applicable to nuclear medicine services with the applicable regulator in the Facility's state/territory jurisdiction. | | |
| Indicator iii | Each nuclear medicine technologist can demonstrate participation in nuclear medicine CPD activity. | | |
| Indicator iv | If a technologist operates a gamma CT unit for Attenuation Correction (AC) and Anatomic Correlation (AnC), appropriate training in operation of the CT component is demonstrated. | | |
| **16.4.3** | **Trainee Nuclear Medicine Technologists** | | |
| Indicator i | The practice holds an ANZSNM accreditation certificate in relation to any trainee nuclear medicine technologists working at the facility. | | |
| Indicator ii | Trainees are supervised at all times by an accredited nuclear medicine technologist (rosters to indicate supervision). | | |

| Clause | Standard | QM Cross reference | Comments |
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| **16.4.4** | **Qualifications – Nuclear Medicine Medical Physicist** | | |
| Indicator i | The medical physicists providing support are accredited in nuclear medicine physics by the ACPSEM or the relevant jurisdiction authority. | | |
| Indicator 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. | | |
| **16.5.1** | **Responsibility of the Nuclear Medicine Specialist**<br>The specialist in NM shall comply with the Responsibility of the Specialist requirements in the AANMS Standards. | | |
| Indicator i | Nuclear medicine specialists are responsible for :<br>• the quality and safety of all nuclear medicine services provided by personnel at the facility<br>• assuring the nuclear medicine service provided is appropriate for the presenting condition of the patient | | |
| Indicator ii | Personnel are properly trained, qualified and competent to perform each procedure in which they are directed to participate. | | |
| Indicator iii | • delegate responsibility to other persons to perform patient care tasks. | | |
| Indicator 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. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **16.5.2** | **Responsibility of the Nuclear Medicine Technologist**<br>A nuclear medicine technologist's responsibilities shall comply with the AANMS Standards. | | . |
| Indicator i | Facility's records demonstrate that the nuclear medicine technologist responsibilities include radiopharmaceutical preparation and administration, imaging and data processing and the full range of nuclear medicine procedures under the supervision of the nuclear medicine specialist. | | |
| **16.5.3** | **Nuclear Medicine - Supervision of Service**<br>Supervision in the practice of nuclear medicine shall comply with AANMS Standards. | | |
| Indicator i | Protocols ensure that the nuclear medicine specialist is available to personally attend the patient during the conduct of the nuclear medicine examination. | | |
| Indicator ii | They ensure that the nuclear medicine specialist determines the appropriateness of and monitors the quality of the procedure. | | |
| Indicator iii | These protocols ensure that the nuclear medicine specialist is able to assess and influence the outcome of the examination. | | |
| Indicator iv | These protocols extend to out-of-hours arrangements. | | |
| **16.5.4** | **Nuclear Medicine - Technical Service Manual** | | |
| Indicator i | The practice maintains a nuclear medicine procedure manual which has been established and is maintained by the nuclear medicine specialist/s. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | This manual includes for each procedure performed by the practice:<br>• A summary of patient conditions that may affect the physician's interpretation of the nuclear medicine procedure.<br>• A description of instruments used and the control settings, and the technical and analytic steps followed in performing the procedure which complies with the requirements of the AANMS Standards.<br>• 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.<br>• Medical literature citations when appropriate for a more thorough understanding of the procedure.<br>• A description of any special quality assurance measures specific to a procedure.<br>• A definition of quality control limits if appropriate.<br>• Instructions on any preliminary actions to be taken in case of deviation from acceptable limits before referring the problem to the nuclear medicine specialist.<br>• Examples of typical indications for performing procedure.<br>• Details of required quality control procedures. | | |
| Indicator iii | This manual is reviewed biennially (every two years) by the nuclear medicine specialist. | | |
| Indicator iv | Superseded procedures are clearly notated and are retained by the practice until such time as the retention period for reports relating to such procedures has expired. | | |
| **16.5.5** | **Modification to Procedures** | | |
| Indicator i | The Facility notates both the patient records and the consultation report (as determined by the nuclear medicine specialist's directions) for any examinations where procedures are modified. | | |
| **16.5.6** | **Nuclear Medicine - Interpretation and Timeliness of Reporting of Results**<br>Facilities shall comply with the reporting standards contained in the AANMS Standards. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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. | | |
| Indicator ii | Rosters demonstrate that the nuclear medicine specialist complies with the reporting requirements applicable to the jurisdiction of the Facility. | | |
| Indicator iii | Contents of reports contain the requirements listed in the AANMS Standards. | | |
| Indicator iv | Reports are generally provided to within 24 hours of the service being provided. | | |
| Indicator 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. | | |
| Indicator 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. | | |
| **16.6.1** | **Nuclear Medicine Facility Safety**<br>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. | | |
| Indicator i | All toxic, irritant or caustic chemicals are appropriately labelled, and personnel are trained in use of such materials. | | |
| Indicator ii | Suitable eye protection devices, impervious aprons and means for flushing materials from the skin or eyes rapidly in the event of accidental splashing are readily available in the practice. | | |
| Indicator iii | Materials presenting a biological or other hazards are carefully handled and in accordance with a documented protocol to minimise risks to personnel and patients. | | |
| Indicator iv | Eating and drinking is prohibited in patient care and laboratory areas of the practice. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator vi | Nuclear medicine waste materials are disposed of according to regulatory requirements. | | |
| Indicator vii | Aseptic technique is used when penetrating patient skin. | | |
| **16.6.2** | **Nuclear Medicine - Radiation Safety**<br>The facility shall comply with all applicable radiation safety regulations. | | |
| Indicator i | All applicable radiation licenses pertaining to nuclear medicine are retained at the practice site. | | |
| Indicator ii | Radiation safety policies and procedures contained in the practice's radiation safety manual specific to the practice's nuclear medicine services comply with all relevant radiation safety regulations, including notification of maladministration. | | |
| Indicator iii | Personnel are trained in radiation safety techniques according to the manual and have periodic in-service reviews. | | |
| Indicator iv | Facility records confirm that personnel are monitored by TLD badges (or other regulatory compliant dosimeters). | | |
| Indicator v | 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. | | |
| Indicator vi | Procedures and resources have been implemented which ensure the correct handling of accidents involving radioactive materials and subsequent decontamination which complies with the relevant jurisdiction regulations. | | |
| Indicator vii | A CTDI (milliGrays) and DLP (dose length product – milliGrays per centimetre) value for each CT component of a Gamma CT study is recorded and is available with the patient's images. | | |
| Indicator 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. | | |
| Indicator ix | The Facility undertakes dose calibration surveys with regular assessment of prescribed radiopharmaceutical do | | |
| Indicator x | The Facility ensures that administered activity for diagnostic and therapeutic procedures complies (generally within +/– 10%) with what has been prescribed. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **16.6.3** | **Radioisotopes – Preparation, Handling, Administration**<br>Facilities performing NM services shall comply with the safety standards contained in the AANMS Standards. | | |
| Indicator 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. | | |
| Indicator ii | Radioactive material dispensed for administration to patients is calculated according to established protocols. | | |
| Indicator iii | 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**<br>Facilities performing NM services shall comply with the standards regarding blood products contained in the AANMS Standards. | | |
| Indicator i | The facility performs labelling of blood or blood products in-house, and has established a blood-labelling protocol which is adhered to by all applicable personnel under the supervision of the NM specialist. | | |
| Indicator ii | The service ensures the correct re-administration of the blood products to the correct patient. | | |
| Indicator iii | Blood products are prepared in aseptic conditions using at least a Class II enclosed system. | | |
| Indicator iv | Externally supplied blood and/or blood products are verified for:<br>a. patient identification upon receipt, and again immediately prior to administration; and<br>b. radioactivity, with any discrepancy of more than 50% from the prescribed activity for diagnostic procedures, shall be confirmed with the nuclear medicine specialist/physician to administration. | | |
| **16.6.5** | **Handling of Biological Materials.** | | |
| Indicator i | The facility ensures that glassware contaminated with toxic or biologic materials is made safe as soon as practicable after use. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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. | | |
| Indicator iii | Appropriate care is exercised in handling sera and other materials. | | |
| Indicator iv | Due care is taken to avoid uncontrolled release of any potentially infectious material. | | |
| **16.6.6** | **Cardiopulmonary Resuscitation and Basic Life Support**<br>All personnel involved in the provision of NM services shall be trained and retain competency in CPR services appropriate to the level of services provided by the facility. | | |
| Indicator 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** | | |
| Indicator i | Written information and instructions is 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). | | |

| Clause | Standard | QM Cross reference | Comments |
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| **16.7.1** | **Nuclear Medicine Patient Records** | | |
| Indicator i | The Facility ensures that the patient record identifies:<br>• Patient name, date of birth and unique identifier<br>• Name of the requesting medical practitioner<br>• Request date<br>• Name of the responsible nuclear medicine specialist<br>• 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<br>• Type, activity, route and injection site for any radioactive or non-radioactive substances administered to the patient<br>• The name of the nuclear medicine technologist performing the service (where applicable)<br>• The date that the service was performed<br>• 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 | | |
| Indicator ii | The Facility ensures that all nuclear medicine patient reports contain:<br>• Patient name, date of birth and unique identifier<br>• Name of the requesting medical practitioner<br>• Name and signature of the responsible nuclear medicine specialist<br>• 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<br>• 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **17 ULTRASOUND** | | | |
| **17.1.1** | **Equipment**<br>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. | | |
| Indicator 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 equipment with following capability:<br>• Colour Doppler including power Doppler<br>• Spectral (pulsed) Doppler<br>• M-mode scanning<br>• Linear transducer of frequency 12 MHz or greater<br>• Linear transducer of frequency 7 MHz or greater<br>• Curved linear array transducer of frequency 2.5–5 MHz<br>Transvaginal transducer. | | |
| Indicator ii | Where the practice offers general ultrasound services it has equipment with the following capability:<br>• Colour Doppler including power Doppler<br>• Spectral (pulsed) Doppler<br>• Linear transducer of frequency 7 MHz or greater<br>• Curved linear array transducer of frequency 2.5–5 MHz | | |
| Indicator iii | Where the practice offers cardiac ultrasound services it has equipment with the following capability:<br>• Colour Doppler including power Doppler<br>• Spectral (pulsed) Doppler<br>• Continuous and pulsed-wave Doppler<br>• Linear transducer of frequency 2.5 MHz<br>• M-mode scanning<br>• 2D scanning. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator iv | Where the practice offers vascular ultrasound services it has equipment with the following capability:<br>• Colour Doppler including power Doppler<br>• Spectral (pulsed) Doppler<br>• Linear transducer of frequency 7 MHz or greater<br>• Curved linear array transducer of frequency 5 MHz | | |
| Indicator v | Where the practice offers urological ultrasound services it has equipment with the following capability:<br>• Colour Doppler including power Doppler<br>• Spectral (pulsed) Doppler<br>• Curved linear array transducer of frequency 2.5–5 MHz<br>Endorectal transducer. | | |
| Indicator vi | Where the practice offers obstetric and gynaecological ultrasound services it has equipment with the following capability:<br>• Colour Doppler including power Doppler<br>• Spectral (pulsed) Doppler<br>• M-mode scanning<br>• Curved linear array transducer of frequency 2.5–5 MHz<br>• Transvaginal transducer. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator vii | Where the practice provides Musculoskeletal Ultrasound services it has equipment with the following capability<br>• Colour Doppler including power Doppler<br>• Linear transducer of frequency 12 MHz or greater<br>• Linear transducer of frequency 17 MHz or greater | | |
| | Where the Practice provides paediatric ultrasound services, it has equipment with the following capability:<br>• Colour Doppler, including power Doppler<br>• Spectral (pulsed) Doppler<br>• Linear transducer of frequency 7 MHz or greater<br>• Curved linear array transducer of frequency 5 MHz<br>• C8-5 curved array (tight convex) transducer<br>• C5-1 curved array transducer<br>• C9-2 curved array transducer<br>• Small footprint high-frequency linear transducer (hockey stick). | | |
| Indicator ix | Monitors used for ultrasound examinations have a minimum colour/monochrome resolution of 1024 x 768. | | |
| **17.1.2** | **Equipment – Maintenance and Upgrades**<br>All ultrasound equipment is maintained appropriately and meets currently accepted specifications. | | |
| Indicator 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 | | |
| Indicator 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. | | |
| Indicator iii | It ensures that ultrasound equipment (hardware and software) is not more than 10 years old, or 15 years if the equipment has been significantly upgraded with appropriate software, such that the software is equivalent to that of a machine less that 10 years old. | | |

| Clause | Standard | QM Cross reference | Comments |
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| **17.2.1** | **Qualifications – Sonographer**<br>The practice shall ensure that its sonographers are appropriately qualified and accredited. | | |
| Indicator i | The practice ensures that its sonographers hold current ASAR membership. | | |
| Indicator ii | n/a NZ reference | | |
| Indicator iii | It holds a copy of the current annual ASAR membership receipt for each of its sonographers. | | |
| Indicator iv | It can demonstrate that each of its sonographers follows the ASA Code of Conduct. | | |
| **17.2.2** | **Qualifications – Student Sonographers**<br>The practice shall ensure that its student sonographers are appropriately qualified and accredited. | | |
| Indicator i | The practice ensures that its student sonographers hold current ASAR membership. | | |
| Indicator ii | n/a NZ reference | | |
| Indicator iii | It holds a copy of the current annual ASAR membership receipt for each student sonographer. | | |
| Indicator iv | It can demonstrate that each of its student sonographers follows the ASA Code of Conduct. | | |
| **17.2.3** | **CPD – Radiologists**<br>The radiologist providing ultrasound services shall participate in ultrasound specific CPD. | | |
| Indicator i | The 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**<br>The practice shall ensure that its sonographers and student sonographers comply with the requirements of an ASAR approved CPD program. | | |
| Indicator i | The practice ensures that its sonographers and student sonographers hold current ASAR membership. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| **17.3.1** | **Student Sonographers**<br>All student sonographers must have on-site supervision by a radiologist or a sonographer accredited by ASAR in the relevant field/s of practice at all times. | | |
| Indicator i | The practice ensures that its professional supervision arrangements provide for on-site supervision of student sonographers by either the radiologist or an ASAR-accredited sonographer so delegated by the radiologist. | | |
| Indicator ii | It ensures that supervising sonographers are accredited by the ASAR in the fields of practice in which they are supervising. | | |
| **17.3.2** | **Sonographers Performing Ultrasound Examinations in Remote Locations**<br>Sonographers performing ultrasound examinations in rural and remote locations shall have appropriate professional supervision and clinical guidance from the reporting radiologist. | | |
| Indicator i | The practice meets the criteria for 'rural and remote' status for Medicare. | | |
| Indicator ii | The sonographer meets the requirements under items 17.2.1 and 17.2.4 in these standards. | | |
| Indicator iii | Where a student sonographer is performing these examinations, he/she meets the requirements under items 17.2.2 and 17.2.4 in these standards and has either:<br>a. completed one year of directly supervised training that has included the full scope of ultrasound examinations which he/she is performing at the practice; OR<br>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. | | |
| Indicator iv | During the conduct of each ultrasound examination the radiologist is readily contactable to discuss the procedure with the sonographer or student sonographer and influence the examination. | | |
| Indicator 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. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator 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. | | |
| Indicator vii | This supervision of student sonographers is supported by the additional resource of an ASAR accredited 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. | | |
| Indicator 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**<br>The radiologist shall be readily contactable to discuss and if necessary, alter the conduct of the imaging examination in consideration of the examination request. | | |
| Indicator i | The practice's professional supervision arrangements ensure the provision of clinically directed scanning and appropriate triaging for all ultrasound services. | | |
| Indicator ii | Within these arrangements the 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. | | |
| Indicator iii | The professional supervision arrangements recognise that a radiologist may need to personally attend the patient in order to examine the patient prior to an ultrasound examination proceeding in order to determine the optimum imaging pathway for the patient. | | |
| **17.3.4** | **Performance of Ultrasound Examinations**<br>Ultrasound scanning of the patient shall be performed by the radiologist, the sonographer acting on behalf of the radiologist, or the radiologist and sonographer in collaboration. | | |
| Indicator i | The radiologist has implemented a system for communication with the sonographer. This communication may be verbal and/or by sonographer work sheets and/or annotated images. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | The practice's professional supervision protocols and rostering for ultrasound examinations ensure that the 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. | | |
| Indicator 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 radiologist while the patient is on site. | | |
| Indicator iv | The Practice ensures that its clinical radiologists providing ultrasound services are responsible for determining:<br>• How much of an ultrasound examination should be shown and demonstrated to a patient<br>• •What examination information can be independently passed on to a patient by the sonographer | | |
| Indicator 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 Results**<br>The responsibility for the conduct of the study and the production of the report lies with the radiologist. The 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.<br>It is expected that all sonographer worksheets will be appropriately stored and filed with the request form. | | |
| Indicator i | The report issued to referring clinician contains relevant clinical details and ultrasound findings and draws conclusions pertinent to the patient and the clinical indicators for the study and complies with the Clinical Radiology Written Report Guideline. | | |

| Clause | Standard | QM Cross reference | Comments |
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| Indicator ii | The Practice can demonstrate that the request form and the sonographer worksheet are appropriately stored in the patient's electronic medical records. | | |
| Indicator 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. | | |
| **17.4.1** | **Ultrasound Safety**<br>The practice shall ensure that it meets all safety requirements for the ultrasound services it provides. | | |
| Indicator i | The practice ensures that sonographers and 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. | | |
| Indicator 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. | | |
| Indicator iii | It meets all regulatory requirements in relation to ultrasound safety. | | |
| Indicator 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. | | |
| **17.4.2** | **Ultrasound – Infection Control**<br>The Practice holds a readily accessible copy of the ASUM/ACIPC Guidelines for Reprocessing Ultrasound Transducers and adheres to the protocols outlined.<br>The Practice adheres to the infection control protocols for the environment in which a patient is being examined. | | |
| Indicator i | The Practice ensures that sonographers and radiologists are familiar with the contents of this guideline. | | |
| Indicator 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 | | |
| Indicator iii | The Practice ensures it maintains a record of their Infection Control activity regarding transducers. | | |

| Clause | Standard | QM Cross reference | Comments |
|---|---|---|---|
| Indicator iv | The Practice meets regulatory requirements in relation to the hygiene of the scanning environment. | | |