

ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MI 001 Specific Criteria for Medical Imaging

1. INTRODUCTION

This document describes the specific requirements to be complied by radiology services facilities before they can be accredited.

This document shall be studied on conjunction with the document, "ISO/IEC 15189:2007 Medical laboratories - Particular requirements for quality and competence" specifies the quality management system requirements particular to medical laboratories, and other technical notes published by SAC-SINGLAS.

The field of Medical Imaging includes procedures covering the use of radiography, ultrasound, mammography, computerised tomography, angiography, magnetic resonance, nuclear medical and bone mineral densitometry.

2. ORGANISATION AND MANAGEMENT

- 2.1 Examinations shall be performed by a medical practitioner specialist registered with the Singapore Medical Council as a specialist in the field of diagnostic radiology as required in the Private Hospitals and Medical Clinics (PHMC) Act in the practice of his or her specialty who is available to monitor and influence the conduct and diagnostic quality of the examination. The medical specialist shall be certified with the Specialist's Accreditation Board (SAB) of the Ministry of Health. In addition to the qualifications as defined in the PHMC Act, the radiology service is also expected to demonstrate the following:
 - a. The supervising specialist in charge of the facility shall be clearly identified.
 - b. The supervising specialist shall be a medical practitioner registered with the Singapore Medical Council as a specialist in the field of diagnostic radiology as recognised by the Ministry of Health.
 - c. The supervising specialist shall demonstrate competency in radiology services by having completed one of the following:
 - i. Completed a radiology training programme which included a specific curriculum in radiology services,
 - ii. Completed at least 6 months of radiology fellowship training,
 - iii. Demonstrated clinical experience in supervision and interpretation of images.
- 2.2 Medical Imaging Facilities are to comply with the Radiation Protection Act and the subsidiary regulations.

2.3 The requirements pertaining to personnel working in different disciplines within medical imaging are as below:

a. Mammography

Supervising Specialists - The mammography supervising specialists shall view a minimum of 480 mammograms per year.

Radiographer/ Mammographer – All Radiographers/ Mammographers shall have completed a training programme approved by the Head of Department or supervising specialist. The Radiographer / Mammographer should participate in at least 10 hours per year of continuing medical education relevant and appropriate to mammography.

b. Ultrasound

Supervising Specialists - Ultrasound specialists who interpret ultrasound images shall hold current (not greater than 3 years) optometrists reports and shall wear any prescribed optical aids while reporting.

Ultrasonographer / Sonographer – All Ultrasonographers / Sonographers shall complete a training programme approved by the Head of Department or possess an advanced diploma or higher qualification in Ultrasound. The Ultrasonographer / Sonographer should participate in continuing medical education with at least 10 hours relevant or appropriate to Ultrasound.

c. MR Imaging

Supervising Specialists – MR Imaging specialists shall have demonstrated clinical experience in supervision and interpretation of at least 1000 cases of MRI of the brain, spine, musculo-skeletal system and other relevant anatomic regions. He/she who interprets MR images shall hold current (not greater than 3 years) optometrists reports and shall wear any prescribed optical aids while reporting.

MR Radiographer – All MR Radiographers shall have completed a training programme approved by the Head of Department or possess an MSc in MRI or cross-sectional imaging. The MR Radiographer should participate in continuing medical education with at least 10 hours relevant or appropriate to MRI.

d. CT Scanning

Supervising Specialists - Requirements for the CT scanning supervising specialist may be expected to vary according to the type and complexity of examinations carried out, with the requirements within a major teaching facility being more rigorous than those in a small private radiology service. All specialists who interpret CT scans shall hold current (not greater than 3 years) optometrists reports and shall wear prescribed optical aids while reporting.

CT Radiographer – All CT Radiographers shall complete a training programme approved by the Head of Department or possess a MSc in CT or cross-sectional imaging. He/She shall also possess a R1 Licence according to the Radiation Protection Act. The MR Radiographer shall participate in continuing medical education with at least 10 hours relevant or appropriate to CT.

e. Nuclear Medicine

Supervising Nuclear Medicine Specialist - The supervising Nuclear Medicine Specialist shall be certified by the Specialist's Accreditation Board (SAB) of the Ministry of Health. This NM specialist shall demonstrate clinical experience in supervision and interpretation of at least 1000 scans with a minimum of 200 scans in any one year.

Nuclear Medicine Radiographer - Nuclear Medicine Radiographers shall complete a training programme approved by the Head of Department or possess a degree in Nuclear Medicine. He/She shall also possess a R1 registration according to the Radiation Protection Act. The Nuclear Medicine Radiographer should participate in continuing medical education with at least 10 hours relevant or appropriate to Nuclear Medicine.

f. Projection / Plain Film Radiography

Supervising Specialist - The supervising projection/ plain film specialist shall be at least a Registrar grade, with clinical experience in the interpretation of at least 1000 examinations in any one year. All specialists who interpret plain film examinations shall hold current (not greater than 3 years) optometrists reports and shall wear any prescribed optical aids while reporting.

Radiographer - All radiographers shall possess a diploma or degree in Radiography. Radiographer shall participate in continuing medical education with at least 10 hours relevant or appropriate to this field.

2.4 The following details the requirements of other personnel working in a radiology service: -

Nurses – Each nurse shall hold current registration with the Singapore Nurses Board. Nurses involved in medical imaging practice shall have adequate training/experience in such practice.

Training/Experience in Sedation and Monitoring – Staff administering sedation and monitoring sedated patients shall be adequately trained in the safe and correct usage of the equipment and in the management of sedated patients.

Training /Experience in Anaesthesia and Monitoring – Staff administering general anaesthesia shall be trained anaesthetists with appropriate assistance.

Training /Experience in Resuscitation – The practice shall ensure there is adequate staff training in CPR, appropriate management of contrast reaction and the use of resuscitation equipment. There shall be a designated staff member at each site to ensure resuscitation equipment and drugs et are present and in a state of readiness.

2.5 Each unit should exercise supervision of the staff for compliance with the ISO 15189:2007 requirements. In general, the supervision entails the following:

MRI

- 2.6 Each MRI unit must have one or more supervising radiographers with overall responsibility for
 - a. Running the unit,
 - b. Supervising the staff, and
 - c. Setting standards within the unit, including assuring the examinations are supervised by suitably qualified radiologists and MRI technologists, and assuring the quality of the images and reports.
- 2.7 One supervising radiologist must be designated as the nominated supervising radiologist for each MRI machine and will be the point of contact for administration purposes.

- 2.8 All radiologists (working under the supervising radiologists) must have the responsibility for
 - a. Reviewing clinical indications for examinations,
 - b. Specifying the use and dosage of contrast agents, specifying the pulse sequences being performed, and
 - c. Assuring the quality of both the images and interpretations.

Nuclear Medicine

- 2.9 A nuclear medicine specialist must be responsible for all components of nuclear medicine service including:
 - a. Determining the appropriateness of and monitoring the quality of the procedure,
 - b. Maintain all necessary licences for the use and storage of each radionuclide,
 - c. Assessing and influencing the outcome of the procedure, and
 - d. Providing a final scan report.

Supervision of Trainees

- A qualified specialist shall available to provide appropriate on-site direct supervision of trainee nuclear medicine specialists at all times inhours, and be available to provide advice and backup at all times outof-hours,
- b. All trainee radiographers must have on-site supervision by a qualified radiographer or specialist at all times,
- c. All trainee sonographers must have on-site supervision by a specialist, or a sonographer at all times,
- d. All trainee nuclear medicine technologists must have on-site supervision by a nuclear medicine technologist at all times,
- e. Medical Imaging nurses being trained in medical imaging practices to assist in medical imaging practices shall be supervised by the nurse unit manager or specialist.

Radiation Safety Officer

- 2.10 Each practice must appoint a Radiation Safety Officer (RSO) with the approval of the director, Centre for Radiation Protection and Nuclear Science (CRPNS), National Environment Agency (NEA). The RSO is responsible in:
 - a. Ensuring that the practice is adhering to the Radiation Protection Act and the Radiation Protection Regulation,
 - b. Assisting the radiation licensee to ensure radiation safety in the workplace,
 - c. Monitor changes in legislation,
 - d. Coordinate record keeping relating to radiation safety,
 - e. Investigate any radiation incidents & accidents involving either patient(s) or staff.

3. REFERENCE RESOURCES

- 3.1 Medical Imaging protocols shall be documented describing the performance of all procedures preformed by the practice. These protocols shall include all necessary information including that for:
 - a. Patient management,
 - b. Imaging procedures appropriate to specific clinical indications,
 - c. Deviations from standard imaging protocols,
 - d. Operation of equipment,
 - e. Quality control procedures,
 - f. Necessary remedial action e.g. adverse event management,
 - g. Records to be kept, and
 - h. Safety issues/ Precautionary issues,
- 3.2 Manuals and documents shall be maintained for all Medical Imaging procedures The procedure manual should include for each procedure performed:
 - A summary of patient conditions that may affect the interpretation of the nuclear medicine procedure (e.g. Posture, time and content of previous drug dosage, diet, time of day),
 - b. A description of any special quality assurance measures specific to the particular procedure, and

- c. A definition of quality control limits, if appropriate and instructions on any preliminary actions to be taken in case of deviation from the acceptable limits before referring the problem to the nuclear medicine specialist
- 3.3 All medical imaging services shall hold, have direct access to, a comprehensive range of current specialist text books, scientific journals and other reference literature appropriate and relevant to the scope of activities of the facility.
- 3.4 All images, raw data and quality control data shall be stored for a minimum of 5 years.
- 3.5 A daily log or equivalent record of all patients' studies must be retained according to the appropriate statutory requirements or for a minimum of 3 years whichever is longer.
- 3.6 The following must be recorded either in one consolidated patient record or practice records:
 - a. Patient's name and either NRIC number or other satisfactory identifier,
 - Requesting practitioner's name,
 - c. Type of imaging procedure performed as identified in the practice procedure manual and, where necessary, an explanation of any modification to the procedure,
 - d. Type, activity, route and injection site of any radioactive or nonradioactive substance (such as contrast agents) administered to the patient,
 - e. Name of radiographer and specialists performing the procedure,
 - f. Date of procedure,
 - g. Description of findings,
 - h. Interpretative information, including, if appropriate, background on the predictive value of the procedure or expected values on a reference population, to assist referring practitioners in understanding the results of the procedure, and
 - i. Identification of the responsible specialist.
- 3.7 A record of the following should also be kept, if appropriate:
 - A description of any unusual features prior to, during or following the study,
 - Supplementary information e.g. evidence of previous surgery, to include sketch and use of radioactive markers, when the interpretation of the study may be influenced by the results of the study,

- c. Comments on the quality of the study, and
- d. Deviation(s) from the procedure as described in the procedure manual.
- 3.8 Where technical data applicable to a group of patients' studies is not recorded in individual patients' records, there must be sufficient cross-referencing to enable that data to be retrieved for a specific patient study if required.
- 3.9 Drugs used for sedation and further management shall be recorded in the patient's medical record, along with times of administration and details of any adverse reaction.
- 3.10 All studies shall have representative images recorded which shall be available to the referring doctor. The records shall have patient identification, the date and, where necessary, time of the study and the practice name (and preferably the site) imprinted on them. The identity of the person who performed the study must be available either on the image or other associated records such as the worksheet, request form, etc.
- 3.11 The labelling of medical images must be sufficiently comprehensive to ensure that they be unequivocally traced to the patient and to enable their interpretation. Films must be labelled with a permanent identification label, preferably a "flash" label, rather then a stick-on label which details:
 - a. Practice name.
 - b. Site name,
 - c. Patient's full name,
 - d. Patient identification, and
 - e. Examination date.
- 3.12 Documented policies and practices must follow all radiation safety policies and procedures according to appropriate legislation, which aim to minimise radiation exposure. Documented policies and procedures must be available for the safe use of radionuclides and ionising radiation for medical imaging.
- 3.13 Policies and procedures for all infection control issues including sterilisation/ disinfection must be documented.
- 3.14 Documented policies and procedures must be available for the safe disposal of contaminated/ medical and radioactive waste which must be in accordance with relevant regulations.

Mammography

- 3.15 Radiopaque markers indicating laterality (R/L) and projection/ view (MLO/CC):
 - a. Placed near the aspect of the breast closest to the axilla,
 - b. Placed on the cassette so they can be read from overhead, and
 - c. Large enough to be clearly readable without being distracting.
- 3.16 Cassette/ screen must be uniquely identified on screen to identify screens with artifacts or defects.
- 3.17 With the exception of the markers indicating laterally and view, all labels must be placed as far from the breast as possible.

Nuclear Medicine

- 3.18 For Nuclear Medicine, the following information shall be included for Angertype gamma cameras and PET/CT scanners (unless the following information is described in the procedure manual):
 - a. Camera identification,
 - b. Collimator type,
 - c. Window settings for each radionuclide imaged, Patient orientation (eg. Supine, sitting, etc),
 - d. View obtained, including orientation of detector, if relevant, and number of heads used for multi-head cameras,
 - e. Total image counts, and
 - f. time required to record image

For other instruments such as multi-head cameras, thyroid uptake probes etc, appropriate data analogous to those described for single-crystal cameras.

- 3.19 A documented policy must be available for the wearing of proper laboratory attire that includes lab coats, footwear, scrubs, requirements for Operating Theatre (OT), angiography, etc.
- 3.20 Provision of resources shall be listed for devices that are MRI compatible

4. ACCOMODATION AND ENVIRONMENTAL CONDITIONS

- 4.1 All medical imaging services should be expected to adequately provide for at least the following items relevant to accommodation:
 - a. Patient waiting area,
 - b. Patient interview and preparation areas,
 - c. Patient change cubicles,
 - d. Facilities for secure storage of patient belongings,
 - e. Signage in relation to restricted areas,
 - f. Equipment console and operating areas,
 - g. Facilities for the performance of administrative duties,
 - h. Film viewing and reporting areas,
 - i. Temperature and humidity control,
 - j. Resuscitation and Revival Equipment,
 - k. Facilities for data storage,
 - I. Areas for storage of equipment accessories and consumables,
 - m. Provision for the safe emergency exit, and
 - n. To deal with the situation in the event of Helium Boil Off

Legislation Pertaining to Radiation Safety

- 4.2 Practices must be aware and comply with legislation covering:
 - Radiation shielding and protection of patients, staff and premises,
 - b. Installation of warning lights and appropriate signage,
 - c. Use of protective and monitoring devices,
 - d. Adherence to dose and exposure limits for radiation workers, staff and members of the public, and
 - e. Adherence to dose guidance levels for patients.
- 4.3 Documented safety policies and procedures must be reviewed at least annually by the supervising specialist(s)

Magnetic Resonance Imaging

4.4 They must take into consideration potential interactions of the magnetic field with ferro-magnetic objects in the environment of the scanner. They must also

consider potential hazards posed by objects implanted within the patient as well as within personnel in the area.

4.5 Policies must include:

- a. Exclusion of the general population outside the 5 Gauss line with appropriate warning signs, and
- Procedures to screen patients and all other personnel entering the MRI examination room for intracranial aneurysm clips, cardiac pacemarkers, intra-ocular foreign bodies and other contraindicated devices
- 4.6 MRI safety education must be provided for all staff accessing the MRI area.
- 4.7 An MR facility may be expected to adequately provide for at least the following specialist facilities relevant to the accommodation of the MR Imaging equipment:
 - a. Definition of 5 gauss line,
 - b. Controlled access to the imaging room and appropriate signage,
 - c. Temperature and humidity control for computing equipment,
 - d. Detection of Helium boil-off, Oxygen depletion, and
 - e. Communication with the patient during examination
- 4.8 All equipment in the MRI imaging facility shall be MRI compatible.

Nuclear Medicine

- 4.9 Appropriate procedures and resources for handling accidents involving radioactive materials and for subsequent decontamination must be available.
- 4.10 Radiation monitoring equipment for the detection of contamination and radiation exposure levels must be available.
- 4.11 Materials presenting a hazard of airborne transport should be handled in fume hoods.
- 4.12 Provisions for emergency eyewash should be clearly identified and appropriately labelled.
- 4.13 Suitable protective clothing/ equipment such as eye protective devices, impervious aprons should be available.
- 4.14 There should be provisions for flushing materials from the skin rapidly in the event of accidental splashing.

- 4.15 Nuclear Medicine facility may be expected to adequately provide for at least the following specialist items/facilities relevant to the accommodation of NM imaging equipment:
 - a. Radioisotope preparation and storage ("hot laboratory") facilities,
 - b. Personnel decontamination facilities,
 - c. Radioactive waste disposal facilities,
 - d. Controlled access to the imaging room and appropriate signage,
 - e. Communication with the patient being examined, and
 - f. Sedation and general anaesthesia facilities

Interventional Radiology and Angiography

- 4.16 The angiography suite must be of sufficient size to allow easy patient transfer from bed to table, to allow room for all fixed hardware and movable hardware such as physiological monitors and any patient support systems and to allow adequate space for the operating team and support personnel.
- 4.17 Interventional radiology and angiography: Negative pressure and appropriate air exchange shall be maintained in these facilities.

5 IMAGING PROCEDURES

- 5.1 All procedures must reflect current practice.
- 5.2 Aseptic techniques shall be followed.
- 5.3 When a procedure is modified in the best interests of a patient, the modification must be noted in the patient's record or in the report.
- 5.4 Policies shall be in place, documented and approved by the specialist in performing methods that have been modified.

Administration of Radionuclides

- 5.5 The activity of the radioactive material to be dispensed for administration to patients shall be calculated according to an established protocol.
- 5.6 The activity of radioactive material to be administered to each patient shall be measured just prior to administration.
- 5.7 The standard activity of radioactive material administrated for each procedure must be established and recorded in the procedure manual.

Handling of Radioactive Substances

- 5.8 Appropriate procedures must be maintained for the identification of radiation areas and the receipt, storage and disposal of radioactive substances.
- 5.9 The facility must possess radiation safety and radioactive waste manuals, which clearly stipulates the proper use, handling and disposal of radioactive substances.

Radiopharmaceuticals

- 5.10 Onsite refers to preparation of radiopharmaceuticals at the facility. Off site refers to sites where radiopharmaceuticals are utilised only.
- 5.11 For radiopharmaceuticals prepared on-site:
 - a. The volume and quantity of radioactivity eluted from the generator/ vial must be measured and recorded with suitable precautions taken to minimise personnel exposure during such measurements,
 - b. Each batch of generator must be checked for the breakthrough of the parent nuclei,
 - c. Preparations must be prepared according to product labelling or documented procedures established in-house,
 - d. Aseptic procedures must be used when handling all components and preparations for potential parenteral or ophthalmic administration,
 - e. Radiopharmaceutical purity and labeling efficiency must to be checked routinely, and
 - f. Reagent kits and prepared radiopharmaceuticals must be stored according to established criteria or according to instructions specified by the kit insert (e.g. product labelling).
- 5.12 Patient identification must be verified prior to administration of radiopharmaceuticals.
- 5.13 Appropriate records must be maintained of the following:
 - a. Radiopharmaceutical receipt,
 - Radiopharmaceutical preparation,
 - Radiopharmaceutical disposal,
 - d. Adverse reactions to radiopharmaceuticals,
 - e. Misadministration and other recordable events, and
 - f. Actions taken in response to problems identified in any areas

Blood Products

- 5.14 For radionuclide tagging of blood and blood products performed on-site
 - a. Only one patient's blood shall be processed at a time,
 - b. Only one specimen shall be handled at a time to avoid the hazards associated with handling blood and the risk of swapping samples,
 - c. Blood shall be processed in aseptic conditions,
 - d. Tagging procedures shall be standardised in-house, documented and followed,
 - e. Tagging efficiency and other quality control criteria including stability shall be established, and
 - f. Tagged products shall satisfy the required standard before being administered to patients unless otherwise determined by the supervising specialist.
- 5.15 There may be instances where standard protocols/ procedures will need to be amended to accommodate to presenting features and/ or clinical details. In such cases, these amended practices shall be approved by the specialist, and facilities must keep a record for:
 - a. Varying the standard documented protocols, and
 - b. The changes adopted.
- 5.16 Any changes adopted should offer benefit to the patient over those currently in use.
- 5.17 Appropriate records must be maintained of the following
 - a. Tagging of patient blood and blood products,
 - b. Adverse reactions to tagged product,
 - c. Misadministration and incidence, and
 - d. Actions taken in response to any problems identified.

6 EQUIPMENT - SPECIFICATIONS AND AVAILABILTY

Diagnostic Ultrasound

- 6.1 Equipment for vascular studies must be capable of colour Doppler imaging.
- 6.2 Transvaginal probes should be available for pelvic and obstetric scans

6.3 Instruments for musculoskeletal studies should be equipped with probes of frequency 7.5 MHz or greater.

Diagnostic Mammography

6.4 Mammography must only be performed on dedicated mammographic equipment which has an adequate device for compression and a grid.

Interventional Radiology

- 6.5 For sites performing angiography, a fixed high resolution (at least 512 x 512 and preferably 1024 x 1024 matrix) image intensification system with at least a 25cm field, digital acquisition and subtraction is required. This provides increased speed of image acquisition, periprocedure table-side image review reduced radiation dose to patients and staff and potential reduction in contrast volumes with consequent benefits. Serial film changes are not required unless digital acquisition is unavailable.
- 6.6 Mobile image intensifiers are not recommended for diagnostic angiography on a routine basis as they may have limitations in real-time image quality, stored image data handling, permanent image quality ie. hard copy, comparative increase in radiation dose to the patients and staff, increased contrast material requirements and as their output is less than 50kW this leads to inferior images in thick body parts.
- 6.7 Cineradiology is not recommended for diagnostic angiography on a routine basis because of increased radiation and contrast material doses.

<u>Injector</u>

6.8 The angiographic injector shall be capable of varying injector volumes and rates and have appropriate safety mechanisms to prevent over-injection.

Supplies

6.9 There shall be sufficient supplies of devices for the range of interventional procedures performed and for the treatment of possible complications.

Sedation Equipment and Monitoring Sedated Patients

- 6.10 Equipment for sedation and monitoring of sedated patients shall be available on site, and in the case of MRI, within the examination room.
- 6.11 Equipment shall be appropriate for the patient population and the procedure(s) performed.

- 6.12 Drugs and equipment for the management of potential complications of sedation shall be immediately available.
- 6.13 If intravenous sedation is performed, equipment for continuous pulse oximetry shall be used.
- 6.14 For paediatric patients, sedation monitoring equipment shall be capable of measuring saturating end tidal CO₂ and non-invasive blood pressure. There shall be separate saturation monitoring for the recovery area and there shall be facilities and equipment for the endotracheal intubation of children.
- 6.15 Equipment for sedation and monitoring of sedated patients within the MRI examination room shall be certified MRI-compatible.

Anaesthesia and Monitoring

- 6.16 Where appropriate to patients and procedure(s) performed, equipment for general anaesthesia and the monitoring of patients shall be available on site, and in the case of MRI, within the examination room.
- 6.17 Paediatric anaesthetist shall be available for paediatric cases.
- 6.18 Anaesthetic monitoring equipment shall be capable of measuring saturating end tidal CO₂ and non-invasive blood pressure.
- 6.19 There shall be separate saturation monitoring for recovery area and there shall be facilities and equipment for endotracheal intubation of children.

Resuscitation Equipment

6.20 Appropriate resuscitation equipment shall be available on site for contrast reactions.

Interventional Radiology

6.21 There must be ready access to complete emergency resuscitation equipment and drugs, and staff shall be trained in their use.

Nuclear Medicine

6.22 Facilities shall be available for cardio-pulmonary resuscitation and basic life support appropriate to the level of cardiac stress testing performed.

EQUIPMENT CHECKS

- 6.23 All equipment shall be subjected to regular maintenance in accordance with the manufacturers' specifications and procedures manuals.
- 6.24 Radiation measuring devices such as gamma, beta counters and isotope calibrators and Geiger Muller tubes need to be checked for accuracy and precision, by means of a regular Quality Assurance Program.
- 6.25 Acceptance testing is intended to measure quantifiable system parameters which may then be compared to the manufacturer's specification. A complete evaluation of the system performance shall be conducted by a qualified service engineer after completion of installation and prior to patient imaging.
- 6.26 Preventive maintenance shall be scheduled, performed and recorded by qualified personnel on a regular basis.
- 6.27 Testing of system parameters pertaining to each piece of equipment shall be documented. E.g. for MRI, the system parameters shall include:
 - a. Magnetic field homogeneity,
 - b. RF shield integrity,
 - c. RF calibration,
 - d. System signal to noise ratio,
 - e. Signal uniformity,
 - f. Geometrical distortion, and
 - g. Slice thickness and positioning accuracy or equivalent tests of gradient performance and RF pulse characteristics.

7. PATIENT MANAGEMENT

- 7.1 All patients shall have access to appropriate information to make an informed decision including:
 - a. Pre-procedure preparation and/or instructions, and
 - b. Post-procedure and/or discharge instructions.
- 7.2 Patient waiting areas shall be located and, if necessary shielded, so that exposure from radiation sources is as low as reasonably achievable **Sedation and Anaesthesia**

- 7.3 The site shall ensure that sedated patients are discharged in the care of a responsible adult after appropriate recovery, with appropriate instructions concerning driving, operation of equipment, etc.
- 7.4 The site shall develop guidelines for identification of patients not suitable for intravenous sedation in the absence of an anaesthetist.

Patient Identification

- 7.5 There shall be procedures to ensure that every report is correctly identified to the patient.
- 7.6 On presentation, patient identification and details shall be verified. Discrepancies on the request/ referral forms must be shall and a record kept of the outcome shall be maintained.
- 7.7 Records relating to any given patient shall be uniquely identified through all stages of the procedure. Such records shall include worksheets, checklists, films, etc. Identification may be achieved by use of a unique session number, patient's full name, identification number, date of birth, etc.

Patient Needs Assessment

7.8 Information relevant to the studies shall be obtained and recorded prior to the examination. Relevant information may include allergies, pregnancy status and previous studies. Additional specific information shall be obtained and recorded prior to patients undergoing special examinations such as MRI, angiography, prostate biopsy.

Patient Infection Control

Multi-dose Vials of Contrast Media

- 7.9 The use of multi-dose vials of contrast media or radiopharmaceuticals is acceptable if the following procedures are used:
 - a. Withdrawal of contrast media or radiopharmaceuticals under strict aseptic conditions,
 - b. Use of new needles and syringes for re-entering vials even for the same patient's use, and
 - c. Discarding of any contrast media or radiopharmaceuticals beyond their expiration time.

Patient Preparation for Interventional Radiology

- 7.10 Adequate provision must be made for patient preparation and observation post-procedure. This may be within the radiology department, a short stay unit or in the hospital wards.
- 7.11 Personnel, equipment and facilities shall be available for emergency resuscitation.

Patient Safety

7.12 Female patients of childbearing age shall be queried if they are pregnant. If they are or are suspected to be pregnant, the specialist shall decide whether to proceed with the procedure. If the specialist decides to proceed, the patient shall be advised of the risk involved and documented evidence shall be available.

Diagnostic Mammography

7.13 The average glandular dose as determined by the doctor must not exceed 2mGys (200mrads) per view, using the RMI-156 phantom or another equivalent constitution specific doses.

Fluoroscopy

- 7.14 A log of screening times for all fluoroscopic examinations shall be kept.
- 7.15 An appropriately equipped emergency cart shall be immediately available to treat serious adverse reactions and for resuscitation in case of respiratory or cardiac arrest within the MRI suite.

Nuclear Medicine

- 7.16 Instructions shall be given to the patient, in particular for therapeutic procedures involving potentially larger exposures.
- 7.17 Appropriate procedures regarding pregnant and breast feeding patients shall be observed, including warning signs, verbal enquiry and the issue of special instructions to the patient when required.

8.0 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

- 8.1 At the time of installation (as part of the commissioning procedure) and after major maintenance or software upgrades, quality control procedures shall be performed.
- 8.2 Quality control procedures shall be performed regularly in accordance with manufacturer's recommendations.
- 8.3 Criteria used for the assessment of quality control results and the action to take in the event of unacceptable results shall be documented.
- 8.4 A record shall be kept of corrective action taken in response to unacceptable quality control results and shall include
 - a. Equipment evaluation,
 - b. Suspension of patient measures, and
 - c. Reanalysis of quality control data.
- 8.5 Table 1 specifies the recommended calibration and performance checks of equipment commonly used in medical imaging facilities.
- 8.6 A monthly check for laser printers shall be required for all modalities in Table 1.

9.0 WASTE MANAGEMENT AND OCCUPATIONAL SAFETY

- 9.1 The practice is to comply with the Radiation Protection Act 2007.
- 9.2 Regarding waste management, the practice is recommended to refer to ISO 14001:2004 (Environmental management systems Requirements with quidance for use).
- 9.3 Regarding Occupational Safety, the practice is recommended to refer to OHSAS 18001:2007 (Occupational Health & Safety Management / SS 506 part 1:2004 (Occupational safety and health (OSH) management system).

TABLE 1: RECOMMENDED CALIBRATION AND PERFORMANCE CHECKS OF EQUIPMENT COMMONLY USED IN MEDICAL IMAGING FACILITIES

A) General Radiography: Plain film

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
1	Reject Film Analysis	Monthly	No. of reject films/images & reasons for reject	Reject rate should be at 5% of total general radiography workload according to published literature. (based on conventional)	To ensure a system of tracking rejected images and reasons for reject in order to improve quality of imaging
2	Light beam diaphragm test	Monthly	Alignment of light beam	Acceptance range: +/- 1 cm	To ensure light beam diaphragm is effectively restricting the x-ray beam to the area lit by the collimator light to prevent repeat x-rays due to inaccuracies of the collimator light
3	kVp accuracy / consistency test	Quarterly / Yearly	kVp output by X-ray generator	Acceptance range: +/- 5% deviation	To ensure correct kVp output in radiation exposure
4	mAs accuracy / consistency test	Quarterly / Yearly	mAs output by X-ray generator	Acceptance range: +/- 5% deviation	To ensure correct mAs output in radiation exposure

B) <u>Mammography</u>

Mammography Quality Control to be performed according to American College of Radiology (ACR) Quality Control Manual 1999

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
1	Optical Density Test	Daily	Optical Density	+/- 0.15 from baseline OD	-
2	Processor Sensitometry test	Daily	a) Speed Index (SI)	Within +/- 0.15 of established operating levels	Procedure can be found in American College of Radiology – Mammography Quality control Manual
			b) Control Index (CI)	Within +/- 0.15 of established operating levels	-
			c) Value of Base + Fog (BF)	< +0.03 of established operating level	-
3	ACR Phantom Image test	Weekly	a) Film background OD	Manufacturer recommendation	Procedure can be found in American College of Radiology – Mammography Quality control Manual
			b) Contrast	Baseline +/- 0.05	-

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
			c) Test object Score	Minimum 4 Fibers, 3 Specks group, 3 Masses	-
			d) Density Difference	>/= 0.40	-
4	Reject Analysis	Monthly	Percentage of rejects over total film use	< 5%	Film that are rejected are evaluated based on Positioning, Exposure, Artifacts and Others
5	AEC Calibration Test	Quarterly	Optical Density	OD of film fall within +/- 0.15 of the mean OD for 2cm,4cm and 6 cm Perpex	This should be in a range of 1.6-2.0
6	Screen Film Contact	Six-monthly	Poor contact will seen as darker area	Material use : wire mesh of 40 wires per inch Dark area should not be more than 10 mm	Procedure can be found in American College of Radiology – Mammography Quality control Manual
7.	Darkroom Fog Test	Six-monthly	Optical Density Difference	Less than or equal to 0.05 for 2 minutes exposure to safelight	Difference in Densities are measure on two different area that are exposed and unexposed to safelight
8	Compression Force Test	Six-monthly	Compression force	= 10kg</td <td>Optional, some centres are done by the engineer</td>	Optional, some centres are done by the engineer

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
9	Densitometer Calibration Check	Six-monthly	Optical Density	Material use: Calibration Verification Reference Strip by Manufacturer and X-RITE step Densitometer compare strip value with measured OD.	-
				It must fall within +/- 0.03 OD for 0 to 3.0 OD and +/- 3% for 3.0 – 4.0 OD	
10	Screen Uniformity Test	Yearly	a) Standard Deviation of Optical Density	< 0.05	-
			b) Difference in Max. and Min Optical Density	< 0.30	-
11	View-box check	Weekly	Check for marks	No marks seen	Procedure can be found in American College of Radiology – Mammography Quality control Manual
		Yearly	a) Luminance b) I luminance	a) 3000 cd/sq m b) <50 lux	Once can visualize detail at an optical density of 3.10

C) <u>Ultrasound</u>

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
1.	Sonographic Scanner	2 times / year	Display monitor set- up and fidelity	Number of grey scale pattern steps visible should not decrease more than 2.	Verification that contrast and brightness settings are in baseline positions. Evaluation of number of grey scale test pattern steps visible. Evaluation of clarity of displayed text.
2.	Sonographic Scanner	2 times / year	Image uniformity	Evaluation of a uniform region of tissue-mimicking phantom and identification of deviation from smooth tissue texture.	No significant non-uniformities
3.	Sonographic Scanner	2 times / year	Depth of penetration/ visualisation	<6 mm change in depth of penetration/ visualisation.	Evaluation of maximum depth of either ultrasound speckle or object perception.
4.	Sonographic Scanner	2 times / year	Hard copy fidelity	No significant change from baseline images.	Comparison of on-screen image and hard copy image. Verification that the weakest echoes visible on the display are visible in the hard copy image. Comparison with baseline image.

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
5.	Sonographic Scanner	2 times / year	Distance Accuracy	Vertical measurement error less than 1.5 mm or 1.5%. Horizontal measurement error less than 2 mm or 2%.	Measurement of known distances in vertical and horizontal directions.
6.	Sonographic Scanner	2 times / year	Anechoic object imaging	No major distortion or change from baseline performance.	Evaluation of image quality. Comparison with baseline images.
7.	Sonographic Scanner	2 times / year	Axial resolution	Resolution ≤□1 mm. No significant change from baseline values.	Evaluation of full-width half- maximum (FWHM) from profile. OR Evaluation of filament targets in an axial resolution grouping.
8.	Sonographic Scanner	2 times / year	Lateral resolution or response width	FWHM < 0.8 mm Image width or spacing between targets < 1.5 mm. No major change from baseline values.	Measurement of filament image width. OR Evaluation of FWHM from image profile OR Evaluation of filament targets in a lateral resolution grouping.
9.	Sonographic Scanner	2 times / year	Ring down or dead zone	Dead zone < 4 mm (for > 7 MHz transducer).	Imaging of filament targets near scanning window. OR Evaluation of image texture features.

Source: Appendix M, BreastScreen Aoearoa National Policy and Quality Standards – Feb 2004

Based on American Association of Physicists in Medicine (AAPM) recommendations and American College of Radiology Ultrasound (ACR 1998 a) and Ultrasound Guided Breast Biopsy Accreditation Programmes,

ACR 1998 b (ACR 1998 b.).

D) <u>Nuclear Medicine</u>

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	Acceptance Criteria General Procedures and / or Remarks
1.	Gamma Camera	Daily	Photopeak & Energy window setting	⁵⁷ Cobalt flood source or ^{99m} Technetium unsealed check source or other suitable sources	Photopeak centered for radionuclide with a 20% energy window.
		Daily	Uniformity (Extrinsic or Intrinsic)	⁵⁷ Cobalt flood source or ^{99m} Technetium point source or other suitable sources	Measure central & useful FOV integral & differential uniformity. Reference*
		Weekly	Centre of Rotation (COR) Only for SPECT gamma cameras	^{99m} Technetium check source	COR error <0.5pixels Method specified by equipment vendor.
		Quarterly	Spatial Resolution	4-quardrant bar phantom	Measure FWHM = 1.75 x smallest resolvable spacing. Reference*
		At least quarterly or when necessary	Energy & Uniformity correction tables	⁵⁷ Cobalt flood source or ^{99m} Technetium point source	Method specified by equipment vendor.

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	Acceptance Criteria General Procedures and / or Remarks
		At acceptance testing	Sensitivity	99mTechnetium source	Measure counts/minute/activity. Reference*
		At acceptance testing	Count rate characteristics	Varying ^{99m} Technetium activities	Measure & plot observed counts/time versus activity. Reference*
2.	Dose calibrator	Daily	Constancy with long half-life radionuclides	Calibrated & traceable sealed reference sources of ¹³⁷ Caesium & ⁵⁷ Cobalt	Percentage difference between measured & theoretical activities <5% for ¹³⁷ Caesium & ⁵⁷ Cobalt
		Semi annually	Linearity response to ^{99m} Technetium	Varying 99mTechnetium activities	Measure the decaying 99mTechnetium over 4 half-lives. Plot semi-log of activity versus time to obtain decay graph of 99mTechnetium
3	PET/CT	Daily	CT quality	CT Phantom	Generally <±4 Hounsfield units
		Daily	PET	Sealed ⁶⁸ Ge phantom	Range between 1.5 to 3 Chi squared
		Daily	PET & CT bed alignment test	Sealed ⁶⁸ Ge phantom	Test to ensure PET & CT images are aligned

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	Acceptance Criteria General Procedures and / or Remarks
4	DEXA	Daily	Repeatability of the phantom's BMD results	Anthropomorphic (or quasi-anthropomorphic) phantom	Long term statistical analysis of mean BMD value within a tolerance of ±1.5% or manufacturer's limit

Reference*: NEMA NU 1-1994 Performance Measurements of Scintillation Cameras, NEMA: National Electrical Manufacturers' Association

Reference**: NEMA NU2-2001 PET performance standards

FOV: Field of View

E) Magnetic Resonance Imaging

Reference: American Collage of Radiology MRI Quality Manual (2004)

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria/ General Procedures and / or Remarks
1.	MRI scanner	At least weekly	General Condition of the system	Table motion, console function, RF door seal, room temperature, patient monitors, cryogen levels, and other aspects of the imaging environment
2.	MRI scanner	At least quarterly	Centre Frequency and Transmitter Gain	 Centre Frequency Record center frequency value on ACR phantom or manufacturer's phantom Automated analysis and recording often available on modern MRI systems Specific but not sensitive Action Criteria:
				 Action Criteria: Change in Hz from previous day > 2 * resonant frequency in MHz suggestive of Magnet drift and RF instability Transmitter Gain Reflects power required to optimize RF pulse: Depends on coil, phantom, pulse sequence, etc. Should remain constant over time if nothing in pulse

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria/ General Procedures and / or Remarks
3.	MRI scanner	At least quarterly	Geometric Distortion	 Criterion: ± 2 mm Measure distance along main axes of phantom Compare with known values Potential Causes of Geometric Accuracy Failures: Phantom mispositioning Gradient miscalibration Bo inhomogeneity Ferromagnetic objects in magnet Poor magnet shimming Gradient non-linearity Inappropriate receiver bandwidth Poor eddy current compensation Combination of two or more of above

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria/ General Procedures and / or Remarks
4.	MRI scanner	At least annually	High Contrast Resolution	Criterion: Must be able to resolve 1.0 mm holes vertically and horizontally.
				Evaluate conspicuity of holes arranged in two square arrays
				Specific but not sensitive
				 Action Criteria: Any reduction in # of holes seen suggestive of:
				- Increased eddy currents
				- Poor gradient calibration
				- Poor Bo uniformity
				- Reduced stability of system
5.	MRI scanner	At least	Low Contrast	Criterion ≥ 9 spokes
		annually	Resolution	Sensitive but not specific
		 Action Criteria: Slice used dependent on Bo field strength. Sustained 5 row decrease in number of hole sets seen. Suggestive of: 		
				- Reduced stability of system

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked		ceptance Crit marks	eria/ G	eneral Prod	cedures and / or
7.	MRI scanner	At least weekly	Film Quality Control	•	View SMPTE patches Film 6 on 1, 4 Plot OD of 10 Observe film f Action Criteria SMPTE patch 0 10% 40% 90%	on 1 if %, 40% for artifa a: OD 2.45 2.10 1.15 0.30	necessary 6 & 90 & pate acts Control Limit ±0.15 ±0.15 ±0.15 ±0.08	on densitometer. I levels: 0/5% & 95/100% I ches Check optical densities of

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria/ General Procedures and / or Remarks	
8.	MRI scanner	At least annually	Magnetic Field Homogeneity	Magnetic field homogeneity can be characterized using FWHM of resonance peak.	
9.	MRI scanner	At least annually	Slice Position Accuracy	 Criterion: < 5mm Uses Crossed-Wedges as Reference for Positioning and Slice Spacing Accuracy MRAP pass criterion: magnitude of bar length difference ≤ 5 mm. The actual displacement is ½ of the measured difference. Causes of poor performance: Operator error Table positioning shift Miscalibrated gradients High Bo inhomogeneities 	
10.	MRI scanner	At least annually	Slice Thickness Accuracy	 Criterion: 5.0±0.7 mm Slice thickness measured should be ± 0.7 mm of prescribed value 	

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria/ General Procedures and / or Remarks
11.	MRI scanner	At least annually	Radiofrequency Coil Checks	 Must assess SNR, uniformity, and ghosting ratio for every volume coil. Signal-to-noise ratio: Percentage integral uniformity: Criterion: PIU ≥ 87.5% Ghost Ratio: Criterion: ≤ 0.025
12.	MRI scanner	At least annually	Inter-Slice Radiofrequency Interference	-
13.	MRI scanner	At least annually	Soft-Copy Displays (Monitors)	 Max luminance (WL/WW min): ≥90 Cd/m2 Min luminance: <1.2 Cd/m2 Luminance uniformity: Each of the luminance values obtained at the four corners of the screen should be within 30% of the maximum value measured at the center (WL/WW min). Resolution: Use SMPTE 100% contrast patterns Spatial accuracy: Use SMPTE grid pattern
14.	MRI scanner	At least twice yearly	MRI contrast injectors	Specific QA tests by service vendor

F) <u>CT Scanner</u>

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	General Procedures and / or Remarks
1	CT scanner	Daily	 Visual Inspection: All panel switches, lights & technique indicators Radiation exposure warning light at control and entrance doors X-ray production indicator on equipment Aural communication CCTV camera & monitor Protocols/technique chart 		 All panel switches, lights & technique indicators are functional Verify radiation exposure warning lights are functional X-ray production indicator is functional (both audio & visual indicator) Verify aural communication between patient & operator is functional Verify CCTV camera & monitor is functional Protocol/ technique chart is readily available for reference

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	General Procedures and / or Remarks
2	CT scanner	Daily	Warm up and Air-calibration	-	 Ensure gantry is cleared of the CT table & other objects Perform the standard
					 warm up & air calibration. Take note of any system error/message during the process
3	CT scanner	Daily	 CT Number for water Homogeneity test & standard deviation Noise Image uniformity Artifact evaluation 	Water phantom	 Mean HU of each ROI should be within 0 +/- 5 HU for water Standard deviation should be <10 Check image for uniformity appearance & any presence of artifacts, such as streaks & ring artifacts
4	CT scanner	At least once every 6 months	Table position accuracy	Ruler with mm markings, tape	The actual table movement must be within +/- 1mm of the expected table movement

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	General Procedures and / or Remarks
5	CT scanner	At least once every 6 months	Slice locator to slice location illuminator registration accuracy (verify the visible light slice locator illuminates the same location as is indicated by the topographic slice locator indicator on the operator's console)	 A large scan phantom such as a CTDI phantom Straight pin Tape 	The needle to appear within 2mm of the planned scan slice
6	CT scanner	At least once every 6 months	Distance Measurement accuracy	Phantom containing objects with known dimensions such as Catphan or CTDI phantom	The measured values must be within 1% of the actual measurement
7	CT scanner	Preferably once annually	Slice thickness accuracy	Catphan or equivalent phantom	The measured values must be within the specified tolerance quoted by the vendor. Alternatively, the measured values should be within +/- 1mm for nominal slice thickness of 5 to 15mm; & within 0.5mm for slice thickness <5mm

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	General Procedures and / or Remarks
8	CT scanner	Preferably once annually	Collimator accuracy for different slice thickness	 A piece of packed film, pen & ruler. Alternatively with dedicated vendor software 	 The measured width shall be within +/- 4mm of the slice thickness selected Alternatively, the use of dedicated vendor software may also be used for this test
9	CT scanner	Preferably once annually	Light-Field Accuracy	 A piece of packed film, push-pin, pen, ruler Alternatively with dedicated vendor software 	 The distance between the center of the opaque line & line connecting the holes in the film shall not exceed 2mm Alternatively, the use of dedicated vendor software may also be used for this test
10	CT scanner	Preferably once annually	CT Dose Index (to compare exposure readings to manufacturer specified CTDI values)	CTDI Body and Head phantoms, CT probe and electrometer	Body & Head Phantom Test: The CTDI values must be within +/- 25% of the manufacturer's specifications

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	General Procedures and / or Remarks
11	CT scanner	At least once annually	Low contrast resolution	Catphan or equivalent phantom	Compare the observed results to the expected results provided by the vendor. Determine whether the observed results are within the specified tolerances quoted by the vendor
12	CT scanner	At least once annually	High contrast resolution	Catphan or equivalent phantom	Compare the observed results to the expected results provided by the vendor. Determine whether the observed results are within the specified tolerances quoted by the vendor.
13	CT scanner	At least once annually	Exposure Reproducibility	 CTDI Body or Head phantom, CT probe and electrometer Alternatively, an electrometer with appropriate detector may also be used to perform this test. 	 Make 4 exposures at a specified technique Record the exposure values The exposure value shall not exceed the mean exposure by +/- 5% of the mean exposure value

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Standard or Reference Materials/Equipment	General Procedures and / or Remarks
					This test may also be carried out on the stationary x-ray tube using an electrometer with appropriate detector
14	CT scanner	At least once annually	mAs Linearity	 CTDI Body or Head phantom, CT probe and electrometer Alternatively, an electrometer with appropriate detector may also be used to perform this test. 	 Compare the output of the individual mAs values to the exposure dose values. The percentage of linearity in exposure dose values must not exceed 10% This test may also be carried out on the stationary x-ray tube using an electrometer with appropriate detector
15	CT scanner	At least twice annually	CT contrast injectors		Specific QA tests by service vendor