ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MI 001
Specific Criteria for Medical Imaging

Technical Note MI 001, 25 October 2021
The SAC Accreditation Programme is managed by Enterprise Singapore

1. INTRODUCTION

1.1 This document describes the specific requirements the radiology facility needs to comply with to be accredited.

1.2 The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', SAC-01, SAC 02, SAC SINGLAS 001 and SAC SINGLAS 003 – MED/MI published by SAC-SINGLAS shall be studied in conjunction with this document.

1.3 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 The examinations shall be performed under the supervision of one of the following, as required in the Private Hospitals and Medical Clinics (PHMC) Act:

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. As evidence of continuing competence in the interpretation and reporting of these examinations, the supervising practitioner should have CME in accordance with SMC requirements. The CME should include general Radiology and a minimum of 200 x-ray studies reported per year is recommended in order to maintain skills.

d. Alternatively, 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 500 mammograms per year.

Mammography Radiographer– All Mammography Radiographers shall be diagnostic radiographers registered with the Allied Health Professionals Council and 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

Ultrasound Radiographer / Sonographer – All Ultrasound radiographers / Sonographers shall complete a training programme approved by the Head of Department or possess an advanced diploma or higher qualification in Ultrasound. The Ultrasound Radiographer / 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.

MR Radiographer – All MR Radiographers shall be diagnostic radiographers registered with the Allied Health Professionals Council and 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.

CT Radiographer – All CT Radiographers shall be diagnostic radiographers registered with the Allied Health Professionals Council and have completed a training programme approved by the Head of Department or possess a MSc in CT or cross-sectional imaging. The CT 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 / technologist - Nuclear Medicine Radiographers/ technologist shall complete a training programme approved by the Head of Department or possess a degree in Nuclear Medicine. 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 - A specialist medical practitioner registered with the SMC as a specialist in the field of diagnostic Radiology. As evidence of continuing competence in the interpretation and reporting of these examinations, the supervising practitioner should have CME in accordance with SMC requirements. A minimum of 200 x-ray studies reported per year is recommended in order to maintain skills and should also include general radiography.

Radiographer - All radiographers shall be diagnostic radiographers registered with the Allied Health Professionals Council and shall possess a recognised 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. Facilities shall maintain appropriate procedures and records of training provided to the nurses.

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 are present and in a state of readiness.

2.5 Each unit should exercise supervision of the staff for compliance with the ISO 15189:2012 requirements. In general, the supervision entails the following:

2.5.1 **MRI**

a. Each MRI unit must have one or more supervising radiographers with overall responsibility for:

i. Running the unit,

ii. Supervising the staff, and

iii. 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.

b. 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.

c. All radiologists (working under the supervising radiologists) must have the responsibility for:

i. Reviewing clinical indications for examinations,

ii. Specifying the use and dosage of contrast agents, specifying the pulse sequences being performed, and

iii. Assuring the quality of both the images and interpretations.

2.5.2 **Nuclear Medicine**

a. A nuclear medicine specialist must be responsible for all components of nuclear medicine service including:

i. Determining the appropriateness of and monitoring the quality of the procedure,

ii. Maintain all necessary licences for the use and storage of each radionuclide,

iii. Assessing and influencing the outcome of the procedure, and

iv. Providing a final scan report.

2.6 Supervision of Trainees

a. A qualified specialist shall be available to provide appropriate on-site direct supervision of trainee nuclear medicine specialists at all times in-hours, and be available to provide advice and backup at all times out-of-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.

2.7 Radiation Safety Officer

Each practice must appoint a Radiation Safety Officer (RSO) The RSO is responsible in:

a. Ensuring that the practice is adhering to the Radiation Protection Act and the subsidiary's Regulations,

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 performed 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. 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 Some quality control images, records and data shall be stored for the lifetime of the machine while others such as raw data shall be kept for a minimum period defined by the institution.

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,

b. 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 non-radioactive 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. A description of any unusual features prior to, during or following the study,

b. 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 than 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 sterilization / 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.

3.15 **Specific Documentation Requirement for Mammography**

3.15.1 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.

3.15.2 Cassette/ screen must be uniquely identified on screen to identify screens with artifacts or defects.

3.15.3 With the exception of the markers indicating laterally and view, all labels must be placed as far from the breast as possible.

3.16 **Specific Documentation Requirement for Nuclear Medicine**

3.16.1 For Nuclear Medicine, the following information shall be included for Anger-type gamma cameras, SPECT/CT 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.

3.17 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.

3.18 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,
l. 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

4.2 Legislation Pertaining to Radiation Safety

Practices must be aware and comply with legislation covering:

a. 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,
f. Reporting of radiation accident and serious reportable events

4.3 Documented safety policies and procedures must be reviewed at least annually by the supervising specialist(s)

4.4 Specific Requirement for Magnetic Resonance Imaging

4.4.1 Practices must take into consideration potential interactions of the magnetic field with ferro-magnetic objects in the environment of the scanner.

Consideration must also be given for potential hazards posed by objects implanted within the patient as well as within personnel in the area.

4.4.2 Policies must include**:**

a. Exclusion of the general population outside the 5 Gauss line with appropriate warning signs, and

b. Procedures to screen patients and all other personnel entering the MRI examination room for intracranial aneurysm clips, cardiac pacemarkers, intra-ocular foreign bodies and other contraindicated devices.

4.4.3 MRI safety education must be provided for all staff accessing the MRI area.

4.4.4 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

4.4.5 All equipment in the MRI imaging facility shall be MRI compatible.

4.5 **Specific Requirement for Nuclear Medicine**

4.5.1 Appropriate procedures and resources for handling accidents involving radioactive materials and for subsequent decontamination must be available.

4.5.2Radiation monitoring equipment for the detection of contamination and radiation exposure levels must be available.

4.5.3 Materials presenting a hazard of airborne transport should be handled in fume hoods.

4.5.4 Provisions for emergency eyewash should be clearly identified and appropriately labelled.

4.5.5 Suitable protective clothing/ equipment such as eye protective devices, impervious aprons should be available.

4.5.6 There should be provisions for flushing materials from the skin rapidly in the event of accidental splashing.

4.5.7 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. Decontamination facilities.

4.5.8 To comply with the MOH standards for the provision of Nuclear Medicine imaging, therapy and assay services, 28 May 2019.

4.6 **Specific Requirement for Interventional Radiology and Angiography**

4.6.1 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.

4.6.2 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.

5.5 **Administration of Radionuclides**

5.5.1 The activity of the radioactive material to be dispensed for administration to patients shall be calculated according to an established protocol.

5.5.2 The activity of radioactive material to be administered to each patient shall be measured just prior to administration.

5.5.3 The standard activity of radioactive material administrated for each procedure must be established and recorded in the procedure manual.

5.6 Handling of Radioactive Substances

5.6.1 Appropriate procedures must be maintained for the identification of radiation areas and the receipt, storage and disposal of radioactive substances.

5.6.2 The facility must possess radiation safety and radioactive waste manuals, which clearly stipulates the proper use, handling and disposal of radioactive substances.

5.7 Requirements on Radiopharmaceuticals

5.7.1 Onsite refers to preparation of radiopharmaceuticals at the facility. Off site refers to sites where radiopharmaceuticals are utilised only.

5.7.2 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. Shielded biosafety cabinet shall be used for radiopharmaceutical compounding,

e. Aseptic procedures must be used when handling all components and preparations for potential parenteral or ophthalmic administration,

f. Radiopharmaceutical purity and labelling efficiency must to be checked routinely, and

g. 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).

5.7.3 Patient identification must be verified prior to administration of radiopharmaceuticals.

5.7.4 Appropriate records must be maintained of the following:

a. Radiopharmaceutical receipt,

b. Radiopharmaceutical preparation,

c. 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

5.8 Blood Products

5.8.1 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.

5.8.2 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 of the approval to deviate from the standard documented protocols and the changes adopted.

5.8.3 Any changes adopted should offer benefit to the patient over those currently in use.

5.8.4 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 AVAILABIILTY

6.1 Diagnostic Ultrasound

6.1.1 Equipment for vascular studies must be capable of colour Doppler imaging

6.1.2 Transvaginal probes should be available for pelvic and obstetric scans

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

6.2 Diagnostic Mammography

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

6.3 Interventional Radiology

6.3.1 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.

6.3.2 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.

6.3.3 Cineradiology is not recommended for diagnostic angiography on a routine basis because of increased radiation and contrast material doses.

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

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

6.3.6 Sedation Equipment and Monitoring Sedated Patients

a. Equipment for sedation and monitoring of sedated patients shall be available on site, and in the case of MRI, within the examination room.

b. Equipment shall be appropriate for the patient population and the procedure(s) performed.

c. Drugs and equipment for the management of potential complications of sedation shall be immediately available.

d. If intravenous sedation is performed, equipment for continuous pulse oximetry shall be used.

e. For paediatric patients, sedation monitoring equipment shall be capable of measuring saturating end tidal CO_2 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.

f. Equipment for sedation and monitoring of sedated patients within the MRI examination room shall be certified MRI-compatible.

6.3.7 Anaesthesia and Monitoring

a. 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.

b. Paediatric anaesthetist shall be available for paediatric cases.

c. Anaesthetic monitoring equipment shall be capable of measuring saturating end tidal CO_2 and non-invasive blood pressure.

d. There shall be separate saturation monitoring for recovery area and there shall be facilities and equipment for endotracheal intubation of children.

6.3.8 Appropriate resuscitation equipment and drugs (for interventional radiology) shall be available on site for contrast reactions and staff shall be trained in their use.

6.4 Nuclear Medicine

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

6.5 EQUIPMENT CHECKS

6.5.1 All equipment shall be subjected to regular maintenance in accordance with the manufacturers' specifications and procedures manuals.

6.5.2 Radiation measuring devices such as gamma, beta counters and dose calibrators and Geiger Muller tubes need to be checked for accuracy and precision, by means of a regular Quality Assurance Program.

6.5.3 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.

6.5.4 Preventive maintenance shall be scheduled, performed and recorded by qualified personnel on a regular basis.

6.5.5 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.

6.5.6 Table 1 specifies the recommended calibration and performance checks of equipment commonly used in medical imaging facilities.

6.5.7 A monthly check for laser printers shall be required for all modalities in Table 1.

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.

7.3 Sedation and Anaesthesia

7.3.1 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.

7.3.2 The site shall develop guidelines for identification of patients not suitable for intravenous sedation in the absence of an anaesthetist.

7.4 Patient Identification

7.4.1 There shall be procedures to ensure that every report and image are correctly identified to the patient.

7.4.2 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.

7.4.3 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.

7.5 Patient Needs Assessment

7.5.1 The written or electronic request, originated from attending Doctor or properly licensed health care worker involved in patient clinical problem shall provide adequate information to show the necessity of the examination and enable appropriate interpretation of result.

7.5.2 Information relevant to the studies 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.

7.6 Patient Infection Control

7.6.1 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.

7.7 Patient Preparation for Interventional Radiology

7.7.1 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.

7.7.2 Personnel, equipment and facilities shall be available for emergency resuscitation.

7.8 Patient Safety

7.8.1 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.

7.8.2 <u>Diagnostic Mammography</u>

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.

7.8.3 Fluoroscopy

a. A log of screening times for all fluoroscopic examinations shall be kept.

b. 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.

7.8.4 Nuclear Medicine

a. Instructions shall be given to the patient, in particular for therapeutic procedures involving potentially larger exposures.

b. 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 Digital radiographic devices shall provide images that conform to the DICOM standard. The details of the requirements in reflected in **Table 2**.

8.6 Details of image acquisition such as kVp, mAs, Patient ID, radiology facility, site, side of study and exposure indicators should be recorded in the DICOM. Exposure indicators should be monitored in a regular basis.

8.7 As a minimum quality check, a test image such as AAPM TG18-QC test pattern should be captured, transmitted, archived, retrieved and displayed at appropriate intervals.

8.8 As a test of display fidelity, TG18-QC pattern data files sized to occupy the full area used to display images on the monitor should be displayed. As a dynamic range test, both the 5% and 95% areas should be seen as distinct from the respective adjacent 0% and 100% areas.

8.9 Hardcopy imager accuracy and stability testing should also be performed and documented.

9.0 Archiving, retention and retrieval of records:

9.1 The facility shall have a written policy and procedure on record retention, of which the minimum requirements shall be:

Type of record	**Retention period**
Diagnostic images kept by the facility	For hardcopies – 6 years For softcopies – infinite retention period
Diagnostic images given to patients	No retention period
Diagnostic radiology patient records	Lifetime of patient plus 6 years

9.2 Written policy and procedures shall be in place to ensure continuity of care, include internal redundancy systems, backup telecommunication links, disaster recovery and business continuity plane.

9.3 When reports and images are stored electronically, the facility shall have mechanism to ensure the image medium is readable at all ages and labelled with the necessary patient information. Media, such as CD, DVD, USB media, shall be stored in a way to maintain its integrity throughout the retention period.

9.4 It is desirable to have mechanism for secure image sharing over the internet. Procedures shall also be in place for importing images and associated information in standard DICOM from physical media and from internet.

10.0 WASTE MANAGEMENT AND OCCUPATIONAL SAFETY

10.1 The practice is to comply with the Radiation Protection Act and the subsidiary regulations.

10.2 Regarding waste management, the practice is recommended to refer to ISO 14001:2004 (Environmental management systems – Requirements with guidance for use).

10.3 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-1) 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.	To ensure a system of tracking rejected images and reasons for reject in order to monitor standard of radiography.
2	Light beam diaphragm test	Monthly	Alignment of light beam	Acceptance range: +/- 1 cm	To ensure light beam diaphragm is accurately aligned to the x-ray beam to prevent repeat x-rays due to inaccuracies of areas of exposure
3	kVp accuracy / consistency test	Yearly	kVp output by X-ray generator	Acceptance range: +/- 5% deviation	To ensure correct kVp output in radiation exposure
4	mAs accuracy / consistency test	Yearly	mAs output by X-ray generator	Acceptance range: +/- 5% deviation	To ensure correct mAs output in radiation exposure
5	View box check	Weekly	Check for marks	No marks seen	To ensure no artefacts caused by marks on view box
		Yearly	Clean diffuser panel and view box	Check diffuser panel, Inspect wiring Inspect view box Measure light output	-
6.	System - sensitometry	Daily	Run calibration strip and set the	According to the manufacturer's instructions.	-

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
			calibration values		
7.	Imaging quality	Monthly	Review for artefacts	No artifact should be detected	-

A-2) Processing Facilities

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
	For Conventional Radiographic (Plain Film) equipment	Annually	Condition of the darkroom (Darkroom integrity, Safe light conditions)	No light leakage	
		Annually	Conditions of all the film screen cassettes	Film and screen should be in good contact No artifact	
		Daily	Film Processor Control Chart Sensitometry of film*	Base + fog index should be: Less than 0.25 Optical Density (OD) - (Other than mammogram) Variation of speed index should be less than 10 % Variation of contrast index should be less than 10 % daily	

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
	For Computed Radiographic (CR) Equipment	Semi-annually and when necessary	Conditions of imaging plates a. Cleaning of imaging plates b. Sensitivity (Uniformity) Test	No artifact on images	
		Weekly	Film Printer* Monitoring Sensitometry of film	Refer to the manufacturer guideline	
	For Digital Radiography (DR) Equipment	Monthly	Calibration of Flat Panel Detector (FPD)	Refer to the manufacturer guideline	
		Weekly	Film Printer* Monitoring Sensitometry of film	Refer to the manufacturer guideline	
	Leakage and Scattered Radiation	Annually	Exposure rate at every occupied area outside the x-ray room and at the position normally occupied by the operator at the control area	Less than 10 µSv per hour	Use of Survey meter

		Annually	Exposure from the leakage radiation at 1 meter from the x-ray tube per hour at every rating specified by the manufacturer	1.0 mGy (100mR) per hour	Use of Survey meter

* If this applicable to the department.

3. Performance and Safety Standard: General X-Ray Equipment

	Parameters	Frequency	Optimum Achievable Standard	General Procedures and / or Remarks
1	X-ray Generator i. Accuracy of kV (kilovolt) ii. Accuracy of exposure time iii. Exposure reproducibility	Acceptance, tube change, annually	Maximum deviation: 5% or 5 kV whichever is greater Maximum deviation: 10% Coefficient of variation (COV) less than 10%	$Coeficient\ of\ variation\ (\%) = \frac{standard\ deviation\ x\ 100\%}{Average\ of\ measured\ mR\ (milli\ Roentgen)}$
	iv. Exposure linearity		Maximum deviation: 10%	$Coeficient\ of\ Linearity\ (\%) = \frac{\left(\frac{mR}{mAs_{max}} - \frac{mR}{mAs_{min}}\right) x\ 100\%}{\frac{mR}{mAs_{max}} - \frac{mR}{mAs_{min}})}$

Parameters		Frequency	Optimum Achievable Standard	General Procedures and / or Remarks
2	<u>X-Ray Beam Limitation</u> i. Beam Collimation (Light/x-ray field congruence) ii. Beam Perpendicularity	Acceptance, tube change, annually	Maximum misalignment: 2% of source-image distance (SID). Less than 2°	
3	X-Ray beam filtration: Half-Value Layer (HVL)	Acceptance, tube change, annually	*Refer to Appendix (A)* *	
4	<u>Image Quality</u> i. Resolution ii. Contrast	Acceptance, tube change, annually	Not less than 1.25 lines pair / mm Average value is 11-12 discs visible	
5	Focal Spot Size	Acceptance, tube change	Less than two nominal focus (< 2 $f_{nominal}$)	

Reference:
1. ACR–AAPM–SIIM PRACTICE GUIDELINE FOR DIGITAL RADIOGRAPHY
2 National Council On Radiation Protection and Measurements, NCRP Report No.99, Quality Assurance for Diagnostic Imaging.
3 AAPM. Report of Task Group No. 10. 1998

B) Mammography

Film screen Mammography

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	-
			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	-
			b) Contrast	Baseline +/- 0.05	-
			c) Test object Score	Minimum 4 Fibers, 3 Specks group, 3 Masses	-
			d) Density Difference	≥ 0.40	-

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
4	Reject Analysis	Monthly	Percentage of rejects over total film use	< 5%	Films 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	Dark area should not be more than 10 mm	Material use : wire mesh of 40 wires per inch
7.	Darkroom Fog Test	Six-monthly	Optical Density Difference	≤ 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	Optional, some centres are done by the engineer
9	Densitometer Calibration Check	Six-monthly	Optical Density	+/- 0.03 OD for 0 to 3.0 OD and +/- 3% for 3.0 – 4.0 OD	Material use: Calibration Verification Reference Strip by Manufacturer and X-RITE step Densitometer compare strip value with measured OD.

S/N	Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
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

CR Mammography System

S/N		Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria
1	Mammography Unit and CR Reader QA	Automatic Exposure Control (AEC) Calibration Testing	Quarterly	Use of 4cm perspex, designated test cassette and consistent AEC detector position. Record either S value or exposure index	S value ±10% of mean for same thickness ± 20% of mean for different thickness (2,4,6 cm) Exposure Index ± 40 of mean for same thickness ± 80 of mean for different thickness (2,4,6 cm)
		System Quality (Phantom) Testing	Weekly	Obtain phantom image using ACR approved phantom. Measurement of optical densities at consistent points on the image to obtain system OD and contrast.	S value Range 50 – 150, with a tolerance of ±10% from baseline value Exposure Index: Range = 2750 – 3100 with a tolerance of ± 40 from baseline value mAs = baseline ± 15% Optical density = aim ± 0.15 Contrast = baseline ± 0.05

S/N		Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria
		AEC Consistency 4cm Perspex Phantom testing	Daily	Use of 4cm perspex, designated test cassette and consistent AEC detector position. Record either S value or exposure index	S value Range 50-150 Tolerance ±10% from baseline Exposure Index Range 1900-2400 Tolerance ±40 from baseline mAs = baseline ±15%
		Compression	Six monthly	Compression Force	Max. motorised compression force in range 150 – 200 newtons (15-20kg)

S/N		Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria
2	Imaging Plate Test	Sensitivity/Uniformity Test	Six monthly	Record of S value or exposure index and mAs value	S value (SV): SV for different plates same size, should be within ± 10% of the mean of all plates SV for different plates different size, should be within ± 20% of the mean of all plates mAs value for different plates same size, should be within ± 10% of the mean of all plates Exposure Index (EI): EI for different plates same size, should be within ± 40 of the mean of all plates EI for different plates different size, should be within ± 80 of the mean for all plates (or as per manufacturer's specs eg. TQT)
		Fog Test	Annually	1. Erase an IP before test 2. Paste the coin to the cassette front of erased IP 3. Leave the cassette at its storage location for 8 hours 4. Remove coin and process the IP 5. Examine the image to see if	Coin should not be visible

				coin is visible	
		Plate Erasure	Daily		
		Cleaning	6 monthly or When necessary		
3	Printer Test	SMPTE/TG 18 Test pattern	Monthly	Print SMPTE/TG 18 test pattern on mammographic film.	5% and 95% contrast squares should be distinguishable. Finest horizontal and vertical line pairs should be visible in all 4 corners. Lines should be straight and even. No artefacts.
		Sensitometry	Daily	Print sensitometric stepwedge on mammographic film.	Speed index : baseline ± 0.15 Contrast index : baselime ± 0.15 Base + fog : baseline ± 0.03 Dmax: >3.5 or manufacturer's recommendation

DR Mammography System

S/N		Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria
1	Mammography Unit	Automatic Exposure Control (AEC) Calibration Testing	Quarterly	Use consistent AEC detector position 2,4,6 cm	Maximum relative deviation for mean pixel value should not exceed 10%
		System Quality (Phantom) Testing	Weekly	Use an ACR approved phantom	Phantom images should clearly show 5 fibres, 4 speck groups and 4 masses.
		Image Receptor Homogeneity/Detector Uniformity	Quarterly or vendor recommendation	Use vendor specific test tool.	Maximum deviation in MPV in ROI< ± 15% of MPV in central ROI
		Artefact Evaluation	Monthly or vendor recommendation	Use vendor specific test tool.	No clinically relevant artefacts such as defective pixels, clusters of defective pixels or defective lines and columns.
		Compression	Six monthly	Compression force	Maximum motorised compression force in range 150-200 N (15-20kg)
2	Printer Test	SMPTE/TG 18 Test pattern	Monthly	Print SMPTE/TG 18 test pattern on mammographic film.	5% and 95% contrast squares should be distinguishable. Finest horizontal and vertical line pairs should be visible in all 4 corners. Lines should be straight and even.

					No artefacts.
		Sensitometry	Daily	Print sensitometric step-wedge on mammographic film.	Speed index : baseline ± 0.15 Contrast index : baselime ± 0.15 Base + fog : baseline ± 0.03 Dmax: >3.5 or manufacturer's recommendation

Digital Display Systems

S/N		Type of test	Frequency of Check	Parameters to be Checked	Acceptance Criteria
1	Monitor QC	SMPTE/TG 18 Test pattern on the monitor	Weekly	5% and 95% contrast squares should be distinguishable. Finest horizontal and vertical line pairs should be visible in all 4 corners. Lines should be straight and even. No artefacts.	All criteria should be met.
2	Monitor Cleanliness	Monitor inspection	Daily		Free from dust, fingerprints and other marks

References:

1. Mammography Quality Control to be performed according to American College of Radiology (ACR) Quality Control Manual 1999
2. The Digital Mammography Quality Control Manual 2016, American College of Radiology

C) Ultrasound

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
1.	Ultrasound machine and all transducer	1. On commission and change of transducer 2. At routine servicing at least twice yearly	Physical and mechanical inspection	-	-
			Image uniformity and artifact survey	No significant non-uniformities or artefacts	Evaluation of a uniform region of tissue-mimicking phantom and identification of deviation from smooth tissue texture.
			Contrast resolution (also referred to as anechoic object imaging)	No major distortion or change from baseline performance.	Evaluation using phantom. Comparison with baseline images.
			Ring down or dead zone	1) Below 7mm for frequency ≤ 3mHz 2) Below 5 mm for frequency 3 < f <7mHz 3) Below 3 mm for frequency ≥ 7mHz	Evaluation of the distance from front face of transducer to first identifiable echo.

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
	Ultrasound machine and all transducer	1. On commission and change of transducer	Geometric accuracy (also referred to as distance accuracy)	Vertical measurement error ≤1.5 mm or 1.5%. Horizontal measurement error ≤ 2 mm or 2%.	Measurement of known distances in vertical and horizontal directions.
			System sensitivity (also referred to as depth of penetration / visualization)	≤ 6 mm change from baseline.	Evaluation of a tissue-mimicking phantom Measurement of maximum depth of object perception.
			Spatial resolution a) Axial b) Lateral	Axial resolutions: • ≤ 1 mm (transducers > 4mHz) • ≤ 2 mm (transducers < 4 mHz) Lateral resolution – table II, reference 1	Evaluation of full-width half-maximum (FWHM) from profile. OR Evaluation of filament targets in an axial or lateral resolution grouping. No major change from baseline values.

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
2.	Ultrasound machine display	1. On commission and change of transducer 2. At routine servicing at least twice yearly	Fidelity of US machine display monitor	Number of grey-scale pattern steps visible should not decrease by more than 2 from control value.	Grey scale test pattern and clarity of displayed text. Verification that contrast and brightness settings are in baseline positions.
3.	Electronic image display	1. On commission and change of transducer	Fidelity of hardcopy or display device used for primary interpretation (eg PACS).	Verification that the weakest echoes visible on the display are visible on hardcopy images or PACS monitor images.	Comparison of machine display images and hardcopy or PACS monitor images.

***For those systems with spectral Doppler and colour-flow imaging capabilities, evaluations of these capabilities should be performed.**

References:

1) Real-time B-mode ultrasound quality control test procedures: A Report of AAPM Ultrasound Task Group No.1. Goodsitt and Carson et al. Med. Phys.25(8), August 1998, p 1385-1406.
2) American College of Radiology ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real time Ultrasound Equipment. Revised 2016 (CSC/BOC). Accessed 20 Nov 2020
3) American Institute of Ultrasound in Medicine AIUM Standards and Guidelines for Accreditation of Ultrasound Practice. Re-approved 16 Jun 2020. Accessed 20 Nov 2020.

Routine Quality Assurance for Diagnostic Ultrasound Equipment (AIUM) Accessed 20 Nov 20205) Royal College of Radiologists Standards for the provision of an ultrasound service. (pg 5 – Standards for ultrasound equipment) Approved 2014, reviewed 2017. Accessed 20 Nov 2020

D) Nuclear Medicine

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

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
		At acceptance testing	Count rate characteristics	Measure & plot observed counts/time versus activity.	Varying ^{99m}Technetium activities
2.	Dose calibrator	Daily	Constancy with long half-life radionuclides	Percentage difference between measured & theoretical activities <5% for ^{137}Caesium & ^{57}Cobalt	Use of Calibrated & traceable sealed reference sources of ^{137}Caesium & ^{57}Cobalt
		Semi annually	Linearity response to ^{99m}Technetium	Varying ^{99m}Technetium activities	Measure the decaying ^{99m}Technetium over 4 half-lives. Plot semi-log of activity versus time to obtain decay graph of ^{99m}Technetium
3	PET/CT	Daily	CT quality	Generally < $\pm$4 Hounsfield units	CT Phantom
		Daily	PET	Range between 1.5 to 3 Chi squared	Use of Sealed ^{68}Ge phantom
		Daily	PET & CT bed alignment test	Test to ensure PET & CT images are aligned	Sealed ^{68}Ge phantom
		Quarterly	2-D-3-D Radioactivity concentration calibration	Deviation less than 5 % from the manufacturer's value	Use of Sealed ^{68}Ge phantom or fillable ^{18}F phantom

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

* FOV: Field of View

Reference:

1) NEMA NU 1-1994 Performance Measurements of Scintillation Cameras, NEMA: National Electrical Manufacturers' Association
2) NEMA NU2-2001 PET performance standards

E) Magnetic Resonance Imaging

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedure 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	Weekly	Centre Frequency and Transmitter Gain	Centre Frequency - Change in Hz from previous day > 2 * resonant frequency in MHz suggestive of Magnet drift and RF instability Transmitter Gain • Should remain constant over time if nothing in pulse sequence or hardware has changed	• Record center frequency value on ACR phantom or manufacturer's phantom • Reflects power required to optimize RF pulse: • Depends on coil, phantom, pulse sequence, etc.

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedure and/ or Remarks
3.	MRI scanner	Weekly	Geometric Distortion	• Criterion: ± 2 mm	• Measure distance along main axes of phantom • 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 Procedure and/ or Remarks
4.	MRI scanner	Weekly	High Contrast Resolution	• 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	Weekly	Low Contrast Resolution	• Criterion ≥ 9 spokes	• Slice used dependent on Bo field strength. Sustained 5 row decrease in number of hole sets seen. Suggestive of: • - Reduced stability of system

<table>
<tr><th>S/N</th><th>Type of Instrument Or Equipment</th><th>Frequency of Check</th><th>Parameters to be Checked</th><th>Acceptance Criteria</th><th>General Procedure and/ or Remarks</th></tr>
<tr><td>6.</td><td>MRI scanner</td><td>At least weekly</td><td>Film Quality Control</td><td>• View SMPTE pattern, verify gray levels: 0/5% & 95/100% patches
•
<table><tr><th>SMPTE patch</th><th>OD</th><th>Control Limit</th></tr><tr><td>0</td><td>2.45</td><td>±0.15</td></tr><tr><td>10%</td><td>2.10</td><td>±0.15</td></tr><tr><td>40%</td><td>1.15</td><td>±0.15</td></tr><tr><td>90%</td><td>0.30</td><td>±0.08</td></tr></table>• Absence of artifacts</td><td>• Film SMPTE test pattern and check optical densities of the grayscale patches within it.
• Film 6 on 1, 4 on 1 if necessary
• Plot OD of 10%, 40% & 90 & patches
• Observe film for artifacts</td></tr>
<tr><td>7.</td><td>MRI scanner</td><td>At least annually</td><td>Magnetic Field Homogeneity</td><td>• Magnetic field homogeneity can be characterized using FWHM of resonance peak.</td><td></td></tr>
</table>

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedure and/ or Remarks
8.	MRI scanner	At least annually	Slice Position Accuracy	• Criterion: < 5mm • MRAP pass criterion: magnitude of bar length difference ≤ 5 mm. • The actual displacement is ½ of the measured difference.	• Uses Crossed-Wedges as Reference for Positioning and Slice Spacing Accuracy • Causes of poor performance: - Operator error - Table positioning shift - Miscalibrated gradients - High Bo in homogeneities
9.	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	
10.	MRI scanner	At least annually	Radiofrequency Coil Checks	• Signal-to-noise ratio: • Percentage integral uniformity: Criterion: PIU ≥ 87.5% • Ghost Ratio: Criterion: ≤ 0.025	• Must assess SNR, uniformity, and ghosting ratio for every volume coil.

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedure and/ or Remarks
11.	MRI scanner	At least annually	Inter-Slice Radiofrequency Interference	-	
12.	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
13.	MRI scanner	At least twice yearly	MRI contrast injectors	• Specific QA tests by service vendor	•

Reference:

1) American College of Radiology MRI Quality Control Manual (2004)

F) CT Scanner

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	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 activation indicator on equipment • Aural communication • CCTV camera & monitor • Protocols/technique chart	-	• Verify all the radiation safety indicators and patient care accessories are functional • Protocol/ technique chart is readily available for reference
2		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

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
3	CT scanner	Daily	• CT Number for water • Homogeneity test & standard deviation • Noise • Image uniformity • Artifact evaluation	• Mean HU of each ROI should be within 0 ± 5 HU for water • Standard deviation should be <10	• Water phantom / vendor test phantom • Check image for uniformity appearance & any presence of artifacts, such as streaks & ring artifacts
4		Half yearly during preventive maintenance service	Table position accuracy	The actual table movement must be within ± 1mm of the expected table movement	Ruler with mm markings, tape
5			Co-incidence of internal scan plane lights and scan plane	The needle to appear within 2mm of the planned scan slice	• Water phantom or equivalent, tape, pin
6			Distance Measurement accuracy	The measured values must be within 1% of the actual measurement	Phantom with known dimensions such as vendor test phantom

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
7	CT scanner	Yearly	Image scan width	The measured values must be within the specified tolerance quoted by the vendor. Alternatively, the measured values should be within +/- 1mm for scan width of 5 to 15mm; & ≤ 0.5mm for slice thickness <5mm	Vendor test software or equivalent phantom
8			Low contrast resolution	Based on manufacturer's specification	• Compare the observed results to the expected results provided by the vendor. • Determine whether the observed results are within the specified vendor test software or equivalent phantom
9			High contrast resolution	Based on manufacturer's specification	Vendor test software or equivalent phantom
10			X-ray generator: Tube potential (kVp)	Within 5%	Use of electrometer

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters to be Checked	Acceptance Criteria	General Procedures and / or Remarks
11	CT scanner	Yearly	X-ray generator: Exposure time accuracy	Within 10%	Use of electrometer
12			CT contrast injector	Based on vendor's specification	Specific QC tests by service vendor.

Table 2: Requirement for digital imaging devices

S/N	Type of Instrument Or Equipment	Parameters to be Checked
1	AEC devices	i) To perform calibration before use ii) Annual check on the calibration status.
2	Imaging plates	Regular maintenance shall be performed and each imaging plate has an unique identification number.
3	Compression	i) Labeled if irreversible compression has been applied and the compression ratio. ii) Ensure no loss of clinically significant information. iii) Consistent presentation of images on workstation is essential.
4	PACs	i) Sufficient bandwidth to deliver expected volumes of images in a timely fashion. ii) Adequate error checking capability. iii) Fast and easy navigation between new and old studies. iv) Window level and adjustment tools. v) Hanging protocols that address the selection of image series and display format shall be flexible and tailored to user preferences with proper labeling and orientation. vi) Calculate and display accurate linear measurements and pixel value determination as appropriate for the modality – eg HU for CT studies.

S/N	Type of Instrument Or Equipment	Parameters to be Checked
5	Display	At the start of use and annual performance check: i) Evaluated for significant pixel defects.. ii) Pixel pitch about 0.200 mm and no larger than 0.210 mm. iii) Reference to ISO 9241 on the guidelines on maximum number of pixel defects. iv) Documentation of allowed pixel defects should be provided by manufacturer.
6	Display resolution	i) Resolution shall be at least 2.5 lp/mm ii) Diagonal display distance is about 80% of the viewing distance. iii) At 2/3 m this corresponds to a diagonal size of 53 cm. iv) An aspect ratio, width to height of 3:4 or 4:5 is recommended. v) all display monitors used for primary interpretation shall be tested monthly.
7	Luminance	At ambient: i) Luminance shall be less than 1/4th of the luminance of the darkest gray level. ii) Contrast response of diagnostic monitors should be within 10% of the GSDF – gray scale display function over the full LR
		At minimum luminance: i) Luminance shall be at least 1.0 cd/m2 for diagnostic interpretation.
		A maximum luminance: i) Ratio of L max to L min shall be greater than 250. ii) L max of diagnostic monitors shall be at least 350 cd/m2 with L min of 1.0 cd/m2.
8	White point	CIE daylight standard D65 white point shall correspond to colour temperature of about 6500 degrees F.

Table 3: Useful Beam Filtration and Half-Value Layer (HVL) Requirements

Minimum total filtration in the useful beam

Normal operational kVp of the apparatus	Minimum total filtration in the useful beam
Below 70 kVp	1.5 mm Al equivalent
70 kVp to 100 kVp	2.0 mm Al equivalent
Above 100 kVp	2.5 mm Al equivalent

ii. Half-Value Layer (HVL)

Tube voltage operating range	Measured operating potential	Minimum HVL (mm Al)
Below 50 kVp	30	0.3
	40	0.4
	49	0.5
50 kVp to 70 kVp	50	1.2
	60	1.3
	70	1.5
Above 70 kVp	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3
	120	3.2
	130	3.5
	140	3.8
	150	4.1