# SERVICE STANDARD 14 : RADIOLOGY SERVICES

*PREAMBLE*
*Radiology is a branch of medicine that uses imaging technology to screen, diagnose, and management of diseases. Radiology services comprises of, diagnostic and interventional radiology. Medical practitioners who specialise in radiology are called radiologists. Diagnostic radiology examinations include:*

*• General Radiography*
*• Ultrasound*
*• Computed Tomography (CT)Fluoroscopy/Angiography, Magnetic Resonance Imaging (MRI)*
*• Mammography*
*• Bone Mineral Densitometry (BMD)*

*Interventional Radiology*
*Interventional radiology (IR) is a medical subspecialty of radiology utilising minimally invasive image guided procedure to diagnose and treat diseases in nearly every organ system. IR procedures have become an integral part of medical care and supplanted many major surgical procedures.*

*Some of the examples of interventional radiology procedures include:*

*• Needle biopsies e.g liver, lung, bone, and thyroid gland.*
*• Venous sampling e.g adrenal and petrosal sinus*
*• Drainage procedures e.g Nephrostomy/PTBD*
*• Vascular access procedures e.g. PICC/Chemoport /IJC insertion • Embolization to control bleeding and devascularise tumor/ abnormal vessels e.g trauma haemorrhage, Uterine artery embolization /AVM/Aneurysm*
*• Unblock the blockage vessels e.g. Stroke thrombectomy/Vasculoplasty/stenting*
*• Ablation therapy*
*• Cancer treatments e.g TACE/SIRT*

## TOPIC TOPIC 14.1
## ORGANISATION AND MANAGEMENT

### STANDARD STANDARD 14.1.1
STANDARD 14.1.1:

The Radiology Services shall provide safe and efficient radiological services. The services shall be coordinated with other departments and services of the Facility.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.1.1.1 | Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Radiology Services are clearly documented and | NA | | | NA | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | measurable that indicates safety, quality and patient centred care. These reflect the roles and aspirations of the service and the needs of the community. These statements are monitored, reviewed and revised as required accordingly and communicated to all staff<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Vision, Mission and values statements of the Facility are available, endorsed and dated by the Governing Body. — NA<br>2. Goals and objectives of the Radiology Services in line with the Facility statements are available, endorsed and dated. — NA<br>3. These statements are communicated to all staff (orientation programme, minutes of meeting, etc) — NA<br>4. Achievement of goals and objectives are monitored, reviewed and revised accordingly. — NA | | | | | |
| 14.1.1.2<br>CORE | There is an organisation chart which:<br>a) provides a clear representation of the structure, functions and reporting relationships between the Person In Charge (PIC), Head and staff of the Radiology Services;<br>b) is accessible to all staff and clients;<br>c) includes off-site services if applicable;<br>d) is revised when there is a major change in any of the following:<br>i) organisation;<br>ii) functions;<br>iii) reporting relationships;<br>iv) staffing patterns; category and distribution<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC), Head and staff of the Radiology Services. — NA<br>2. Organisation chart of the service is endorsed, dated and accessible. — NA<br>3. The organisation chart is revised when there is a major change in any of the items (d)(i) to (iv). — NA | NA | | | NA | |
| 14.1.1.3 | Regular staff meetings, which include medical practitioners are held between the Head of Service and staff with sufficient regularity to discuss issues and matters pertaining to the operations of the Radiology Services. Minutes are kept; decisions and resolutions made during meetings shall be accessible, communicated to all staff of the service and implemented. | NA | | | NA | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |

| EVIDENCE OF COMPLIANCE | | |
|---|---|---|
| 1. | Minutes are accessible, disseminated and acknowledged by the staff. | NA |
| 2. | Attendance list of members with adequate representatives of the service. | NA |
| 3. | Frequency of meetings as scheduled. | NA |
| 4. | Discussion and resolutions are implemented (Problems not solved to be brought forward in the next meeting until resolved). | NA |

| | | | | | |
|---|---|---|---|---|---|
| 14.1.1.4 | The Radiology Services staff participate in the following:<br><br>a) where applicable, the clinical aspects of patient care and other radiological matters in the Facility;<br><br>b) Communications with the relevant services and participation in education programmes organised by the Facility, interdepartmental meetings/committees, and education programmes organised by external bodies. | NA | | | NA | |

| EVIDENCE OF COMPLIANCE | | |
|---|---|---|
| 1. | Attendance in department/Facility-wide mortality and morbidity meetings or conferences | NA |
| 2. | Participation in interdepartmental clinical radiological discussion/conference and multidisciplinary meetings. | NA |
| 3. | Department/Facility-wide Continuing Medical Education (CME) programme. | NA |
| 4. | Attendance in conferences and courses organised by professional bodies. | NA |

| | | | | | | |
|---|---|---|---|---|---|---|
| 14.1.1.5 | The Head of Radiology Services is involved in the planning, justification and management of budget and resource utilisation of the services.<br><br>The Head of the Service could be the Person In Charge (PIC) of the Facility in the event where there is no resident radiologist in the Facility. Where there is no resident radiologist, the following shall be applicable:<br><br>i) In the case of government facilities, the services shall be overseen and supervised by the state radiologist or the assignee. | NA | | | NA | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | ii) In the case of private facilities, the services shall have access and suitable arrangement with an off-site radiologist who shall provide interpretation of the findings of procedures, guidance, and support with regards to the safety, standardisation of procedures and equipment in addition to providing supervision for staff competency and privileges.<br><br>EVIDENCE OF COMPLIANCE<br>1. Minutes of Facility-wide management meeting — NA<br>2. Documented evidence on request for allocation of budget and resources (staffing, equipment, etc) for the service. — NA<br>3. Approved budget and resources. — NA | | | | | |
| 14.1.1.6 | The Head of Radiology Services is involved in the appointment and/or assignment of staff.<br><br>EVIDENCE OF COMPLIANCE<br>1. Records on staff interview (if applicable) — NA<br>2. Appointment/assignment letter of Head of Service — NA<br>3. Job description of Head of Service — NA<br>4. Records on staff deployment — NA<br>5. Duty roster — NA | NA | | | NA | |
| 14.1.1.7 | Appropriate statistics and records shall be maintained in relation to the provision of Radiology Services and used for managing the services and patient care purposes.<br><br>EVIDENCE OF COMPLIANCE<br>1. Records are available but not limited to the following:<br>a) workload/census; — NA<br>b) annual report; — NA<br>c) accident/incident reports; — NA<br>d) staffing number and staff profile; — NA<br>e) staff training records; — NA<br>f) data on performance improvement activities, including performance indicators. — NA | NA | | | NA | |

TOPIC TOPIC 14.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD STANDARD 14.2.1
The Radiology Services shall be directed by a qualified radiologist and assisted by qualified support staff to achieve the services' goals and objectives; and there is a continuing education programme to enhance human resource development.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.2.1.1 CORE | The Head and staff of the Radiology Services shall be individuals qualified by education, training, experience and certification to commensurate with the requirements of the various positions. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Records on credentials of Head of Service and staff required to fill up the posts within the service (to match the complexity of the Facility and services) and certification/registration. | NA | | | | |
| | 2. | Appointment/assignment letters | NA | | | | |
| | 3. | Certification | NA | | | | |
| | 4. | Training and competency records | NA | | | | |
| | 5. | Credentialing and Privileging | NA | | | | |
| | 6. | Valid professional Annual Practising Certificate (APC) where relevant. | NA | | | | |
| | 7. | Practising radiologist registered with National Specialist Register (NSR). | NA | | | | |
| 14.2.1.2 | The authority, responsibilities and accountabilities of the Head of Radiology Services are clearly delineated and documented. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Appointment/assignment letter for Head of Service. | NA | | | | |
| | 2. | Description of duties and responsibilities | NA | | | | |
| 14.2.1.3 | Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the services. | | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Number of staff and qualification should commensurate with workload. | NA | | | | |
| | 2. | Staffing pattern; category and distribution | NA | | | | |
| | 3. | Duty roster | NA | | | | |
| | 4. | Census and statistics | NA | | | | |
| 14.2.1.4 | There are written and dated specific job descriptions for all categories of staff that include:<br><br>a) qualifications, training, experience and certification required for the position;<br><br>b) lines of authority;<br><br>c) accountabilities, functions and responsibilities,<br><br>d) reviewed when required and when there is a major change in any of the following:<br>i) nature and scope of work;<br>ii) duties and responsibilities;<br>iii) general and specific accountabilities;<br>iv) qualifications required and privileges granted;<br>v) staffing patterns;<br>vi) Statutory Regulations.<br><br>e) administrative and clinical functions. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Updated specific job description is available for each staff that includes but not limited to as listed in (a) to (e). | NA | | | | |
| | 2. | Job description includes specialisation skills | NA | | | | |
| | 3. | Relevant privileges granted where applicable | NA | | | | |
| | 4. | The job description is acknowledged by the staff and signed by the Head of Service and dated. | NA | | | | |
| 14.2.1.5 | Personnel records on training, staff development, leave and others are maintained for every staff.<br><br>Note: | | | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Staff personal record may be kept in Human Resource Department as per Facility policy.<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Staff personal records include:<br>a) staff biodata — NA<br>b) qualification and experience; — NA<br>c) evidence of current registration; — NA<br>d) training record; — NA<br>e) competency record and privileging; — NA<br>f) leave record; — NA<br>g) confidentiality agreement. — NA | | | | | | |
| 14.2.1.6 | All radiographic procedures shall be carried out by appropriately qualified, competent and privileged personnel<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Qualified radiographer to carry out radiographic procedures — NA<br>2. Credentialing and privileging processes are in place. — NA<br>3. Documented evidence on conferment of privileging rights (with valid period). — NA | NA | | | NA | | |
| 14.2.1.7 | A radiologist and radiographer shall be on duty or be available on call after normal working hours.<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Duty roster of the department/service — NA<br>2. On-call roster — NA | NA | | | NA | | |
| 14.2.1.8 | There is structured orientation programme for all newly appointed staff to the Radiology Services including medical practitioners and for those new to specific areas that include the following:<br><br>a) explanation of the goals, objectives, policies and procedures of the Facility and those of the Radiology Services;<br><br>b) lines of authority and areas of responsibility; | NA | | | NA | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | c) explanation of particular duties and functions;<br><br>d) explanation of the methods of assigning clinical care and the standards of clinical practice;<br><br>e) hand over communication;<br><br>f) processes for resolving practice dilemmas;<br><br>g) information about safety procedures;<br><br>h) training in basic/advanced life support techniques;<br><br>i) methods of obtaining appropriate resource materials;<br><br>j) staff appraisal procedures for the Radiology Services;<br><br>k) education on Patient and Family Rights;<br><br>l) education on MSQH Standards requirements.<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Policy requiring all new staff to attend a structured orientation programme. — NA<br>2. There is Radiology Services orientation programme with relevant topics not limited to topics covered from (a) to (l). — NA<br>3. . Attendance list — NA | | | | | |
| 14.2.1.9 | There is evidence of training needs assessment and staff development plan which provides the knowledge and skills required for staff to maintain competency in their current positions and future advancement.<br><br>**EVIDENCE OF COMPLIANCE**<br>1. Training needs assessment is carried out and gaps identified. — NA<br>2. A staff development plan based on training needs assessment is available. — NA<br>3. Training schedule/calendar is in place. — NA<br>4. Training module — NA | NA | | | NA | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 14.2.1.10 | There are continuing education activities for staff including medical practitioners to pursue professional interests and to prepare for current and future changes in practice.<br>EVIDENCE OF COMPLIANCE<br>1. Contents of training programme — NA<br>2. Training records on continuing education activities are kept and maintained for each staff. — NA<br>3. Certificate of attendance/diploma/degree — NA | NA | | | NA | |
| 14.2.1.11 | Staff including medical practitioners receive evaluation of their performance at the completion of the probationary period and annually thereafter, or as defined by the Facility.<br>EVIDENCE OF COMPLIANCE<br>1. Performance appraisals for staff including medical practitioners are completed upon probationary period and as an annual exercise. — NA | NA | | | NA | |
| 14.2.1.12 | In a teaching hospital, the Radiology Services shall provide educational needs and teaching for undergraduates and postgraduates without compromising patient safety and comfort.<br>EVIDENCE OF COMPLIANCE<br>1. Records on training provided to undergraduate and postgraduate students — NA | NA | | | NA | |
| 14.2.1.13 | In Facilities which have teaching and research responsibilities, the staffs of the Radiology Services give their cooperation or participate in the teaching and research programmes.<br>EVIDENCE OF COMPLIANCE<br>1. Records on participation or cooperation in teaching and research programme — NA | NA | | | NA | |

TOPIC TOPIC 14.3
POLICIES AND PROCEDURES

STANDARD STANDARD 14.3.1
There are written and dated policies and procedures for all activities of the Radiology Services. These policies and procedures reflect current standards of radiology/ diagnostic imaging practices, relevant regulations, statutory requirements and the purposes of the services. There should be available Throughout the Facility, a list of procedures requiring informed consent specific to radiology/diagnostic imaging procedures should be available. Possible risks and complications arising from procedures should be documented either in specific consent forms or in patient's medical record.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.3.1.1 CORE | There are written policies and procedures for the Radiology Services, which are consistent with the overall policies of the Facility, regulatory requirements and current standard practices. These policies and procedures are signed, authorised and dated. There is a mechanism for and evidence of a periodic review at least once in every three years. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Documented policies and procedures for the service. | NA | | | | |
| | 2. | Policies and procedures are consistent with regulatory requirements and current standard practices. | NA | | | | |
| | 3. | Evidence of periodic review of policies and procedures. | NA | | | | |
| | 4. | The policies and procedures are endorsed and dated. | NA | | | | |
| 14.3.1.2 | The policies and procedures shall be developed by the Radiology Services staff in consultation with representatives from other related services. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Policies and procedures show evidence of cross references to relevant sources that are involved in the processes. | NA | | | | |
| | 2. | Minutes of meeting between relevant departments. | NA | | | | |
| 14.3.1.3 | Current policies and procedures are communicated to all staff. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Training and briefing on the current policies and procedures/ with minutes of meetings | NA | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 2. Circulation list and acknowledgement — NA | | | | | |
| 14.3.1.4<br>CORE | Written policies and procedures with adequate records are maintained and shall include but not limited to the following;<br>a) General operational policy<br>b) Exam scheduling of patients<br>c) Performing Radiological examinations<br>d) Reporting, consultation, and Image management<br>e) Safety in Radiology e.g<br>• Radiation Safety<br>• MR Safety<br>• Drugs and Contrast Media safety; management of complications<br>• Infection control<br>• Fire Safety<br>• Occupational Safety<br><br>f) communication with referrer, nursing, and other relevant staff on matters related to the services provided.<br><br>g) informed consent;<br><br>h) identification of patients, correct procedure, correct site before performing the investigation;<br><br>i) radiological examinations in areas other than the Radiology Department<br><br>j) care of patients having special needs including those who are critically ill and those needing isolation, physically or mentally challenged patients, paediatric and geriatric patients, pregnant staff and patients, person under custody, highly infectious patients.<br><br>k) Relevant procedures and safety measures for each radiological modality where necessary.<br><br>l) Handling of patient's valuables.<br><br>m) Patients and family rights<br><br>n) Contingency plan<br><br>EVIDENCE OF COMPLIANCE | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1. | Departmental policies and procedures, which include all items above | NA | | | | |
| | 2. | Standard anaesthetic and drug administration records are maintained, and statutory regulations relating to the control of drugs are followed. | NA | | | | |
| | 3. | Investigative procedures performed are documented. | NA | | | | |
| 14.3.1.5<br>CORE | There is EVIDENCE OF COMPLIANCE with policies and procedures. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Compliance with policies and procedures through: | | | | | | |
| | a) | interview of staff on practices; | NA | | | | | |
| | b) | verify with observation on practices; | NA | | | | | |
| | c) | results of audit on practices; | NA | | | | | |
| | d) | verify practices in line with established policies and procedures. | NA | | | | | |
| 14.3.1.6 | Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws, and statutory requirements are accessible to staff. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Copies of related documents are accessible for staff reference. | NA | | | | | |
| 14.3.1.7 | Radiological investigation or procedure will be performed upon request by a medical practitioner or when deemed as indicated by a radiologist. Such requests will be made in writing and contain sufficient clinical information to justify the examination. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Policy on request for radiological investigation or procedure. | NA | | | | | |
| | 2. | Clinical indication/information is available on the request form/clinical order entry prior to the examination. | NA | | | | | |
| 14.3.1.8 | Reports on radiological examinations are made by a radiologist. In the absence of a radiologist, the interpretation of the examination shall be made by a competent medical practitioner. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Reports of radiological examinations are made by a radiologist/medical practitioner under the supervision of a radiologist. | NA | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2. | All radiological reports shall be signed and stamped by radiologist and/or medical practitioner based on the local policy. | NA | | | | |
| 14.3.1.9 | The special radiological examination excluding plain radiograph) for inpatients shall be reported within two (2) days. A copy of report shall be kept in the patient's medical record. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Special radiological reports are available within 2 days. | NA | | | | |
| | 2. | Reports of special radiological procedures are made by a radiologist. | NA | | | | |
| | 3. | Copy of radiological report is kept in the patient's medical record. | NA | | | | |
| 14.3.1.10 | The radiologist shall consult with the referring practitioner immediately when there are critical or unexpected findings. There is evidence of documentation of this consultation. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Documented evidence that the clinician has been informed on the critical or unexpected findings. | NA | | | | |
| 14.3.1.11 | Hard or soft copy images shall be made available for every radiological examination performed. The radiological finding/report shall be documented and be available. Where hard copies need to be stored in the Facility, these shall be stored vertically in an air-conditioned room with suitable environmental conditions to prevent fungus and in a manner for easy retrieval. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Policy on handing of films or soft copy images by staff or patients. | NA | | | | |
| | 2. | Documented evidence on films/images tracking system | NA | | | | |
| | 3. | Proper storage of films/Images | NA | | | | |
| 14.3.1.12 | Where the policy of the Facility allows patients to take their films home, they shall be advised to take proper care of the films and make them available whenever necessary. In Facilities where the films are not returned to patients, films may be given on loan for the purpose of obtaining a second opinion | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Policy for allowing patient to take their films home and the documented evidence of implementation. | NA | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2. | Policy on request for loan of films for purpose of second opinion. | NA | | | | |
| 14.3.1.13 | Proper documented instructions are available and safety precautions are implemented for the protection of patients and staff who are exposed to hazardous equipment. References are based on the following statutory regulations:<br><br>a) Atomic Energy Licensing Act 1984 (Act 304)<br><br>b) Atomic Energy Licensing Act 1984 (Act 304): Radiation Protection (Licensing) Regulations 1986<br><br>c) Atomic Energy Licensing Act 1984 (Act 304): Atomic Energy Licensing (Basic Safety Radiation Protection) Regulations 2010 | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Standard operating procedures for radiological safety precautions are available and implemented. | NA | | | | |
| | 2. | Verification on practice during survey. | NA | | | | |
| 14.3.1.14 | Staff shall ensure that patient exposure is kept as low as reasonably achievable using time, distance, shielding as well as collimation during radiological examination whilst providing images of diagnostic quality for radiological interpretation. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Documented policy on radiation protection. This is a mandate to protect patients from unnecessary radiation exposure. | NA | | | | |
| | 2. | Observe the practice during survey | NA | | | | |
| 14.3.1.15 | There are written procedures for: management of<br><br>a) Adverse drug or contrast media reaction anaphylactic reaction.<br><br>b) complication of diagnostic and therapeutic interventional procedures.<br><br>There is easy access to emergency and resuscitation equipment and medical alerts. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1. | Documented procedures for management of adverse drug or contrast media reaction, anaphylactic reaction, or any complications during radiological procedures. | NA | | | | |
| | 2. | Evidence of access to/availability of emergency and resuscitation equipment and medical supplies. | NA | | | | |
| 14.3.1.16 | Guidelines for patient preparation and procedures for radiological examinations shall be available to all relevant staff. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | The documented standard operational procedures and protocols for all radiological examinations must be available | NA | | | | |
| 14.3.1.17 | A technical manual for equipment shall be available within the Radiology Services | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Technical manual for equipment is available. | NA | | | | |
| 14.3.1.18 | There is a policy to ensure safety and confidentiality of all images. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | verify on user access and control on all images. | NA | | | | |
| 14.3.1.19 CORE | There is a Radiation Safety Committee comprising a designated Radiation Protection Officer and representatives from other services using ionising equipment.<br><br>a) Minutes or issues raised at the Radiation Safety Committee meetings shall be brought to the attention of the Head of clinical services and other users of radiology services.<br><br>b) In smaller facilities (with two or less general or dental x-ray machines), , radiation issues should be an agenda in the Safety Committee meeting. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Evidence of Radiation Safety Committee | NA | | | | |
| | 2. | Terms of Reference | NA | | | | |
| | 3. | Minutes of meetings, minimum of two (2) meetings per year | NA | | | | |
| | 4. | The committee's monitoring activities include: | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | a) | radiation safety measures; | NA | | | | |
| | b) | review records on staff radiation exposure; | NA | | | | |
| | c) | review all recordable and reportable adverse events and incidents; | NA | | | | |
| | d) | plan and oversee training needs and programme on radiation protection and safety. | NA | | | | |
| 14.3.1.20 | Staff involved in the operating of ionising equipment shall undergo medical examinations in accordance with Atomic Energy Licensing Act 1984 (Act 304) and Regulations on Basic Safety Radiation Protection 2010. Full medical examination and a full blood examination to be conducted by a registered medical practitioner:<br><br>a) pre-employment medical examination;<br><br>b) regular medical examination (at least once in three years and more frequent for those exposed to higher ionizing radiation);<br><br>c) termination/completion of services. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Evidence of medical examination by medical practitioner including full blood count and chest x-ray as per items (a) to (c). | NA | | | | |
| 14.3.1.21<br>CORE | Staff working with ionising radiation are monitored regularly. The exposure readings shall be sent to and reported by a licensed laboratory. The radiation exposure results of every staff shall be monitored by the Radiation Safety Officer.<br>For staff having exceeded the maximum permissible dose, there is a protocol for reporting, investigation, and immediate and long term remedial actions. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Record on individual staff radiation exposure dose. | NA | | | | |
| | 2. | Result on exposure reading from licensed agency/laboratory approved by Atomic Energy Licensing Board (AELB), Malaysia. | NA | | | | |
| | 3. | Protocol for reporting, investigation and action taken for staff having exceeded the maximum permissible dose. | NA | | | | |

TOPIC TOPIC 14.4
FACILITIES AND EQUIPMENT

STANDARD STANDARD 14.4.1
The Radiology Services shall be provided with sufficient space, suitable equipment and adequate supplies for the safe performance of all radiological services provided.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.4.1.1 | There are adequate and appropriate facilities and equipment with proper utilisation of space to enable staff to carry out their professional, teaching and administrative functions. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Adequate and proper utilisation of space and equipment in compliance with relevant Act, Regulations and standards. | NA | | | | |
| | 2. | Appropriate type of equipment to match the complexity of services | NA | | | | |
| | 3. | Adequate facilities and equipment at each patient care area for safe care. (e.g. defibrillators, emergency cart, hand washing facilities etc) | NA | | | | |
| | 4. | Easy access and clear exit routes | NA | | | | |
| | 5. | Absence of overcrowding | NA | | | | |
| 14.4.1.2 | There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Certification of equipment from certified bodies, e.g. the Atomic Energy Licensing Board and Licensing Authority, Medical Device Authority (MDA) etc. as EVIDENCE OF COMPLIANCE to the relevant standards and Acts | NA | | | | |
| | 2. | Testing, commissioning and calibration records (certificates or stickers) | NA | | | | |
| 14.4.1.3 CORE | There is evidence that the facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance and calibration activities, to ensure the facilities and equipment are in good working order. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1. | Planned Preventive Maintenance records such as schedule, stickers, etc. | NA | | | | |
| | 2. | Planned Replacement Programme where applicable | NA | | | | |
| | 3. | Complaint records | NA | | | | |
| | 4. | Asset inventory | NA | | | | |
| 14.4.1.4 CORE | Facilities and equipment shall be assessed for safety at yearly intervals by independent radiation experts (Class H license holders certified by Medical Radiation Regulatory Division Ministry of Health). Records on such assessment shall be kept. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Certificate from Class H license holders | NA | | | | |
| | 2. | Records on Quality Control report | NA | | | | |
| 14.4.1.5 | Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment, e.g. Computed Tomography (CT), Magnetic Resonance Imaging (MRI), mammography, etc. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | User training records | NA | | | | |
| | 2. | Competency assessment record | NA | | | | |
| | 3. | Evidence of privileging | NA | | | | |
| | 4. | List of staff trained and privileged to operate and maintain specialised equipment | NA | | | | |
| 14.4.1.6 CORE | Staff working with ionising equipment shall wear appropriate monitoring devices to be assessed periodically.<br><br>Patients are given appropriate radiation protection during radiological examination. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Verification on practices for staff and patient | NA | | | | |
| | 2. | Documented evidence of personal radiation protective device testing and record | NA | | | | |
| 14.4.1.7 | Multilingual signs warning women of childbearing age with regards to radiation exposure and pregnancy shall be prominently displayed. | | | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | EVIDENCE OF COMPLIANCE<br>1. Availability of multilingual signs warning women of childbearing age. NA | | | | | | |
| 14.4.1.8 | There shall be suitable changing rooms for patients and facilities to keep their personal valuables.<br><br>EVIDENCE OF COMPLIANCE<br>1. Changing room and facilities to keep patient's valuables. NA | | NA | | | NA | |
| 14.4.1.9 | There is adequate space or area for patient preparation and observation pre and post radiological procedure.<br><br>EVIDENCE OF COMPLIANCE<br>1. Adequate space for patient preparation and observation pre and post radiological procedures. NA<br>2. Verification on practices during survey NA | | NA | | | NA | |
| 14.4.1.10 | There is designated area for patient and accompanying person for ;<br><br>a) breast feeding patients<br><br>b) special handling/need patient e.g. Irradiated patient, psychiatric patient and person under custody.<br><br>c) consultation, grievances and physical privacy<br><br>EVIDENCE OF COMPLIANCE<br>1. Ensure available space for (a) to (c) NA | | NA | | | NA | |

TOPIC TOPIC 14.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD STANDARD 14.5.1
There are safety and performance improvement programmes to improve staff performance, clinical practices and ethical standards of the Radiology Services. There is evidence that the statistical data collected are analysed and utilised for the ongoing improvement of the Radiology Services.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.5.1.1 | There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the Radiology Services. The process includes:<br><br>a) Planned activities<br><br>b) Data collection<br><br>c) Monitoring and evaluation of the performance<br><br>d) Action plan for improvement<br><br>e) Implementation of action plan<br><br>f) Re-evaluation for improvement<br><br>Innovation is advocated. | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | |
| | 1. Planned performance improvement activities include (a) to (f) — NA | | | | | |
| | 2. Records on performance improvement activities. — NA | | | | | |
| | 3. Minutes of performance improvement meetings — NA | | | | | |
| | 4. Performance improvement studies — NA | | | | | |
| | 5. Records on innovation if available — NA | | | | | |
| 14.5.1.2 | The Head of Radiology Services has in a written document assigned responsibilities to appropriate individuals/team/committees for safety, performance improvement and risk management activities within the services. | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Minutes of meetings | NA | | | | |
| | 2. | Letter of assignment of responsibilities | NA | | | | |
| | 3. | Terms of Reference/Job description | NA | | | | |
| 14.5.1.3 | The Head of Radiology Services shall ensure that the staffs are trained and incident reports which are complete, promptly reported, investigated, discussed by the staff with learning objectives and forwarded to the Person In Charge (PIC) of the Facility. Incidents reported have had Root Cause Analysis done and action taken within the agreed time frame to prevent recurrence. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | System for incident reporting is in place, which include: | | | | | |
| | a) | Training of staff | NA | | | | |
| | b) | Policy on incident reporting | NA | | | | |
| | c) | Methodology of incident reporting | NA | | | | |
| | d) | Register/records of incidents | NA | | | | |
| | 2. | Completed incident reports | NA | | | | |
| | 3. | Root Cause Analysis | NA | | | | |
| | 4. | Corrective and preventive action plans | NA | | | | |
| | 5. | Remedial measure | NA | | | | |
| | 6. | Minutes of meetings | NA | | | | |
| | 7. | Acknowledgment by Head of Service and PIC/Hospital Director | NA | | | | |
| | 8. | Feedback given to staff regarding incident reporting. | NA | | | | |
| 14.5.1.4 | The Head of Radiology Services shall ensure the provision of high quality performance through ongoing patient safety, quality improvement and risk management programmes of the Facility. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Plans for patient safety, quality improvement and risk management. | NA | | | | |
| 14.5.1.5 | There is a Clinical Risk Management Team that provides appropriate peer group structure for performing the safety and performance improvement activities to accomplish clinical care evaluation. | | | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Minutes of meetings | NA | | | | |
| | 2. | Terms of reference of the Clinical Risk Management Team | NA | | | | |
| | 3. | Reports | NA | | | | |
| 14.5.1.6 | The Clinical Risk Management Team shall:<br><br>a) review all clinical risk assessments, incident reports, audits, safety and performance improvement activities;<br><br>b) be involved in specific multidisciplinary committees, such as Radiation Safety, Infection control, Morbidity and Mortality committee<br><br>Whatever structure is utilised, provision is made for review and analysis of the clinical work of each individual unit or function of the Radiology Services. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Documentation of reviews of risks such as radiation hazards, Mortality and Morbidity reviews, etc | NA | | | | |
| | 2. | Reports on clinical risk assessment | NA | | | | |
| 14.5.1.7 | There is identification and stratification of risks and measures to protect the safety of patients, staff and visitors in the Radiology Services. The measures may include but not limited to:<br><br>a) radiology reporting – timeliness, accuracy of reports;<br><br>b) quality of examination;<br><br>c) clinical information;<br><br>d) complication of radiological examination;<br><br>e) viewing condition;<br><br>f) consent;<br><br>g) communication skill;<br><br>h) equipment; | | | NA | | | NA | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | i) training, competency and experience<br><br>EVIDENCE OF COMPLIANCE<br>1. Risk register on type of risks identified — NA<br>2. Stratification of risks — NA<br>3. Measures undertaken to address identified risks to protect the safety of patients, staff and visitors. — NA | | | | | |
| 14.5.1.8<br>CORE | There is tracking and trending of specific performance indicators not limited to but at least two (2) of the following:<br>a) For Facility with Radiologist<br>i) percentage of reject/ retake of plain radiographs (Target < 5%)<br>ii) percentage of reject / retake of mammogram images (Target < 3%)<br>iii) percentage of radiological examination and radiographic errors, i.e., wrong marker, use of primary markers, wrong site x-rayed, wrong patient x-rayed.<br>iv) complication rate for post-interventional procedures<br>v) Perfect, Good, Moderate, Inadequate (PGMI) audits for mammography (Target: ≥97% for Perfect, Good and Moderate)<br>vi) percentage of patients with significant pneumothorax/haemorrhage requiring intervention following percutaneous interventional procedures in the thorax, abdomen and pelvis (Target: ≤10%)<br>vii) percentage of patients with waiting time of ≤60 minutes for commencement of ultrasound examination (Target: >90%)<br>viii) turnaround time of ≤2 days for final report of special radiological examination done on inpatients (Target: ≥97%)<br>ix) turnaround time of ≤14 days for final report of special radiological examination done on outpatients (Target: ≥90%)<br>x) percentage of patients developed significant contrast media extravasation following CT examination with intravenous (IV) contrast media (Target: <1%)<br>b) For Facility without resident radiologist<br>i) percentage of accurate interpretation of x-rays films by medical officers as reported by radiologist [in reference indicator to indicator (i)]<br>ii) percentage of reject / retake of plain radiograph; (Target <5%)<br>iii) percentage of radiographic errors, i.e. wrong marker, use of primary markers, wrong site x-rayed, wrong patient x-rayed<br><br>EVIDENCE OF COMPLIANCE<br>1. Specific performance indicators monitored. — NA<br>2. Records on tracking and trending analysis. — NA | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 3. | Remedial measures taken where appropriate | NA | | | | |
| 14.5.1.9 | Feedbacks on results of safety and performance improvement activities are regularly communicated to the staff and relevant authority. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Results on safety and performance improvement activities are accessible to staff. | NA | | | | | |
| | 2. | Evidence of feedback via communication on results of performance improvement activities through direct counselling, meetings and continuing education activities. | NA | | | | | |
| | 3. | Minutes of service/committee meetings. | NA | | | | | |
| 14.5.1.10 | Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff and patients is preserved. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Documentation on performance improvement activities and performance indicators. | NA | | | | | |
| | 2. | Policy statement on anonymity on patients and providers involved in performance improvement activities. | NA | | | | | |

TOPIC TOPIC 14.6
SPECIAL REQUIREMENTS

STANDARD STANDARD 14.6.1
VIEWING SYSTEM FOR REPORTING
The Facility shall use appropriate viewing boxes and display monitor to conduct the reporting of radiological images in satisfactory conditions.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.1.1 | Viewing boxes requirements for reporting radiographs by radiologists are as follows:<br><br>a) RADIOGRAPHIC VIEWING (non-mammographic)<br>i) Radiographic illuminators:<br><br>• ● Luminance preferably between 1500-3000 cd/m2<br>• ● Uniformity of illuminator (maximum deviation < 15%)<br>• ● Uniformity of colour bulbs within the department (white or moderate white–blue with flicker-free illumination)<br>• ● Sufficient size for at least 2 radiographs (>40 x 80 cm)<br>• ● Possibility of collimation on the size of the radiographs<br>• ● Viewing box mounting shall be at an appropriate level for reviewing.<br><br>ii) Special viewing possibilities:<br><br>• ● To evaluate details in film areas of high densities (D=2-3), optimum brightness shall be of 4000-6000 cd/m2<br><br>iii) Magnifying glass or lens:<br><br>• ● magnifying factor 2-3<br><br>iv) Illumination conditions in the room: | NA | | | NA | |

- ● 50 – 100 lux at the place of the viewer (with the viewer 'off')
- ● Room lighting shall have 'dimmer switch' control

(Reference: Quality Control of Radiographic Illuminators and associated viewing equipment by E Hartmann and F E Stieve, BIR Report 18, 135-7)

b) MAMMOGRAPHIC VIEWING
i) Luminance of viewing boxes: > 3500 cd/m2 (nit) for mammography with variable illumination capability.
ii) Room ambient illumination level: 50 lux or less (with viewer 'off').
iii) Collimation to size of mammographic film (Reference: ACR Guidelines)

c) DISPLAY MONITOR
i) Viewing workstation for reporting all examinations shall be of medical grade 1-3 MP.
ii) Minimum requirement of 5 MP for mammography
iii)iMac as DICOM viewer is allowed for image processing.

d) FREQUENCY OF TESTING FOR VIEWING BOXES AND DISPLAY MONITOR
i) at commissioning;
ii) after replacement of bulb or front panel of viewing box;
iii) yearly for viewing box
iv) 6 monthly for display/PACS monitor

| EVIDENCE OF COMPLIANCE | | |
|---|---|---|
| 1. | The radiographic illuminators comply with parameters in (a)(i) to (a)(iv). | NA |
| 2. | The mammographic viewer comply with (b)(i) to (b)(iii) and C) ii) | NA |
| 3. | Display monitor comply with c) i-iii and d) I & iv | NA |
| 4. | Evidence of testing for viewing boxes and display monitor . | NA |

STANDARD STANDARD 14.6.2

TELERADIOLOGY

The Facility shall ensure high quality, final radiology reports and reliable, personalised teleradiology services that result in referring physician satisfaction and continually improve processes and workflows to enable the attending radiologists to provide the best patient care possible.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.2.1 | The Facility that has this service shall ensure that guidelines on telemedicine from the Ministry of Health (TELERADIOLOGY Unit) are complied with.<br><br>EVIDENCE OF COMPLIANCE<br>1. Copy of guidelines on telemedicine from the Ministry of Health (Teleradiology Unit) are available on-site. — NA | NA | | | NA | |
| 14.6.2.2 | There are policies and procedures for:<br><br>a) monitoring and evaluating the effective management, safety and proper performance of acquisition, digitisation, compression, transmission, archiving and retrieval functions of the system;<br><br>b) patient confidentiality is maintained;<br><br>c) training on the use of teleradiology equipment;<br><br>d) security of software and hardware;<br><br>e) timeliness of report;<br><br>f) contingency plan for system failure, emergency and disaster.<br><br>EVIDENCE OF COMPLIANCE<br>1. Policies and procedures for (a) to (f) are available. — NA<br>2. Records on training — NA | NA | | | NA | |

## STANDARD STANDARD 14.6.3
ULTRASOUND

Ultrasound Diagnostic Services shall provide a comprehensive and reliable service performed by radiologists or credentialed and privileged medical practitioners/sonographers and reported by specialists.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.3.1 | The ultrasound examination shall be performed by a radiologist/trained and privileged medical practitioner or sonographer. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Evidence of credentialing and privileging of staff where applicable. | NA | | | | | |
| | 2. | Records on training | NA | | | | | |
| 14.6.3.2 | All ultrasound examinations shall be interpreted and reported by a radiologist/the specialists in their area of expertise or trained and privileged medical practitioners. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Evidence of credentialing and privileging of medical practitioners. | NA | | | | | |
| | 2. | Records on training | NA | | | | | |

STANDARD STANDARD 14.6.4
MOBILE X-RAYS AND MOBILE C-ARM

There are functional and safe equipment and facilities that meet the regulatory requirements for the Mobile X-Rays and Mobile C-Arm services in the Facility. The Mobile X- Rays and C-Arm shall be operated by a qualified radiographer.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.4.1 | Where Mobile X-Rays and Mobile C-Arm machines are used as static units, the facilities shall meet the requirements as per regulations for x-ray room/fluoroscopy room. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Certificate for static units by Class H license holder | NA | | | | |
| | 2. | Facilities and equipment comply with relevant Act, Regulations and standards. | NA | | | | |
| 14.6.4.2 | C-arm in the operating theatre shall be operated by a qualified radiographer. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Records on qualification of radiographer | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |
| 14.6.4.3 | The operating theatre where fluoroscopy is constantly used shall have radiation shielding. In the other rooms where there is no radiation shielding, the radiation scatter outside the room should be monitored. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Facilities comply with relevant Act, Regulations and standards. | NA | | | | |
| | 2. | Records on monitoring on radiation scatter by the appropriately qualified personnel/agency. | NA | | | | |
| 14.6.4.4 | When mobile x-rays are performed in the wards, efforts should be made to ensure that the neighbouring patients are protected adequately from scatter radiation. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1. | Standard operating procedures for using of mobile radiography in the wards. | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |
| 14.6.4.5 | The requirements on shielding and monitoring shall be applicable in other locations where fluoroscopy and mobile machines are routinely used, e.g. Intensive Care Unit (ICU), Coronary Care Unit (CCU), Coronary Rehabilitation Ward (CRW) and Emergency Services. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Availability of standard operating procedures for mobile radiography and fluoroscopy in other locations. | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |
| 14.6.4.6 | There are guidelines on the handling, transport and storage of mobile x-ray machines and their accessories. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Availability of guidelines on the handling, transport and storage of mobile x-ray machines and their accessories. | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |

## STANDARD STANDARD 14.6.5
BONE DENSITOMETER

Bone Densitometry shall only be performed in appropriate and safe facilities in accordance with the requirements of the Ministry of Health and Atomic Energy Licensing Act (Act 304) to reduce radiation exposure and optimise the diagnostic quality of the scans. Records shall be maintained for each bone densitometer unit.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.5.1 | The room used for Bone Densitometer shall meet the required specifications for such facilities in accordance with the requirements of the Ministry of Health and Atomic Energy Licensing Act (Act 304).<br>EVIDENCE OF COMPLIANCE<br>1. Certification from Class H license holder — NA<br>2. Facilities and equipment comply with relevant Act, Regulations and standards. — NA | NA | | | NA | |
| 14.6.5.2 | Bone densitometry examination shall be performed by a qualified radiographer. The radiographer shall be adequately trained, credentialed and privileged.<br>EVIDENCE OF COMPLIANCE<br>1. Evidence of credentialing and privileging of the radiographer — NA<br>2. Records on training. — NA | NA | | | NA | |
| 14.6.5.3 | There is evidence that the competency of the radiographer performing the examination is assessed by performing the precision testing.<br>EVIDENCE OF COMPLIANCE<br>1. Documentation of competency test — NA | NA | | | NA | |

## STANDARD STANDARD 14.6.6
MAMMOGRAPHY

The Facility ensures that mammography services shall be performed only by adequately trained, credentialed and privileged radiographer/mammographer as per policy of the Facility. A radiologist trained to read mammograms shall report on the mammogram images. The facilities and equipment for mammography examinations shall be safe and routine Quality Control is performed to ensure reliable results.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.6.1 | Mammography shall be performed by a qualified female radiographer. The mammographer shall be adequately trained, credentialed and privileged. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Evidence of credentialing and privileging of relevant staff. | NA | | | | |
| | 2. | Records on training | NA | | | | |
| 14.6.6.2 | All mammography shall be interpreted and reported by a radiologist. All mammography may be interpreted by the specialists in their areas of expertise. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Evidence of credentials of radiologist (Registration with National Specialist Register) | NA | | | | |
| | 2. | Sampling of mammography report. | NA | | | | |
| 14.6.6.3 | There is evidence that the mammographers and the radiologists reporting the mammogram attend regular relevant continuing medical education (CME). | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Records on continuing medical education for relevant staff. | NA | | | | |
| 14.6.6.4 | The mammographer responsible for quality control (QC) is specifically trained to perform routine QC tests. The results are used to troubleshoot and for quality improvement. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Documentation of QC test. | NA | | | | |
| | 2. | Evidence of quality improvement done. | NA | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 14.6.6.5<br>CORE | The mammograms produced are audited following the Perfect, Good, Moderate and Inadequate (PGMI) classifications with evidence of documentation.<br><br>EVIDENCE OF COMPLIANCE<br>1. Documentation on PGMI audits. NA | | NA | | | NA | |

STANDARD STANDARD 14.6.7
MAGNETIC RESONANCE IMAGING (MRI)

MRI shall be performed by a qualified, trained, and privileged radiographer. All MRI examinations shall be interpreted and reported by a radiologist/specialist. There are policies and procedures addressing the safety, operations and maintenance of the MRI equipment.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.7.1 | Magnetic Resonance Imaging (MRI) examination shall be performed by a qualified radiographer. The radiographer shall be adequately trained, and privileged. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Evidence of privileging of radiographer | NA | | | | |
| | 2. | Records on training. | NA | | | | |
| 14.6.7.2 | All MRI examinations shall be interpreted and reported by a radiologist. All MRI examinations may be interpreted by the specialists in their areas of expertise. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Evidence of credentials of radiologist (Registration with National Specialist Register) | NA | | | | |
| | 2. | Sampling of MRI examination reports | NA | | | | |
| 14.6.7.3 CORE | There are policies and procedures addressing the safety, operations and maintenance of the MRI equipment. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Policies and procedures for safety, operations and maintenance of the MRI equipment. | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |
| | 3. | Check on ancillary and maintenance workers/staff on their knowledge of safety and compliance | NA | | | | |
| 14.6.7.4 | There are guidelines for the handling of the following patients:<br><br>a) ambulatory;<br><br>b) on wheelchair and trolley; | | NA | | | NA | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | c) requiring oxygen support;<br>d) critically ill patients or on ventilator;<br>e) infants and children;<br>f) patients with implants;<br>g) patients with special needs<br>h) pregnant patient;<br>i) patients with or suspected renal failure.<br>j) infectious disease patients<br>k) Polytrauma patients<br>**EVIDENCE OF COMPLIANCE**<br>1. Availability of guidelines for handling of patients as indicated in (a) to (k) for MRI examination. — NA<br>2. Verification on practices during survey — NA | | | | | |
| 14.6.7.5 | There shall be procedures for handling of emergencies, e.g. quenching, fire outbreak, accidents in the magnet room etc.<br>**EVIDENCE OF COMPLIANCE**<br>1. Availability of procedures on handling of clinical and non clinical emergencies. — NA | NA | | | NA | |
| 14.6.7.6 | There shall be provision for MRI compatible patient and staff safety equipment.<br>**EVIDENCE OF COMPLIANCE**<br>1. Availability of MRI compatible equipment. — NA | NA | | | NA | |

## STANDARD STANDARD 14.6.8
COMPUTED TOMOGRAPHY (CT)

The Facility ensures that CT examinations are performed on selective patients and they are provided with current and accurate information about its benefits and risks . The staffs performing CT examination are adequately trained, and privileged. Adherence to relevant regulations and guidelines regarding safety and use of ionizing radiation are observed by the imaging personnel. The CT scan facilities and equipment are monitored regularly by a medical physicist to ensure that the equipment is functioning properly and taking optimal images.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.8.1 | Computed Tomography (CT) examination shall be performed by a qualified radiographer. The radiographer shall be adequately trained, and privileged.<br>EVIDENCE OF COMPLIANCE<br>1. Evidence of privileging of relevant staff. — NA<br>2. Records on training. — NA | NA | | | NA | |
| 14.6.8.2 | Imaging personnel and the facilities shall adhere to regulations and guidelines regarding the use of ionizing radiation, e.g. Atomic Energy Licensing Act (Act 304), Atomic Energy Licensing Board (AELB), and Atomic Energy Licensing (Basic Safety Radiation Protection) Regulation 2010.<br>EVIDENCE OF COMPLIANCE<br>1. Verification on practices during survey on adherence to relevant Regulations and guidelines. — NA | NA | | | NA | |
| 14.6.8.3 | The CT scan room shall meet the required specifications for such facilities in accordance with the requirements of the Ministry of Health and Atomic Energy Licensing Act (Act 304).<br>EVIDENCE OF COMPLIANCE<br>1. Certification from Class H license holder — NA<br>2. Facilities and equipment comply with relevant Act, Regulations and standards. — NA | NA | | | NA | |
| 14.6.8.4 | All CT scan examinations shall be interpreted and reported by a radiologist. All CT scan examinations may be interpreted by the specialists in their areas of expertise.<br>EVIDENCE OF COMPLIANCE | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1. | Evidence of credentials of radiologist (Registration with National Specialist Register) | NA | | | | |
| | 2. | Sampling of CT scan examination reports. | NA | | | | |
| 14.6.8.5 | There are policies and procedures addressing the safety, operations and maintenance of the CT scan equipment.<br><br>EVIDENCE OF COMPLIANCE | | | NA | | | NA | |
| | 1. | Policies and procedures on safety, operations and maintenance of the CT scan equipment. | NA | | | | |
| | 2. | Verification on practices during survey on compliance with policies and procedures | NA | | | | |
| 14.6.8.6 | Documented indications and justifications are available for the use of CT scan, e.g. prolong headache, head trauma, solitary pulmonary nodule, low back pain, CT colonoscopy, CT coronary and/or other relevant conditions as deemed by the services.<br><br>EVIDENCE OF COMPLIANCE | | | NA | | | NA | |
| | 1. | Indications for CT scan are available and documented in patient's medical record. | NA | | | | |
| 14.6.8.7 | There are guidelines for the handling of the following patients:<br><br>a) ambulatory;<br><br>b) acute stroke<br><br>c) requiring oxygen support;<br><br>d) critically ill patients or on ventilator;<br><br>e) infants and children;<br><br>f) patients with special needs<br><br>g) pregnant patient;<br><br>h) patients with or suspected renal failure.<br><br>I) infectious disease patients; | | | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | j) Polytrauma patients<br>EVIDENCE OF COMPLIANCE<br>1. Guidelines for the handling of patients as indicated in (a) to (j) — NA | | | | | | |
| 14.6.8.8 | The imaging equipment is monitored regularly by a medical physicist to ensure that the equipment is functioning properly, taking optimal images and radiation safety is ensured.<br>EVIDENCE OF COMPLIANCE<br>1. Records on monitoring of CT machine by medical physicist are available. — NA<br>2. Evidence of patient dose monitoring is available — NA | NA | | | NA | | |

## STANDARD STANDARD 14.6.9
ANGIOGRAPHY

Angiography examinations shall be performed by qualified, and privileged radiologist and medical practitioner in a safe facility that meets the specifications of the Ministry of Health and Atomic Energy Licensing Act (Act 304) and its subsidiary regulations as well as adherence to regulatory requirements on the use of ionizing radiation, e.g. Atomic Energy Licensing Board (AELB), Atomic Energy Licensing (Basic Safety Radiation Protection) Regulation 2010. There are policies, procedures and guidelines to ensure patient and staff safety.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.9.1 | Angiography examinations shall be performed by privileged radiologist, assisted by radiographer and nurses. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Evidence of privileging of radiologist/relevant staff. | NA | | | | |
| | 2. | Records on training. | NA | | | | |
| 14.6.9.2 | There are specific policies and procedures that include but not limited to:<br>a) patient identification and verification of the nature of investigation;<br>b) informed consent;<br>c) infection control;<br>d) angiography diagnostic and therapeutic procedures;<br>e) management of patient pre and post procedures;<br>f) operations and maintenance of the angiography equipment.<br>g) radiation safety and dose monitoring | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Specific policies and procedures which include but not limited to items (a) to (g). | NA | | | | |
| | 2. | Verification on practices during survey on compliance with policies and procedures | NA | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 14.6.9.3 | Imaging personnel and the facilities for angiography shall adhere to regulations and guidelines regarding the use of ionizing radiation, e.g. Atomic Energy Licensing Act (Act 304), Atomic Energy Licensing Board (AELB), Atomic Energy Licensing (Basic Safety Radiation Protection) Regulation 2010.<br>EVIDENCE OF COMPLIANCE<br>1. Verification on practices during survey on compliance to relevant Regulations and guidelines. — NA | NA | | | NA | |
| 14.6.9.4 | The angiography room shall meet the required specifications for such facilities in accordance with the requirements of the Ministry of Health and Atomic Energy Licensing Act (304) and its subsidiary regulations.<br>EVIDENCE OF COMPLIANCE<br>1. Certification from Class H license holder — NA<br>2. Facilities and equipment comply with relevant Act, Regulations and standards. — NA<br>3. Room to be equipped with HEPA (High Efficiency Particulate Air) filter — NA | NA | | | NA | |
| 14.6.9.5 | All angiography examinations shall be interpreted and reported by privileged radiologist. All angiography examinations may be interpreted by the specialists in their areas of expertise.<br>EVIDENCE OF COMPLIANCE<br>1. Evidence of privileging of radiologist. — NA<br>2. Records on training. — NA<br>3. Sampling of angiography reports. — NA | NA | | | NA | |
| 14.6.9.6<br>CORE | There is evidence of special handling and compliance with guidelines to ensure patient and staff safety;<br>a) critically ill patients or on ventilator;<br>b) infants and children;<br>c) patients with special needs<br>d) pregnant patient;<br>e) patients with or suspected renal failure.<br>f) highly infectious cases;<br>g) Polytrauma patients<br>h) radiation safety | NA | | | NA | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | i) handling of catheters, monitoring equipment, radiopharmaceutical agent and waste (in collaboration with nuclear medicine team) and other items.<br>j) complication of diagnostic and therapeutic interventional radiological procedures | | | | | | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Policies and procedures on radiation safety and handling of catheters, radiopharmaceutical agent and waste(in collaboration with nuclear medicine team), monitoring equipment and other items. | NA | | | | |
| | 2. | Verification on practices during survey on compliance with policies and procedures | NA | | | | |
| 14.6.9.7<br>CORE | Support services such as anaesthetic and critical care services, emergency and resuscitation equipment are easily accessible. | | | NA | | | NA |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Evidence of access to anaesthetic and critical care services, emergency and resuscitation equipment | NA | | | | |

STANDARD STANDARD 14.6.10
PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (PACS)

Where PACS is used, the Facility shall ensure that there are adequate provisions for the secure use, access and maintenance of the system, both within and outside the main Radiology Services/Department.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|
| | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.10.1 | There shall be adequate provisions with regards to the secure use, access and maintenance of the Picture Archiving and Communications System (PACS), both within and outside the Radiology Services/Department. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Policies and procedures on secure use, access and maintenance of the PACS. | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |
| 14.6.10.2 | There is a policy to ensure safety and confidentially of images archived. | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | |
| | 1. | Policy on safety and confidentially of images archived | NA | | | | |
| | 2. | Verification on practices during survey | NA | | | | |

## STANDARD STANDARD 14.6.11
DARKROOM AND FILM PROCESSORS

The Head of Radiology Services should ensure safety precautions are taken to provide a safe environment within the darkroom to address safety aspects of staff and radiological films.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.11.1 | The darkroom or area/equipment shall be equipped with an effective exhaust system and adequate ventilation. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Adequate exhaust and ventilation systems in the darkroom area. | NA | | | | | |
| | 2. | Odour-free environment. | NA | | | | | |
| 14.6.11.2 | The Radiology Services shall ensure safety precautions are taken to avoid accidental light exposure to films | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Provision for accidental light exposure such as:- | | | | | | |
| | a) | light tight single or double door; | NA | | | | | |
| | b) | door bell; | NA | | | | | |
| | c) | darkroom safe light. | NA | | | | | |
| 14.6.11.3 | Existing facilities ensure safety aspects of staff | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Clutter-free room for safe movement of staff. | NA | | | | | |
| | 2. | General cleanliness of the room. | NA | | | | | |
| | 3. | Observation on safety aspects of darkroom during survey. | NA | | | | | |

STANDARD STANDARD 14.6.12
DISPOSAL OF CHEMICAL WASTE

The Facility has proper arrangements for the storage and disposal of chemical waste as defined in the Environmental Quality Act 1974 (Act 127) and subsequent amendments and the subsidiary legislation referring to scheduled waste.

| CRITERION NO. | CRITERIA FOR COMPLIANCE | | | SELF RATING | FACILITY COMMENTS | SURVEYOR FINDINGS | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | AREAS FOR IMPROVEMENT / RECOMMENDATIONS | SURVEYOR RATING | RISK |
| 14.6.12.1 | There are proper arrangements made for the labelling, storage and disposal of chemical waste as defined in the Environmental Quality Act 1974 (Act 127) and subsequent amendments and the subsidiary legislation and Atomic Energy Licensing Act 1984 referring to scheduled waste. | | | NA | | | NA | |
| | EVIDENCE OF COMPLIANCE | | | | | | | |
| | 1. | Standard operating procedures on storage and disposal of chemical waste. | NA | | | | | |
| | 2. | Verification on practices during survey | NA | | | | | |

| SERVICE SUMMARY | |
|---|---|
| - | |
| OVERALL RATING : | NA |
| OVERALL RISK : | - |