CRITERIA FOR ACCREDITATION OF A GENERAL RADIOGRAPHY DEPARTMENT

Prepared by: SADCAS Advisory Committee - MIAS	**Approved by**: Chief Executive Officer	**Approval Date**: 2022-03-29 **Effective Date**: 2022-03-29

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1. PURPOSE AND SCOPE

The purpose of this document is to define the general, technical and specific requirements to be met by X-ray facilities in the field of Medical Imaging requiring accreditation to ISO 15189.

2. ABBREVIATIONS

CD: Compact Disk
CT: Computed Tomography
Dicom: Digital Imaging and Communications in Medicine
EHR: Electronic Health Record
EMR: Electronic Medical Record
HVAC: Heat Ventilation and Air Circulation
IAEA: International Atomic Energy Agency
ID: Identity
MRI: Magnetic Resonance Imaging
PACS: Picture Archiving and Communication System
QA: Quality Assurance
RIS: Radiology Information System
RSO: Radiation Safety Officer
SOP: Standard Operating Procedure

3. GENERAL REQUIREMENTS

3.1 Service Provided

3.1.1 The scope of activities of the General Radiography shall indicate which services are provided on-site and which are not.

3.1.2 For the procedures carried out on-site, the Radiography Service shall indicate the extent to which such procedures are carried out:

- Type of procedure;
- Instructions;
- Standard or limited examination;
- Analysis with clinical data; and
- Single study, Follow ups, Serial etc.

3.1.3 Where any radiology procedures are referred to another Radiology Service for radiographic examination, such information shall be provided by the referring imaging Physician or facility i.e.

- Identity of patient;
- Identity of referrer;
- Date of referral;
- Reasons for referral; and
- History of patient.

3.2 **Examination Procedures**

3.2.1 **General Radiography**

3.2.2 Patient Preparation

- The department shall have procedures to prepare the patient physically, physiologically and psychologically. The procedure shall be explained to the patient.
- Women of reproductive age shall be asked or tested to confirm their pregnancy status, and records maintained.

3.2.3 Room preparation

- The department must have protocols to prepare the room prior to the procedure.

3.2.4 Equipment preparation

- The department must have protocols to prepare equipment prior to the procedure.

4. RISK MANAGEMENT

4.1.1 Each department shall have a risk register (standardised requirements) and a Radiation Safety Officer (RSO) assigned to manage and control risks for the protection of patient, staff and facility**.**

4.1.2 To support this, each department shall have the following policies which shall be monitored and complied with:

4.1.2.1. Radiation Protection Policy;

4.1.2.2. Radiation Safety Training Policy;

4.1.2.3. Personnel Radiation Monitoring Policy;

4.1.2.4. Personal Protective Equipment Policy;

4.1.2.5. Pregnant women staff policy;

4.1.2.6. Special and Vulnerable Different User Groups policy;

- Paediatrics
- Pregnant patients

4.1.2.7. Authorisation and list of procedures for X-ray;

4.1.2.8. Protected zones policy;

- Showing Entering and exiting points and monitoring of controlled access zones.

4.1.2.9. Display and written warning signs policy;

4.1.2.10. Patient Identification Policy;

4.1.2.11. Incident reporting policy;

4.1.2.12. Safety and security Policy;

4.1.2.13. Infection control policy;

4.1.2.14. Occupational risk and hazard notices policy;

4.1.2.15. Hazardous materials policy;

4.1.2.16. Fire risk and personnel fire training policy;

4.1.2.17. Moving and handling heavy objects policy;

4.1.2.18. Psychological risks policy;

4.1.2.19. Data Protection Policy;

4.1.2.20. Staffing levels policy;

4.1.2.21. Financial loss policy;

4.1.2.22. Litigation proof policy;

4.1.2.23. Patient death reporting policy;

4.1.2.24. Privacy and confidentiality policy;

4.1.2.25. Continuous professional development policy;

4.1.2.26. Image storage policy;

4.1.2.27. Professional indemnity policy;

4.1.2.28. Spill and control of slip policy;

4.1.2.29. Violence and aggression policy;

4.1.2.30. Dose reference levels policy;

4.1.2.31. Decontamination of X-ray detectors and/or cassettes policy; and

4.1.2.32. Repetitive strain injury policy.

4.2 Infection control standard precautions should be guided by level of criticality as indicated below:

4.2.1 **Semi-critical procedures** were receptor contacts mucous membranes and non-intact skin used during wound procedures such as surface X-ray (broken skin):

- High level disinfection and use of sheath is required for semi-critical procedures.

4.2.2 **Noncritical procedures** were receptors only contact healthy intact skin such as surface X-ray:

- Low level disinfection is required.

4.3 Each Department shall:

4.3.1 Monitor and review the effectiveness of its X-ray policy and procedures.

4.3.2 Clearly outline responsibilities of staff performing X-ray procedures.

4.3.3 Ensure that all equipment is in good working order, operating correctly, effectively decontaminated prior to use and safely and regularly maintained.

4.3.4 Ensure there is a protocol for:

- Electrical hazards; and
- Fire hazards.

4.3.5 Patient support and immobilisation guidelines shall be available including who may be able to assist or hold the patient. Infant immobilisers must be available.

5. INFRASTRUCTURE AND ENVIRONMENT

5.1.1 Each General Radiography department for general procedures except paediatric shall have at least the following:

5.1.2 Area for administration, clerk, reception and section supervisors;

5.1.3 Adequate Communication telephone lines for communication in different rooms;

5.1.4 Close access to a toilet changing area and privacy at X-ray room or reception;

5.1.5 Reporting area;

5.1.6 File Cabinet;

5.1.7 Storage for Linens and Equipment;

5.1.8 Film Viewer; and

5.1.9 Counter Top and Sink with hot and cold water;

5.2 Each X-ray room must have the following;

5.2.1 A minimum room size of $16m^2$;

5.2.2 Wall thickness reference document;

5.2.3 Waiting area;

5.2.4 Epoxy or non-slippery floor;

5.2.5 Lead lined doors;

5.2.6 Interlocked doors;

5.2.7 Sub waiting area;

5.2.8 Confidentiality in examination rooms for all procedures;

5.2.9 Overhead Lights Dimmer to avoid glare in all procedures;

5.2.10 Dual Level Lighting (bright and dim);

5.2.11 Emergency Oxygen;

5.2.12 Suction Line;

5.2.13 Space for X-ray system;
5.2.14 Dedicated power 0utlet;

5.2.15 Circuit breaker protected and easily accessible;

5.2.16 Network Interface;

5.2.17 457 mm (18 inches) distance of X-ray system from wall or objects;

5.2.18 Stool;

5.2.19 Footswitch;

5.2.20 Examination Table – 1930 x 610 mm (76 x 24 inches);

5.2.21 Door – at least 762 mm (30 inches);

5.2.22 Optimum Heat Ventilation and Air Circulation (HVAC) system;

5.2.23 Ventilation should be supported through windows or air conditioning system;

- Picture Archiving and Communication System (PACS) and Radiology Information System (RIS) should recommended to avoid dust accumulation.

5.2.24 Drip stands and disposal skips for the majority of types of clinical waste;

5.2.25 Stepping stool;

5.2.26 Time services are offered must be displayed; and

5.2.27 Information for patients and their clinicians must be provided.

6. RADIOLOGY EQUIPMENT, MEDICATION, CONTRASTS AND CONSUMABLES.

For all procedures depending on level of expertise, the department shall have documented procedures for handling equipment, medication and consumables.

6.1 Equipment

6.1.1 Radiographic equipment management processes for both mobile and fixed units shall include:

- Selection of equipment;
- Procurement of equipment;
- Equipment set-up and applications training;
- User Acceptance and Testing Certification;
- Maintenance and repair;
- Annual checks by medical physicist or equally qualified medical expert;
- Equipment modifications;
- Replacement plan;
- Hired equipment;
- Quality Assurance procedures;
- Phantom integrity;
- Image quality;
- Reporting of equipment faults and adverse events;
- Availability of Service level agreements and schedules for maintenance of equipment;
- Arrangement with medical physicist for other quality assurance (QA) procedures;
- Have an equipment inventory record;

- An equipment management program should be available for Ancillary equipment such as PPE, Printers, resuscitation equipment and consumables; and
- Emergency equipment must be nearby and easily available.

6.1.2 Equipment shall be operated by trained and qualified personnel.

6.2 **Medication**

6.2.1 Each department shall have an emergency drug trolley within the vicinity of the department and easily available in the event of an emergency.

6.2.2 Each department must have preparatory procedure with instructions on medication use ensuring there is proper storage.

6.2.3 Each department shall ensure drugs are administered by qualified personnel such as:

- a Radiologist;
- a registered nurse; or
- a competent Practitioner trained to administer drugs.

6.2.4 Expiry dates of medications shall be verified.

6.3 **Consumables**

6.3.1. The department should have a stock management program and processes to ensure there are no stock outs.

6.3.1 Each department must have a proper place for the storage of films to ensure they are:

- Kept in a cool and dry area, away from heat sources;
- With optimum temperature of between 10-24 degrees;
- Kept at 30 to 50% humidity;
- away from chemical fumes; and
- have diagnostic quality

7. PRE - EXAMINATION PROCESS

7.1. The department shall have protocols to:

- Capture patient records;
- Schedule examinations taking into account turnaround time for each procedure and infectious control in case of infectious diseases such as tuberculosis;
- Cater for non-ambulatory patients, patient escorted by ambulance and senior citizens;
- Assess the completeness and accuracy of a request form with the following minimum requirements according to International Atomic Energy Agency (IAEA);

  - Patient information i.e., patient names, date of birth, address, contact details such as hospital ward or phone number and pregnancy status:
  - Examination information i.e., study requested, clinical indication and date of request:
  - Referrer information i.e., referring practitioners' signature, name and contact details;
- Identify patient positively with any form of approved identity particulars such as National ID, driving licence or any other form of recognised patient identity;
- Ensure triaging and emergency recognition of conditions such as trauma, infectious diseases and ambulant patients on Oxygen;
- Take clinical history and explain procedure to patient with reassurance.
- Evaluate appropriateness of examination on presented clinical context for each case.
- Review prior tests (clinical, laboratory tests, prior imaging)
- Properly instruct patients prior to procedure.
- Conduct quality assurance assessments to ensure that:
  - There is no visible damage on equipment
  - The machine is clean and disinfected to avoid risk of infecting patients
  - Cables are kept clean
  - Cassettes or Detectors are kept clean
  - Cassette covers are kept clean
  - The room is clean and adequately prepared
  - There is optimum screen resolution

8. EXAMINATION PROCESSES

8.1. Protocols should be in place to outline the responsibilities of the practitioner such as to check:

- Request form authenticity;
- Billing and payment confirmation;
- Patient identification;
- Patient clinical information;
- Previous examinations and other clinical data;
- For availability of resources

8.2. Standard Operating Procedures (SOPs) shall be available for:

- Deciding on appropriate technique and views to be used for each case;
- Preparing the patient for procedure in the room;
- Deciding on the need for any person to assist or hold patient;
- Achieving optimization of adaptive techniques and image quality to produce accurate diagnosis;
- Critically analysing acquired images and deciding on the need for further interrogation;
- Monitoring the patient;
- Evaluating quality of diagnostic images;
- Communication of findings and advice on further management;
- Dismissing patients; and
- Preparing room for next patient.

9. ENSURING QUALITY OF EXAMINATION RESULTS

9.1. The department shall have protocols to:

- verify coherence between produced images and written report;
- check validity of results;
- conduct peer reviews;
- proof read and sign reports;
- monitor patient results delivery;
- follow up on patients with referrers;
- monitor multidisciplinary teams reviewing X-ray study reports; and
- verify turnaround times.

9.2. A record of all examinations shall be kept for regular audits (weekly, monthly).

9.3. A second opinion shall be sought in difficult cases.

10. REPORTING

10.1. An Xray report shall be written and signed off by a Radiologist. Their name and signature must be appended. Each report should include:

- The title;
- Patient identification;
- Demographics;
- Date;
- Recipients;
- Clinical history;
- Clinical observations made by the Practitioner;
- Comparison with previous studies, if available and pertinent information recorded;
- Statement of scope of examination (targeted or survey) and technique used;
- Analysis of the significant lesion(s) or finding(s);
- Correlation with physical, mammographic Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) finding(s);
- Overall assessment or impression; and
- Management recommendations.

10.2. Report shall be given to patient except:

- Where provisions to deliver the report to the Clinician are available
- The patient is incapacitated; or
- Where there is Electronic Medical Record (EMR) and/or Electronic Health Record (EHR);

10.3. Reporting times should be specified by international guidelines;

- Routine results;
- Urgent results; and
- Critical results.

10.4. For those conditions triaged as emergency or found as critical reports must be communicated within an hour.

- Urgent results must be communicated within 24 hours.
- Routine results must be communicated as soon as they are ready.
- Retention times for reports before they are destroyed should be as specified by international standards and local regulatory requirements.

11. POST EXAMINATION PROCEDURES

11.1. The department shall have protocols for archiving and delivery of image results (Email, Compact Disk (CD), films) Delivery of image reports.

11.2. The department shall have protocols for back up of image results and reports.

12. PERSONNEL AND STAFFING

12.1. The staffing levels of a general X-ray department should be according to the number of equipment, working hours, patient volume and scope of services.

12.2. Each department offering general X-ray services must ensure that:

- Every staff meet a certain level of competency/proficiency before undertaking examinations;
- Every staff is registered to practice in their field of expertise;
- Every staff has a portfolio of their continuous professional development and learning;
- A record of all examinations is kept for regular audits (weekly, monthly); and
- A second opinion is sought in difficult cases.

13. INFORMATION MANAGEMENT SYSTEM

13.1. Every institution shall have an Information Management System which:

- Allows capturing of patient identification data;
- Handles Billing and Coding;
- Supports storage and transfer of patient Imaging data such as PACS;
- Monitors turnaround times;
- Should be able support teleradiology as it may improve clinical outcomes;

- Must be able to record annotations and other examination meta data such as exposure indices; and
- Has current Dicom license.

13.2. The network bandwidth where PACS is used should allow smooth transfer and movement of images as required by the system.

13.3. Any radiology staff who uses the system should be competent.

13.4. All monitors for viewing images must have a standard resolution appropriate for diagnosis 1-2MP.

13.5. Archive guidelines should be in place for storage of images appropriate to country requirements.

13.6. There must be work and software security protocols in place to ensure data protection.

14. REFERENCES

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APPENDIX - AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Subclause	Description of Change		
Issue 1	-	-	-	SADCAS CEO	2022-03-29