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RPA-AUT/RQ-04/DIR/14

RADIATION PROTECTION AUTHORITY OF ZIMBABWE

RADIATION PROTECTION ACT (CHAPTER 15:15)

REQUIREMENTS FOR MEDICAL X-RAY FACILITIES

a) Administrative Requirements

i. Completion and submission of the attached Authorization Application Form. The Form and the Guide for filling the Form could also be downloaded from the RPAZ website at www.rpaz.co.zw.
ii. Payment of applicable authorization fees in accordance with SI 134 0f 2012
iii. Type of licence application
iv. Purpose of application
v. Appointment of the legal person

b) Personnel/Training requirements

i. Radiographer / radiologist/ x ray operator with recognized training and registered with local professional board.
ii. Appointment of/designation of a Radiation Safety officer (RSO) indicating his job description and authority to stop unsafe practice.
iii. Working experience of radiographers/ radiologists/ x ray operators
iv. Copies of academic professional qualifications and CVs of staff and letters of their appointments.

c) Facility and Equipment design

a) The floor area of the room shall be at least 20m^2 and the ceiling 3m above the floor for General X Ray and 25m(2)for Computerised Tomography CT room
b) Wall thickness shall be equivalent to 2mm lead or plastered double solid brick walls (25cm thick) or 15cm concrete.
c) All doors shall be lined with 2mm lead and should have an overlap of at least 2cm with the frame.
d) All the entrances to x-ray rooms shall have sliding doors.
e) A red warning light synchronized to the machine shall be fitted at the entrance to the examination room, above the door.
f) Doors shall be fitted with a mechanical interlock system.
g) A radiation warning sign (trefoil) shall be posted on all entrances.

h) Warning notices shall be written and posted on all entrances in English, Shona and Ndebele.
i) Windows shall be at least 2m above the ground outside.
j) An operator's control cubicle/shield fitted with a 30x 30 cm window of 2mm lead equivalent must be provided and positioned in the room such that the least possible exposure is received by the operator.
k) Dose rates within the control cubicle shall be less than 2.5μSv per hour.
l) The primary wall shall be at least 2.5mm thick lead with no windows on it. The darkroom shall not be constructed behind this wall.
m) At least 2 lead aprons and gonad shields shall be provided and a changing area made available.
n) The darkroom shall be light proof, have a safelight, have an extractor fan and be ideally linked to the X-ray room via a maze.

Additional Requirements for CT scanning equipment

i. Acceptance test/ Commissioning test
ii. Maintenance and repair programme
iii. Quality control test
iv. Calibration certificates.

d) Application for Authorization

The application for shall include

I) Radiation Protection Programme

The Radiation Protection Programme for *an application for authorization* should include the following:

- Details of the Operator including qualifications of RSO and Qualified Experts where appropriate Identification of the individual(s) representing the operator;
- Details of qualifications and training in radiation protection of workers engaged in activities that involve or could involve occupational exposure;
  Details of Qualification of personnel as specified in S.I 62 of 2011 are to be included practices involving medical exposure, "the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the registration or licence; or a statement that only Medical Practitioners with qualifications in radiation protection specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorized source" as required.
- Justification for engaging in the regulated activity or practice for…..shall be submitted including copies of operating and maintenance procedures. For significant risk radiation sources, unusual or complex practices, or consumer products, a justification for engaging in the regulated activity or practice s;

- A plan of the premises with an assessment of the nature, magnitude and likelihood of exposures attributable to the radiation source(s) made by the Radiation Protection Officer or a Qualified Expert; shall be submitted.

- The occupational radiation protection programme, including arrangements for monitoring of workers and the workplace, and the provision and maintenance of personal protective equipment and equipment for radiation detection;
- For practices involving medical exposure, information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes;
- Radiation protection of the public, where appropriate, with all pathways of exposure taken into account;
- Arrangements to ensure safety of sources;
- A radioactive waste management , including the management of disused sources, return to supplier policy
- Emergency Preparedness Plan arrangements and financial arrangements for a radiological emergency, where appropriate"

ii) Personnel/Worker Protection

1) Licensees should ensure that all persons engaged in activities that involve occupational radiation exposure are provided with suitable and adequate protective clothing and Individual monitoring devices.

2) The appropriate protective clothing and devices should include lead equivalent aprons, thyroid shields, protective eye wear and gloves
    - Aprons should be equivalent to at least 0.25 mm Pb if the X-ray equipment operates up to 100kV and 0.35 mm Pb if it operates above 100kV.
    - Aprons should be stored on hangers and not folded for storage
    - Aprons should be tested at approximately 12-18 months intervals for shielding integrity.
    - Any suspected damage to the Apron should be reported immediately and the apron not used until it has been tested and declared safe
    - Additional Requirements for Interventional Radiology
    - Interventional radiology staff should always use 0.5mm lead equivalent protective devices.
    - Thyroid protection should be used be by interventionist (radiologist, cardiologist, neuroradiologist etc.)when using high radiation doses and dose rates during interventional radiology procedures
3) Proper use of a suspended protective barrier between the patient and the interventionist should be used to reduce the need for separate thyroid protection.
4) All lead vinyl material should comply with relevant international standards. They should be tested soon after purchase and the regularly at least every year.
5) Mobile Radiography
    - Staff using mobile X-ray equipment should make available a lead protective apron to any person who is required to remain less than 2m from the patient under examination.
6) If conventional (adult) x ray equipment is used for babies and small children, the grid should be removed wherever applicable. AEC must be calibrated for different sizes and stature of children.
7) Female workers shall be advised by the licensee or registrant that it is desirable to notify the employer of pregnancy. Once a female worker has notified the employer that she is pregnant, the employer shall adapt the working conditions in respect of occupational

exposure so as to ensure that the embryo is afforded the same broad of protection which is required for members of the public. The notification of pregnancy shall not be considered a reason to exclude a female worker from work.

8) Any person between the ages of 16 – 18 year shall not be allowed to work in controlled areas unless supervised and only for training purposes.

iii) Quality assurance program.

The licensees and/or registrant should establish a comprehensive Quality assurance program for radiation protection, safety and image quality that is compliance with applicable regulations and is within terms and conditions of authorisation.

1) The quality assurance program shall include:
   - Procedures to ensure that the medical exposures are in accordance with those prescribed by a medical practitioner
   - Patient dose evaluation
   - Quality control of the x ray system
   - Training and continuing education of staff
   - Clinical audits
   - Procedures for remedial actions, follow up and result evaluation
2) The quality control procedures manual should contain protocols for performing the different tests with indications on:
   - The measuring instruments or tools to be used
   - The operational details
   - The level of qualification required to the staff performing the test
   - The recommended frequency
   - The limiting values for and tolerances in the results

3) The following procedures should be included:
   - Acceptance tests are performed on new equipment to demonstrate that it is performing within the manufacturers specifications and criteria
   - Performance tests are specific tests that are performed on the x ray system in use after a certain amount of time has elapsed
   - Constancy tests
   - Status tests (full testing at longer periods eg annually)
   - Calibration of quality control test equipment
   - Follow up of any corrective actions required as a result of quality control tests
4) The quality control instruments include the following:
   - Instruments to check the electromechanical performance of the X ray system
   - Instruments to verify the accuracy of the radiation control settings eg KVP meter
   - Ionisation chambers and electrometers to measure and absorbed dose
   - Phantoms to measure image quality e.g. spatial resolution

e) Inspection

Furthermore, upon receipt of your completed application form, applicable fees and documents reflecting the requirements listed above, a date shall be fixed for inspection of your facility. The authorizations shall be issued upon a satisfactory report of the inspection exercise.