South African Health Products
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GUIDELINE FOR MINIMUM REQUIREMENTS FOR FIXED DIAGNOSTIC X-RAY INSTALLATIONS

This guideline stipulates the regulatory requirements for installations of fixed diagnostic X-ray units. Every medical diagnostic X-ray must meet the design safety specifications outlined in this document. The manufacturer / vendor must obtain a license to install from South African Health Products Regulatory Authority (SAHPRA) prior to importing or installing the X-ray equipment.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue and published for implementation	Oct 2009
2	– Content structured on the new SAHPRA Guideline Template – A unique document number SAHPGL-RDN-XR-04 allocated to this Guideline	August 2022

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Contents

Glossary

Abbreviation/ Term	Meaning
BSS	Basic Safety Standards
FFD	Focal Film Distance
ICRP	International Commission of Radiation Protection
IEC	International Electrotechnical Commission
MED	Medical Exposure Directive
SAHPRA	South African Health Products Regulatory Authority

1. INTRODUCTION

The system of radiation protection used in developing the guideline is based on the recommendations of the International Commission for Radiological Protection (ICRP). The conceptual framework adopted by ICRP in its publication No.103 (ICRP, 2007) builds on the system of dose limitation central to earlier ICRP documents such as ICRP 60 (1991) and ICRP 26 (1977). This system is embodied in various European Directives most notably the Basic Safety Standards (BSS) (EC, 1996a) and the Medical Exposure Directive (MED) (EC, 1997).

The South African health products regulatory authority (SAHPRA) recommends the location, structural design, and equipment layout of X-ray rooms must be carefully considered from a radiation protection perspective. The radiation protection should consider the safety of radiation workers, patients, and the public. This is easier when X-ray facilities are not designed as stand-alone rooms and are planned as part of an integrated radiology/imaging department with its supporting areas and services.

1.1 Purpose

To guide the X-ray units' installers on the minimum requirements for proper installation of the fixed X-ray units and safety standards required during installation. To lay down guidelines regarding specifications of medical x-ray units.

1.2 Scope

The document is drafted for all the manufacturers / vendors installing X-ray units to make sure that the units comply with all the listed requirements in terms of technical data (table size, FFD, etc)

2. LEGAL PROVISION

The Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973) govern the safe use of x-ray equipment in South Africa.

3. MINIMUM REQUIREMENTS

3.1 High-Tension Generator

3.1.1 **Electric power rating**

The minimum acceptable power rating is: -

3.1.2 **High frequency generators: 12 kW at 100 kV (The high-tension voltage ripple shall be no larger than 4%, measured at 100 kV (kVp) and 100 mA);**

- Three phase, 12-pulse or constant potential generators: 12 kW at 100 kV;

- Three phase, 6 pulse generators: 16 kW at 100 kV; and
- Single phase generators: 24 kW at 100 kV.

Note: An imaging system of at least a 400 speed should be incorporated in the above-mentioned systems

3.1.3 **Nominal X-ray tube voltage**

The nominal X-ray tube voltage (highest available kV) shall be at least 120 kV.

3.1.4 **Exposure time**

i. Values of exposure time need not be displayed.

ii. The shortest reproducible exposure time (measured as the time during which the kV is 75% of the selected value) shall be 5 ms or shorter.

iii. The shortest (total) exposure time shall be equal to or less than 10 ms.

iv. The maximum exposure time should not be longer than 2.5s.

3.1.5 **Electric energy rating**

i. The maximum nominal electric energy (total available energy for one single exposure), measured at 100 kV and a tube loading time not exceeding 2.5 s, shall be at least:

ii. 25 kWs for high frequency, three phase (12 pulse) and constant potential generators;

iii. 33 kWs for three phase (6 pulse) generators; and

iv. 50 kWs for single phase generators.

3.1.6 **Generator control panel**

The following switches or controls shall be available:

i. ON / OFF;

ii. kV-selector.

iii. mAs-selector or mA and time-selector.

iv. Anode rotation.

v. Exposure. The exposure switch should be mounted on the control panel, so that the operator must stand behind a protective screen or wall during exposures; and

vi. A light signal shall indicate if the generator is READY for the selected tube loading. The actual tube loading (exposure) shall be indicated with a sound and/or a light signal.

3.2 The X-Ray Tube

3.2.1 **Focal spot**

i. A rotating anode must be used.

ii. The focal spot of the X-ray tube shall have a nominal size no larger than 1 mm, measured according to IEC 336.

iii. For dual focus at least one focus to be a maximum of 1 mm

3.2.2 **Anode**

The anode angle shall be in the range of 12 - 15°. (An anode angle of 12° easily permits an X-ray field of 45 x 45 cm without visible heel effect at the expected working conditions).

3.2.3 **Tube rating**

Tube rating shall be compatible with the X-ray generator.

3.2.4 **Tube filtration**

i. Minimum total filtration for three phase (6 & 12 pulse), constant potential, and high frequency: 2.5 mmAl

ii. Minimum total filtration for single phase: 3.5 mmAl

3.2.5 **Collimator**

i. To be multi-leaf and manually operated with full field illumination.

ii. X-ray / light field coincidence to be within 2 cm on the 43 cm x 43 cm field at 100 cm.

iii. A rotating flange between the collimator and the tube must be supplied to provide diagonal collimation

3.3 Tube Assembly (U-ARM)

3.3.1 It is necessary to use a design which will ensure that the X-ray tube can always be aligned with the cassette holder in a rigid and stable way, i.e. providing precise and simple centering of the X-ray beam.

3.3.2 The X-ray tube and cassette holder shall be mounted in such a way that a recumbent patient can also be examined with a horizontal X-ray beam.

3.3.3 A gauge shall be installed to indicate tube assembly rotation (degrees).

3.3.4 Devices shall be installed to indicate the focus-film distance.

3.3.5 Brakes for tube assembly: Mechanical and/or electromagnetic.

3.3.6 Variable focus-film distance (fixed not acceptable): 1000 mm - 1500 mm

3.3.7 Height above floor for horizontal beam:

- minimum height of 500 mm or less; and
- maximum height at least 1600 mm.

3.3.8 Tube/cassette-holder arm angulation from vertical and horizontal position: ±30°

3.4 Tube Assembly (Tube Coloumn with Table and Erect Bucky)

3.4.1 A moving floor-to-ceiling / wall mounted, or rail system tube column is required.

3.4.2 It is necessary to use a design which will ensure that the X-ray tube can always be aligned with the cassette holder in a rigid and stable way, i.e., providing precise and simple centering of the X-ray beam.

3.4.3 The X-ray tube and cassette holder shall be mounted in such a way that a recumbent patient can also be examined with a horizontal X-ray beam.

3.4.4 The longitudinal movement of the tube column to be at least 150 cm. FFD from erect Bucky to be at

3.4.5 least 150 cm. It shall also be possible to use a FFD of 100 cm on the erect Bucky.

3.4.6 The FFD must be indicated on the table Bucky as well as erect Bucky.

3.4.7 A gauge shall be installed to indicate tube assembly rotation (degrees).

3.4.8 Rotation of the tube arm around its horizontal axis to be at least from -90° to +90°.

3.4.9 Rotation of the tube arm around its vertical axis to be at least from -90° to +90°.

3.4.10 Rotation of the tube around its own axis to be at least from -10° to +10°.

3.4.11 Vertical movement of the tube arm to be at least 150 cm from the tabletop.

3.4.12 The centre of the horizontal beam must be aligned with the centre of the erect Bucky for the entire movement of the Bucky.

3.4.13 Brakes for tube assembly: Mechanical and/or electromagnetic.

3.5 Bucky Table

3.5.1 **Floating-top table**

3.5.1.1 The tabletop shall be able to support a patient weighing at least 110 kg, sitting in the middle of the table, without appreciable distortion.

3.5.1.2 The equivalent density of the tabletop should not be more than 1.5 mm Al.

3.5.1.3 Minimum table width: 650 mm

3.5.1.4 Minimum table length: 2000 mm

3.5.1.5 Minimum table height (table-top to floor): 700 mm

3.5.1.6 Longitudinal movement: at least -600 mm to +600 mm

3.5.1.7 Lateral movement: at least -120 mm to +120 mm

3.5.1.8 Centre lock must be available.

3.5.1.9 Brakes for table movement: Electromagnetic.

3.5.1.10 The distance between the tabletop and film plane shall not exceed 80 mm.

3.5.2 **Trolley**

3.5.2.1 The examination table shall be a trolley if and only if a U-arm is comprised in the system. .

3.5.2.2 The trolley shall at least be able to support a patient weighing 110 kg, sitting in the middle of the table, without appreciable distortion.

3.5.2.3 The equivalent density of the top should not be more than 1.0 mm Al.

3.5.2.4 The design of the trolley must permit the use of the cassette holder in horizontal position under the trolley in such a way that the distance between the top of the trolley and the film plane shall not exceed 80 mm. In this position it must be possible to use the trolley as a floating-top table, so that the longitudinal midline of the trolley can be offset -120 mm to +120 mm or more from the midline of the cassette holder.

3.5.2.5 The trolley shall have large wheels with locks on at least two of them.

3.5.2.6 Dimensions: -

- Minimum trolley width: 650 mm;
- Minimum trolley length: 2000 mm;
- Minimum trolley height: 700 mm; and
- Minimum diameter of wheels: 100 mm

3.6 Erect Bucky

a) Wall / floor mounted stand.

b) Vertical movement from ±750 mm to ±1800 mm from floor.

c) Cassette tray for standard sizes 130 mm x 180 mm to 350 mm x 430 mm.

3.7 Anti-scatter Grid

Focused anti-scatter grid(s) must be supplied. The grid ratio shall be 10:1 with a line density of 35-60 lines/cm. The grid shall be large enough to cover a vertical film format of 35 cm x 43 cm. If the 35 cm x 43 cm format will be used in transversal position, the grid must be 43 cm x 43 cm. The focal range for the grids in the erect as well as table Bucky shall be such that chest radiography with an FFD of 150 cm and general radiography with an FFD of 100 cm can be done.

4. REFERENCES

The following related documents are referenced:

4.1 EC, 1997. Council Directive 97/43/Euratom on the health protection of individuals against the dangers of ionizing radiation in relation to medical exposures. Official Journal of the European Communities, L180,09/07/1997, p. 22-27.

4.2 ICRP. 2007. Recommendations of the International Commission on Radiological Protection, ICRP Publication 103, Annals of the ICRP, 37, (2-4).

4.3 IEC, 2008. Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance. Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment, International Electrotechnical Commission, IEC: 60601-1-3:2008.

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline for Minimum Requirements for Fixed Diagnostic X-Ray Installations, revised October 2009. It will be reviewed on this timeframe or as and when required.