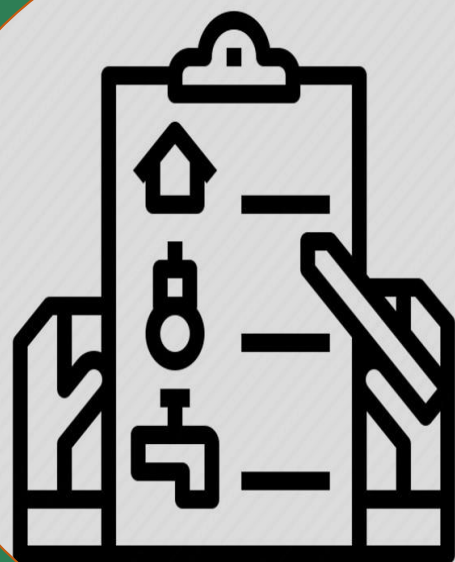




Office of Health Standards Compliance
Ensuring quality and safety in health care

Regulatory Tertiary Hospital Inspection Tool v1.0



Health Technology Services/**Clinical
Engineering**



Facility:

Date:

- **Tool Name:** Regulatory Tertiary Hospital Inspection Tool v1.0
- **HEs Type:** Hospitals
- **Sector:** Public
- **Specialization:** Tertiary
- **Created By:** Health Standards Development and Training

8 Health Technology Services/Clinical Engineering

Domain 8.3 CLINICAL SUPPORT SERVICES

Sub Domain 8.3.1 13 Medical equipment

Standard 8.3.1.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

Criterion 8.3.1.1.1 13(2)(a) The health establishment must ensure that equipment is licensed where required from the relevant licensing body.

8.3.1.1.1.1 Medical equipment is licensed.

Assessment type: Document - **Risk rating:** Vital measure

Equipment is licensed in terms of article 3(1) of the Hazardous Substances Act, 1973 (Act 15 of 1973).

Equipment that requires licensing will include but is not limited to Radiology units general purpose, Radiology units chest, Radiology units dental, Radiology units mobile, Radiology/Fluoroscopy general purpose, CT scanner, Absorptimeters (bone densitometer), CT stimulator, Radiotherapy simulator. Request a list of medical equipment that must be licensed. Randomly sample five items from the list and check if license issued by the regulatory body is available and valid. Score 1 if license is available and valid and 0 if not license is not available.

Score	Comment	
Aspects	Score	Comment
1. Equipment 1		
2. Equipment 2		
3. Equipment 3		
4. Equipment 4		
5. Equipment 5		

Criterion 8.3.1.1.2 13 The health establishment must adhere to a planned schedule for maintaining medical equipment.

8.3.1.1.2.1 Maintenance plan for medical equipment is available.

Assessment type: Document - **Risk rating:** Vital measure

Request the medical equipment maintenance plan for the previous twelve months, the maintenance plan must be aligned to the manufacturer's instructions of each equipment. In cases where the original manufacturer's instructions are not available, a guiding

document developed by the local engineering/maintenance department (can be health establishment, district, provincial) must be available.

Not applicable: Never

Score	Comment

8.3.1.1.2.2 Medical equipment is maintained.

Assessment type: Document - **Risk rating:** Vital measure

Medical equipment must be maintained as documented in the maintenance plan which is aligned to manufacturer’s instructions. Randomly sample twenty medical equipment maintenance records from the previous twelve months and verify whether equipment has been maintained in line with maintenance plan. Score 1 if equipment was maintained as documented in the maintenance plan and score 0 if equipment was not maintained as documented in the maintenance plan.

Score	Comment	
Aspects	Score	Comment
1. Medical equipment 1		
2. Medical equipment 2		
3. Medical equipment 3		
4. Medical equipment 4		
5. Medical equipment 5		
6. Medical equipment 6		
7. Medical equipment 7		
8. Medical equipment 8		
9. Medical equipment 9		
10. Medical equipment 10		
11. Medical equipment 11		
12. Medical equipment 12		
13. Medical equipment 13		
14. Medical equipment 14		
15. Medical equipment 15		

16. Medical equipment 16		
17. Medical equipment 17		
18. Medical equipment 18		
19. Medical equipment 19		
20. Medical equipment 20		



Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health. To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Tertiary Hospitals.

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- The Provincial Departments of Health for their input and comments during the consultation phase.

It is hereby certified that the Regulatory Tertiary Hospital Inspection Tools version 1.0 was developed by the Health Standards Compliance.

SIGNATURE:

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