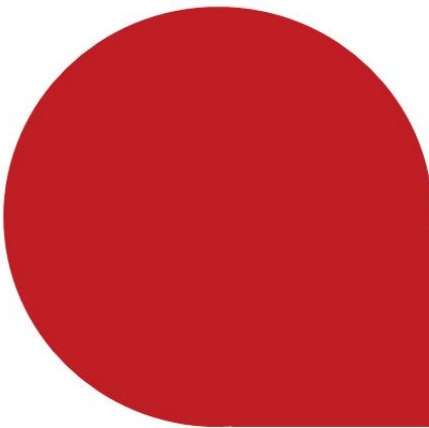




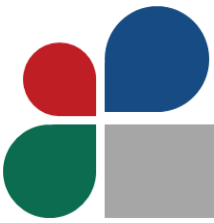
Office of Health Standards Compliance  
Ensuring quality and safety in health care



v1.2

**Health Technology Services/  
Clinical Engineering**

**Regulatory Private Acute  
Hospital Inspection tool**



## 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.

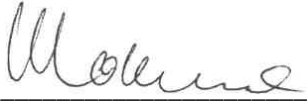
To achieve this mandate, standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Private Acute Hospitals.

### **Acknowledgements**

There are many people who have contributed to the development of the Regulatory Private Acute Hospital Inspection Tools Version 1.2. The Office of Health Standards Compliance wishes to extend most heartfelt acknowledgement and gratitude to the following:

- The WHO technical team for providing guidance on the very first draft inspection tools database
- OHSC CEO Dr Siphwe Mndaweni and Executive Manager for Health Standards Design, Systems and Support Ms Winnie Moleko for providing strategic and operational support.
- Former Health Standards Development and Training unit Director Dr Grace Labadarios
- Systems, Data Analysis and Research unit Director Dr Thabiso Makola who is also the Acting Director for Health Standards Development and Training unit
- The Health Standards Development and Training unit (Mr Jabu Nkambule who led the team and worked tirelessly with the leadership of Hospital Association of South Africa (HASA) during various development stages of the tool, Ms Florina Mokoena, Ms Mosehle Matlala, Ms Busisiwe Mashinini) and contract workers Ms Thesia Pather and Ms Busi Ngubane for the development of the Private Acute Hospital Inspection tools.
- The internal OHSC teams Compliance Inspectorate; Systems, Data Analysis and Research for their contribution during the development of the Inspection tools and Information Technology and Communication and Stakeholder Relations for providing support.
- Provincial Department of Health private hospital licensing units personnel (Ms Pinki Belot - Free State Province, Ms Dimakatso Moeketsi and Ms Zandile Nzuza - Kwa-Zulu Natal -Province, Ms Kim Jacobs - Western Cape Province, Ms Bulelwa Peter - Eastern Cape Province, Ms Pakama Nqadala - Northern Cape Province, Ms Lindiwe Mkhathshwa - Mpumalanga Province, and Ms Patience Ntamane - Gauteng Province) for their valuable input and support.
- The Certification and Enforcement Committee of the OHSC Board for reviewing the tools and for recommending to the Board for approval.
- The Hospital Association of South Africa (HASA) for their commitment and constructive engagements during the consultative process and for affording the OHSC an opportunity to conduct scoping visits in the private hospital health establishments.

It is hereby certified that these Regulatory Private Acute Hospital Inspection tools version 1.2 was developed by the Office of Health Standards Compliance.



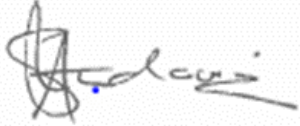
Ms. WMoleko

Executive Manager

Health Standards Development

Analysis and Support

Date: 31/03/2022



Dr. S. Mndaweni

Chief Executive Officer

Date: 31/03/2022

Facility:
Date:

- **Tool Name:** Regulatory Private Acute Hospital inspection tool v1.2 - Final
- **HEs Type:** Hospitals
- **Sector:** Private
- **Specialization:** Private Acute Hospital
- **Created By:** Health Standards Development and Training

## 8 Health Technology Services/Clinical Engineering

### Domain 8.2 CLINICAL GOVERNANCE AND CLINICAL CARE

#### Sub Domain 8.2.1 7 Clinical management

**Standard 8.2.1.1 7(1)** The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

**Criterion 8.2.1.1.1 7** The health establishment implements process to ensure environmental cleanliness.

**8.2.1.1.1.1** All cleaning work completed is verified by the cleaning supervisor or delegated person.

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

Daily inspections will ensure the cleanliness of the unit. The person responsible for overseeing the cleaning service must inspect the unit daily to confirm that cleaning has been carried out according to the schedule and that all areas attended to have been effectively cleaned. Monitoring tools (including, but not limited to, checklists/ tick sheets) listing all cleaning tasks must be completed for each room or area. Not applicable: Never

Score	Comment

**Standard 8.2.1.2 7(2)** (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

**Criterion 8.2.1.2.1 7** The health establishment implements process to ensure environmental cleanliness.

**8.2.1.2.1.1** The health technology/Clinical Engineering unit is observed to be clean.

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

Inspector to observe general cleanliness of the unit including but not limited to whether the unit is free of dirt, dust and stains. Not applicable: Never

Score	Comment

**Criterion 8.2.1.2.2 7** The health establishment must adhere to a planned schedule for maintaining medical equipment.

**8.2.1.2.2.1** Records from the previous 12 months show that equipment is maintained according to a planned schedule, in line with the manufacturer's instructions.

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

For the equipment listed below, examine the planned preventive maintenance schedule in the unit as well as the manufacturer's instructions and the maintenance schedule. Determine whether the service intervals in the maintenance schedule correspond with the manufacturer's instructions. In the event that manufacturer's instructions are not available, they may be replaced by documented guidance from the local health technology team. Score 1 if this requirement is met and 0 if not met. Score NA (not applicable) where the health establishment does not use the equipment listed.

Score	Comment

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Unit 1 Maintenance schedule available

Aspects	Score	Comment
1. Anaesthetic machine(s)		
2. Ventilator(s)		
3. Defibrillator(s)		
4. Automated external defibrillator (AED/s)		
5. Non-invasive blood pressure (NIBP) machines		
6. Infusion pumps		
7. Blood gas analyser machine(s)		
8. Syringe pumps		
9. Cardiac monitors		
10. Cardiotocograph machines		
11. Sonar machine		
12. Vascular Doppler		
13. ANC Doppler		
14. Theatre beds		
15. Echo machine		
16. Intracranial pressure monitor		
17. Lung function test machine		
18. 12-lead electrocardiograph (ECG)		
19. Haemodialysis machine		
20. Cardiac output monitor		

Unit 2 Schedule aligned to manufacturer's instructions

Aspects	Score	Comment
1. Anaesthetic machine(s)		
2. Ventilator(s)		

3. Defibrillator(s)		
4. Automated external defibrillator (AED/s)		
5. Non-invasive blood pressure (NIBP) machines		
6. Infusion pumps		
7. Blood gas analyser machine(s)		
8. Syringe pumps		
9. Cardiac monitors		
10. Cardiotocograph machines		
11. Sonar machine		
12. Vascular Doppler		
13. ANC Doppler		
14. Theatre beds		
15. Echo machine		
16. Intracranial pressure monitor		
17. Lung function test machine		
18. 12-lead electrocardiograph (ECG)		
19. Haemodialysis machine		
20. Cardiac output monitor		

Unit 3 Maintained according to schedule

Aspects	Score	Comment
1. Anaesthetic machine(s)		
2. Ventilator(s)		
3. Defibrillator(s)		
4. Automated external defibrillator (AED/s)		
5. Non-invasive blood pressure (NIBP) machines		
6. Infusion pumps		
7. Blood gas analyser machine(s)		
8. Syringe pumps		

9. Cardiac monitors		
10. Cardiotocograph machines		
11. Sonar machine		
12. Vascular Doppler		
13. ANC Doppler		
14. Theatre beds		
15. Echo machine		
16. Intracranial pressure monitor		
17. Lung function test machine		
18. 12-lead electrocardiograph (ECG)		
19. Haemodialysis machine		
20. Cardiac output monitor		

**8.2.1.2.2.2** Each machine has a log and service history.

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

Sample a minimum of five machine and check if the records of the service history for each machine are done according to the manufacture’s guide. Where records are not available, the machine must have been serviced at least within the previous financial year. Records must be available, even if the service is outsourced. Score 1 if compliant and 0 if not.

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

**Criterion 8.2.1.2.3 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.**

**8.2.1.2.3.1** A policy or standard operating procedure or procedure or guideline for the management of medical equipment is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes

made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment	
Aspects	Score	Comment
1. Recording of equipment in a register		
2. Training on the use of equipment		
3. Equipment is calibrated and serviced as per manufacturers recommendations		
4. Equipment is cleaned and decontaminated as per manufacturer's instructions		
5. Loan of equipment is documented and followed up.		

**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 or devices have a copy of the required license.

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

Medical equipment or devices that require licensing must have the license issued by the relevant licensing body or authority or regulator. This includes but is not limited to medical equipment generating ionising radiation. Request a list of medical equipment or devices and verify whether a license or certificate is available for each of the items on the list. Score 1 if the license or certificate is available and 0 if not available. Not applicable: Never. Reference: <https://www.sahpra.org.za/radiationcontrol/> <https://www.sahpra.org.za/medical-devices/>

Score	Comment

**Domain 8.4 GOVERNANCE AND HUMAN RESOURCES**

**Sub Domain 8.4.1 20** Occupational health and safety

**Standard 8.4.1.1 20(1)** The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

**Criterion 8.4.1.1.1 20(2)(b)** Awareness of safety and security issues must be promoted

**8.4.1.1.1.1** The emergency evacuation plan is prominently displayed.

**Assessment type:** Observation - **Risk rating:** Essential measure

The evacuation plan must include amongst others: route/directions to be followed during evacuation, emergency exits and assembly point(s). This must be displayed. Not applicable: Never

Score	Comment



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**8.4.1.1.1.2** The healthcare personnel are familiar with the emergency evacuation procedure.

**Assessment type:** Staff interview - **Risk rating:** Essential measure

Interview three health care personnel to establish whether they are able to explain the evacuation procedure as illustrated in the evacuation plan. Score 1 if they explain the procedure as illustrated in the evacuation plan and 0 if not. Where no evacuation plan is available, this measure must be scored 0.

Score	Comment

Aspects	Score	Comment
1. Healthcare personnel 1		
2. Healthcare personnel 2		
3. Healthcare personnel 3		

**Domain 8.5 FACILITIES AND INFRASTRUCTURE**

**Sub Domain 8.5.1 14** Management of buildings and grounds

**Standard 8.5.1.1 14(1)** The health establishment and their grounds must meet the requirements of the building regulations.

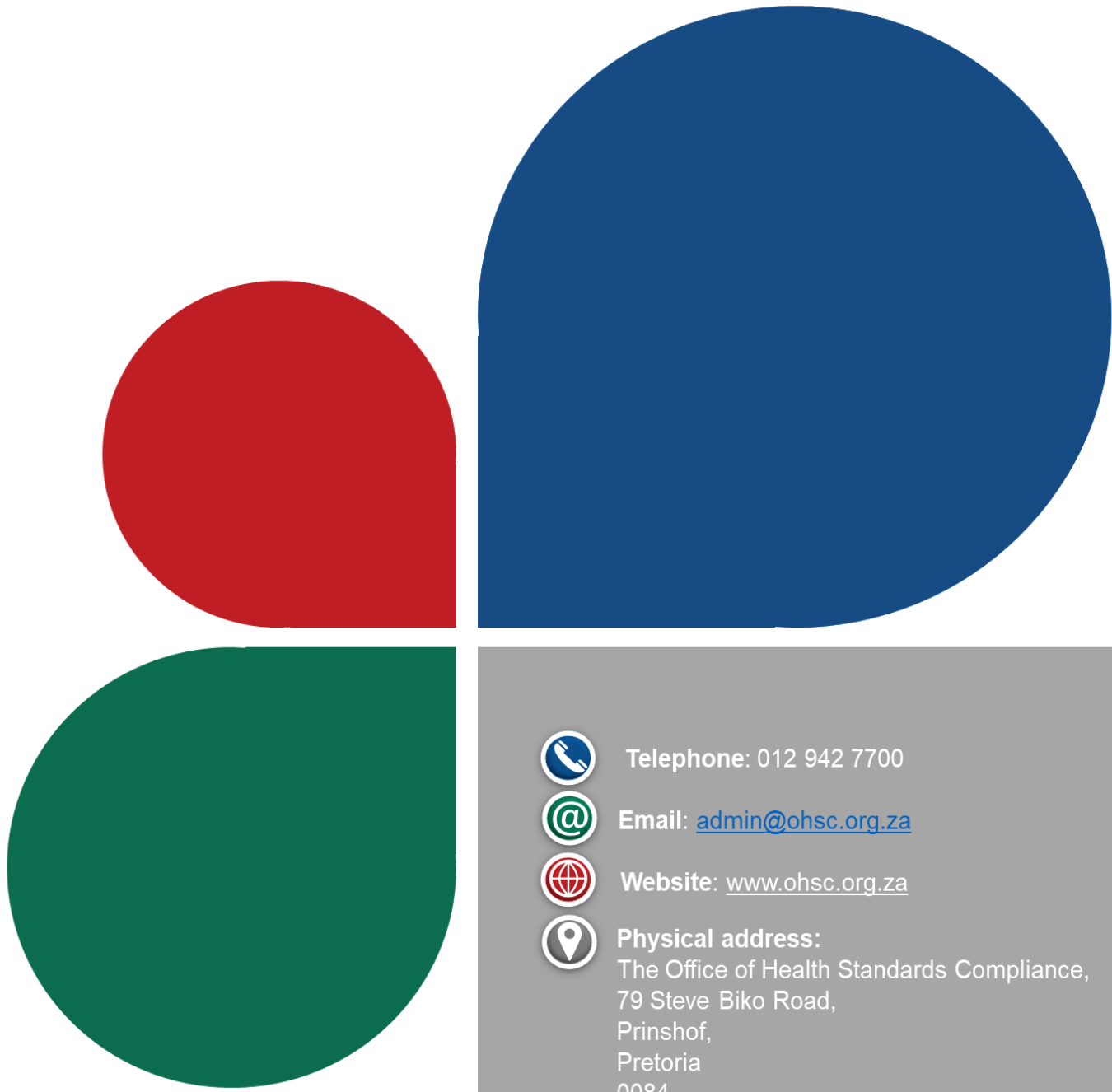
**Criterion 8.5.1.1.1 14(2)(b)** The health establishment must as appropriate for the type of buildings and grounds of the establishment have a maintenance plan for buildings and the grounds.

**8.5.1.1.1.1** No obvious safety hazards are observed during the visit.

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

Inspect the surroundings for maintenance-related safety hazards in the unit, including but not limited to loose electrical wiring, collapsing ceiling or roof, collapsing doors or any other type of safety hazards that represent a risk to the health and safety of personnel, users and visitors. Not applicable: Where there is no standalone health technology/Clinical Engineering unit.

Score	Comment



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**ISBN:**

978-0-620-90157-4