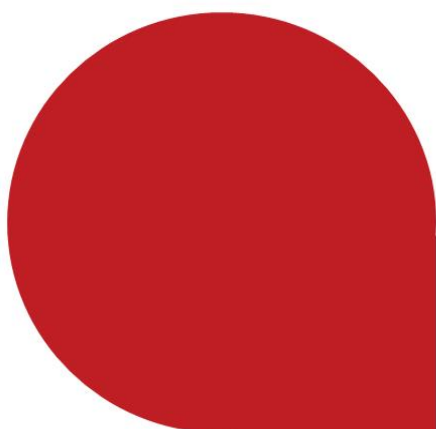




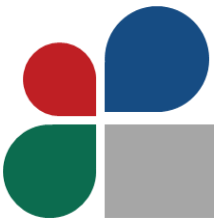
Office of Health Standards Compliance
Ensuring quality and safety in health care



v1.2

Pharmaceutical Stores

**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.

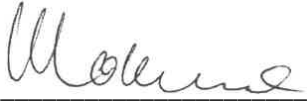
To achieve this mandate, standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Private Acute Hospitals.

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
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- 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.
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- Provincial Department of Health private hospital licensing units' personnel (Ms Pinki Belot - Free State Province, Ms Dimakatso Moeketsi and Ms Zandile Nzuzwa - 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.



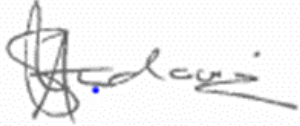
Ms. W Moleko

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

46 Pharmaceutical Stores

Domain 46.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 46.2.1 7 Clinical management

Standard 46.2.1.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 46.2.1.1.1 7 The health establishment implements process to ensure environmental cleanliness.

46.2.1.1.1.1 All cleaning work completed is verified by the supervisor or delegated health care personnel.

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 of all cleaning tasks must be completed for each room or area. Not applicable: Never

Score	Comment

46.2.1.1.1.2 The 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 46.2.1.1.2 7 Healthcare providers are informed on the health establishment and their specific responsibilities.

46.2.1.1.2.1 Health care personnel have been informed about the policy or standard operating procedure or procedure or guideline for management of medical supplies.

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

Documented evidence that personnel have been informed about the policy or standard operating procedure or procedure or guideline for management of medical supplies must be available. This could include but is not limited to distribution lists which include personnel signatures to indicate they have read and understood the document (which must be dated and signed), proof of attendance at meetings where policies, guidelines and standard operating procedures are discussed, or similar evidence for electronic distribution which could include but not limited to email distribution or documents deposited in intranet or other electronic platforms. Not applicable: Never

Score	Comment

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Domain 46.3 CLINICAL SUPPORT SERVICES

Sub Domain 46.3.1 10 Medicines and medical supplies

Standard 46.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 46.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

46.3.1.1.1.1 The health establishment has a system to order medical supplies.

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

Observe if there is a manual or electronic system to order medical supplies in place. Not applicable:

Never

Score	Comment

46.3.1.1.1.2 The stock control system shows minimum and maximum levels and/or reorder/preferred levels for medical supplies.

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

Each item held as stock must have documented minimum, maximum and/or reorder/preferred levels. These levels must be recorded on the bin cards or equivalent. The system may be manual or electronic. Not applicable: Never

Score	Comment

46.3.1.1.1.3 Physical stock corresponds to stock control system.

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

Randomly select five items held as stock and verify whether their availability corresponds with the balance indicated on the bin cards or equivalent. The system may be manual or electronic.

Score	Comment

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

46.3.1.1.1.4 A stock take for medical supplies was conducted in the previous 12 months.

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

Evidence must be available in the form of a report or other documented evidence including a variance report, indicating that a stock take has been completed in the previous 12 months. Document must be signed and dated. Not applicable: Never

Score	Comment

Criterion 46.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

46.3.1.1.2.1 Medical supplies/consumables are available in the pharmaceutical stores.

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

The unit is expected to have a list of basic medical supplies/consumables according to the needs of the users. Request the list of medical supplies/consumables for the unit and randomly select twenty-five items and check whether the selected items are available and not expired (where applicable). Score 0 if any of the selected items are not available or they are expired or if there is no list of medical supplies/consumables available. Not applicable: Never

Score	Comment

46.3.1.1.2.2 Medical supplies are stored and managed in compliance with medical supply management principles.

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

Verify whether the medical supplies storage area complies with the aspects listed below. Score 1 if the aspect is compliant and 0 if not compliant. Where medical supplies are not stored in the ward, score NA.

Score	Comment

Aspects	Score	Comment
1. Pharmaceutical stores has sufficient space in storage area for orderly arrangement of stock and proper stock rotation. Explanatory note: Verify that medical supplies are not stored up to the ceiling or against windows. There should be sufficient space to move around the storage area without the risk of falling or injury while attempting to locate and retrieve medical supplies.		
2. Storage area is free of cracks, holes or signs of water damage.		
3. Storage area is clean (shelves are dusted, floor is swept, and walls are clean).		

4. Medical supplies are stored according to a classification system.		
5. Medical supplies are not stored in direct contact with floor (i.e. on a shelf or pallet).		

Domain 46.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 46.4.1 20 Occupational health and safety

Standard 46.4.1.1 20(1) The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

Criterion 46.4.1.1.1 20(2)(b) Awareness of safety and security issues must be promoted

46.4.1.1.1.1 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

46.4.1.1.1.2 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 46.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 46.5.1 14 Management of buildings and grounds

Standard 46.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 46.5.1.1.1 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.

46.5.1.1.1.1 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. This will include but is 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:

Never

Score	Comment

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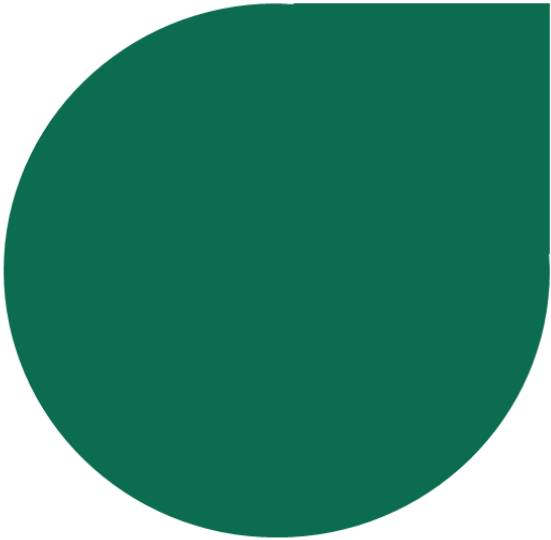
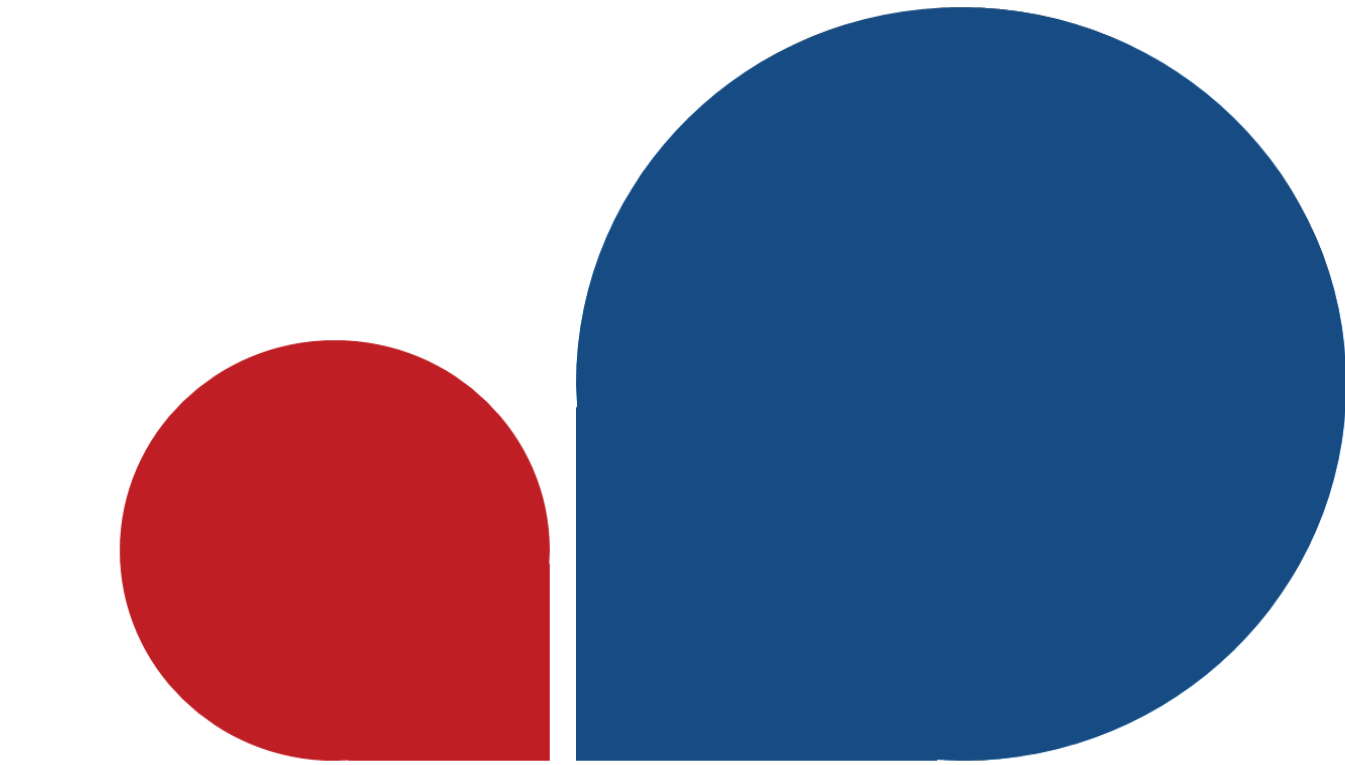
Criterion 46.5.1.1.2 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

46.5.1.1.2.1 The pharmaceutical stores has a functional air conditioner(s).

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

Verify whether the air conditioner(s) switches on and off and provides cold/cool air to the room in accordance with the temperature setting. Not applicable: Never

Score	Comment



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