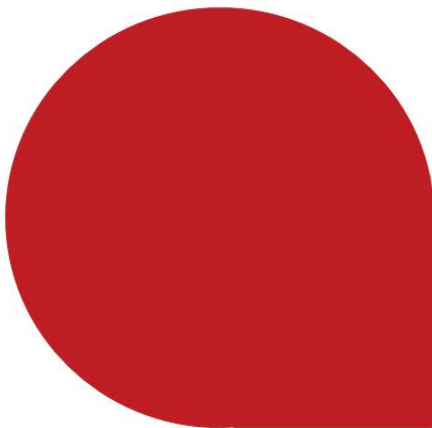




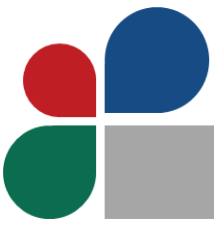
Office of Health Standards Compliance
Ensuring quality and safety in health care



v1.2

**Medical Records_ Storage
And Archives**

**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.

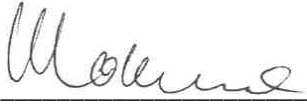
To achieve this mandate, standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Private Acute Hospitals.

Acknowledgements

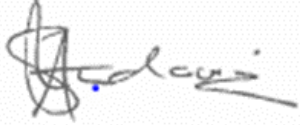
There are many people who have contributed to the development of the Regulatory Private Acute Hospital Inspection Tools Version 1.2. The Office of Health Standards Compliance wishes to extend most heartfelt acknowledgement and gratitude to the following:

- 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. 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

36 Medical Records_ Storage And Archives

Domain 36.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 36.2.1 6 User health records and management

Standard 36.2.1.1 6(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

Criterion 36.2.1.1.1 6(2)(a) The health establishment must have a health record filing, archiving, disposing, storage and retrieval system which complies with the law.

36.2.1.1.1.1 The policy or standard operating procedure or procedure or guideline for the key functions of health records management 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. Accessing of user records		
2. Requests for user records		
3. Tracking of user records		
4. Filing of user records		
5. Storage of user records		
6. Archiving of records		
7. Disposal of records		

36.2.1.1.1.2 Health record department personnel responsible for records management have received training or induction in the management of health records.

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

Documented evidence of training or induction is required, including, but not limited to, training certificates for external training attended, or attendance registers for in-house training or induction.

Documentation must confirm the aspects of records management covered by the training or induction. Score 1 if the documented evidence is available and 0 if not available.

Score	Comment

Unit 1 Healthcare personnel 1

Aspects	Score	Comment
1. Accessing of user records		
2. Requests for user records		
3. Tracking of user records		
4. Filing of user records		
5. Storage of user records		
6. Archiving of records		
7. Disposal of records		

Unit 2 Healthcare personnel 2

Aspects	Score	Comment
1. Accessing of user records		
2. Requests for user records		
3. Tracking of user records		
4. Filing of user records		
5. Storage of user records		
6. Archiving of records		
7. Disposal of records		

Unit 3 Healthcare personnel 3

Aspects	Score	Comment
1. Accessing of user records		
2. Requests for user records		
3. Tracking of user records		
4. Filing of user records		
5. Storage of user records		

6. Archiving of records		
7. Disposal of records		

Criterion 36.2.1.1.2 6(2)(c) The health establishment must secure health records with appropriate security control measures in the records storage area and in the clinical service area in accordance with the Protection of Personal Information Act, 2013 (Act No. 4 of 2013).

36.2.1.1.2.1 The health records storage and archive area complies with the requirements listed below.

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

Inspect the room used to store health records and archives to verify whether it complies with the requirements listed below. Score 1 if compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Access control measures are in place. Explanatory note: This includes, but is not limited to, a functional and monitored lockable security gate, strong room door, access-controlled door or closed-circuit television		
2. "No unauthorised entry" sign on door to records storage area		
3. Storage area has aisles and shelves that are labelled		
4. Storage area has counter and/or sorting table		
5. Functional electric lighting		
6. Storage area is kept clean and dust free		
7. Storage area is free of rodents and other pests		

Standard 36.2.1.2 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 36.2.1.2.1 6 The health establishment must ensure that confidential information or user-identifiable data is not divulged without prior consent as per legislation.

36.2.1.2.1.1 The health establishment complies with the standard operating procedure for obtaining consent if user-identifiable information is communicated.

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

Select three records from the previous 12 months of users who have given consent to release their identifiable information to a third party, including, but not limited to, lawyers, insurance companies and statutory bodies. Score 1 if a signed consent form is available and 0 if not available. Score NA (not applicable) where no such requests have been made in the past 12 months. NB: Zero reporting must be available if there were no requests.

Score	Comment

Aspects	Score	Comment
1. Record 1		
2. Record 2		
3. Record 3		

Sub Domain 36.2.2 7 Clinical management

Standard 36.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 36.2.2.1.1 7 The health establishment implements process to ensure environmental cleanliness.

36.2.2.1.1.1 All cleaning work completed is verified by the supervisor or delegated personnel.

Assessment type: Document - **Risk rating:** Essential measure All work completed is verified by the supervisor or delegated personnel.

Score	Comment

36.2.2.1.1.2 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 and stains. Not applicable: Never

Score	Comment

Criterion 36.2.2.1.2 7 Healthcare providers are informed on the health establishment and their specific responsibilities.

36.2.2.1.2.1 Health care personnel have been informed about the policy or standard operating procedure or procedure or guideline of the unit and health establishment.

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 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. Score 1 if such evidence is available and score 0 if it is not available.

Score	Comment

Aspects	Score	Comment

1. Confidentiality of user health records		
2. Security of health records		
3. Obtaining user consent if user-identifiable information is to be communicated to a third party		

Domain 36.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 36.4.1 20 Occupational health and safety

Standard 36.4.1.1 20(1) The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

Criterion 36.4.1.1.1 20(2)(b) Awareness of safety and security issues must be promoted

36.4.1.1.1.1 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

36.4.1.1.1.2 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 36.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 36.5.1 14 Management of buildings and grounds

Standard 36.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 36.5.1.1.1 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.

36.5.1.1.1.1 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, roof, 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

--	--

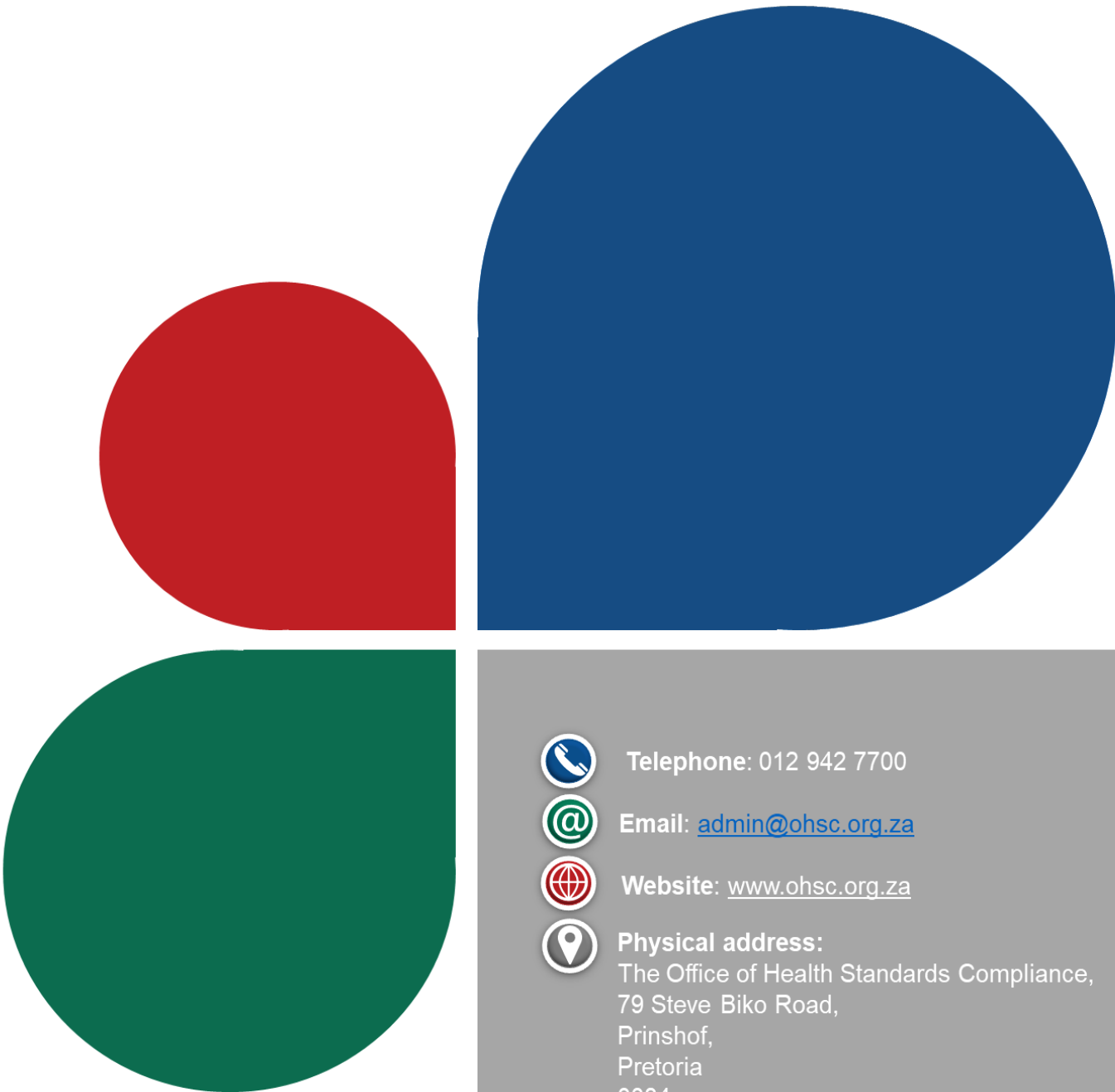
Criterion 36.5.1.1.2 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

36.5.1.1.2.1 The unit has natural ventilation or functional mechanical ventilation.

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

The national building regulations stipulate that satisfactory ventilation is only provided by forcing outdoor air into a space mechanically or passively through either ducting or apertures open to the outside, including, but not limited to, windows or ventilation grilles. Verify whether the medical records and archive has natural ventilation (windows and doors that can be opened) or functional mechanical ventilation (i.e. a ducting system). Not applicable: Never

Score	Comment



Telephone: 012 942 7700



Email: admin@ohsc.org.za



Website: www.ohsc.org.za



Physical address:

The Office of Health Standards Compliance,
79 Steve Biko Road,
Prinshof,
Pretoria
0084



Postal Address:

Private Bag X21
Arcadia
0007



ISBN:

978-0-620-90157-4