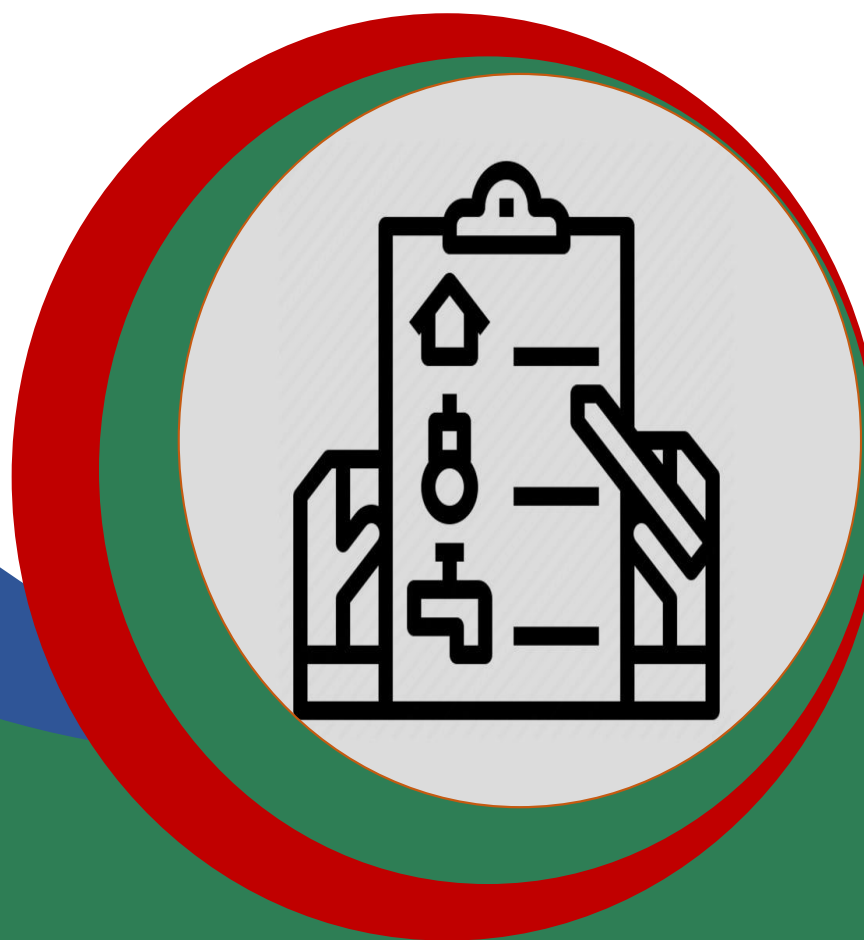




Office of Health Standards Compliance
Ensuring quality and safety in health care

Regulatory Tertiary Hospital Inspection Tool v1.0



Diagnostic Imaging Services



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

10 Diagnostic Imaging Services

Domain 10.1 USER RIGHTS

Sub Domain 10.1.1 22 Waiting times.

Standard 10.1.1.1 22 The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

Criterion 10.1.1.1.1 22 **Waiting times are monitored and improvement plans are implemented.**

10.1.1.1.1.1 Compliance with waiting time target(s) in the unit is monitored.

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

Request the previous six months' tools used for monitoring waiting times at the unit.

Not applicable: Never

Score	Comment

Domain 10.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 10.2.1 6 User health records and management.

Standard 10.2.1.1 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 10.2.1.1.1 6(2)(b) **The health establishment must ensure confidentiality of health records.**

10.2.1.1.1.1 Confidentiality of health records is maintained.

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

In line with section 14 of the National Health Act. Observe how user health records are managed in the unit and determine whether unauthorised individuals would be able to access the information in the health records. This includes but not limited to the complete health record of the user attending diagnostic imaging unit, diagnostic imaging request forms, diagnostic images or reports, health records used for clinical audits or other administrative purposes. This requirement applies to digital as well as paper-based records. Electronic records must be safeguarded with passwords or any other security measures.

Not applicable: Never

Score	Comment

Sub Domain 10.2.2 7 Clinical management.

Standard 10.2.2.1 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 10.2.2.1.1 7 **The management of emergency resuscitations must be guided and monitored to improve user outcomes.**

10.2.2.1.1.1 Emergency trolley is stocked with medicines, medical supplies and equipment.

Assessment type: Observation - **Risk rating:** Non-negotiable measure

Inspect the contents of the emergency trolley against the aspects listed below. Score 1 if the aspect listed is available, functional and not expired (where applicable) and score 0 if the aspect is not available, not functional or expired (where applicable).

Score	Comment	
Aspects	Score	Comment
Devices to open and protect airway.		
1. Laryngoscope handle (As determined by the user profile seen in the unit)		
2. Straight blade for laryngoscope (a minimum of two different sizes as determined by the user profile seen in the unit and resuscitation protocol)		
3. Curved blade for laryngoscope (a minimum of two different sizes as determined by the user profile seen in the unit and resuscitation protocol)		
4. Endotracheal tubes-adult (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
5. Endotracheal tubes-paediatric (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
6. Oropharyngeal airway (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol, must accommodate both adult and paediatric users)		
7. Plaster or ties for endotracheal tubes		
8. Lubricating gel		
Equipment for difficult Intubation.		
9. Introducer		
10. Laryngeal mask airway (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol)		
11. Magill forceps (adult)		
12. Magill forceps (paediatric)		
Devices to deliver oxygen/ventilate users.		
13. Manual resuscitator device or bag and valve mask (adult)		
14. Manual resuscitator device or bag and valve mask (paediatric)		
15. Oxygen masks- re breather (adult).		
16. Oxygen Mask- re breather (paediatrics).		
17. Portable oxygen cylinder. Explanatory note: An oxygen cylinder fitted with a regulator to adjust the flowrate must be available.		
Equipment to diagnose and treat cardiac dysrhythmias.		

18. Automated external defibrillator (AED) with pads or defibrillator with conducting gel, pads, paddles and electrodes		
19. Cardiopulmonary resuscitation board		
Devices to gain intravascular access.		
20. Intravenous administration sets		
21. IV Cannulae (a minimum of three different sizes that accommodate both adult and paediatric users)		
Medicine.		
22. Emergency medicines according to local protocol are available and have not expired.		

10.2.2.1.1.2 Medical supplies and equipment for resuscitation are available.

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

Inspect whether medical supplies and equipment used for resuscitation is available. The items may be available in the trolley or vicinity of the trolley. Score 1 if the aspect listed is available, functional and not expired (where applicable) and score 0 if the aspect is not available, not functional or expired (where applicable).

Score	Comment	
Aspects	Score	Comment
1. Chlorhexidine or Alcohol swabs		
2. Eye protection		
3. Facemask		
4. Gloves		
5. Spare batteries for laryngoscope		
6. Spare bulb (where applicable)		
7. Syringe (a minimum of five different sizes)		
8. Catheter tip syringe 50ml		
9. Needles (a minimum of five different sizes)		
10. Scissors		
11. Tourniquet		
12. Stethoscope		
13. Nasogastric tube (a minimum of four different sizes as determined by the user profile seen in the unit).		

14. Suction catheter (a minimum of four different sizes as determined by the user profile seen in the unit).		
15. Suction devices (portable)		
16. Yankhauer suction		
17. Nasal cannula		
18. Blood administration set		
19. Local resuscitation protocol or Resuscitation Algorithm		

10.2.2.1.1.3 The emergency trolley and emergency equipment is checked in accordance with agreed unit practice.

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

Request a documented practice for checking the emergency trolley and verify whether it is checked as documented. This will include but is not limited to checking of the defibrillator/Automated External Defibrillator. Request documented records of checking from the previous month.

Not applicable: Never

Score	Comment

Criterion 10.2.2.1.2 7 Health care personnel receive ongoing in-service education according to their roles and responsibilities.

10.2.2.1.2.1 Health care personnel receive training in the use of medical equipment.

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

This includes, but is not limited to, orientation records demonstrating that in-service training or training by the supplier of new equipment has been conducted. Training must be provided for each health care personnel for each item of equipment they will be required to use in the course of performing their duties.

Not applicable: Where there was no new equipment introduced in the past twelve months.

Score	Comment

Criterion 10.2.2.1.3 7 Users and health care personnel must be protected against ionising radiation exposure.

10.2.2.1.3.1 Radiation unit health care personnel wear dosimeters.

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

To protect radiation unit health care personnel from exposure to radiation, dosimeters must be worn to monitor their exposure levels. The dosimeters must not have expired. Randomly sample three health care personnel and observe whether dosimeters are worn. Score 1 if compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Health care personnel 1		
2. Health care personnel 2		

3. Health care personnel 3		
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10.2.2.1.3.2 Each radiographic imaging room has an exposure chart.

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

This may be in the form of a document or an electronic panel in the machine.

Not applicable: Never

Score	Comment

10.2.2.1.3.3 A report of radiation safety measures is available.

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

The report from the previous six months must reflect actions taken to limit radiation exposure. This report will include but not limited to checking of radiation levels in the unit, reports from dosimeter readings.

Not applicable: Never

Score	Comment

10.2.2.1.3.4 A clearly visible safety notice for pregnant women is displayed outside the radiographic imaging rooms.

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

This serves to protect pregnant users and health care personnel from unnecessary exposure to radiation. The notice must be visibly displayed.

Not applicable: In ultrasound scanning areas.

Score	Comment

10.2.2.1.3.5 Dosimeter readings are monitored.

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

Documented evidence must reflect the exchange of dosimeters on a monthly basis for each member of health care personnel issued with a dosimeter. The dosimeter reading or dose must be recorded on the document.

Not applicable: Never

Score	Comment

Criterion 10.2.2.1.4 7 The management of used and soiled linen must meet infection prevention and control requirements.

10.2.2.1.4.1 The unit has a designated, access-controlled area for the storage of dirty linen.

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

Dirty linen must be stored in closed bags in a designated area (dirty linen room). The door of the dirty linen room must be kept closed and access to the room must be restricted. Reference: Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework 2020, page 70

Not applicable: Never

Score	Comment

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Criterion 10.2.2.1.5 7 The health establishment must have a functional quality management system.

10.2.2.1.5.1 Quality improvement plans are developed by health care personnel.

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

Request the quality improvement plan of the unit from the previous six months. Verify whether the aspects listed below are documented. Score 1 if aspect is documented and 0 if not. Score not applicable where no gaps have been identified.

Score	Comment	
Aspects	Score	Comment
1. Gaps identified		
2. Activities required to address gaps		
3. Health care personnel responsible		
4. Time frames		

10.2.2.1.5.2 Corrective action has been taken to improve the quality of service provided where gaps are identified.

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

Evidence must be available that the action specified in the quality improvement plan was implemented.

Not applicable: Where there were no gaps identified.

Score	Comment

Sub Domain 10.2.3 8 Infection prevention and control programmes.

Standard 10.2.3.1 8(1) The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

Criterion 10.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

10.2.3.1.1.1 Hand washing facilities are available.

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

Select three areas in the unit and inspect the handwashing facilities for the items listed below. Score 1 If the item is available and 0 if not available.

Score	Comment

Unit 1 Area 1

Aspects	Score	Comment
1. Functional hand wash basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Taps are functional and not broken. Explanatory note: Taps must be elbow or non-touch operated in user care areas.		

3. Plain liquid soap		
4. Wall mounted soap dispenser		
5. Paper towel dispenser with disposable hand paper towels		
6. General waste container. Explanatory note: Containers used for the temporary storage of general waste should be leak proof, intact, corrosive resistant and have a tight-fitting lid. The container must be lined with the appropriate colour coded liner. (Practical Manual: Implementation of the National Infection Prevention and Control Strategic Framework page 82 and page 84).		

Unit 2 Area 2

Aspects	Score	Comment
1. Functional hand wash basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Taps are functional and not broken. Explanatory note: Taps must be elbow or non-touch operated in user care areas.		
3. Plain liquid soap		
4. Wall mounted soap dispenser		
5. Paper towel dispenser with disposable hand paper towels		
6. General waste container. Explanatory note: Containers used for the temporary storage of general waste should be leak proof, intact, corrosive resistant and have a tight-fitting lid. The container must be lined with the appropriate colour coded liner. (Practical Manual: Implementation of the National Infection Prevention and Control Strategic Framework page 82 and page 84).		

Unit 3 Area 3

Aspects	Score	Comment
1. Functional hand wash basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Taps are functional and not broken. Explanatory note: Taps must be elbow or non-touch operated in user care areas.		
3. Plain liquid soap		
4. Wall mounted soap dispenser		
5. Paper towel dispenser with disposable hand paper towels		

6. General waste container. Explanatory note: Containers used for the temporary storage of general waste should be leak proof, intact, corrosive resistant and have a tight-fitting lid. The container must be lined with the appropriate colour coded liner. (Practical Manual: Implementation of the National Infection Prevention and Control Strategic Framework page 82 and page 84).		
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10.2.3.1.1.2 Alcohol based hand rub is available.

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

Select three areas and observe whether alcohol-based hand rub is available. Score 1 if available and 0 if not available.

Score	Comment	
Aspects	Score	Comment
1. Area 1		
2. Area 2		
3. Area 3		

10.2.3.1.1.3 Posters on hand hygiene are displayed.

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

Select three areas and observe whether posters on hand hygiene are displayed. This could be a single hand hygiene poster or individual posters for hand washing or correct use of alcohol-based hand rub. Score 1 if available and 0 if not available.

Score	Comment	
Aspects	Score	Comment
1. Area 1		
2. Area 2		
3. Area 3		

Criterion 10.2.3.1.2 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

10.2.3.1.2.1 Linen rooms or storage cupboards or trolleys are adequately stocked and well organised.

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

Inspect the area where linen is stored to determine whether the aspects listed below are compliant. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. There is a designated area for the storage of linen		
2. Clean linen is available.		

3. Linen is stored on shelves		
4. The area or cupboard is well organised		

Criterion 10.2.3.1.3 8(2)(d) The health establishment must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.

10.2.3.1.3.1 Personal protective equipment is worn.

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

Using the checklist below, verify whether protective clothing and equipment are worn. Score 1 if the items are worn and 0 if not worn.

Not applicable where at the time of the inspection personnel are not in a situation in which they are required to wear protective clothing.

Score	Comment

Unit 1 Area 1

Aspects	Score	Comment
1. Lead aprons or lead skirt and jacket		
2. Shield X-ray gloves		
3. Thyroid shields		
4. Non – sterile or sterile gloves		
5. Disposable gowns or aprons		
6. Protective face shields or goggles		
7. Face masks or N95 or KN95 or FFP2 respirators or approved equivalent		

Unit 2 Area 2

Aspects	Score	Comment
1. Lead aprons or lead skirt and jacket		
2. Shield X-ray gloves		
3. Thyroid shields		
4. Non – sterile or sterile gloves		
5. Disposable gowns or aprons		
6. Protective face shields or goggles		
7. Face masks or N95 or KN95 or FFP2 respirators or approved equivalent		

Unit 3 Cleaner

Aspects	Score	Comment
1. Domestic gloves		
2. Disposable gowns or aprons		
3. Protective face shields or goggles		
4. Face masks or N95 or KN95 or FFP2 respirators or approved equivalent		

Sub Domain 10.2.4 9 Waste management.

Standard 10.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 10.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

10.2.4.1.1.1 The unit has appropriate containers for disposal of all types of waste.

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

Verify whether the waste containers listed below are available. Health care risk waste containers must have the appropriate international hazard symbol and be marked as prescribed in SANS 10248-1: Management of Health Care Waste, Part 1: Management of health care risk waste from a health facility. Score 1 if the waste container is available and 0 if not available. Where a particular type of waste is not generated in the unit, score not applicable.

Score	Comment	
Aspects	Score	Comment
1. Infectious non-anatomical waste (red)		
2. Sharps (yellow)		
3. Radioactive waste (no colour coding)		
4. General waste (black, beige, white or transparent packaging may be used)		

Criterion 10.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

10.2.4.1.2.1 The service level agreement for safe disposal of toxic chemicals, radioactive waste is monitored for compliance.

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

Evidence may include signed monitoring checklists, minutes of meetings and reports comprising indicators/services as per the service level agreement.

Not applicable: Where the unit does not generate toxic chemicals and radioactive waste.

Score	Comment

10.2.4.1.2.2 Remedial action is taken to rectify breaches identified.

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

A document reflecting actions taken to rectify identified breaches of the terms of the service level agreement must be available.

Not applicable: Where no breaches were identified.

Score	Comment

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10.2.4.1.2.3 There is a temporary healthcare risk waste storage area.

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

In all areas where waste is held for collection and removal to the central storage area, a designated area for temporary storage of waste must be available. Some health establishments will have a purpose-built temporary waste storage area, others will utilise a specific area within the available space. Score 1 if the aspect is compliant and 0 if not compliant, or where there is no designated area.

Score	Comment	
Aspects	Score	Comment
1. Space available to store waste containers		
2. Area is well ventilated		
3. Area is well lit		
4. Area has impervious floor surfaces (waterproof or resistant, not cracked)		

Criterion 10.2.4.1.3 9 Films and reagents must be stored and disposed of according to guidelines.

10.2.4.1.3.1 Health care personnel can explain how to store and dispose of films and reagents.

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

Interview three health care personnel to determine whether they are able to explain the process for storing and discarding films and reagents. Score 1 if they can explain the process as described in the relevant standard operating procedure of the unit and 0 if they cannot explain the process. Score not applicable in health establishments that do not use imaging films and reagents.

Score	Comment	
Aspects	Score	Comment
1. Health care personnel 1		
2. Health care personnel 2		
3. Health care personnel 3		

Sub Domain 10.2.5 21 Adverse events.

Standard 10.2.5.1 21(1) The health establishment must have a system to monitor and report all adverse events.

Criterion 10.2.5.1.1 21(2)(b) The health establish.

ent must have systems in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events.

10.2.5.1.1.1 Health care personnel are aware of the procedure to report adverse events.

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

Interview three health care personnel to establish their awareness on reporting of adverse events Score 1 if they are able to explain the aspects listed below and 0 if not.

Score	Comment

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Unit 1 Health care personnel 1

Aspects	Score	Comment
1. Types of adverse events that might happen in the unit (give three examples)		
2. How to report adverse events in the unit?		
3. Feedback processes on reported adverse events. Explanatory notes: This could include but not limited to formal feedback on the progress, outcome and quality improvement plans)		

Unit 2 Health care personnel 2

Aspects	Score	Comment
1. Types of adverse events that might happen in the unit (give three examples)		
2. How to report adverse events in the unit?		
3. Feedback processes on reported adverse events. Explanatory notes: This could include but not limited to formal feedback on the progress, outcome and quality improvement plans)		

Unit 3 Health care personnel 3

Aspects	Score	Comment
1. Types of adverse events that might happen in the unit (give three examples)		
2. How to report adverse events in the unit?		
3. Feedback processes on reported adverse events. Explanatory notes: This could include but not limited to formal feedback on the progress, outcome and quality improvement plans)		

Domain 10.3 CLINICAL SUPPORT SERVICES

Sub Domain 10.3.1 13 Medical equipment.

Standard 10.3.1.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

Criterion 10.3.1.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

10.3.1.1.1.1 Functional essential equipment is available in the unit.

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

Essential equipment to deliver basic user care must be available in the unit. Request the list of medical equipment for the unit and randomly sample ten different items and check whether the sampled equipment is available and functional. Check whether the sampled equipment is available and functional. Document the name of the non-compliant equipment that was sampled. Score 1 if the sampled item is available and functional or 0 if not available or not functional or if the list is not available.

Score	Comment

Aspects	Score	Comment
1. Equipment 1		
2. Equipment 2		
3. Equipment 3		
4. Equipment 4		
5. Equipment 5		
6. Equipment 6		
7. Equipment 7		
8. Equipment 8		
9. Equipment 9		
10. Equipment 10		

Domain 10.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 10.5.1 15 Engineering services.

Standard 10.5.1.1 15(1) The health establishment must ensure that engineering services are in place.

Criterion 10.5.1.1.1 15(2) The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

10.5.1.1.1.1 Piped oxygen or oxygen cylinder is available in the unit.

Assessment type: Observation - **Risk rating:** Non-negotiable measure

This is to ensure that users have access to oxygen when required. Verify whether piped oxygen or oxygen cylinder is available and functional in the unit.

Not applicable: Never

Score	Comment

10.5.1.1.1.2 Piped or portable suction is available in the unit.

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

This is to ensure that users have access to suction when required. Verify whether piped or portable suction is available and functional in the unit.

Not applicable: Never

Score	Comment



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

SIGNATURE: 
MS. WINNIE MOLEKO
EXECUTIVE MANAGER: HEALTH STANDARDS, DEVELOPMENT ANALYSIS AND SUPPORT

DATE: 09/05/2024

SIGNATURE: 
DR MATHABO MATHEBULA
CHIEF OPERATIONS OFFICER: OHSC

DATE: 10/05/2024

SIGNATURE: 
DR SIPHIWE MNDAWENI
CHIEF EXECUTIVE OFFICER: OHSC

DATE: 10/05/2024

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

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