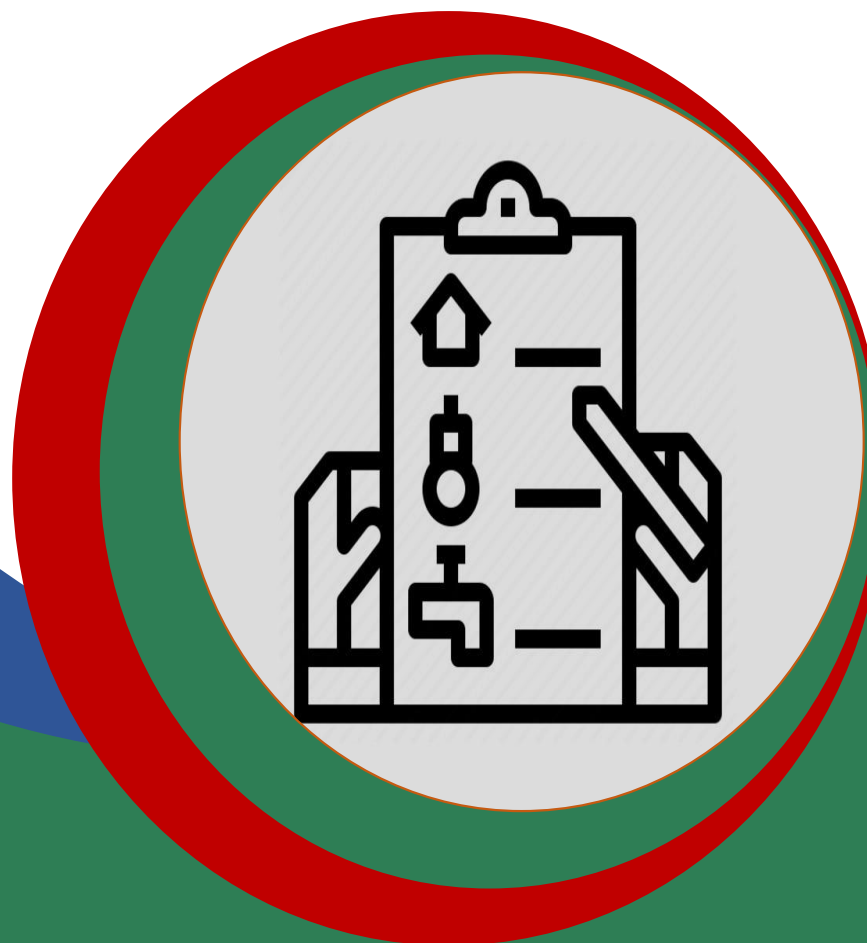




Office of Health Standards Compliance
Ensuring quality and safety in health care

Regulatory Tertiary Hospital Inspection Tool v1.0



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

31 CSSD

Domain 31.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 31.2.1 7 Clinical management.

Standard 31.2.1.1 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 31.2.1.1.1 7 Standard operating procedures for decontamination processes must be available.

31.2.1.1.1.1 Health care personnel are able to explain the procedure for sterilising used instruments.

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

Interview three health care personnel responsible for sterilisation and ask them to describe how they perform sterilisation of instruments from start to finish according to the standard operating procedure. Score 1 if the aspect is described and 0 if not described.

Score	Comment

Unit 1 Healthcare personnel 1

Aspects	Score	Comment
1. Personal protective equipment to be worn, including caps, goggles, masks, gauntlet gloves and plastic aprons.		
2. Clean sink to be filled with water and detergent.		
3. Detergent solution to be constituted in accordance with manufacturer's instructions.		
4. Instruments to be fully immersed in solution.		
5. Instruments to be brushed, to remove all visible material. Explanatory note: These actions must be performed while holding the instruments under water.		
6. Instruments to be rinsed.		
7. Instruments to be dried before disinfecting.		
8. Sterile packaging to be done according to procedure.		
9. In-pack chemical indicator to be placed in all sets and towels.		
10. Tracking system indicators to be marked on packs and sets.		
11. Storage to ensure integrity of materials.		

Unit 2 Healthcare personnel 2

Aspects	Score	Comment
1. Personal protective equipment to be worn, including caps, goggles, masks, gauntlet gloves and plastic aprons.		
2. Clean sink to be filled with water and detergent.		
3. Detergent solution to be constituted in accordance with manufacturer's instructions.		
4. Instruments to be fully immersed in solution.		
5. Instruments to be brushed, to remove all visible material. Explanatory note: These actions must be performed while holding the instruments under water.		
6. Instruments to be rinsed.		
7. Instruments to be dried before disinfecting.		
8. Sterile packaging to be done according to procedure.		
9. In-pack chemical indicator to be placed in all sets and towels.		
10. Tracking system indicators to be marked on packs and sets.		
11. Storage to ensure integrity of materials.		

Unit 3 Healthcare personnel 3

Aspects	Score	Comment
1. Personal protective equipment to be worn, including caps, goggles, masks, gauntlet gloves and plastic aprons.		
2. Clean sink to be filled with water and detergent.		
3. Detergent solution to be constituted in accordance with manufacturer's instructions.		
4. Instruments to be fully immersed in solution.		
5. Instruments to be brushed, to remove all visible material. Explanatory note: These actions must be performed while holding the instruments under water.		
6. Instruments to be rinsed.		
7. Instruments to be dried before disinfecting.		
8. Sterile packaging to be done according to procedure.		
9. In-pack chemical indicator to be placed in all sets and towels.		
10. Tracking system indicators to be marked on packs and sets.		
11. Storage to ensure integrity of materials.		

31.2.1.1.1.2 The unit is segregated into service areas.

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

To comply with infection prevention and control procedures, the unit must be segregated into the service areas listed below. Score 1 if the unit has the segregated area and 0 if areas are not segregated.

Score	Comment	
Aspects	Score	Comment
1. Dirty area/section (for cleaning and inspection of equipment)		
2. Clean area/section (assembly, packaging and sterilisation)		
3. Sterile packs storage area		
4. The set-up of the unit allows flow of instruments from dirty to clean areas. Explanatory note: The set-up of the unit must allow the sterilisation processes to progress from the dirty area, where used instruments are received, to the clean area, where sterilised instruments are stored and issued.		

Criterion 31.2.1.1.2 7 Health care personnel receive ongoing in-service education according to their roles and responsibilities.

31.2.1.1.2.1 Health care personnel working with reprocessing or sterilisation of medical devices are trained.

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

Select two health care providers and two cleaning personnel and request the training records which includes but is not limited to attendance registers. Verify whether health care personnel have been trained in the past two years. Score 1 if the health care personnel workers have been trained and 0 if not.

Score	Comment

Unit 1 Health care provider 1

Aspects	Score	Comment
1. Sterilisation procedures		
2. Use of sterilisation equipment		
3. Hand hygiene		
4. Use of personal protective equipment		

Unit 2 Health care provider 2

Aspects	Score	Comment
1. Sterilisation procedures		
2. Use of sterilisation equipment		
3. Hand hygiene		
4. Use of personal protective equipment		

Unit 3 Cleaning personnel 1

Aspects	Score	Comment
1. Hand hygiene		
2. Use of personal protective equipment		

Unit 4 Cleaning personnel 2

Aspects	Score	Comment
1. Hand hygiene		
2. Use of personal protective equipment		

Criterion 31.2.1.1.3.7 Procedures to minimise the risk of health care-associated infections must be implemented.

31.2.1.1.3.1 An emergency eyewash station or eyewash kit is available.

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

The emergency eyewash station or eye wash kit must be easily accessible.

Not applicable: Never

Score	Comment

31.2.1.1.3.2 Sterile sealed eyewash kit is checked.

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

Request documented evidence from the previous month indicating when the eyewash kit was checked for leaks and expiry dates.

Not applicable: Never

Score	Comment

Criterion 31.2.1.1.4.7 The management of used and soiled linen must meet infection prevention and control requirements.

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

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

The area used to store dirty linen must have a door.

Not applicable: Never

Score	Comment

Criterion 31.2.1.1.5.7 The success of sterilisation procedures must be monitored.

31.2.1.1.5.1 Sterilisation failures are documented.

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

Any identified failures must be documented to provide a record for further analysis. Request records for the previous six months.

Not applicable: Where no failures are identified.

Score	Comment

31.2.1.1.5.2 Sterilisation failures are investigated.

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

Sterilisation failures must be investigated to determine the cause of the failure. Investigation report(s) for the previous six months must be available.

Not applicable: Where no failures are identified.

Score	Comment

31.2.1.1.5.3 Action plans are implemented to address gaps identified in the sterilisation process.

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

Addressing gaps identified during the investigation will prevent further failures from the same cause.

Not applicable: Where no gaps have been identified.

Score	Comment

Criterion 31.2.1.1.6 7 The health establishment must have a functional quality management system

31.2.1.1.6.1 Quality improvement plans are developed by health care personnel.

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

Request the quality improvement plan of the unit from the previous six months. Verify whether the aspects listed below are documented. Score 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		

31.2.1.1.6.2 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 31.2.2 8 Infection prevention and control programmes.

Standard 31.2.2.1 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 31.2.2.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

31.2.2.1.1.1 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).		

31.2.2.1.1.2 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		

31.2.2.1.1.3 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 31.2.2.1.2 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

31.2.2.1.2.1 Linen rooms or storage cupboards 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 0 if the unit does not have a designated area with a door that can be kept closed.

Score	Comment	
Aspects	Score	Comment
1. Designated area for storage of linen		
2. Linen is stored on shelves		
3. Area is well organised		

Criterion 31.2.2.1.3 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.

31.2.2.1.3.1 Personal protective equipment is worn.

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

Verify whether the protective clothing and equipment listed below is worn. Score 1 if the item is worn and 0 if not worn. Score not applicable where at the time of the inspection, health care personnel are not in a situation in which they are required to wear protective clothing.

Score	Comment

Unit 1 Receiving area:

Aspects	Score	Comment
1. Gloves – non-sterile		
2. Disposable gowns or aprons		
3. Protective eyewear (face shields or goggles)		
4. Face masks		

Unit 2 Sterilisation area:

Aspects	Score	Comment
1. Gloves – non-sterile		
2. Disposable gowns or aprons		
3. Protective eyewear (face shields or goggles)		
4. Face masks		

Sub Domain 31.2.3 9 Waste management.

Standard 31.2.3.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 31.2.3.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

31.2.3.1.1.1 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. General waste (black, beige, white or transparent packaging may be used)			

Criterion 31.2.3.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

31.2.3.1.2.1 Sharps are safely managed and discarded.

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

Select three areas and verify whether sharps, needles and the collection of sharps are correctly managed. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment		
Aspects	Score	Comment	
1. Sharps containers available at site of use			
2. Sharps containers have correctly fitting lids			

31.2.3.1.2.2 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 not applicable for any aspects not found in the temporary waste storage 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/resistant, not cracked)			

Domain 31.3 CLINICAL SUPPORT SERVICES

Sub Domain 31.3.1 13 Medical equipment.

Standard 31.3.1.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

Criterion 31.3.1.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

31.3.1.1.1.1 Functional essential equipment is available.

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

Request the list of medical equipment for the unit and randomly sample ten items on the equipment list. Check whether the selected equipment is available and functional. Document the name of the noncompliant equipment that was sampled. Score 0 if a selected item on the equipment list is 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		

31.3.1.1.1.2 The unit manager has determined the number of surgical packs required for the unit.

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

To ensure sufficient sterile packs are available for the sterilisation unit to cover all theatres and procedures that are performed at the health establishment, it is necessary to determine the requirements for the unit, i.e. how many sterile packs are required to ensure that all theatres and procedures are covered.

Not applicable: Never

Score	Comment

31.3.1.1.1.3 The unit has a method for tracking surgical packs issued from and returned to the central sterile services department.

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

This may be a register to track sterile packs sent to and received from the theatres and other functional areas. The purpose of the system is to ensure that the sterilisation unit keeps track of all sterile packs.

Not applicable: Never

Score	Comment

31.3.1.1.1.4 Sterile packs are stored in a designated area.

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

Inspect the area where sterile packs are 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. Designated area for the storage of sterile packs. Explanatory note: Storage could include but not limited to room or cupboards.		
2. Area is well organised		
3. Packs are stored in a manner that ensures their integrity. Explanatory note: The storage of sterile packs must be in such a way that it prevents physical damage to packages, avoids exposure of packages to moisture and or becoming soiled. Packages should not be stored in a manner that will crush, bend, puncture, or compress them.		

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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