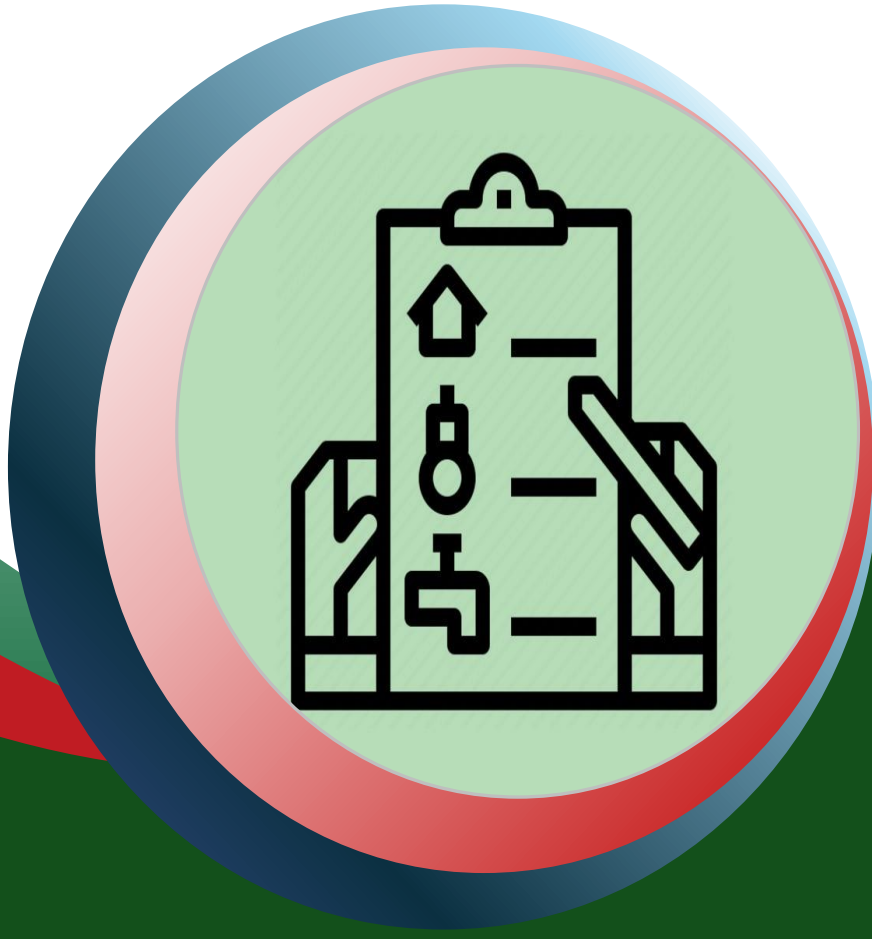
OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

Regulatory Central Hospital Inspection Tool v1.0



Outpatient Department

Facility: Date:

- **Tool Name:** Regulatory Central Hospital Inspection Tool v1.0
  HEs Type: Hospitals
- **Sector:** Public
- **Specialization:** Central
- **Created By:** Health Standards Development and Training

12 Outpatient Department

Domain 12.1 USER RIGHTS

Sub Domain 12.1.1 4 User information.

Standard 12.1.1.1 4(1) The health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.

Criterion 12.1.1.1.1 4(2)(a)(ii) The health establishment must provide users with information relating to service opening and closing times.

12.1.1.1.1.1 Legible signage at the entrance to the unit indicates the days and times when various services are offered.

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

The service operating times must be displayed at the entrance of the unit. The information must be legible.

Not applicable: Never

Score	Comment

Sub Domain 12.1.2 5 Access to care.

Standard 12.1.2.1 5(3) The health establishment must maintain a system of referral as established by the responsible authority.

Criterion 12.1.2.1.1 5(4)(b) The health establishment must ensure that a copy of the referral document is kept in the user's health record.

12.1.2.1.1.1 Copies of referral documents or forms are available at the initiating health establishment.

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

Request the copies of referral document or form of the last three users referred out of the health establishment in the previous three months. Score 1 if the referral document or form contains the aspect listed below and score 0 if the aspect listed below is not documented. Score not applicable if there were no users referred out in the previous three months.

Score	Comment

Unit 1 Document 1

Aspects	Score	Comment
1. Name of user		
2. Name of referring health establishment		

3. Name of referring health care provider		
4. Name of receiving health establishment		
5. Reason for referral		
6. Summary of clinical details. Explanatory note: This will include but not limited to presenting complaints, examination and findings, investigations conducted, diagnosis and treatment provided.		

Unit 2 Document 2

Aspects	**Score**	**Comment**
1. Name of user		
2. Name of referring health establishment		
3. Name of referring health care provider		
4. Name of receiving health establishment		
5. Reason for referral		
6. Summary of clinical details. Explanatory note: This will include but not limited to presenting complaints, examination and findings, investigations conducted, diagnosis and treatment provided.		

Unit 3 Document 3

Aspects	**Score**	**Comment**
1. Name of user		
2. Name of referring health establishment		
3. Name of referring health care provider		
4. Name of receiving health establishment		
5. Reason for referral		

6. Summary of clinical details. Explanatory note: This will include but not limited to presenting complaints, examination and findings, investigations conducted, diagnosis and treatment provided.		

Sub Domain 12.1.3 22 Waiting times.

Standard 12.1.3.1 22 The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

Criterion 12.1.3.1.1 22 Waiting times are monitored and improvement plans are implemented.

12.1.3.1.1.1 Compliance with waiting time targets in the unit is monitored.

Assessment type: Document - **Risk rating:** Essential measure
Request the previous six months' tools used for monitoring waiting times.
Not applicable: Never

Score	Comment

12.1.3.1.1.2 The locally agreed target waiting time is displayed.

Assessment type: Observation - **Risk rating:** Essential measure
The waiting time must be displayed in an area that is easily visible to waiting users.
Not applicable: Never

Score	Comment

Domain 12.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 12.2.1 6 User health records and management.

Standard 12.2.1.1 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 12.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

12.2.1.1.1.1 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 various areas within the unit (this will include but not limited to public areas, clinical areas) and determine whether unauthorised individuals would not be able to access the information in the health records. This will include the health records of users waiting to be seen, users who have already been seen but their records have not yet been returned to the records storage area/room, health records being used for clinical audit or other administrative purposes, or health records outside the records storage area/room for any other reason. Such records should be kept in a manner which safeguards against unauthorised access to the content of the record. Electronic records must be safeguarded with passwords or any other security measures.
Not applicable: Never

Score	Comment

Standard 12.2.1.2 6(3) The health establishment must create and maintain a system of health records of users in accordance with the requirements of section 13 of the Act.

Criterion 12.2.1.2.1 6(4)(b) The health establishment must record information relating to the examination and health care interventions of users.

12.2.1.2.1.1 A clinical assessment and management plan for the user is recorded.

Assessment type: Patient record audit - **Risk rating:** Vital measure

Select three health records of users who were seen in the unit at the time of inspection or health records from the previous month and verify compliance with statutory requirements for record keeping. Score 1 if the aspect is recorded and 0 if not recorded.

Score	Comment

Unit 1 User health record 1

Aspects	Score	Comment
1. Vital signs		
2. Physical examination findings		
3. Investigations requested (where applicable)		
4. Results of investigations requested.		
5. Provisional diagnosis		
6. DSM V (applicable to mental health care users only)		
7. Treatment plan		
8. Date of each entry		
9. Time of each entry		
10. Designation of signatory		
11. Medicines administered (where applicable).		
12. Each entry signed by health care provider making entry		

Unit 2 User health record 2

Aspects	Score	Comment
1. Vital signs		
2. Physical examination findings		
3. Investigations requested (where applicable)		
4. Results of investigations requested.		
5. Provisional diagnosis		
6. DSM V (applicable to mental health care users only)		
7. Treatment plan		

8. Date of each entry		
9. Time of each entry		
10. Designation of signatory		
11. Medicines administered (where applicable).		
12. Each entry signed by health care provider making entry		

Unit 3 User health record 3

Aspects	**Score**	**Comment**
1. Vital signs		
2. Physical examination findings		
3. Investigations requested (where applicable)		
4. Results of investigations requested.		
5. Provisional diagnosis		
6. DSM V (applicable to mental health care users only)		
7. Treatment plan		
8. Date of each entry		
9. Time of each entry		
10. Designation of signatory		
11. Medicines administered (where applicable).		
12. Each entry signed by health care provider making entry		

Standard 12.2.1.3 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 12.2.1.3.1 6 A documented procedure which describes the information to be collected and discussed during the process to obtain informed consent is implemented, in accordance with Chapter 2 of the National Health Act(Section 7).

12.2.1.3.1.1 Informed consent forms are completed correctly.

Assessment type: Patient record audit - **Risk rating:** Vital measure

Select three health records of users who were seen at the time of inspection or health records from the previous three months and an informed consent for an operation, procedure or treatment was signed. Check whether the details listed below are recorded on the consent forms. Score 1 if the if recorded and 0 if it is not recorded.

Score	**Comment**

Unit 1 User health record 1

Aspects	Score	Comment
1. Names and surname of user		
2. Age, Identity number or date of birth of user		
3. The exact nature of operation/ procedure or treatment, including side, where relevant.		
4. Consent form is signed by user, the legal guardian or any person legally responsible for the user. Explanatory note: Signatory providing consent is legally entitled to give informed consent in accordance with section 7 of the National Health Act 61 of 2003, HPCSA, Booklet 4 and Section 129 of the Children's Act 38 of 2005.		
5. Consent form is signed by health care provider obtaining the consent. Explanatory note: This must be a health care provider legally entitled to obtain the consent in accordance with HPCSA booklet 4, section 4.		
6. Consent form is dated.		
7. All entries on form are legible.		

Unit 2 User health record 2

Aspects	Score	Comment
1. Names and surname of user		
2. Age, Identity number or date of birth of user		
3. The exact nature of operation/ procedure or treatment, including side, where relevant.		
4. Consent form is signed by user, the legal guardian or any person legally responsible for the user. Explanatory note: Signatory providing consent is legally entitled to give informed consent in accordance with section 7 of the National Health Act 61 of 2003, HPCSA, Booklet 4 and Section 129 of the Children's Act 38 of 2005.		
5. Consent form is signed by health care provider obtaining the consent. Explanatory note: This must be a health care provider legally entitled to obtain the consent in accordance with HPCSA booklet 4, section 4.		
6. Consent form is dated.		
7. All entries on form are legible.		

Unit 3 User health record 3

Aspects	Score	Comment

1. Names and surname of user		
2. Age, Identity number or date of birth of user		
3. The exact nature of operation/ procedure or treatment, including side, where relevant.		
4. Consent form is signed by user, the legal guardian or any person legally responsible for the user. Explanatory note: Signatory providing consent is legally entitled to give informed consent in accordance with section 7 of the National Health Act 61 of 2003, HPCSA, Booklet 4 and Section 129 of the Children's Act 38 of 2005.		
5. Consent form is signed by health care provider obtaining the consent. Explanatory note: This must be a health care provider legally entitled to obtain the consent in accordance with HPCSA booklet 4, section 4.		
6. Consent form is dated.		
7. All entries on form are legible.		

Sub Domain 12.2.2 7 Clinical management.

Standard 12.2.2.1 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 12.2.2.1.1 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.

12.2.2.1.1.1 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 (if applicable) and score 0 if the aspect is not available, not functional or expired (if 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).		
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 that accommodate both adult and paediatric users).		
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 masks - re breather (paediatric)		
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 as determined by the user profile seen in the unit and resuscitation protocol).		
Medicine.		
22. Emergency medicines according to local protocol are available and have not expired.		

12.2.2.1.1.2 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 (if applicable) and score 0 if the aspect is not available, not functional or expired (if 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		

12.2.2.1.1.3 The emergency trolley and emergency equipment are 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 12.2.2.1.2 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.

12.2.2.1.2.1 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 such training has been conducted, in-service training, or training by the supplier of new equipment. Training must be provided for each health care provider, 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 12.2.2.1.3 7 Procedures to minimise the risk of health care-associated infections must be implemented.

12.2.2.1.3.1 The storage of sterile packs ensures the integrity of materials.

Assessment type: Observation - **Risk rating:** Essential measure
The manner in which sterile packs are stored must prevent physical damage to packages, avoid exposure of packages to moisture. Packages should not be stored in a manner that will crush, bend, puncture, or compress them. Therefore, packs should not be wet or have water damage, they should be intact (not opened or torn).
Not applicable: Where sterile packs are not kept in the unit.

Score	Comment

Criterion 12.2.2.1.4 7 The health establishment must report information on health care associated infections and notifiable diseases to the appropriate public health agencies.

12.2.2.1.4.1 National guidelines are followed for all notifiable medical conditions.

Assessment type: Document - **Risk rating:** Vital measure
Assess whether the health establishment complies with the requirements for recording and reporting of notifiable diseases listed below. The evidence may be obtained electronically or manually. Score 1 if compliant and 0 if not compliant.

Score	Comment

Aspects	Score	Comment

1. Notifiable medical conditions are to be recorded in the notification booklet or entered electronically into a web-based system. Explanatory note: The health establishment must be aware of the number of cases of different notifiable diseases presenting, to identify emerging trends as early as possible and report them to the relevant authority. Examine the register or electronic system to verify whether all diagnosed notifiable diseases have been recorded.		
2. All notifiable diseases are reported using the prescribed form or electronically in a web-based system. Explanatory note: View submissions from the previous six months. The health establishment should produce evidence that the reports have been sent paper based or an electronic notification to the public agency. This could be via a fax, email, post or a messenger.		

Criterion 12.2.2.1.5 7 The management of used and soiled linen must meet infection prevention and control requirements.

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

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

Criterion 12.2.2.1.6 7 The health establishment must have a functional quality management system.

12.2.2.1.6.1 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 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		

12.2.2.1.6.2 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 12.2.3 8 Infection prevention and control programmes.

Standard 12.2.3.1 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 12.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area. 12.2.3.1.1.1 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, except in toilets		
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, except in toilets		

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, except in toilets		
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).		

12.2.3.1.1.2 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		

12.2.3.1.1.3 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 12.2.3.1.2 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

12.2.3.1.2.1 The unit manager has determined the linen requirements for the unit .

Assessment type: Document - **Risk rating:** Essential measure
It is necessary to determine the linen requirements for the unit, to ensure sufficient linen is available for all users to receive clean linen. It is also necessary to determine how many linen items must be available in the linen storage area for routine linen changes, and to respond to episodes of dirtying or soiling of linen. A document indicating linen requirements for the unit must be available.
Not applicable: Never

Score	Comment

12.2.3.1.2.2 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	Comment

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

Criterion 12.2.3.1.3 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.

12.2.3.1.3.1 Personal protective equipment is worn.

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

Using the checklist below, verify whether protective clothing and equipment is worn. Score 1 if the items are 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 Consulting room 1

Aspects	Score	Comment
1. Non-sterile or sterile 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		

Unit 2 Consulting room 2

Aspects	Score	Comment
1. Non-sterile or sterile 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		

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 12.2.4 9 Waste management.

Standard 12.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 12.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

12.2.4.1.1.1 The unit has appropriate containers for the 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 healthcare 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 outpatient department, 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 can be used)		

Criterion 12.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

12.2.4.1.2.1 Sharps are safely managed and discarded.

Assessment type: Observation - **Risk rating:** Vital measure
Select three clinical areas in the outpatient department and verify whether sharps and needles are correctly managed. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

Unit 1 Clinical area 1

Aspects	Score	Comment
1. Sharps containers available at site of use.		
2. Sharps containers have correctly fitting lids.		
3. Needles are not recapped before disposal (not applicable where safety engineered devices, i.e. built-in safety devices for recapping or retracting the needle are used). Explanatory note: This does not apply where it is not possible to see inside the sharps container.		
4. Syringes with attached needles are discarded in their entirety.		

Unit 2 Clinical area 2

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

3. Needles are not recapped before disposal (not applicable where safety engineered devices, i.e. built-in safety devices for recapping or retracting the needle are used). Explanatory note: This does not apply where it is not possible to see inside the sharps container.		
4. Syringes with attached needles are discarded in their entirety.		

Unit 3 Clinical area 3

Aspects	Score	Comment
1. Sharps containers available at site of use.		
2. Sharps containers have correctly fitting lids.		
3. Needles are not recapped before disposal (not applicable where safety engineered devices, i.e. built-in safety devices for recapping or retracting the needle are used). Explanatory note: This does not apply where it is not possible to see inside the sharps container.		
4. Syringes with attached needles are discarded in their entirety.		

12.2.4.1.2.2 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	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)		

Sub Domain 12.2.5 21 Adverse events.
Standard 12.2.5.1 21(1) The health establishment must have a system to monitor and report all adverse events.
Criterion 12.2.5.1.1 21(2)(b) The health establishment must have systems in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events.

12.2.5.1.1.1 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

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 12.3 CLINICAL SUPPORT SERVICES

Sub Domain 12.3.1 10 Medicines and medical supplies.

Standard 12.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 12.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

12.3.1.1.1.1 The stock control system shows minimum and maximum levels and/or reorder levels for medicine.

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

Randomly sample five items held as stock and verify whether minimum, maximum and/or reorder levels are documented. The levels must be recorded on the bin cards or equivalent. The system may be manual or electronic. Score 1 if compliant and 0 if not compliant.

Score	Comment

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

12.3.1.1.1.2 Stock levels of medicine on the shelves correspond with recorded stock levels in the stock control system.

Assessment type: Observation - **Risk rating:** Essential measure
Randomly sample five items held as stock and verify the number of items available against the balance indicated on the bin cards or equivalent. The system may be manual or electronic. Score 1 if compliant and 0 if not compliant

Score	Comment

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

12.3.1.1.1.3 The entries in the schedule 5 and/or 6 drug register are complete.

Assessment type: Document - **Risk rating:** Vital measure
All columns in the registers must be completed comprehensively. Any omitted information noted during the review of the register will receive a non-compliant score. Verify whether all sections of the register have been completed correctly.
Not applicable: Never

Score	Comment

12.3.1.1.1.4 Schedule 5 and 6 medicines in stock correspond with the balance recorded in the register.

Assessment type: Document - **Risk rating:** Vital measure
Randomly sample three medicines from the schedule 5 and 6 medicine cupboard and verify whether the quantity available corresponds with the balance recorded in the register. Score 1 if there is correspondence 0 if not.

Score	Comment

Aspects	Score	Comment
1. Medicine 1		
2. Medicine 2		
3. Medicine 3		

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

Assessment type: Observation - **Risk rating:** Essential measure
Randomly sample five items held as stock and verify whether minimum, maximum and/or reorder levels are documented. The levels must be recorded on the bin cards or equivalent. The system may be manual or electronic. Score 1 if compliant and 0 if not compliant.

Score	Comment

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

12.3.1.1.1.6 Physical stock of medical supplies corresponds with stock control system.

Assessment type: Observation - **Risk rating:** Essential measure
Randomly sample 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 1 if there is correspondence and 0 if not.

Score	Comment

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

Criterion 12.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

12.3.1.1.2.1 Basic medical supplies (consumables) are available.

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

Request the list of medical supplies/consumables for the unit and randomly sample five items from each of the categories listed below and check whether the selected items are available and not expired (where applicable). Document the name of the non-compliant items that were sampled. Score 1 if the sampled item is available and not expired (where applicable) or 0 if not available or expired or if there is no list of medical supplies/consumables available.

Score	Comment

Aspects	Score	Comment
Surgical supplies		
1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		
Dressing supplies		
6. Item 1		
7. Item 2		
8. Item 3		
9. Item 4		
10. Item 5		
Laboratory supplies		
11. Item 1		
12. Item 2		
13. Item 3		
14. Item 4		
15. Item 5		
Other supplies		
16. Item 1		

17. Item 2		
18. Item 3		
19. Item 4		
20. Item 5		

Sub Domain 12.3.2 13 Medical equipment.
Standard 12.3.2.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.
Criterion 12.3.2.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

12.3.2.1.1.1 Functional essential equipment is available in the unit.

Assessment type: Observation - **Risk rating:** Vital measure
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. 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 12.5 FACILITIES AND INFRASTRUCTURE
Sub Domain 12.5.1 15 Engineering services.
Standard 12.5.1.1 15(1) The health establishment must ensure that engineering services are in place.
Criterion 12.5.1.1.1 15(2) The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.
12.5.1.1.1.1 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

12.5.1.1.1.2 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 Central Hospitals.

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It is hereby certified that the Regulatory Central 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: 9/05/2024

SIGNATURE:
DR MATHABO MATHEBULA
CHIEF OPERATIONS OFFICER: OHSC
DATE: 10/05/2024

SIGNATURE:
DR SIPHIWE MNDAWENI
CHIEF EXECUTIVE OFFICER: OHSC
DATE: 10/04/2024

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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