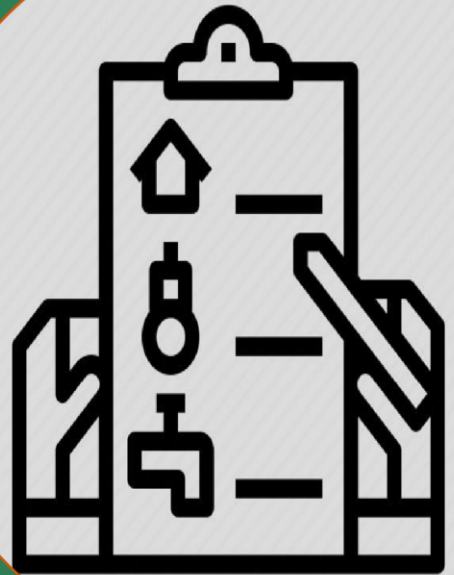




# OHSC

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

# Regulatory Tertiary Hospital Inspection Tool v1.0



## High Care Unit



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

## 20 High Care Unit

### Domain 20.2 CLINICAL GOVERNANCE AND CLINICAL CARE Sub

#### Domain 20.2.1 6 User health records and management.

**Standard 20.2.1.1 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 20.2.1.1.1 6(2)(b)** The health establishment must ensure confidentiality of health records.

**20.2.1.1.1.1** 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 health records of users admitted to the unit, health records being used for clinical audits or other administrative purposes or health records outside the records storage area or room of the unit for any other reason. Such records should be kept in a manner that safeguards against unauthorised access to the content of the health record. User records may be placed at the foot end of the bed but must not be left open for people to be able to read them when a health care provider is not present. Electronic records must be safeguarded with passwords or any other security measures.

Not applicable: Never

Score	Comment

**Standard 20.2.1.2 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 20.2.1.2.1 6(4)(b)** The health establishment must record information relating to the examination and health care interventions of users.

**20.2.1.2.1.1** 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 have been admitted in the unit for at least three days 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 compliant and 0 if not compliant. Score not applicable for aspects not applicable to user.

Score	Comment

#### Unit 1 User health record 1

Aspects	Score	Comment
1. Allergies(if any)		

2. Co-morbidities(where applicable)		
3. Diagnosis		
4. Results of laboratory investigations requested		
5. Vital signs. (Explanatory note: This will include but is not limited to Axilla temperature, Core temperature, Pulse, Pulse Rhythm, Blood pressure, Respiration, Saturation, Mean Arterial Pressure, Central Venous Pressure(CVP ).		
6. Urine analysis (Where applicable)		
7. Blood glucose (where applicable)		
8. Blood gas (where applicable)		
9. Intake and Output monitored. (Explanatory note: This will include but is not limited to IV Fluids; Urine output, stool, drains)		
10. Oral feeds (where applicable).		
11. Medicines administered (signed, dated, time of administration and dose recorded)		
12. Routine care documented (Explanatory note: This will include but is not limited to catheter care, bathing, eye care, mouthcare, pressure areas/position change)		
13. Nursing assessment and care plan		
14. Progress notes		
15. Date of each entry		
16. Time of each entry		
17. Designation of signatory		
18. Each entry signed by health care provider making entry		

#### Unit 2 User health record 2

Aspects	Score	Comment
1. Allergies(if any)		
2. Co-morbidities(where applicable)		
3. Diagnosis		
4. Results of laboratory investigations requested		
5. Vital signs (Explanatory note: This will include but is not limited to Axilla temperature, Core temperature, Pulse, Pulse Rhythm, Blood pressure, Respiration, Saturation, Mean Arterial Pressure, Central Venous Pressure(CVP ).		

6. Urine analysis (Where applicable)		
7. Blood glucose (where applicable)		
8. Blood gas (where applicable)		
9. Intake and Output monitored (Explanatory note: This will include but is not limited to IV Fluids; Urine output, stool, drains)		
10. Oral feeds (where applicable).		
11. Medicines administered (signed, dated, time of administration and dose recorded)		
12. Routine care documented (Explanatory note: This will include but is not limited to catheter care, bathing, eye care, mouthcare, pressure areas/position change)		
13. Nursing assessment and care plan		
14. Progress notes		
15. Date of each entry		
16. Time of each entry		
17. Designation of signatory		
18. Each entry signed by health care provider making entry		

Unit 3 User health record 3

Aspects	Score	Comment
1. Allergies(if any)		
2. Co-morbidities(where applicable)		
3. Diagnosis		
4. Results of laboratory investigations requested		
5. Vital signs (Explanatory note: This will include but is not limited to Axilla temperature, Core temperature, Pulse, Pulse Rhythm, Blood pressure, Respiration, Saturation, Mean Arterial Pressure, Central Venous Pressure(CVP ).		
6. Urine analysis (Where applicable)		
7. Blood glucose (where applicable)		
8. Blood gas (where applicable)		
9. Intake and Output monitored (Explanatory note: This will include but is not limited to IV Fluids; Urine output, stool, drains)		

10. Oral feeds (where applicable).		
11. Medicines administered (signed, dated, time of administration and dose recorded)		
12. Routine care documented (Explanatory note: This will include but is not limited to catheter care, bathing, eye care, mouthcare, pressure areas/position change)		
13. Nursing assessment and care plan		
14. Progress notes		
15. Date of each entry		
16. Time of each entry		
17. Designation of signatory		
18. Each entry signed by health care provider making entry		

**Standard 20.2.1.3 6(5)** The health establishment must have a formal process to be followed when obtaining informed consent from the user.

**Criterion 20.2.1.3.1 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).**

**20.2.1.3.1.1** 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 it is 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, legal guardian (for minors) or 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, legal guardian (for minors) or 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, legal guardian (for minors) or 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 20.2.2 7 Clinical management.**

**Standard 20.2.2.1 7(1)** The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

**Criterion 20.2.2.1.1 7(2)(a)** The health establishment must ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel.

**20.2.2.1.1.1** Standardised treatment protocols and guidelines for management of diseases/ conditions are available.

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

Treatment protocols and guidelines for users admitted in the unit must be available. Request protocols used to manage medical conditions of users.

Not applicable: Never

Score	Comment

**Standard 20.2.2.2 7(2)** (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

**Criterion 20.2.2.2.1 7** Standardised procedures to identify and mitigate clinical risk must be implemented during the care of vulnerable users. **20.2.2.2.1.1** Risk assessments are conducted on users.

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

Select three health records of users admitted in the unit at the time of inspection or health records from the previous month. Verify whether risk assessments are documented . The formal risk assessments including but not limited to Waterlow or Norton scale to determine the user’s risk for developing pressure ulcer/injury and the Morse fall scale to determine the user’s risk of falling. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. User health record 1		
2. User health record 2		
3. User health record 3		

**20.2.2.2.1.2** Safety checks are performed on invasive lines, tubes and filters.

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

Select three health records of users admitted in the unit at the time of inspection or health records from the previous month. Verify whether invasive lines, invasive tubes and filter days are monitored and changed as required. This will include but is not limited to peripheral lines, arterial lines, central lines, nasogastric tubes, endotracheal tubes, urinary catheter, closed suction units and ventilator filters. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. User health record 1		

2. User health record 2		
3. User health record 3		

**20.2.2.2.1.3** Safety alarms are set on user management equipment.

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

Select three health records of users admitted in the unit at the time of inspection or health records from the previous month. Verify whether alarm for ventilators and patient monitors are set and documented in the health record. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. User health record 1		
2. User health record 2		
3. User health record 3		

**Criterion 20.2.2.2.2 7** The health establishment must implement systems to ensure that blood and blood products are available and administered safely.

**20.2.2.2.2.1** Administration of blood is recorded.

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

Select three health records of users admitted in the unit or health records from the previous month of users who had blood administered and verify whether the aspects listed below are documented. Score 1 if the aspect is documented and 0 if not documented. Score not applicable if there were no users who had blood administered.

Score	Comment

Unit 1 User health record 1

Aspects	Score	Comment
1. Clinical indication for blood		
2. Type of blood required.		
3. Informed consent completed and signed.		
4. User's documentation checked prior to administration of blood. Explanatory note: The blood type, rhesus factor, date when blood was donated and expiry date must be crosschecked with the user information prior to administration of blood		
5. Confirmation of user's identity prior to administration of blood.		



6. User's vital signs documented prior to administration of blood.		
7. User's vital signs documented during administration of blood		
8. User's vital signs documented post administration of blood.		
9. Details of transfusion documented. Explanatory note: This must include the start and finish time, how many units were administered, any reaction, and observations.		

#### Unit 2 User health record 2

Aspects	Score	Comment
1. Clinical indication for blood		
2. Type of blood required.		
3. Informed consent completed and signed.		
4. User's documentation checked prior to administration of blood. Explanatory note: The blood type, rhesus factor, date when blood was donated and expiry date must be crosschecked with the user information prior to administration of blood		
5. Confirmation of user's identity prior to administration of blood.		
6. User's vital signs documented prior to administration of blood.		
7. User's vital signs documented during administration of blood		
8. User's vital signs documented post administration of blood.		
9. Details of transfusion documented. Explanatory note: This must include the start and finish time, how many units were administered, any reaction, and observations.		

#### Unit 3 User health record 3

Aspects	Score	Comment
1. Clinical indication for blood		
2. Type of blood required.		
3. Informed consent completed and signed.		
4. User's documentation checked prior to administration of blood. Explanatory note: The blood type, rhesus factor, date when blood was donated and expiry date must be crosschecked with the user information prior to administration of blood		
5. Confirmation of user's identity prior to administration of blood.		
6. User's vital signs documented prior to administration of blood.		

7. User's vital signs documented during administration of blood		
8. User's vital signs documented post administration of blood.		
9. Details of transfusion documented. Explanatory note: This must include the start and finish time, how many units were administered, any reaction, and observations.		

**Criterion 20.2.2.2.3 7 Systems must be in place to facilitate user identification.**

**20.2.2.2.3.1** All users admitted in the unit wear identity bands.

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

Select three users in the unit and verify whether they are wearing identity bands in accordance with standard operating procedure.

Score 1 if users are wearing identification and 0 if not.

Score	Comment	
Aspects	Score	Comment
1. User 1		
2. User 2		
3. User 3		

**Criterion 20.2.2.2.4 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.**

**20.2.2.2.4.1** 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
<b>Devices to open and protect airway</b>		
1. Laryngoscope handle		
2. Curved blade for laryngoscope (a minimum of two different sizes as determined by the user profile seen in the unit and resuscitation protocol)		
3. Endotracheal tubes- adult (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
4. Oropharyngeal airway (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
5. Plaster or ties for endotracheal tubes		

6. Lubricating gel		
<b>Equipment for difficult Intubation.</b>		
7. Introducer		
8. Laryngeal mask airway (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
9. Magill forceps (adult)		
<b>Devices to deliver oxygen/ventilate users.</b>		
10. Manual resuscitator device or bag and valve mask (adult)		
11. Oxygen masks rebreather		
12. Portable oxygen cylinder. Explanatory note: An oxygen cylinder fitted with a regulator to adjust the flowrate must be available.		
<b>Equipment to diagnose and treat cardiac dysrhythmias.</b>		
13. Automated external defibrillator (AED) with pads or defibrillator with conducting gel, pads, paddles and electrodes.		
14. Cardiopulmonary Resuscitation board		
<b>Devices to gain intravascular access.</b>		
15. Intravenous administration sets		
16. IV Cannulae (a minimum of three different sizes)		
<b>Medicine.</b>		
17. Emergency medicines according to local protocol are available and have not expired.		

**20.2.2.4.2** 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. Apron		
6. Spare batteries for laryngoscope		
7. Spare bulb (where applicable)		
8. Syringe (a minimum of three different sizes)		
9. Catheter tip syringe 50ml		
10. Needles (a minimum of three different sizes)		
11. Scissors		
12. Tourniquet		
13. Stethoscope		
14. Nasogastric tubes (a minimum of three different sizes)		
15. Suction catheters (a minimum of three different sizes)		
16. Suction devices (portable)		
17. Nasal cannula		
18. Blood administration set		
19. Intravenous fluid regulating machine.		
20. Local resuscitation protocol or Resuscitation Algorithm		

**20.2.2.2.4.3** 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 20.2.2.2.5 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.**

**20.2.2.2.5.1** 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 personnel member 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 20.2.2.2.6 7 Procedures to minimise the risk of health care-associated infections must be implemented.**

**20.2.2.2.6.1** Health care-associated infections are monitored.

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

The occurrence of health care-associated infections must be monitored and reported to the infection prevention and control team for analysis and interpretation. Request evidence from the previous three months.

Not applicable: Never

Score	Comment

**20.2.2.2.6.2** Procedures to reduce the incidence of commonly occurring health care-associated infections are implemented.

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

This includes, but is not limited to, the implementation of IPC bundles, such as catheter-acquired urinary tract infection (CAUTI), central line-associated bloodstream infection (CLABSI) and surgical site infection.

(SSI) . Request evidence from the previous three months.

Not applicable: Never

Score	Comment

**20.2.2.2.6.3** Corrective action is taken to improve compliance where gaps are identified.

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

Should the audit demonstrate incomplete adherence to the procedures, action must be taken to improve compliance. This includes but is not limited to quality improvement plans. Request evidence from the previous three months.

Not applicable: Where no gaps are identified.

Score	Comment

**20.2.2.2.6.4** 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

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**Criterion 20.2.2.2.7 7 The management of used and soiled linen must meet infection prevention and control requirements.**

**20.2.2.2.7.1** 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

**Criterion 20.2.2.2.8 7 The health establishment must have a functional quality management system.**

**20.2.2.2.8.1** 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		

**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 20.2.3 8 Infection prevention and control programmes.**

**Standard 20.2.3.1 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 20.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.**

**20.2.3.1.1.1** 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).		

**20.2.3.1.1.2** 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		

**20.2.3.1.1.3** 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		
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**Criterion 20.2.3.1.2 8(2)(b) The health establishment must provide isolation units or cubicles where users with contagious infections can be accommodated.**

**20.2.3.1.2.1** Isolation room meets the requirements.

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

Inspect the isolation rooms to verify whether they contain the aspects listed below. Score 1 if the aspect is present and 0 if not present.

Score	Comment	
Aspects	Score	Comment
<b>General requirements to be inspected at all times.</b>		
1. Single room with door that closes. Explanatory note: In the case of an outbreak, multiple users may be accommodated in the same room, as long as the room is used exclusively to care for users with the outbreak disease, i.e. "Cohorting" of patients. Sporadic, individual cases must be nursed in a room that accommodates a single user only.		
2. Rooms used for infections requiring airborne precautions have adequate ventilation. Explanatory note: This will be a minimum of a window that opens, but preferably negative pressure ventilation.		
3. Hand wash basin with elbow-operated taps		
4. Bin with a close-fitting lid		
5. Separate toilet facilities. Explanatory note: This may be a dedicated commode, or urinal and bedpan.		
<b>Requirement to be inspected only if there is a user isolated in the room.</b>		
6. Alcohol based hand rub inside room.		
7. Disinfectant outside of room to disinfect surfaces		
8. Disposable gloves		
9. Bio-hazardous tape for labelling of specimens prior to transporting		
10. Poster/Signs affixed outside the room. Explanatory note: This will include the different types of transmission precautions i.e. airborne, contact or droplet and posters regarding visiting restrictions.		
11. Alcohol based hand rub outside room.		
12. People traffic in and out of room to be controlled (i.e. limited number of visitors and personnel)		
13. Appropriate measures for discarding infected linen.		
14. Appropriate measures for disinfection of equipment		

**20.2.3.1.2.2** Terminal cleaning is carried out in isolation rooms.

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

The infection prevention and control link nurse or champion is responsible for ensuring that rooms used for the care of users with infections requiring isolation are adequately cleaned and decontaminated after the user has been moved out of the isolation room. Request documented evidence from the previous three months, this may include but not limited to clearance certificate from the IPC team or checklist for terminal cleaning of isolation rooms completed and signed by the IPC co-ordinator or unit/health facility manager.(Practical Manual for implementation of National IPC Strategic Framework March 2020 page 107).

Not applicable: Never

Score	Comment

**Criterion 20.2.3.1.3 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.**

**20.2.3.1.3.1** 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, i.e. the number of linen items required to ensure that all users have clean linen and are warm enough during their stay in the unit. 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

**20.2.3.1.3.2** 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 20.2.3.1.4 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.**

**20.2.3.1.4.1** 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. 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 Clinical area 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 Clinical area 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 20.2.4 9** Waste management.

**Standard 20.2.4.1 9(1)** The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

**Criterion 20.2.4.1.1 9(2)(a)** The health establishment must have appropriate waste containers at the point of waste generation.

**20.2.4.1.1.1** 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 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 can be used)		

**Criterion 20.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.**

**20.2.4.1.2.1 Sharps are safely managed and discarded.**

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

Select three clinical areas in the high care unit 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 transported in a receiver when sharps containers not in immediate vicinity of procedure. Explanatory note: This is applicable in situations where procedures are carried out in areas where it is not practical to have a sharps container available, e.g. at the user's bedside. Score not applicable if this is not observed during the inspection.		
3. Sharps containers have correctly fitting lids.		
4. 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.		
5. 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 transported in a receiver when sharps containers not in immediate vicinity of procedure. Explanatory note: This is applicable in situations where procedures are carried out in areas where it is not practical to have a sharps container available, e.g. at the user's bedside. Score not applicable if this is not observed during the inspection.		
3. Sharps containers have correctly fitting lids.		
4. 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.		
5. 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 transported in a receiver when sharps containers not in immediate vicinity of procedure. Explanatory note: This is applicable in situations where procedures are carried out in areas where it is not practical to have a sharps container available, e.g. at the user's bedside. Score not applicable if this is not observed during the inspection.		
3. Sharps containers have correctly fitting lids.		
4. 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.		
5. Syringes with attached needles are discarded in their entirety.		

#### 20.2.4.1.2.2 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 20.2.5 21** Adverse events.

**Standard 20.2.5.1 21(1)** The health establishment must have a system to monitor and report all adverse events.

**Criterion 20.2.5.1.1 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.

**20.2.5.1.1.1** 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 20.3 CLINICAL SUPPORT SERVICES**

**Sub Domain 20.3.1 10** Medicines and medical supplies.

**Standard 20.3.1.1 10(1)** The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

**Criterion 20.3.1.1.1 10(2)(a)** The health establishment must implement and maintain a stock control system for medicine and medical supplies.

**20.3.1.1.1.1** 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		

**20.3.1.1.1.2** 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		
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**20.3.1.1.1.3** The entries in the schedule 5 and 6 drug registers 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

**20.3.1.1.1.4** 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		

**20.3.1.1.1.5** 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		
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**20.3.1.1.1.6** 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		

**Criterion 20.3.1.1.2 10(2)(b)** The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

**20.3.1.1.2.1** 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 sampled items are available and not expired (where applicable). Document the name of the noncompliant 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
<b>Surgical supplies</b>		
1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		
<b>Dressing supplies</b>		
6. Item 1		
7. Item 2		
8. Item 3		

9. Item 4		
10. Item 5		
<b>Laboratory supplies</b>		
11. Item 1		
12. Item 2		
13. Item 3		
14. Item 4		
15. Item 5		
<b>Other supplies</b>		
16. Item 1		
17. Item 2		
18. Item 3		
19. Item 4		
20. Item 5		

**Sub Domain 20.3.3 12** Blood services.

**Standard 20.3.3.1 12(1)** Hospitals and CHCs must ensure that users have access to blood and blood products when required.

**Criterion 20.3.3.1.1 12(2)(c)** The health establishment must ensure that adverse blood reactions are reported to a committee in the health establishment that monitor adverse incidents.

**20.3.3.1.1.1** All adverse blood reactions are reported to relevant forum.

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

Manual or electronic minutes from the previous quarter must reflect that the forum has been informed of all adverse blood reactions and that it has considered and discussed the reported incidents. If no incidents were reported, zero reporting must be done.

Not applicable: Where no adverse blood reactions have occurred and there is evidence of zero reporting.

Score	Comment

**20.3.3.1.1.2** Corrective action is taken where adverse blood reactions were reported.

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

Documented evidence of the corrective actions taken to prevent adverse blood reactions . If no incidents occurred in the previous quarter, zero reporting must be done.

Not applicable: Where no adverse blood reactions were reported.

Score	Comment

**Sub Domain 20.3.2 13** Medical equipment.

**Standard 20.3.2.1 13(1)** Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

**Criterion 20.3.2.1.1 13(2)(b)** The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

**20.3.2.1.1.1** Functional essential medical 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. 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 20.5 FACILITIES AND INFRASTRUCTURE Sub**

**Domain 20.5.1 15** Engineering services.

**Standard 20.5.1.1 15(1)** The health establishment must ensure that engineering services are in place.

**Criterion 20.5.1.1.1 15(2)** The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

**20.5.1.1.1.1** Piped oxygen 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 is available and functional in all the clinical areas in the unit.

**Not applicable:** Never

Score	Comment

**20.5.1.1.1.2** Piped 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 suction is available and functional in all the clinical areas in the unit.

Not applicable: Never

Score	Comment

**20.5.1.1.1.3** Oxygen cylinder is available in the unit.

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

An oxygen cylinder fitted with a regulator to adjust the flowrate must be available. Not applicable: Never

Score	Comment

**20.5.1.1.1.4** The oxygen available in the cylinder is above the minimum level.

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

Oxygen levels must not be below the minimum level indicated in the oxygen cylinder gauge. Not applicable: Never

Score	Comment

**20.5.1.1.1.5** 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 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.**

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