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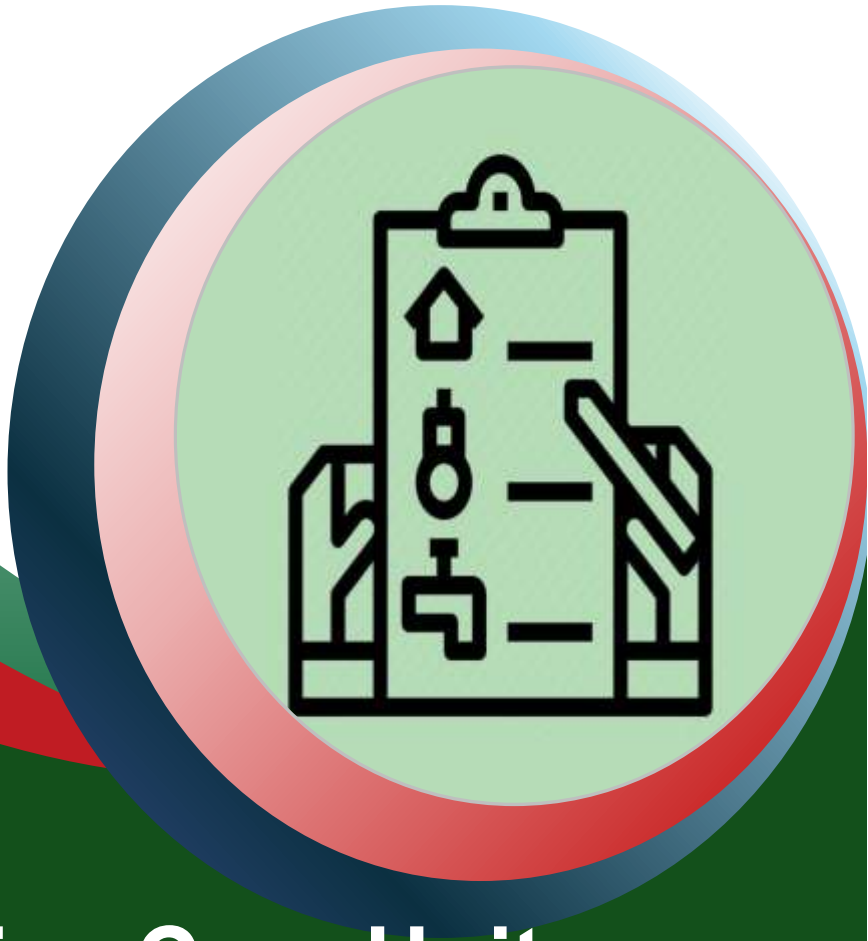
Office of Health Standards Compliance

Ensuring quality and safety in health care

Regulatory Central Hospital Inspection Tool v1.0



Neonatal Intensive Care Unit

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

51 Neonatal Intensive Care Unit

Domain 51.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 51.2.1 6 User health records and management.

Standard 51.2.1.1 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 51.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

51.2.1.1.1.1 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 is 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 51.2.1.2 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 51.2.1.2.1 6(4)(b) The health establishment must record information relating to the examination and health care interventions of users.

51.2.1.2.1.1 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. Apgar score		

2. Birth head circumference		
3. Current head of circumference every 7 days		
4. Birth weight		
5. Current weight		
6. Birth length		
7. Diagnosis		
8. Results of laboratory investigations requested		
9. Vital signs. Explanatory note: This will include but is not limited to Axilla temperature, Core temperature, Pulse, Pulse Rhythm, Blood pressure (where applicable), Respiration, Mean Arterial Pressure, Central Venous Pressure.		
10. Urine analysis (where applicable)		
11. Blood glucose (where applicable)		
12. Ventilation settings/Nasal Canula monitoring		
13. Blood gas (where applicable)		
14. Intake and Output. Explanatory note: This will include but is not limited to IV Fluids; Urine output, stool, drains.		
15. Oral feeds (where applicable).		
16. Medicines administered (signed, dated, time of administration and dose recorded)		
17. Routine care documented. Explanatory note: This will include but is not limited to phototherapy, eye care, mouthcare, buttock care, cord care, pressure areas/position change.		
18. Nursing assessment and care plan		
19. Progress notes		
20. Date of each entry		
21. Time of each entry		
22. Designation of signatory		
23. Each entry signed by health care provider making entry		

Unit 2 User health record 2

Aspects	**Score**	**Comment**
1. Apgar score		

2. Birth head circumference		
3. Current head of circumference every 7 days		
4. Birth weight		
5. Current weight		
6. Birth length		
7. Diagnosis		
8. Results of laboratory investigations requested		
9. Vital signs. Explanatory note: This will include but is not limited to Axilla temperature, Core temperature, Pulse, Pulse Rhythm, Blood pressure (where applicable), Respiration, Mean Arterial Pressure, Central Venous Pressure.		
10. Urine analysis (where applicable)		
11. Blood glucose (where applicable)		
12. Ventilation settings/Nasal Canula monitoring		
13. Blood gas (where applicable)		
14. Intake and Output. Explanatory note: This will include but is not limited to IV Fluids; Urine output, stool, drains.		
15. Oral feeds (where applicable).		
16. Medicines administered (signed, dated, time of administration and dose recorded)		
17. Routine care documented. Explanatory note: This will include but is not limited to phototherapy, eye care, mouthcare, buttock care, cord care, pressure areas/position change.		
18. Nursing assessment and care plan		
19. Progress notes		
20. Date of each entry		
21. Time of each entry		
22. Designation of signatory		
23. Each entry signed by health care provider making entry		

Unit 3 User health record 3

Aspects	**Score**	**Comment**
1. Apgar score		

2. Birth head circumference		
3. Current head of circumference every 7 days		
4. Birth weight		
5. Current weight		
6. Birth length		
7. Diagnosis		
8. Results of laboratory investigations requested		
9. Vital signs. Explanatory note: This will include but is not limited to Axilla temperature, Core temperature, Pulse, Pulse Rhythm, Blood pressure (where applicable), Respiration, Mean Arterial Pressure, Central Venous Pressure.		
10. Urine analysis (where applicable)		
11. Blood glucose (where applicable)		
12. Ventilation settings/Nasal Canula monitoring		
13. Blood gas (where applicable)		
14. Intake and Output. Explanatory note: This will include but is not limited to IV Fluids; Urine output, stool, drains.		
15. Oral feeds (where applicable).		
16. Medicines administered (signed, dated, time of administration and dose recorded)		
17. Routine care documented. Explanatory note: This will include but is not limited to phototherapy, eye care, mouthcare, buttock care, cord care, pressure areas/position change.		
18. Nursing assessment and care plan		
19. Progress notes		
20. Date of each entry		
21. Time of each entry		
22. Designation of signatory		
23. Each entry signed by health care provider making entry		

Standard 51.2.1.3 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 51.2.1.3.1 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). 51.2.1.3.1.1 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 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 detail is recorded and 0 if it is not recorded.

Score	Comment

Unit 1 User health record 1

Aspects	Score	Comment
1. Name and surname of user		
2. Age 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 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. Name and surname of user		
2. Age 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 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. Name and surname of user		
2. Age 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 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 51.2.2 7 Clinical management.

Standard 51.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 51.2.2.1.1 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.

51.2.2.1.1.1 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 and guidelines used to manage medical conditions of users.

Not applicable: Never

Score	Comment

Standard 51.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 51.2.2.2.1 7 Standardised procedures to identify and mitigate clinical risk must be implemented during the care of vulnerable users.

51.2.2.2.1.1 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 assessment includes but is not limited to Waterlow or Norton scale to determine the user's risk for developing pressure ulcer/injury. Score 1 if risk assessment is recorded and 0 if not recorded.

Score	Comment

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

3. User health record 3		

51.2.2.2.1.2 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		

51.2.2.2.1.3 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		

51.2.2.2.1.4 Temperature checks of incubators and radiant warmer beds are done.

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 temperature checks of the incubators / radiant warmers beds are done three hourly. 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		

51.2.2.2.1.5 The ambient room temperature is monitored.

Assessment type: Document - **Risk rating:** Vital measure
Use the checklist below to verify whether the unit room temperature is monitored and is within safe ranges. Score 1 if the aspect is compliant and 0 if not compliant.

Score	**Comment**

Aspects	**Score**	**Comment**
1. The unit room temperature is monitored twice a day. Explanatory note: Request temperature monitoring sheets from the previous three months. This is to assess whether the unit consistently monitors the room temperature.		
2. The temperature of the unit is maintained between 22 and 26 degrees Celsius.		

Criterion 51.2.2.2.2 7 The health establishment must implement systems to ensure that blood and blood products are available and administered safely.

51.2.2.2.2.1 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. 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, date when blood was donated, rhesus factor and expiry date. These details must be cross-checked 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, date when blood was donated, rhesus factor and expiry date. These details must be cross-checked 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, date when blood was donated, rhesus factor and expiry date. These details must be cross-checked 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 51.2.2.2.3 7 Systems must be in place to facilitate user identification.

51.2.2.2.3.1 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 51.2.2.2.4 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.

51.2.2.2.4.1 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
Devices to open and protect airway.		
1. Laryngoscope handle		
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. Endotracheal tubes- neonatal (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
4. Plaster or ties for endotracheal tubes		
5. Lubricating gel		
Equipment for difficult Intubation.		
6. Introducer or Neonatal Bougie/stylets		
7. Magill forceps neonatal		
Devices to deliver oxygen/ventilate users.		
8. Neonatal oxygen mask		
9. Portable oxygen cylinder.		

Explanatory note: An oxygen cylinder fitted with a regulator to adjust the flowrate must be available.		
Devices to gain intravascular access.		
10. Umbilical catheter (a minimum of two different sizes)		
11. Intravenous administration sets		
12. IV Cannulae (a minimum of two different sizes)		
Medicine		
13. Emergency medicines according to local protocol are available and have not expired.		

51.2.2.2.4.2 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. Needles (a minimum of three different sizes)		
10. Scissors		
11. Tourniquet		
12. Stethoscope		
13. Nasogastric tubes (a minimum of two different sizes for neonates)		
14. Suction catheters (a minimum of three catheters for neonates)		
15. Suction devices (portable or fixed)		

16. Neonatal nasal cannulae		
17. Blood administration set		
18. Intravenous Fluid regulating machine.		
19. Syringe Pump		
20. Local resuscitation protocol or Resuscitation Algorithm		
21. Short line –clotless connector		
22. Neopuff		
23. Neonatal saturation probe		
24. Infant ECG pads		
25. Electrode gel		

51.2.2.2.4.3 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 51.2.2.2.5 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.

51.2.2.2.5.1 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 51.2.2.2.6 7 Procedures to minimise the risk of health care-associated infections must be implemented.

51.2.2.2.6.1 Health care-associated infections are monitored.

Assessment type: Document - **Risk rating:** Vital measure
The occurrence of health care associated infections must be monitored closely 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

51.2.2.2.6.2 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 care bundles, such as catheter-acquired urinary tract infection (CAUTI), central line-associated bloodstream infection (CLABSI), surgical site infection (SSI) and ventilator-associated pneumonia (VAP). Request evidence from the previous three months.
Not applicable: Never

Score	Comment

51.2.2.2.6.3 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

51.2.2.2.6.4 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

Criterion 51.2.2.2.7 7 The management of used and soiled linen must meet infection prevention and control requirements.

51.2.2.2.7.1 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 51.2.2.2.8 7 The health establishment must have a functional quality management system.

51.2.2.2.8.1 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		

51.2.2.2.8.2 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 51.2.3 8 Infection prevention and control programmes.
Standard 51.2.3.1 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 51.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area. 51.2.3.1.1.1 Hand washing facilities are available.

Assessment type: Observation - **Risk rating:** Vital measure
Select three areas in the unit and inspect the handwashing facilities for the items listed below. Score 1 If the item is available and 0 if not available.

Score	Comment

Unit 1 Area 1

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

51.2.3.1.1.2 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		

51.2.3.1.1.3 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 51.2.3.1.2 8(2)(b) The health establishment must provide isolation units or cubicles where users with contagious infections can be accommodated.

51.2.3.1.2.1 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
General requirements to be inspected at all times		
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 users. 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		
Requirement to be inspected only if there is a user isolated in the room		
5. Alcohol based hand rub inside room		
6. Disinfectant outside of room to disinfect surfaces		
7. Disposable gloves		
8. Bio-hazardous tape for labelling of specimens prior to transporting		
9. 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.		
10. Alcohol based hand rub outside room		
11. People traffic in and out of room to be controlled (i.e. limited number of visitors and health care personnel)		
12. Appropriate measures for discarding infected linen		
13. Appropriate measures for disinfection of equipment		

51.2.3.1.2.2 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 51.2.3.1.3 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

51.2.3.1.3.1 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

51.2.3.1.3.2 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 51.2.3.1.4 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.

51.2.3.1.4.1 Personal protective equipment is worn.

Assessment type: Observation - **Risk rating:** Vital measure
Using the checklist below, verify whether protective clothing and equipment 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 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		
5. Head gear. (Where applicable).		
6. Over boots (Where applicable)		

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		
5. Head gear. (Where applicable).		
6. Over boots (Where applicable)		

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		
5. Head gear. (Where applicable).		
6. Over boots (Where applicable)		

Sub Domain 51.2.4 9 Waste management.

Standard 51.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 51.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

51.2.4.1.1.1 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 51.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

51.2.4.1.2.1 Sharps are safely managed and discarded.

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

Select three clinical areas in the intensive 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 sharp's 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 sharp's 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 sharp's container.		
5. Syringes with attached needles are discarded in their entirety.		

51.2.4.1.2.2 There is a temporary health care 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 51.2.5 21 Adverse events.
Standard 51.2.5.1 21(1) The health establishment must have a system to monitor and report all adverse events.
Criterion 51.2.5.1.1 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.

51.2.5.1.1.1 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 51.3 CLINICAL SUPPORT SERVICES

Sub Domain 51.3.1 10 Medicines and medical supplies.

Standard 51.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 51.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

51.3.1.1.1.1 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		

51.3.1.1.1.2 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		

51.3.1.1.1.3 The entries in the schedule 5 and 6 drug registers are complete and correct.

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. Not applicable: Never

Score	Comment

51.3.1.1.1.4 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		

51.3.1.1.1.5 The stock control system shows minimum and maximum levels and/or re-order 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		

51.3.1.1.1.6 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 51.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

51.3.1.1.2.1 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 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 51.3.3 12 Blood services.
Standard 51.3.3.1 12(1) Hospitals and CHCs must ensure that users have access to blood and blood products when required.
Criterion 51.3.3.1.1 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.

51.3.3.1.1.1 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

51.3.3.1.1.2 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 51.3.2 13 Medical equipment.
Standard 51.3.2.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.
Criterion 51.3.2.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

51.3.2.1.1.1 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 51.5 FACILITIES AND INFRASTRUCTURE
Sub Domain 51.5.1 15 Engineering services.
Standard 51.5.1.1 15(1) The health establishment must ensure that engineering services are in place.

Criterion 51.5.1.1.1 15(2) The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

51.5.1.1.1.1 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

51.5.1.1.1.2 An oxygen cylinder with pressure gauge is available.

Assessment type: Observation - **Risk rating:** Non-negotiable measure
An oxygen cylinder fitted with a regulator indicating cylinder pressure and an adjustable flow rate must be available.
Not applicable: Never

Score	Comment

51.5.1.1.1.3 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

51.5.1.1.1.4 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

51.5.1.1.1.5 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

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

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.

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