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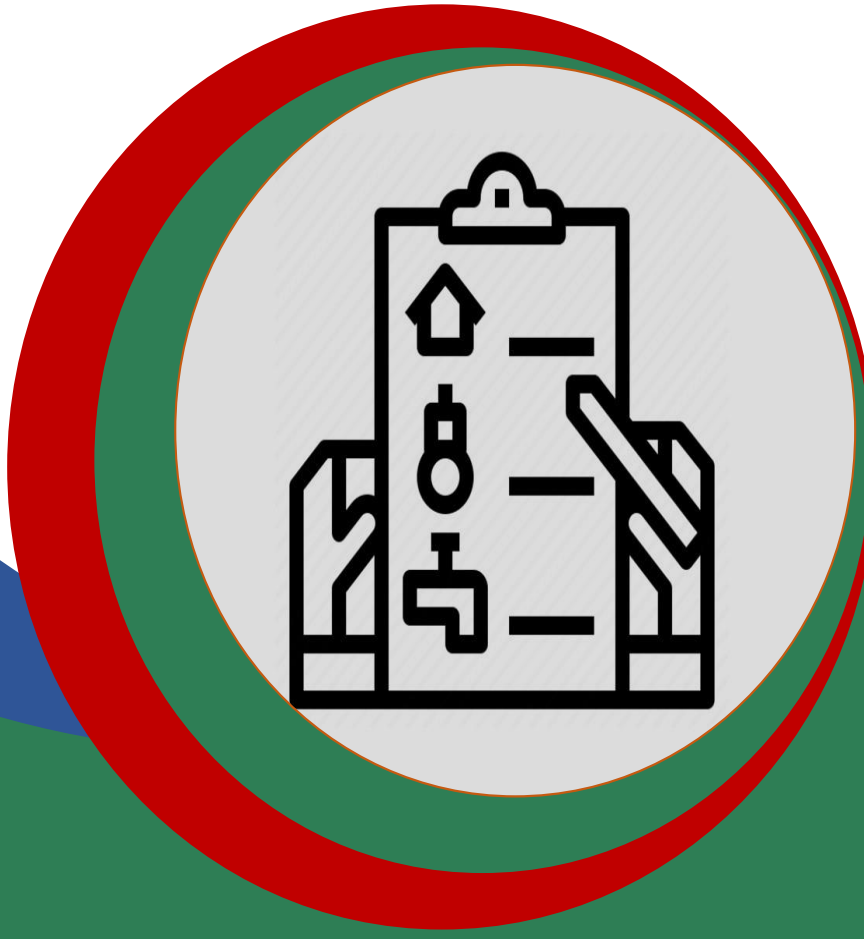
Office of Health Standards Compliance

Ensuring quality and safety in health care

Regulatory Tertiary Hospital Inspection Tool v1.0



Operating Theatre 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

21 Operating Theatre Unit

Domain 21.2 CLINICAL GOVERNANCE AND CLINICAL CARE
Sub Domain 21.2.1 6 User health records and management.
Standard 21.2.1.1 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 21.2.1.1.1 6(4)(b) The health establishment must record information relating to the examination and health care interventions of users.

21.2.1.1.1.1 The operation register is completed comprehensively for all users undergoing surgery.

Assessment type: Document - **Risk rating:** Essential measure
Verify whether all columns in the operation register are completed for every user for the previous month. If information is incomplete for any of the users, score the measure as non-compliant. The register can be manual or electronic. Electronic records must be safeguarded with passwords or any other security measures.
Not applicable: Never

Score	Comment

21.2.1.1.1.2 A register for all anatomical specimens sent to the laboratory is available.

Assessment type: Document - **Risk rating:** Essential measure
Check entries made in the register in the previous three months. Entries must be complete. The register can be manual or electronic.
Not applicable: where no specimens were sent to the laboratory in the previous three months.

Score	Comment

Sub Domain 21.2.2 7 Clinical management.
Standard 21.2.2.1 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.
Criterion 21.2.2.1.1 7 The health establishment implements process to ensure environmental cleanliness.

21.2.2.1.1.1 Cleaning personnel are able to explain how they carry out terminal cleaning or disinfection of the unit and equipment.

Assessment type: Staff interview - **Risk rating:** Essential measure
Interview three cleaning personnel to verify whether they can explain how to carry out terminal cleaning. Score 1 if they can explain the procedure and 0 if they cannot explain the procedure.

Score	Comment

Unit 1 Cleaner 1

Aspects	Score	Comment
1. Personal protective clothing used		
2. Equipment to be used		
3. Type of detergent		
4. Procedure for handling contaminated linen		
5. Procedure for handling medical waste		
6. Criteria for cleaning entire unit		
7. Removal and discarding of used personal protective equipment		

Unit 2 Cleaner 2

Aspects	Score	Comment
1. Personal protective clothing used		
2. Equipment to be used		
3. Type of detergent		
4. Procedure for handling contaminated linen		
5. Procedure for handling medical waste		
6. Criteria for cleaning entire unit		
7. Removal and discarding of used personal protective equipment		

Unit 3 Cleaner 3

Aspects	Score	Comment
1. Personal protective clothing used		
2. Equipment to be used		
3. Type of detergent		
4. Procedure for handling contaminated linen		
5. Procedure for handling medical waste		
6. Criteria for cleaning entire unit		
7. Removal and discarding of used personal protective equipment		

Criterion 21.2.2.1.2 7 The health establishment must implement systems to ensure that blood and blood products are available and administered safely.

21.2.2.1.2.1 Emergency blood is available in a designated area on-site.

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

To meet this requirement, O-negative blood must be available on site. This blood may be found in the South African National Blood Service (SANBS) refrigerator. The health establishment may choose an area such as theatre, the emergency unit or the intensive care unit in which to store the blood.

Not applicable: Where emergency blood is not kept in the unit.

Score	Comment

21.2.2.1.2.2 Administration of blood is recorded.

Assessment type: Patient record audit - **Risk rating:** Vital measure
Select the health records of three users seen 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 product required.		
3. Informed consent completed and signed.		
4. User documentation checked prior to administration. Explanatory note: The blood type, rhesus factor, date when blood was donated, and expiry date must be cross-checked with the user information prior to administration of blood.		
5. Confirmation of user identity prior to administration of blood.		
6. User vital signs documented prior to administration of blood.		
7. User vital signs documented during administration of blood		
8. Details of transfusion documented. Explanatory note: This must include the start and finish time, how many units were transfused, any reaction, and observations.		

Unit 2 User health record 2

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

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

Unit 3 User health record 3

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

Criterion 21.2.2.1.3 7 Systems must be in place to facilitate user identification.

21.2.2.1.3.1 All users 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 21.2.2.1.4 7 Communication during user handover must be standardised to advance user safety.

21.2.2.1.4.1 User safety checks are applied to all users received in theatre.

Assessment type: Patient record audit - **Risk rating:** Vital measure
Select the health records of three users received in the unit at the time of inspection. Verify whether the aspects listed below were documented. Score 1 if the aspect was documented and 0 if not documented.

Score	Comment

Unit 1 User Health record 1

Aspects	Score	Comment
1. User's name. Explanatory note: Users must be encouraged to participate in this identification process. This may include, but need not be limited to, users volunteering their personal information for confirmation.		
2. User date of birth		
3. Procedure to be conducted, including site/side (where relevant)		
4. Results of investigations available in health record (where applicable)		
5. Consent completed correctly.		
6. Time of last oral intake		
7. Medicines administered (where applicable)		
8. Potential safety risks (where applicable)		
9. Special care needs (where applicable)		
10. Allergies (where applicable)		
11. Name and signature of health care provider who received user.		
12. Signature of health care provider who handed user over to theatre.		

Unit 2 User health record 2

Aspects	Score	Comment
1. User's name. Explanatory note: Users must be encouraged to participate in this identification process. This may include, but need not be limited to, users volunteering their personal information for confirmation.		
2. User date of birth		
3. Procedure to be conducted, including site/side (where relevant)		
4. Results of investigations available in health record (where applicable)		
5. Consent completed correctly.		
6. Time of last oral intake		
7. Medicines administered (where applicable)		
8. Potential safety risks (where applicable)		
9. Special care needs (where applicable)		
10. Allergies (where applicable)		
11. Name and signature of health care provider who received user.		

12. Signature of health care provider who handed user over to theatre.		

Unit 3 User health record 3

Aspects	Score	Comment
1. User's name. Explanatory note: Users must be encouraged to participate in this identification process. This may include, but need not be limited to, users volunteering their personal information for confirmation.		
2. User date of birth		
3. Procedure to be conducted, including site/side (where relevant)		
4. Results of investigations available in health record (where applicable)		
5. Consent completed correctly.		
6. Time of last oral intake		
7. Medicines administered (where applicable)		
8. Potential safety risks (where applicable)		
9. Special care needs (where applicable)		
10. Allergies (where applicable)		
11. Name and signature of health care provider who received user.		
12. Signature of health care provider who handed user over to theatre.		

21.2.2.1.4.2 Users are monitored in the recovery room.

Assessment type: Patient record audit - **Risk rating:** Vital measure
Select the health records of three users in the recovery room. Verify whether the aspects listed below are being monitored and documented. Score 1 if the aspect is compliant is 0 if not compliant.

Score	Comment

Unit 1 User health record 1

Aspects	Score	Comment
1. Blood pressure		
2. Pulse		
3. Temperature		
4. Saturation		
5. Respiration rate		

6. Blood loss (where applicable)		
7. Urine output (where applicable)		
8. Level of consciousness		

Unit 2 User health record 2

Aspects	Score	Comment
1. Blood pressure		
2. Pulse		
3. Temperature		
4. Saturation		
5. Respiration rate		
6. Blood loss (where applicable)		
7. Urine output (where applicable)		
8. Level of consciousness		

Unit 3 User health record 3

Aspects	Score	Comment
1. Blood pressure		
2. Pulse		
3. Temperature		
4. Saturation		
5. Respiration rate		
6. Blood loss (where applicable)		
7. Urine output (where applicable)		
8. Level of consciousness		

21.2.2.1.4.3 User safety checks are conducted for users undergoing surgery.

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

Select peri-operative documents of three users who have had surgery at the time of inspection. Verify whether the aspects listed below have been checked and documented. Score 1 if the aspect is compliant and 0 if not compliant. The information could be documented in a checklist or as notes made in the user health record.

Score	Comment

Unit 1 User health record 1

Aspects	Score	Comment
Before induction of anaesthesia:		
1. User identity confirmed		
2. User procedure and site confirmed		
3. Site marked		
4. Precautions taken to maintain skin integrity		
5. Baseline vital signs – pre-anaesthesia		
6. Anaesthesia safety check completed		
7. Pulse oximeter on user and functioning		
8. Allergies documented (Where applicable)		
9. Antibiotic prophylaxis administered (where applicable)		
Before user leaves the operating room:		
10. Name of procedure performed is confirmed.		
11. Swabs counted		
12. Instruments counted		
13. Specimen/s labelled (where applicable)		

Unit 2 User health record 2

Aspects	Score	Comment
Before induction of anaesthesia:		
1. User identity confirmed		
2. User procedure and site confirmed		
3. Site marked		
4. Precautions taken to maintain skin integrity		
5. Baseline vital signs – pre-anaesthesia		
6. Anaesthesia safety check completed		
7. Pulse oximeter on user and functioning		
8. Allergies documented (Where applicable)		
9. Antibiotic prophylaxis administered (where applicable)		

Before user leaves the operating room:		
10. Name of procedure performed is confirmed.		
11. Swabs counted		
12. Instruments counted		
13. Specimen/s labelled (where applicable)		

Unit 3 User health record 3

Aspects	**Score**	**Comment**
Before induction of anaesthesia:		
1. User identity confirmed		
2. User procedure and site confirmed		
3. Site marked		
4. Precautions taken to maintain skin integrity		
5. Baseline vital signs – pre-anaesthesia		
6. Anaesthesia safety check completed		
7. Pulse oximeter on user and functioning		
8. Allergies documented (Where applicable)		
9. Antibiotic prophylaxis administered (where applicable)		
Before user leaves the operating room:		
10. Name of procedure performed is confirmed.		
11. Swabs counted		
12. Instruments counted		
13. Specimen/s labelled (where applicable)		

Criterion 21.2.2.1.5 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.

21.2.2.1.5.1 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 not applicable for items not used in the unit because the category of user is not seen in that unit.

Score	**Comment**

Aspects	Score	Comment
Devices to open and protect airway		
1. Laryngoscope handle – adult.		
2. Laryngoscope handle – paediatric.		
3. Straight blade for laryngoscope (a minimum of two different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
4. Curved blade for laryngoscope (a minimum of two different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
5. Endotracheal tubes-adult (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
6. Endotracheal tubes-paediatric (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol).		
7. Oropharyngeal airway (a minimum of three different sizes as determined by the user profile seen in the unit and resuscitation protocol, must accommodate both adult and paediatric users)		
8. Plaster or ties for endotracheal tubes.		
9. Lubricating gel.		
Equipment for difficult Intubation		
10. Introducer.		
11. Laryngeal mask airway (a minimum of three different sizes that accommodate both adult and paediatric users).		
12. Magill forceps (adult).		
13. Magill forceps (paediatric).		
Devices to deliver oxygen/ventilate users.		
14. Manual resuscitator device or bag and valve mask (adult).		
15. Manual resuscitator device or bag and valve mask (paediatric).		
16. Oxygen masks-rebreather-Adult		
17. Oxygen masks-rebreather-Paediatric		
18. Portable oxygen cylinder. Explanatory note: An oxygen cylinder fitted with a regulator to adjust the flowrate must be available.		
Equipment to diagnose and treat cardiac dysrhythmias.		
19. Automated external defibrillator (AED) with pads or defibrillator with conducting gel, pads, paddles and electrodes.		
20. Cardiopulmonary Resuscitation board		
Devices to gain intravascular access.		

21. Intravenous administration sets.		
22. IV Cannulae (a minimum of three different sizes that accommodate both adult and paediatric users)		
Medicine.		
23. Emergency medicines according to local protocol are available and have not expired.		

21.2.2.1.5.2 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 not applicable for items not used in the unit because the category of user is not seen in that unit.

Score	**Comment**

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

17. Nasal cannula		
18. Blood administration set		
19. Local resuscitation protocol or Resuscitation Algorithm		

21.2.2.1.5.3 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 21.2.2.1.6 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.

21.2.2.1.6.1 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, in-service training or training by the supplier of new equipment. Training must be provided for equipment that health care personnel will be required to use in the course of performing their duties. Request records from the previous 12 months.
Not applicable: Where there was no new equipment introduced in the past twelve months.

Score	Comment

Criterion 21.2.2.1.7 7 Procedures to minimise the risk of health care-associated infections must be implemented.

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

Assessment type: Observation - **Risk rating:** Essential measure
The manner in which sterile packs are stored must prevent physical damage to packages, avoid exposure of packages to moisture. Packages should not be stored in a manner that will crush, bend, puncture, or compress them. Therefore, packs should not be wet or have water damage, they should be intact (not opened or torn).
Not applicable: Never

Score	Comment

Criterion 21.2.2.1.8 7 Implementation of standard operating procedures must be monitored.

21.2.2.1.8.1 Microbiological assessments (particle count and microbiological contamination are performed in accordance with infection control guidelines.

Assessment type: Document - **Risk rating:** Vital measure
Documented evidence of laboratory results for particle counts and microbiological contamination from theatre must be available if major reconstruction has been carried out, where a theatre has been commissioned.
Not applicable: Where a theatre has not been commissioned, no major reconstruction has been carried out.

Score	Comment

Criterion 21.2.2.1.9 7 The management of used and soiled linen must meet infection prevention and control requirements.

21.2.2.1.9.1 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 21.2.2.1.10 7 Infection prevention and control messages must be communicated.

21.2.2.1.10.1 A sign at the entrance to the unit to limit all unauthorised entry is available.

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

Verify whether there is a sign on the door that limits all unauthorised entry.

Not applicable: Never

Score	Comment

Criterion 21.2.2.1.11 7 The health establishment must have a functional quality management system.

21.2.2.1.11.1 Quality improvement plans are developed by health care personnel.

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

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

Score	Comment

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

21.2.2.1.11.2 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

Criterion 21.2.2.1.12 7 The physical environment in the operating theatre department must comply with user safety requirements.

21.2.2.1.12.1 The ambient temperature is maintained between 20 and 24 degrees Celsius.

Assessment type: Document - **Risk rating:** Vital measure
Inspect the temperature records in the unit for the previous three months to verify whether temperatures have been recorded twice daily and documented.
Not applicable: Never

Score	Comment

21.2.2.1.12.2 The humidity is maintained between 30% and 60%.

Assessment type: Document - **Risk rating:** Vital measure
Inspect the humidity levels records in the unit for the previous three months to verify whether humidity levels have been recorded twice daily and documented.
Not applicable: Never

Score	Comment

Sub Domain 21.2.3 8 Infection prevention and control programmes.
Standard 21.2.3.1 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 21.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

21.2.3.1.1.1 Hand washing facilities are available in the scrub or gowning room.

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 Scrub or gowning room 1

Aspects	Score	Comment
1. Splash-limiting stainless-steel basins		
2. Solid, waterproof splash-back panel for sink		
3. Non-touch taps (elbow/foot operated or automated)		
4. Taps high enough to allow hands and forearms to be washed in an upright position under tap		
5. Hot and cold running water		
6. Wall mounted soap dispenser		

7. Antimicrobial liquid soap in non-touch container (elbow operated or automated)		
8. Wall mounted clock		
9. Wall-mounted paper towel dispenser		
10. 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 Scrub or gowning room 2

Aspects	**Score**	**Comment**
1. Splash-limiting stainless-steel basins		
2. Solid, waterproof splash-back panel for sink		
3. Non-touch taps (elbow/foot operated or automated)		
4. Taps high enough to allow hands and forearms to be washed in an upright position under tap		
5. Hot and cold running water		
6. Wall mounted soap dispenser		
7. Antimicrobial liquid soap in non-touch container (elbow operated or automated)		
8. Wall mounted clock		
9. Wall-mounted paper towel dispenser		
10. 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 Scrub or gowning room 3

Aspects	**Score**	**Comment**
1. Splash-limiting stainless-steel basins		
2. Solid, waterproof splash-back panel for sink		
3. Non-touch taps (elbow/foot operated or automated)		
4. Taps high enough to allow hands and forearms to be washed in an upright position under tap		
5. Hot and cold running water		

6. Wall mounted soap dispenser		
7. Antimicrobial liquid soap in non-touch container (elbow operated or automated)		
8. Wall mounted clock		
9. Wall-mounted paper towel dispenser		
10. 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).		

21.2.3.1.1.2 Hand washing facilities are available.

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

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

Score	Comment

Unit 1 Area 1

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

Unit 2 Area 2

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

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

Unit 3 Area 3

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

21.2.3.1.1.3 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		

21.2.3.1.1.4 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 21.2.3.1.2 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

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

Assessment type: Document - **Risk rating:** Essential measure
It is necessary to determine the linen requirements for the unit, to ensure sufficient linen is available. Sufficient linen must be available for surgical procedures and for recovery rooms, including blankets to keep users warm. A document indicating linen requirements for the unit must be available.
Not applicable: Never

Score	Comment

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

Assessment type: Observation - **Risk rating:** Essential measure
Inspect the area where linen is stored to determine whether the aspects listed below are compliant. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

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

Criterion 21.2.3.1.3 8(2)(d) The health establishment must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.

21.2.3.1.3.1 Personal protective equipment is worn.

Assessment type: Observation - **Risk rating:** Vital measure
Using the checklist below, verify whether protective clothing and equipment is worn. Score 1 if the items are worn and 0 if not worn. Score not applicable where at the time of the inspection, health care personnel are not working in a situation in which they are required to wear protective clothing.

Score	Comment

Unit 1 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. Caps		
6. Footwear		

Unit 2 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. Caps		
6. Footwear		

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. Caps		
6. Footwear		

Sub Domain 21.2.4 9 Waste management.

Standard 21.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 21.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

21.2.4.1.1.1 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. Human anatomical waste (red bucket with tight-fitting lid)		
2. Infectious non-anatomical waste (red)		
3. Sharps (yellow)		
4. Chemical waste, including pharmaceutical, cytotoxic or genotoxic pharmaceutical waste (dark green)		
5. General waste (black, beige, white or transparent packaging can be used)		

Criterion 21.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

21.2.4.1.2.1 Sharps are safely managed and discarded.

Assessment type: Observation - **Risk rating:** Vital measure
Select three clinical areas in the 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 containers have correctly fitting lids.		
3. Needles are not recapped before disposal (not applicable where safety engineered devices, i.e., built-in safety devices for recapping or retracting the needle are used). Explanatory note: This does not apply where it is not possible to see inside the sharp's container.		
4. Syringes with attached needles are discarded in their entirety.		
5. Sharps transported in 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. Score not applicable if this is not observed during the inspection		

Unit 2 Clinical area 2

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

3. Needles are not recapped before disposal (not applicable where safety engineered devices, i.e., built-in safety devices for recapping or retracting the needle are used). Explanatory note: This does not apply where it is not possible to see inside the sharp's container.		
4. Syringes with attached needles are discarded in their entirety.		
5. Sharps transported in 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. Score not applicable if this is not observed during the inspection		

Unit 3 Clinical area 3

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

21.2.4.1.2.2 There is a temporary healthcare risk waste storage area.

Assessment type: Observation - **Risk rating:** Essential measure
Freezer temperature maintained at –2 degrees Celsius. Score not applicable where the freezer for waste is not kept in the unit.

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)		
5. Refrigeration facility maintained at –2 degrees Celsius.		

Explanatory note: Score not applicable where the refrigeration facility for waste is not kept in the unit.		
6. All waste in the refrigeration facility is appropriately containerised. Explanatory note: Score not applicable where the refrigeration facility for waste is not kept in the unit.		

21.2.4.1.2.3 A register for all anatomical waste is available.

Assessment type: Document - **Risk rating:** Essential measure
A register must be available for the identification of anatomical waste to prevent loss of body parts/human tissue. Entries made in the register must be complete.
Not applicable: Never

Score	Comment

Sub Domain 21.2.5 21 Adverse events.
Standard 21.2.5.1 21(1) The health establishment must have a system to monitor and report all adverse events.
Criterion 21.2.5.1.1 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.

21.2.5.1.1.1 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 Healthcare 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 Healthcare 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 Healthcare 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 21.3 CLINICAL SUPPORT SERVICES

Sub Domain 21.3.1 10 Medicines and medical supplies.

Standard 21.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 21.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

21.3.1.1.1.1 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		

21.3.1.1.1.2 Stock levels of medicines 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		

21.3.1.1.1.3 The entries in the schedule 5 and 6 drug register are complete.

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

Score	Comment

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

Assessment type: Observation - **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		

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

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

Score	Comment

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

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

Assessment type: Observation - **Risk rating:** Essential measure
Randomly select five items held as stock and verify whether their availability corresponds with the balance indicated on the bin cards or equivalent. 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 21.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

21.3.1.1.2.1 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		
Suturing 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		

21.3.1.1.2.2 Medicines issued from the emergency cupboard are documented.

Assessment type: Document - **Risk rating:** Essential measure
All medicines taken from the emergency cupboard must be documented, including the date of issue, the health care provider taking the medicine and the user for whom the medicine is required. This information must be kept in the emergency cupboard.
Not applicable: Where the unit does not use an emergency cupboard.

Score	Comment

Sub Domain 21.3.3 12 Blood services.
Standard 21.3.3.1 12(1) Hospitals and CHCs must ensure that users have access to blood and blood products when required.
Criterion 21.3.3.1.1 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.

21.3.3.1.1.1 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 the forum 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

21.3.3.1.1.2 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 21.3.2 13 Medical equipment.
Standard 21.3.2.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.
Criterion 21.3.2.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

21.3.2.1.1.1 Functional essential equipment is available in the unit.

Assessment type: Observation - **Risk rating:** Vital measure
Request the list of medical equipment for the unit and randomly sample ten different items on the equipment list. 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 21.5 FACILITIES AND INFRASTRUCTURE
Sub Domain 21.5.1 15 Engineering services.
Standard 21.5.1.1 15(1) The health establishment must ensure that engineering services are in place.

Criterion 21.5.1.1.1 15(2) The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

21.5.1.1.1.1 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 the unit.
Not applicable: Never

Score	Comment

21.5.1.1.1.2 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

21.5.1.1.1.3 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

21.5.1.1.1.4 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 the unit.
Not applicable: Never

Score	Comment

21.5.1.1.1.5 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 Health Standards Compliance.

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