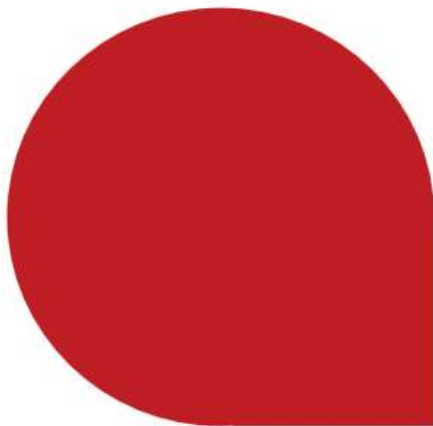




Office of Health Standards Compliance
Ensuring quality and safety in health care



v1.2.1

**Operating Theatre
Unit**

**Regulatory Private Acute
Hospital Inspection tool**

Facility:
Date:

- **Tool Name:** Regulatory Private Acute Hospital Inspection Tool v1.2.1
- **HEs Type:** Hospitals
- **Sector:** Private
- **Specialization:** Private Acute Hospital
- **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 four weeks. If information is incomplete for any of the users, score the measure as non-compliant.

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

A register must be available for all anatomical specimens sent to the laboratory for investigation. Entries made in the register must be complete.

Not applicable: Never

Score	Comment

21.2.1.1.1.3 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. 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. Urine output (where applicable)		
7. Level of consciousness		
8. Wound Inspection		
9. Checking of drains (where applicable)		
10. Circulation checks applicable where limb surgery was done		

Unit 2 User health record 2

Aspects	Score	Comment
1. Blood pressure		
2. Pulse		
3. Temperature		
4. Saturation		
5. Respiration rate		
6. Urine output (where applicable)		
7. Level of consciousness		
8. Wound Inspection		
9. Checking of drains (where applicable)		
10. Circulation checks applicable where limb surgery was done		

Unit 3 User health record 3

Aspects	Score	Comment
1. Blood pressure		
2. Pulse		
3. Temperature		

4. Saturation		
5. Respiration rate		
6. Urine output (where applicable)		
7. Level of consciousness		
8. Wound Inspection		
9. Checking of drains (where applicable)		
10. Circulation checks applicable where limb surgery was done		

Sub Domain 21.2.2 7 Clinical management

Standard 21.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 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 theatre 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. Cleaning personnel must be able to explain the content of the standard operating procedure which describes how this is done. 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. Cleaning equipment to be used		
3. Type of detergent		
4. Procedure for handling linen from contaminated theatre		
5. Procedure for handling medical waste		
6. Criteria for cleaning entire theatre		
7. Management of mobile equipment in theatre		
8. Removal and discarding of used personal protective equipment		

Unit 2 Cleaner 2

Aspects	Score	Comment
1. Personal protective clothing used		
2. Cleaning equipment to be used		
3. Type of detergent		

4. Procedure for handling linen from contaminated theatre		
5. Procedure for handling medical waste		
6. Criteria for cleaning entire theatre		
7. Management of mobile equipment in theatre		
8. Removal and discarding of used personal protective equipment		

Unit 3 Cleaner 3

Aspects	Score	Comment
1. Personal protective clothing used		
2. Cleaning equipment to be used		
3. Type of detergent		
4. Procedure for handling linen from contaminated theatre		
5. Procedure for handling medical waste		
6. Criteria for cleaning entire theatre		
7. Management of mobile equipment in theatre		
8. Removal and discarding of used personal protective equipment		

Criterion 21.2.2.1.2 7 Health care personnel must be informed about standard operating procedure and guidelines.

21.2.2.1.2.1 Health care personnel have been informed about the policy or standard operating procedure or procedure or guideline of the unit and health establishment.

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

Documented evidence that personnel have been informed about the policy or standard operating procedure or procedure or guideline must be available. This could include but is not limited to distribution lists which include personnel signatures to indicate they have read and understood the document (which must be dated and signed), proof of attendance at meetings where policies, guidelines and standard operating procedures are discussed, or similar evidence for electronic distribution which could include but not limited to email distribution or documents deposited in intranet or other electronic platforms. Score 1 if such evidence is available and score 0 if it is not available.

Score	Comment	
Aspects	Score	Comment
1. Identification of users		
2. Management of emergency resuscitations		
3. Standard precautions		
4. Management of adverse events		
5. Storage of Schedule 5 and 6 medicines		
6. Management of medical supplies		

7. Safe use of multi-dose vials		
8. Administration of blood		

Standard 21.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 21.2.2.2.1 7 The health establishment must implement systems to ensure that blood and blood products are available and administered safely.

21.2.2.2.1.1 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. Documented evidence must confirm that blood is 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

21.2.2.2.1.2 Administration of blood is recorded.

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

Select the health records of three users who were administered blood 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 received blood at the time of inspection.

Score	Comment

Unit 1 User health record 1

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

Criterion 21.2.2.2.2 7 Systems must be in place to facilitate user identification.

21.2.2.2.2.1 All users in the operating theatre wear identity bands or any other identification.

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

Select three users in the unit and verify whether they are wearing identity bands or have any identification. Score 1 if users have identification and 0 if not.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. Means of identification applied		
2. Means of identification not causing injury		
3. User identity confirmed by at least two identifiers, including, but not limited to name, date of birth, identity number or hospital number.		
4. Identification used for procedure/surgery		
5. Identification used for users with allergies (where applicable)		

Unit 2 User 2

Aspects	Score	Comment
1. Means of identification applied		
2. Means of identification not causing injury		
3. User identity confirmed by at least two identifiers, including, but not limited to name, date of birth, identity number or hospital number.		
4. Identification used for procedure/surgery		
5. Identification used for users with allergies (where applicable)		

Unit 3 User 3

Aspects	Score	Comment
1. Means of identification applied		
2. Means of identification not causing injury		
3. User identity confirmed by at least two identifiers, including, but not limited to name, date of birth, identity number or hospital number.		
4. Identification used for procedure/surgery		
5. Identification used for users with allergies (where applicable)		

Criterion 21.2.2.3 7 Communication during user handover must be standardised to advance user safety.

21.2.2.3.1 User safety checks are applied to all users transferred to theatre.

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

Select the health records of three users who have attended theatre for procedures at the time of inspection. Verify whether the aspects listed below are documented when the user was received into the operating theatre department. Score 1 if the aspect was documented and 0 if not documented.

Score	Comment

Unit 1 User health record 1

Aspects	Score	Comment
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1. User's name and surname		
2. Hospital number or unique identifier.		
3. Date of birth or identity number		
4. Procedure to be conducted/performed, including site/side (where relevant)		
5. Results of tests available in health record (where applicable)		
6. Informed Consent confirmed		
7. Time of last oral intake documented		
8. Medicines administered and time of administration		
9. Potential safety risks (if any)		
10. Special care needs (if any)		
11. Allergies (if any)		
12. Name and signature of health care provider who received user		
13. Name and signature of health care provider who handed user over to theatre		

Unit 2 User health record 2

Aspects	Score	Comment
1. User's name and surname		
2. Hospital number or unique identifier.		
3. Date of birth or identity number		
4. Procedure to be conducted/performed, including site/side (where relevant)		
5. Results of tests available in health record (where applicable)		
6. Informed Consent confirmed		
7. Time of last oral intake documented		
8. Medicines administered and time of administration		
9. Potential safety risks (if any)		
10. Special care needs (if any)		
11. Allergies (if any)		
12. Name and signature of health care provider who received user		
13. Name and signature of health care provider who handed user over to theatre		

Unit 3 User health record 3

Aspects	Score	Comment
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1. User's name and surname		
2. Hospital number or unique identifier.		
3. Date of birth or identity number		
4. Procedure to be conducted/performed, including site/side (where relevant)		
5. Results of tests available in health record (where applicable)		
6. Informed Consent confirmed		
7. Time of last oral intake documented		
8. Medicines administered and time of administration		
9. Potential safety risks (if any)		
10. Special care needs (if any)		
11. Allergies (if any)		
12. Name and signature of health care provider who received user		
13. Name and signature of health care provider who handed user over to theatre		

21.2.2.2.3.2 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(if any)		
9. Antibiotic prophylaxis given(where applicable)		
Before user leaves the operating room:		
10. Name of procedure performed is confirmed.		
11. Instrument, sponge and needle were counted and are correct		
12. 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(if any)		
9. Antibiotic prophylaxis given(where applicable)		
Before user leaves the operating room:		
10. Name of procedure performed is confirmed.		
11. Instrument, sponge and needle were counted and are correct		
12. 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(if any)		
9. Antibiotic prophylaxis given(where applicable)		
Before user leaves the operating room:		
10. Name of procedure performed is confirmed.		
11. Instrument, sponge and needle were counted and are correct		
12. Specimen/s labelled(where applicable)		

Criterion 21.2.2.4 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.

21.2.2.4.1 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 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.		
Equipment to diagnose and treat cardiac dysrhythmias.		
17. Automated external defibrillator (AED) with pads and pacing cables or defibrillator with conducting gel, pads, paddles and electrodes		
18. Cardiopulmonary Resuscitation board		
Devices to gain intravascular access.		
19. Intravenous administration sets.		
20. IV Cannulae (a minimum of three different sizes that accommodate both adult and paediatric users)		
Medicine.		
21. Emergency medicines according to local protocol are available and have not expired.		

21.2.2.2.4.2 Medical supplies and equipment for resuscitation is 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 tubes (a minimum of five different sizes)		
14. Suction catheters (a minimum of five different sizes)		
15. Suction devices (portable)		
16. Yankhauer suction		
17. Nasal cannula		
18. Blood administration set		
19. Local resuscitation protocol or Resuscitation Algorithm		

21.2.2.2.4.3 The emergency trolley and emergency equipment is checked in accordance with agreed unit practice.

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

Request a documented practice for checking the emergency trolley and verify whether it is checked as documented. This must also include checking of the defibrillator/Automated External Defibrillator.

Request documented records of checking from the previous month.

Not applicable: Never

Score	Comment

Criterion 21.2.2.2.5 7 Implementation of standard operating procedures must be monitored.

21.2.2.2.5.1 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

21.2.2.2.5.2 Particle counts are performed in accordance with infection control guidelines.

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

Evidence of laboratory results for particle counts must be available.

Not applicable: Where the theatre has not been commissioned in the previous twelve months, no major reconstruction has been carried out in the previous twelve months.

Score	Comment

21.2.2.2.5.3 Bacterial swabs are performed in accordance with infection control guidelines.

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

Evidence of laboratory results for bacterial counts must be available.

Not applicable: Where the theatre has not been commissioned in the previous twelve months, no major reconstruction has been carried out in the previous twelve months.

Score	Comment

Criterion 21.2.2.2.6 7 The management of used and soiled linen must meet infection prevention and control requirements.

21.2.2.2.6.1 The theatre department has a designated, access-controlled area for the storage of dirty linen.

Assessment type: Observation - **Risk rating:** Essential measure The area used to store dirty linen must have a door.

Not applicable: Never

Score	Comment

21.2.2.2.6.2 Dirty linen is stored in a dirty linen trolley.

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

The trolley must have a detachable bag into which the dirty linen can be placed.

Not applicable: Never

Score	Comment

Criterion 21.2.2.2.7 7 Infection prevention and control messages must be communicated.

21.2.2.2.7.1 Signage limiting entrance to different areas of theatre is available.

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

Verify whether there is signage that limits unauthorised entry in various part of the theatre.

Not applicable: Never

Score	Comment

Criterion 21.2.2.2.8 7 The health establishment must have a functional quality management system.

21.2.2.2.8.1 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 or implemented to address gaps		
3. Healthcare personnel responsible		
4. Time frames		

21.2.2.2.8.2 Implementation of quality improvement plans is monitored.

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

Evidence must be available that quality improvement activities are implemented by the units. This could include but is not limited to minutes of meetings, reports.

Not applicable: Where there were no gaps identified

Score	Comment

Criterion 21.2.2.2.9 7 The physical environment in the operating theatre department must comply with user safety requirements.

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

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

The temperature in theatre must be checked twice a day and documented. Inspect the records for the previous three months to confirm that the temperature has been maintained between 20 and 24 degrees Celsius.

Not applicable: Never

Score	Comment

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

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

The humidity level in theatre must be checked daily and documented. Inspect the records for the previous three months to confirm that the humidity has been maintained between 30% and 60%.

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/gowning room.

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

Inspect the hand washing facilities in the scrub/gowning room for three theatres to verify whether the items listed below are available. Score 1 if the item is available and 0 if not available.

Score	Comment

Unit 1 Theatre 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. Antimicrobial liquid soap in non-touch container (elbow operated or automated)		
7. Hand sanitiser		
8. Wall mounted clock		
9. Wall-mounted paper towel dispenser		
10. Bins		

Unit 2 Theatre 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. Antimicrobial liquid soap in non-touch container (elbow operated or automated)		

7. Hand sanitiser		
8. Wall mounted clock		
9. Wall-mounted paper towel dispenser		
10. Bins		

Unit 3 Theatre 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. Antimicrobial liquid soap in non-touch container (elbow operated or automated)		
7. Hand sanitiser		
8. Wall mounted clock		
9. Wall-mounted paper towel dispenser		
10. Bins		

21.2.3.1.1.2 Hand washing facilities are available.

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

Verify whether the hand washing items listed below are available in the indicated areas. Score 1 if the item is available and 0 if not available

Score	Comment

Unit 1 Personnel changing areas - male

Aspects	Score	Comment
1. Hand washing basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Poster on correct hand washing technique		
3. Poster on the correct use of alcohol-based hand rub. Explanatory note: Posters must be placed at strategic places and above alcohol dispensers in the health establishment as stipulated in page 33 of Practical Manual for Implementation of IPC Strategic framework March 2020.		
4. Taps		
5. Running water		

6. Plain liquid soap or Chlorhexidine based soap		
7. Wall mounted soap dispenser		
8. Paper towels		
9. Paper towel dispenser		
10. Bin		
11. Alcohol based hand rub		

Unit 2 Personnel changing areas - female

Aspects	Score	Comment
1. Hand washing basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Poster on correct hand washing technique		
3. Poster on the correct use of alcohol-based hand rub. Explanatory note: Posters must be placed at strategic places and above alcohol dispensers in the health establishment as stipulated in page 33 of Practical Manual for Implementation of IPC Strategic framework March 2020.		
4. Taps		
5. Running water		
6. Plain liquid soap or Chlorhexidine based soap		
7. Wall mounted soap dispenser		
8. Paper towels		
9. Paper towel dispenser		
10. Bin		
11. Alcohol based hand rub		

Unit 3 Instrument cleaning area

Aspects	Score	Comment
1. Hand washing basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Poster on correct hand washing technique		
3. Poster on the correct use of alcohol-based hand rub. Explanatory note: Posters must be placed at strategic places and above alcohol dispensers in the health establishment as stipulated in page 33 of Practical Manual for Implementation of IPC Strategic framework March 2020.		
4. Taps		
5. Running water		

6. Plain liquid soap or Chlorhexidine based soap		
7. Wall mounted soap dispenser		
8. Paper towels		
9. Paper towel dispenser		
10. Bin		
11. Alcohol based hand rub		

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 There is a designated area for storage of linen.

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

This could be but not limited to a room or a storage cupboard.

Not applicable: Never

Score	Comment

21.2.3.1.2.2 There is sufficient stock of linen in accordance with the number of users received daily in the unit.

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

The minimum and maximum number of linen items required for all users must be available in the linen storage area as determined by the unit.

Not applicable: Never

Score	Comment

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 Theatre room

Aspects	Score	Comment
1. Gloves – nonsterile		
2. Gloves – sterile		

3. Disposable gowns or aprons		
4. Protective face shields or goggles		
5. Face masks		
6. N95 or KN95 or FFP2 masks or approved equivalent		
7. Theatre caps		
8. Theatre footwear		

Unit 2 Anaesthetic workroom

Aspects	Score	Comment
1. Gloves – nonsterile		
2. Gloves – sterile		
3. Disposable gowns or aprons		
4. Protective face shields or goggles		
5. Face masks		
6. N95 or KN95 or FFP2 masks or approved equivalent		
7. Theatre caps		
8. Theatre footwear		

Unit 3 Recovery area

Aspects	Score	Comment
1. Gloves – nonsterile		
2. Gloves – sterile		
3. Disposable gowns or aprons		
4. Protective face shields or goggles		
5. Face masks		
6. N95 or KN95 or FFP2 masks or approved equivalent		
7. Theatre caps		
8. Theatre footwear		

21.2.3.1.3.2 Cleaning personnel wear personal protective equipment while carrying out their duties.

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, cleaning personnel are not in a situation in which they are required to wear protective clothing.

Score	Comment

Unit 1 Cleaner 1

Aspects	Score	Comment
1. Gloves non-sterile		
2. Domestic rubber gloves. Explanatory note: The gloves must reach up to mid arm and offer protection against chemicals and direct contact with dirt.		
3. Disposable gowns or aprons		
4. Protective face shields or goggles		
5. Face masks		
6. Theatre caps		
7. N95 or KN95 or FFP2 masks or approved equivalent.		

Unit 2 Cleaner 2

Aspects	Score	Comment
1. Gloves non-sterile		
2. Domestic rubber gloves. Explanatory note: The gloves must reach up to mid arm and offer protection against chemicals and direct contact with dirt.		
3. Disposable gowns or aprons		
4. Protective face shields or goggles		
5. Face masks		
6. Theatre caps		
7. N95 or KN95 or FFP2 masks or approved equivalent.		

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 theatre department has appropriate containers for the disposal of all types of waste.

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

Verify whether the waste containers listed below are available. Health care risk waste containers must have the appropriate international hazard symbol and be marked as prescribed in SANS 10248-1: Management of Health Care Waste, Part 1: Management of healthcare risk waste from a health facility. Score 1 if the waste container is available and 0 if not available. Where a particular type of waste is not generated in the theatre department, 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 in clinical areas.

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

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

Score	Comment

Unit 1 Area 1

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

Unit 2 Area 2

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

Unit 3 Area 3

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

21.2.4.1.2.2 A register for anatomical waste indicating the date of placement and date of removal for disposal 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.

Entries made in the register must be complete.

Not applicable: Never

Score	Comment

21.2.4.1.2.3 There is a temporary healthcare risk waste storage area.

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

In all areas where waste is held for collection and removal to the central storage area, a designated area for temporary storage of waste must be available. Some health establishments will have a purpose-built temporary waste storage area, others will utilise a specific area within the available space. Score 1 if the aspect is compliant and 0 if not compliant, or where there is no designated area. Score not applicable for any aspects not found in the intermediate waste storage area in terms of the accompanying explanatory note.

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 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 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 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/preferred levels for medicine.

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

Each item held as stock must have documented minimum, maximum and/or re-order/preferred levels. These levels must be recorded on bin cards, or equivalent. The system may be manual or electronic.

Not applicable: Never

Score	Comment

21.3.1.1.1.2 Stock levels of medicine on the shelves corresponds with recorded 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. 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		

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

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

Select 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 0 if the medicines do not correlate or if any of the columns have not been completed

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

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

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

Each item held as stock must have documented minimum, maximum and/or reorder/preferred levels. These levels must be recorded on bin cards, or equivalent. The system may be manual or electronic.

Not applicable: Never

Score	Comment

21.3.1.1.1.5 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. 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		

21.3.1.1.1.6 A stock management system is in place for medicines in the emergency cupboard.

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

The stock in the emergency cupboard must be managed in the same way as stock on the theatre or in the pharmacy. Minimum, maximum and reorder levels must be determined for all medicines held in the emergency cupboard, and bin cards or equivalent must be completed.

Not applicable: Where the emergency medicine cupboard is not kept in the unit or the health establishment does not keep emergency medicine cupboard.

Score	Comment

21.3.1.1.1.7 Stock on the shelves in the emergency cupboard corresponds with the stock items recorded on the bin cards or equivalent.

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

Select five items in the emergency cupboard to verify whether the number of items on the shelves corresponds with the number of items recorded on the bin cards or equivalent.

Not applicable: Where the emergency medicine cupboard is not kept in the unit or the health establishment does not keep emergency medicine cupboard.

Score	Comment

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. 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		
Other Supplies.		
11. Item 1		
12. Item 2		
13. Item 3		
14. Item 4		
15. 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 emergency medicine cupboard is not kept in the unit or the health establishment does not keep emergency medicine cupboard.

Score	Comment

21.3.1.1.2.3 The name and contact details of the individual on duty for the provision of services after hours are available.

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

A document must be displayed listing the name and contact details of the pharmacist on duty after hours. The document must be signed and dated by the responsible pharmacist.

Not applicable: Where the health establishment does not utilise an after-hours call out system for the pharmacy.

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 documented and reported monthly to the forum responsible for patient safety incidents.

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

There is documented manual or electronic evidence that adverse blood reactions are reported to the relevant forum. Request evidence from the previous quarter. If no incidents were reported, zero reporting must be recorded.

Not applicable: Where no adverse blood reactions have occurred

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 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 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 21.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 21.4.1 19 Human resources management

Standard 21.4.1.1 19(1) The health establishment must ensure that they have systems in place to manage health care personnel in line with relevant legislation, policies and guidelines.

Criterion 21.4.1.1.1 19(2)(a) The health establishment must, as appropriate to the type and size of the establishment, have and implement a human resource plan that meet the needs of the health establishment.

21.4.1.1.1.1 Staffing levels for the unit as determined by activity levels are available.

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

Documented staffing levels for the unit are available. Request staffing levels from the previous three months.

Not applicable: Never

Score	Comment

Sub Domain 21.4.2 20 Occupational health and safety

Standard 21.4.2.1 20(1) The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

Criterion 21.4.2.1.1 20 The health establishment must have a disaster management plan in place, which is communicated to health care personnel and tested annually.

21.4.2.1.1.1 The actions to be taken when the disaster management response is activated are visibly displayed.

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

The actions to be taken by allocated individuals in the event of a disaster must be clearly visible for easy reference during a disaster. This may be displayed in any manner relevant to the size and complexity of the health establishment, including, but not limited to, a single summary sheet of actions to be taken, action cards to be retrieved by allocated individuals to remind them of the tasks for which they are responsible, or any other method chosen by the health establishment.

Not applicable: Never

Score	Comment

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 An oxygen cylinder with pressure gauge is available.

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

An oxygen cylinder fitted with regulator indicating cylinder pressure and adjustable 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 piped 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 Private Acute Hospitals.

Acknowledgments

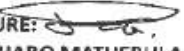
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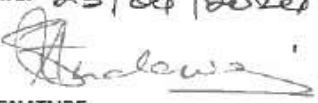
It is hereby certified that the Regulatory Private Acute Hospital Inspection tools version 1.2.1 was updated by the Office of Health Standards Compliance.



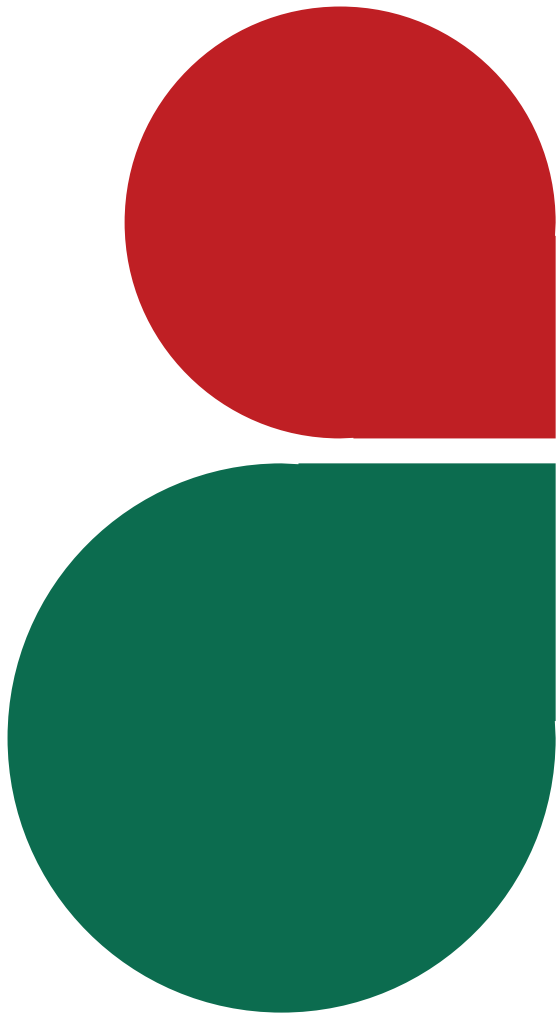
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