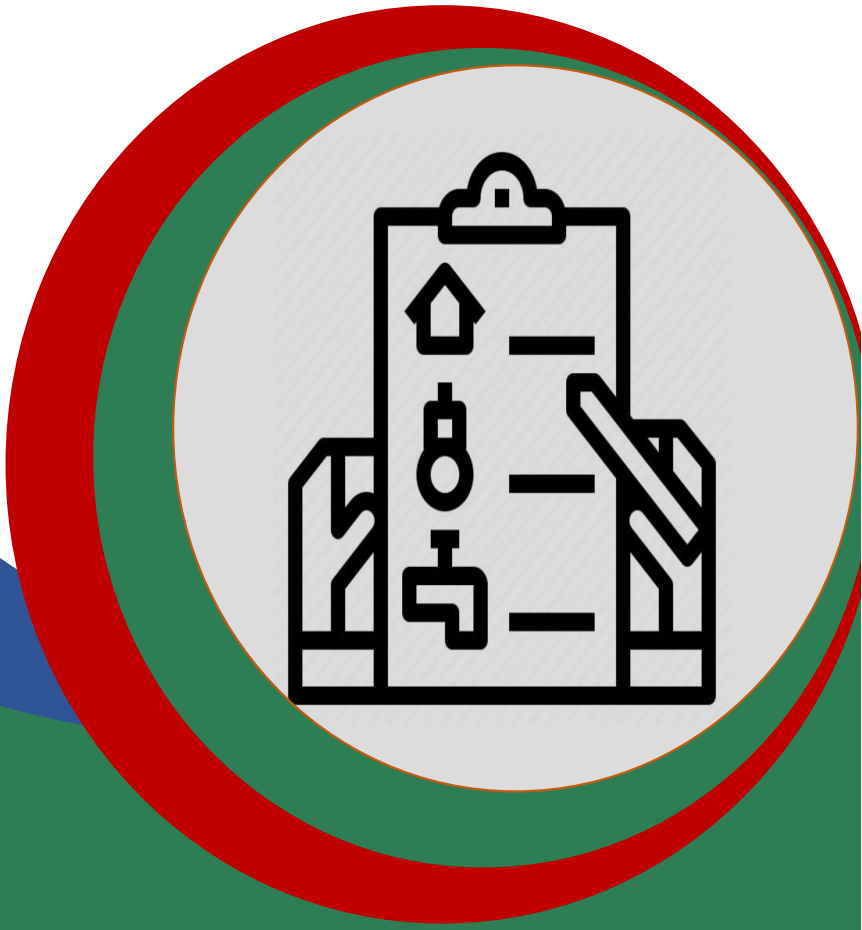
OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

Regulatory Tertiary Hospital Inspection Tool v1.0



Clinical Management Group

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

5 Clinical Management Group (CMG)

Domain 5.1 USER RIGHTS

Sub Domain 5.1.1 5 Access to care

Standard 5.1.1.1 5(1) The health establishment must ensure that users are attended to in a manner which is consistent with the nature and severity of their health condition.

Criterion 5.1.1.1.1 5(2)(a) The health establishment must implement a system of triage.

5.1.1.1.1.1 A standard operating procedure for triage is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. User should be assessed using an approved triage algorithm.		
2. Triage category should be assigned to each user in accordance with the triage algorithm.		
3. Triage category should be documented in the user health record.		
4. User should be directed to the correct waiting or treatment area, in accordance with the triage category assigned.		
5. Users should receive immediate care in accordance with their triage category.		
6. Continuous monitoring of the user as condition/category can change.		
7. Deceased users must be certified dead by the doctor on duty. Reference: https://emssa.org.za/wp-content/uploads/2011/04/SATS-Manual-A5-LR-spreads.pdf		

5.1.1.1.1.2 The algorithm used for triage is available.

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

The algorithm for triage used by the health establishment must be available.

Not applicable: Never

Score	Comment

Criterion 5.1.1.1.2 5(2)(b) The health establishment must ensure access to emergency medical transport for users requiring urgent transfer to another health establishment, and that they are accompanied by a health care provider.

5.1.1.1.2.1 A standard operating procedure for accessing emergency medical transport services is available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Contact number of the emergency medical service(s), including back up number/s		
2. Forms to be completed.		
3. Documents to accompany the user.		

Criterion 5.1.1.1.3 5(2)(c) The health establishment must adhere to clinical guidelines on stabilizing users presenting in an emergency before referring them to another health establishment.

5.1.1.1.3.1 A standard operating procedure for managing psychiatric emergencies is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Identification and management of users at risk. Explanatory note: This will include but not limited to users at risk for suicide, harm to self or others and substance withdrawal.		
2. Prescription for application of restraints.		
3. Criteria for applying restraints. Explanatory note: This will include but not limited to physical, chemical and mechanical restraints.		
4. Safe techniques for applying restraints.		
5. Monitoring required following the application of restraints.		

6. Medicines to be used for chemical restraint.		

Standard 5.1.1.2 5(3) The health establishment must maintain a system of referral as established by the responsible authority.
Criterion 5.1.1.2.1 5(4)(a) The health establishment must ensure that users are provided with information relating to their referral to another health establishment.

5.1.1.2.1.1 A standard operating procedure for referral of users is available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Hospital referral network		
2. Standardised referral register		
3. Standardised patient referral form		
4. Returning referral form		

Domain 5.2 CLINICAL GOVERNANCE AND CLINICAL CARE
Sub Domain 5.2.1 6 User health records and management
Standard 5.2.1.1 6(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.
Criterion 5.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

5.2.1.1.1.1 A standard operating procedure on maintenance of confidentiality of user health records is available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Management of user health records to prevent unauthorised access during the episode of care. Explanatory note: This will include manual and electronic records in user care areas.		
2. Regular updating of software from the developer to prevent security breaches. Explanatory note: Aspect not applicable if health establishment not using electronic health records.		

Standard 5.2.1.2 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 5.2.1.2.1 6 A documented procedure which describes the information to be collected and discussed during the process to obtain informed consent is implemented, in accordance with Chapter 2 of the National Health Act (Section 7).

5.2.1.2.1.1 A standard operating procedure for obtaining informed consent is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. The diagnosis, treatment options and prognosis to be clearly explained to the user. Explanatory note: Treatment options will include but not limited to risks, benefits, probability of success, costs, consequences and follow up care.		
2. The right to refuse treatment and/or withdraw consent at any point prior to the intervention to be explained.		
3. The right to a second opinion before providing consent to be communicated.		
4. Guidance for obtaining consent in an emergency where the user is unable to provide consent and next of kin/legal guardian is not available.		
5. The signatory providing consent must be legally entitled to give informed consent. Explanatory note: Signatory providing consent is legally entitled to give informed consent in accordance with section 7 of the National Health Act 61 of 2003, HPCSA, Booklet 4 and Section 129 of the Children's Act 38 of 2005.		
6. The exact nature of the operation/procedure or treatment, including the site and side where relevant, must be communicated to the user		
7. The user full names must appear on the consent form		
8. The age or date of birth or identity number of users must be reflected on the consent form		
9. Consent form is signed by health care provider obtaining the consent. Explanatory note: This must be a health care provider legally entitled to obtain the consent in accordance with HPCSA booklet 4, section 4		
10. The consent form must be dated		
11. All entries on the form must be legible		

Sub Domain 5.2.2 7 Clinical management

Standard 5.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 5.2.2.1.1 7(2)(a) The health establishment must ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel.

5.2.2.1.1.1 National guidelines on national strategic priority programmes or health initiatives are available.

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

Verify whether the health establishment has copies of the guidelines listed below. Score 1 if the guideline is available and 0 if not available. Electronic or manual documents are acceptable.

Score	Comment

Aspects	Score	Comment
1. Standard Treatment Guidelines and Essential Medicines List for Hospital Level (Adults) 2019 or latest		
2. Standard Treatment Guidelines and Essential Medicines List for Hospital Level (Paediatrics) 2017 or latest		
3. Guidelines for Maternity Care in South Africa 2016 or latest		
4. New-born Care Charts: Management of Sick and Small Newborns in Hospital 2014 or latest		
5. National Consolidated Guidelines for the Management of HIV in Adults, Adolescents, Children and Infants and prevention of Mother to child transmission 2020 or latest		
6. Antiretroviral Treatment Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates (2019) or latest		
7. National Tuberculosis Management Guidelines (2014) or latest		
8. Management of Rifampicin resistance - A clinical reference guide (2019) or latest		
9. Guidelines for the Treatment of Malaria in South Africa (2018) or latest		
10. National Infection Prevention and Control Strategic Framework (2020) or latest		
11. Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework (2021) or latest		
12. Guidelines on Implementation of the Antimicrobial Strategy in South Africa: One Health Approach Governance (2017) or latest		
13. National Guidelines on Epidemic Preparedness and Response (2009) or latest		
14. COVID-19 Infection Prevention and Control Guidelines (2020) or latest		
15. Covid-19 Outbreak investigation: A practical guide and manual for healthcare facilities (2020) or latest		
16. Guidelines for the Prevention and Containment of Antimicrobial Resistance in South African Hospitals (2018) or latest		
17. National clinical guidelines of Post Exposure Prophylaxis in occupational and non-occupational exposures (2020) or latest		
18. Policy Guidelines on 72-hour Assessment of Involuntary Mental Health Care Users (2012) or latest		

19. Policy Guidelines on Seclusion and Restraint of Mental Health Care Users, March (2012) or latest		
20. National Referral Policy for South African Health Services and Implementation Guidelines August (2020) or latest		

Standard 5.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 5.2.2.2.1 7 Formal processes are in place to manage clinical risk.

5.2.2.2.1.1 A standard operating procedure for the management of clinical risk is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Establishment of the clinical risk management structure		
2. Conduction of Clinical risk assessments in clinical units		
3. Identification of clinical hazards		
4. Risk rating of identified hazards		
5. Compilation of the clinical risk register		
6. Standardised approach to clinical risk mitigation		

5.2.2.2.1.2 The terms of reference for the clinical risk management committee are available.

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

Verify whether the aspects listed below are included in the terms of reference. A single structure covering multiple functions will be acceptable or any other configuration of multiple structures. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Interdisciplinary membership required.		
2. Term in office		
3. Roles and responsibilities of forum members		
4. Frequency of meetings		
5. Quorum for the structure		

5.2.2.2.1.3 Annual clinical risk assessments are conducted in every clinical department.

Assessment type: Document - **Risk rating:** Vital measure
The purpose of these assessments is to identify risks to users, healthcare workers, and visitors consequent to receiving care. This will include but not be limited to the risk of exposure to ionising radiation as a result of mobile X-rays being taken in wards and risk assessments related to healthcare associated infections. Inspectors to first determine the clinical areas available in the health establishment and request document from the previous year which must be dated and signed.
Not applicable: Never

Score	Comment

5.2.2.2.1.4 Minutes of the committee indicate that clinical risks are discussed and managed.

Assessment type: Document - **Risk rating:** Vital measure
Manual or electronic minutes from the previous six months must be signed and dated and include an attendance register. (Note that minutes will not be signed if the subsequent meeting has not taken place). The content of the minutes must reflect discussions of clinical risks and their management.
Not applicable: Never

Score	Comment

Criterion 5.2.2.2.2 7 Standardised procedures to identify and mitigate clinical risk must be implemented during the care of vulnerable users.

5.2.2.2.2.1 A standard operating procedure for the care of the terminally ill user is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
Development and implementation of the plan		
1. Development of a multidisciplinary care plan. Explanatory note: The care plan will include but not limited to Pain management, Supportive equipment Prevention of bedsores/ulcers, Psychosocial and spiritual requirements.		
2. User, family and carers included in the development of the care plan.		

5.2.2.2.2.2 A standard operating procedure for conducting risk assessments for mental health users is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The

document can be manual or electronic. The information may be detailed in a single document or in several documents. Not applicable: Where the health establishment do not admit mental health users.

Score	Comment

Aspects	Score	Comment
1. Conduction of risk assessment. Explanatory note: This will include but is not limited to risk for aggression, violence, suicidal ideation, self-harm, substance withdrawal, abscondment		
2. Categorisation of the risk to be documented.		
3. Formal handover of users during shift changes.		
4. User care plan to include specific risk mitigation measures.		
5. Implementation of care plan.		

5.2.2.2.2.3 A standard operating procedure for the management of users admitted for 72-hour observations is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents. Not applicable: Where the health establishment do not admit mental health users.

Score	Comment

Aspects	Score	Comment
1. Formal application for assisted or involuntary admission on Form MHCA 04		
2. Examination of the user by two mental health care practitioners on Form MHCA 05		
3. Notice on decision concerning the application for assisted or involuntary admission on MHCA 07.		
4. Recommendations concerning further treatment on Form MHCA 06.		
5. Recommendation of extension of assisted or involuntary admission to the Mental Health Review Board (MHRB) on Form MHCA 08		
6. Copies of all forms to be kept in the health establishment. Explanatory note: This could be kept in user health records or any other retrievable health records system.		

Criterion 5.2.2.2.3 7 The health establishment must monitor clinical outcomes to improve service delivery.

5.2.2.2.3.1 Health outcomes of the national strategic priority programmes or health initiatives are monitored.

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

Request documents from the previous twelve months and verify that outcome indicators listed below are recorded. Score 1 if the indicator has been monitored. and 0 if not.

Score	Comment

Aspects	Score	Comment
1. Inpatient crude death rate		
2. Average length of stay		
3. Inpatient bed utilisation rates		
4. Inpatient separation neonatal - sum (Definition: Inpatient deaths - Neonatal + inpatient discharges - Neonatal + inpatient transfers out - Neonatal)		
5. Inpatient days neonatal – sum		
6. Inpatient beds neonatal - sum		
7. Live birth under 2500g in facility rate		
8. Maternal mortality in facility ratio		
9. Death under 5 years against live birth rate		
10. Child under 5 years pneumonia case fatality rate		
11. Malaria cases reported (where applicable)		
12. Malaria deaths reported (where applicable)		

5.2.2.2.3.2 Morbidity and mortality statistics are monitored.

Assessment type: Document - **Risk rating:** Vital measure
These statistics must be made available for discussion at management meetings. Request records of statistics discussed at management meetings in the previous quarter.
Not applicable: Never

Score	Comment

5.2.2.2.3.3 Morbidity and mortality meetings are conducted.

Assessment type: Document - **Risk rating:** Vital measure
Manual or electronic minutes from the previous six months must be signed and dated and include an attendance register (Note that minutes will not be signed if the subsequent meeting has not taken place). The content of the minutes must reflect discussions on morbidity and mortality. Some health establishments might have combined sessions/meetings to discuss morbidity and mortality matters.
Not applicable: Never

Score	Comment

5.2.2.2.3.4 Improvement programmes are implemented to address gaps related to mortality and morbidity.

Assessment type: Document - **Risk rating:** Vital measure
Where gaps related to mortality and morbidity statistics are identified quality improvement plans must be developed and implemented to improve performance.
Not applicable: Where no gaps are identified.

Score	Comment

Criterion 5.2.2.2.4 7 The health establishment must implement systems to ensure that blood and blood products are available and administered safely.

5.2.2.2.4.1 A standard operating procedure for the administration of blood and blood products is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Informed consent for transfusion		
2. Doctor’s prescription.		
3. Verification of blood and blood products prior to transfusion		
4. The filters and intravenous administration set to be used		
5. Temperature of blood		
6. Identification of user prior to commencement of transfusion		
7. Monitoring and recording of vital signs. Explanatory note: This will include vital signs monitored prior to commencement, during and post the transfusion		
8. Aseptic technique followed when commencing transfusion.		
9. No medications or other fluid should be added to the blood or blood products.		
10. Process for retaining or returning empty blood product bags to the blood bank.		

Criterion 5.2.2.2.5 7 A functional audit committee that ensures quality use of medicines must be in place.

5.2.2.2.5.1 The terms of reference for the drug utilisation and audit committee or pharmaceutical and therapeutics committee are available.

Assessment type: Document - **Risk rating:** Essential measure
Verify whether the aspects listed below are included in the terms of reference. A single structure covering multiple functions will be acceptable or any other configuration of multiple structures. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Interdisciplinary membership required		
2. Term in office		
3. Roles and responsibilities of forum members		
4. Frequency of meetings		
5. Quorum for the structure		

5.2.2.2.5.2 The minutes of the drug utilisation and audit committee or pharmaceutical and therapeutics committee or relevant structure are available.

Assessment type: Document - **Risk rating:** Essential measure
Manual or electronic minutes from the previous six months must be signed and dated and include an attendance register. (Note that minutes will not be signed if the subsequent meeting has not taken place). The content of the minutes must reflect discussions on actions taken to optimise rational and quality use of medicine.
Not applicable: Never

Score	Comment

Criterion 5.2.2.2.6 7 Systems to mitigate the risk of medicine-related patient safety incidents must be implemented.

5.2.2.2.6.1 A standard operating procedure for safe administration of medicines to users is available.
Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Identification of user prior to administration of medicine.		
2. Confirmation of user prescription. Explanatory note: This includes the correct medicine, dose, route, frequency, duration and validity.		
3. Administration of parenteral medicine		
4. Administration of Schedule 5 and 6 medicines		
5. Process for recording the administration of medicine		
6. Process for reporting medicine errors and adverse drug reactions		

Criterion 5.2.2.2.7 7 Authorisation must be confirmed for all research projects involving users at the health establishment.

5.2.2.2.7.1 A letter of permission from the province or district for each research project at the health establishment is available.

Assessment type: Document - **Risk rating:** Essential measure
Any research project must be authorised by the relevant authority or designated persons. Request copies of authorisation letters for all research projects conducted in the health establishment in the past 12 months. Where no research projects were conducted in the past 12 months, the health establishment can document zero reporting or document in minutes of clinical management group.
Not applicable: Where no research projects were conducted in the health establishment in the past 12 months.

Score	Comment

Criterion 5.2.2.2.8 7 Systems must be in place to facilitate user identification.

5.2.2.2.8.1 A standard operating procedure for identifying users is available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Method of identification. Explanatory note: may include, but need not be limited to, wristbands, photos.		
2. Applying the identification band or item		
3. User identity to be confirmed before each clinical intervention.		
4. The minimum identifiers to be used.		
5. Participation of users in the identification process (where applicable).		
6. Circumstances for removal of identification		
7. Specific precautions for managing at-risk users, Explanatory note: including, but not limited to, babies and intellectually challenged users.		

Criterion 5.2.2.2.9 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.

5.2.2.2.9.1 A standard operating procedure for the management of emergency resuscitations is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Procedure for calling out or mobilisation of resuscitation teams (where applicable).		
2. Documentation of resuscitation details		
3. Referral protocol.		
4. Management of user's family and/or visitors during a resuscitation		
5. Debriefing sessions		

5.2.2.2.9.2 The terms of reference for the resuscitation forum/committee are available.

Assessment type: Document - **Risk rating:** Essential measure
Verify whether the aspects listed below are included and explained in the terms of reference. A single structure covering multiple functions will be acceptable or any other configuration of multiple structures. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Interdisciplinary membership required.		
2. Term in office		
3. Roles and responsibilities of forum members		
4. Frequency of meetings		
5. Quorum for the structure		

5.2.2.2.9.3 Minutes of the structure reviewing resuscitations are available.

Assessment type: Document - **Risk rating:** Vital measure
Manual or electronic minutes from the previous six months must be signed and dated and include an attendance register. (Note that minutes will not be signed if the subsequent meeting has not taken place). The content of the minutes must reflect discussions on improving the management of resuscitations and improving outcomes of future resuscitation attempts.
Not applicable: Where no resuscitation attempts have occurred.

Score	Comment

5.2.2.2.9.4 Remedial action is taken to address gaps identified during the review of resuscitation attempts, to improve resuscitation outcomes.

Assessment type: Document - **Risk rating:** Vital measure
This requirement seeks to ensure that the health establishment takes action to improve the outcome of future resuscitation attempts. Minutes must reflect action taken to ensure that good practices identified are shared with all health care personnel and incorporated into standard operating procedures where relevant, and that health care personnel receive training in response to gaps identified in interventions that could have been managed more successfully.
Not applicable: Where no resuscitation attempts have occurred, or where no gaps were identified.

Score	Comment

Criterion 5.2.2.2.10 7 Standard operating procedures for decontamination processes must be available.

5.2.2.2.10.1 A standard operating procedure for decontamination processes is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Checking and safe handling of used instruments		
2. Procedure for manual cleaning of equipment/instruments		
3. Procedure for decontamination of reusable devices and surgical instruments		
4. Handling of potentially infectious instruments and materials		
5. Safe management and use of hazardous chemicals.		
6. Procedure for packing and assembly of instruments. Explanatory note: Packing to be done according to the manufacturer's instructions and the South African National Standard (SANS, ISO 11607).		
7. Steam sterilisation procedure		
8. Tracking system for product sterilisation, identification, recording and recalls		
9. Responsibilities for various aspects of the decontamination cycle for sterilisation services		

5.2.2.2.10.2 A standard operating procedure for management of sterilisation equipment is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment

1. Performing manual cleaning of equipment		
2. Cleaning of steam autoclaves		
3. Monitoring of steam autoclaves		
4. Testing and use of sterilisation equipment		
5. Quality control of all equipment		
6. Action to be taken in the event of equipment breakdown.		

Criterion 5.2.2.2.11 7 Medicines must be stored and managed in compliance with the Pharmacy Act 53 of 1974, the Medicines and Related Substances Act 101 of 1965 and the relevant rules and regulations.

5.2.2.2.11.1 A standard operating procedure for the management of medicines is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Storage and organisation of medicines		
2. Security and access control to pharmacy		
3. Cold chain management		
4. Emergency medicine cupboard or trolley management (where applicable)		
5. Pest elimination		
6. Management of stock levels. Explanatory note: This will include calculation and use of minimum, maximum and reorder levels, management of stock (bin) cards and/or electronic stock monitoring system		
7. Stocktaking (counting) procedure		
8. Management of short-dated stock		
9. Procurement (ordering and receipt) of medicines		
10. Managing return of stock to the depot		
11. Issuing of medicines		
12. Managing stock transfers between health establishments		

13. Management of expired, obsolete, or user-returned medicines		
14. Procedure for recall of medicines		
15. Storage and control of schedule 6 medicines		

Criterion 5.2.2.2.12 7 A system to manage adverse drug reactions must be implemented.

5.2.2.2.12.1 A standard operating procedure for the reporting of adverse drug reactions is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Name of health establishment reporting adverse drug reaction.		
2. User's details. Explanatory note: This will include but not limited to name, registration number, age and gender, weight, height, unique identifier, allergies (if any).		
3. Details about medicine suspected to have caused the reaction (suspect medicine).		
4. Details of all other medicines the user was taking at the time of the reaction (concomitant medicine).		
5. Date and time of reaction		
6. Description of reaction		
7. Interventions made in response to reaction.		
8. User outcome		
9. Laboratory results, if available		
10. Details of any other medical conditions of the user		
11. Name and qualification of person reporting adverse drug reaction. Reference: https://www.sahpra.org.za/health-productsvigilance/		

5.2.2.2.12.2 Minutes of the forum monitoring adverse drug reactions is available.

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

Manual or electronic minutes from the previous six months must be signed and dated and include an attendance register. (Note that minutes will not be signed if the subsequent meeting has not taken place). The content of the minutes must reflect discussions on the review of adverse drug reactions.

Not applicable: Where no adverse drug reactions were reported.

Score	Comment

Criterion 5.2.2.2.13 7 Standard operating procedures to guide the implementation of infection prevention and control practices must be available.

5.2.2.2.13.1 Standard operating procedures for standard precautions are available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Effective hand hygiene practices		
2. The use of personal protective equipment.		
3. Safe injection practices		
4. Disposal of health care waste		
5. User isolation		
6. Cohorting of users		
7. Care of equipment (cleaning and disinfection of potentially contaminated equipment)		
8. Environmental control (cleaning of environment and all potentially contaminated surfaces)		
9. Handling of linen. Explanatory note: This will include but not limited to clean, dirty and infected linen.		
10. Airborne precautions		
11. Droplet precautions		
12. Contact precautions		
13. Formidable epidemic precautions (all precautionary measures in place to contain progression and prevent spread and complications)		

5.2.2.2.13.2 Standard operating procedures for reducing the risk of health care-associated infections are available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Catheter-acquired urinary tract infection (CAUTI)		
2. Central line-associated bloodstream infection (CLABSI)		
3. Surgical site infection (SSI)		
4. Prevention of ventilator-associated pneumonia (VAP) in adults. (Not applicable if the health establishment does not have facilities to ventilate users)		

5.2.2.2.13.3 Standard operating procedures for infection prevention and control practices cover all aspects of infection prevention and control.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
Management and structure		
1. The allocated person’s daily responsibilities		
2. Training and qualification requirements for the departmental infection prevention and control (IPC) link person		
3. Roles and responsibilities of the multidisciplinary infection prevention and control committee		
4. Procedure to follow when reporting notifiable diseases.		
5. Feedback mechanism to relevant clinical teams for health care-associated infections that are not notifiable.		
Employee development and education programme		
6. Plan for health care personnel development and training in infection prevention and control		
Infection control measures		
7. Measures to be implemented for controlling infection within the health establishment.		
8. Details of the infection surveillance programme, including the collection, analysis and dissemination of statistics.		

9. Audit tool for assessing hand hygiene practices.		

Criterion 5.2.2.2.14 7 Standard operating procedures for the management of complaints must be implemented.

5.2.2.2.14.1 A standard operating procedure for the management of complaints is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Procedure for lodging complaints (including telephonic complaints)		
2. Procedure for acknowledgement of complaints		
3. Procedure for investigating complaints.		
4. Procedure for determining required action to be taken according to severity of complaint (risk rating)		
5. Procedure for identifying patterns in system failures (categorisation)		
6. Procedure for redress		
7. Targets to be met.		
8. Procedure for recording statistical data on complaints.		
9. Monitoring mechanisms and their response timelines		
10. Mechanism to enable children to participate in complaints process.		
11. Mechanisms to enable vulnerable groups such as disabled people, the elderly, the mentally ill, illiterate people, and people speaking foreign languages can easily participate in the complaints process.		

Sub Domain 5.2.3 9 Waste management

Standard 5.2.3.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 5.2.3.1.1 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

5.2.3.1.1.1 A standard operating procedure for handling, storage and safe disposal of waste is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Containerisation		
2. Intermediate storage		
3. Internal transportation		
4. Central storage		
5. Collection		
6. Disposal		
7. Treatment		

Domain 5.3 CLINICAL SUPPORT SERVICES
Sub Domain 5.3.1 12 Blood services
Standard 5.3.1.1 12(1) Hospitals and CHCs must ensure that users have access to blood and blood products when required.
Criterion 5.3.1.1.1 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.

5.3.1.1.1.1 Adverse blood reactions reported to forum are discussed.

Assessment type: Document - **Risk rating:** Vital measure
Manual or electronic minutes from the previous six months must be signed and dated and include an attendance register. (Note that minutes will not be signed if the subsequent meeting has not taken place). The content of the minutes must reflect discussions on reported blood reaction incidents.
Not applicable: Where no adverse blood reactions were reported to the forum.

Score	Comment

5.3.1.1.1.2 Remedial action is taken to prevent the recurrence of adverse blood reactions.

Assessment type: Document - **Risk rating:** Vital measure
Documented evidence must be available reflecting action taken where gaps in the administration of blood or blood products have been identified.
Not applicable: Where no adverse blood reactions were reported and there is evidence of zero reporting.

Score	Comment

Domain 5.4 GOVERNANCE AND HUMAN RESOURCES
Sub Domain 5.4.1 20 Occupational health and safety
Standard 5.4.1.1 20(1) The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.
Criterion 5.4.1.1.1 20 Measures must be in place to minimise the incidence of critical occupationally acquired injuries and diseases.

5.4.1.1.1.1 A standard operating procedure for the cleaning of hazardous and biohazardous spills is available.

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

The aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment, signed and dated by the relevant authority responsible for approving the standard operating procedures, designation of the approver, date of implementation or approval, date of next review (Documents must be reviewed regularly up to the maximum of every 5 years). The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Initial management of the spill. Explanatory note: This may include covering the spill with paper towels or placing a spill sock around a chemical spill.		
2. Details on who to contact to clean up spill		
3. Use and disposal of personal protective equipment.		
4. Cleaning agents to be used and correct dilution		
5. Procedure for cleaning up spills		
6. Cleaning and disinfection of cleaning equipment		
7. Hand hygiene performed as last step in process		

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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