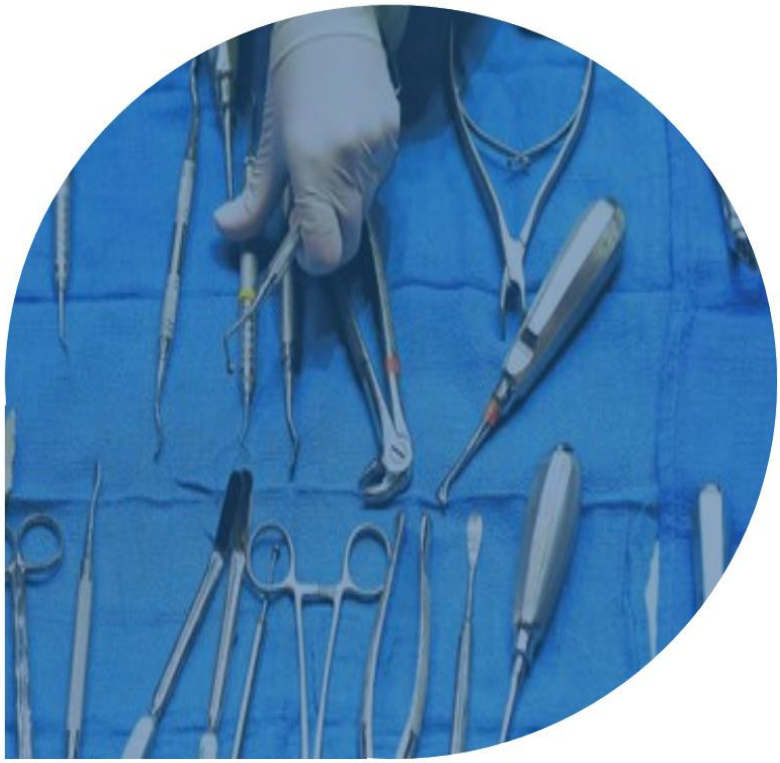
OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care



Healthcare Quality Management

v1.2

Regulatory Private Acute Hospital Inspection tool

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.

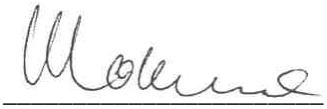
To achieve this mandate, standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Private Acute Hospitals.

Acknowledgements

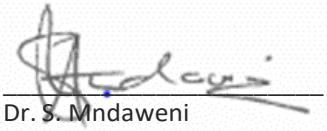
There are many people who have contributed to the development of the Regulatory Private Acute Hospital Inspection Tools Version 1.2. The Office of Health Standards Compliance wishes to extend most heartfelt acknowledgement and gratitude to the following:

- The WHO technical team for providing guidance on the very first draft inspection tools database
- OHSC CEO Dr Siphiwe Mndaweni and Executive Manager for Health Standards Design, Systems and Support Ms Winnie Moleko for providing strategic and operational support.
- Former Health Standards Development and Training unit Director Dr Grace Labadarios
- Systems, Data Analysis and Research unit Director Dr Thabiso Makola who is also the Acting Director for Health Standards Development and Training unit
- The Health Standards Development and Training unit (Mr Jabu Nkambule who led the team and worked tirelessly with the leadership of Hospital Association of South Africa (HASA) during various development stages of the tool, Ms Florina Mokoena, Ms Mosehle Matlala, Ms Busisiwe Mashinini) and contract workers Ms Thresia Pather and Ms Busi Ngubane for the development of the Private Acute Hospital Inspection tools.
- The internal OHSC teams Compliance Inspectorate; Systems, Data Analysis and Research for their contribution during the development of the Inspection tools and Information Technology and Communication and Stakeholder Relations for providing support.
- Provincial Department of Health private hospital licensing units personnel (Ms Pinki Belot - Free State Province, Ms Dimakatso Moeketsi and Ms Zandile Nzuza - Kwa-Zulu Natal -Province, Ms Kim Jacobs - Western Cape Province, Ms Bulelwa Peter - Eastern Cape Province, Ms Pakama Nqadala
  - Northern Cape Province, Ms Lindiwe Mkhatshwa - Mpumalanga Province, and Ms Patience Ntamane - Gauteng Province) for their valuable input and support.
- The Certification and Enforcement Committee of the OHSC Board for reviewing the tools and for recommending to the Board for approval.
- The Hospital Association of South Africa (HASA) for their commitment and constructive engagements during the consultative process and for affording the OHSC an opportunity to conduct scoping visits in the private hospital health establishments.

It is hereby certified that these Regulatory Private Acute Hospital Inspection tools version 1.2 was developed by the Office of Health Standards Compliance.



Ms. WMoleko
Executive Manager
Health Standards Development
Analysis and Support
Date: 31/03/2022



Dr. S. Mndaweni
Chief Executive Officer
Date: 31/03/2022

Facility: Date:

- **Tool Name:** Regulatory Private Acute Hospital inspection tool v1.2 - Final
- **HEs Type:** Hospitals
- **Sector:** Private
- **Specialization:** Private Acute Hospital

Created By: Health Standards Development and Training

6 Healthcare Quality Management

Domain 6.1 USER RIGHTS

Sub Domain 6.1.1 5 Access to care

Standard 6.1.1.1 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 6.1.1.1.1 5(2)(a) The health establishment must implement a system of triage.

6.1.1.1.1.1 A policy or standard operating procedure or procedure or guideline for triage is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must be aligned with an algorithm approved by a recognised national or international body, such as the Emergency Medicine Society of South Africa. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Assess the user using an approved triage algorithm		
2. Assign a triage category to the user in accordance with the triage algorithm		
3. Document the triage category in the user's health record		
4. Direct the user to the correct waiting or treatment area, in accordance with the triage category assigned		
5. Ensure that users triaged as requiring immediate care are transferred directly into the care of the appropriate health care provider, in accordance with their condition and triage category		
6. Deceased users must be certified by the doctor on duty Reference: •https://emssa.org.za/wp-content/uploads/2011/04/SATS-Manual-A5-LR-spreads.pdf		

Criterion 6.1.1.1.2 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.

6.1.1.1.2.1 A policy or standard operating procedure or procedure or guideline for managing psychiatric emergencies is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the

accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained. Score Not applicable if the health establishment does not manage psychiatric emergencies.

Score	Comment

Aspects	Score	Comment
1. Identification and management of users at risk of suicide or self-harm		
2. Identification and management of users at risk of harming others		
3. Identification and management of users at risk of substance withdrawal		
4. How to defuse a potentially violent or aggressive situation without using restraint.		
5. Criteria for applying physical restraint		
6. Safe techniques for applying physical restraint		
7. Monitoring required following the application of physical restraint		
8. Criteria for applying chemical restraint		
9. Use of medicine for chemical restraint		
10. Monitoring required following the application of chemical restraint		
11. Criteria for applying mechanical restraint		
12. Safe techniques for applying mechanical restraint		
13. Monitoring required following the application of mechanical restraint		

Domain 6.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 6.2.1 6 User health records and management

Standard 6.2.1.1 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 6.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

6.2.1.1.1.1 A policy or standard operating procedure or procedure or guideline describing how confidentiality of user health records is maintained in clinical areas is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must address how confidentiality will be maintained. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Score	Comment

Aspects	Score	Comment
1. Management of paper-based records to prevent unauthorised access during the episode of care. Explanatory note: This will include all records in user care areas, i.e. records of users receiving care and records in the user care area for administrative purposes. It may include, but need not be limited to, auditing.		
2. Protection of electronic health records against unauthorised access or viewing. Explanatory note: This may include, but need not be limited to, measures such as locking the screen when leaving the monitor unattended, locking the room where computers used for accessing user information are kept, and adjusting the screen to avoid unauthorised viewing.		
3. Regular updating of software according to alerts from the developer to prevent security breaches Reference: •https://samedical.org/images/attachments/guidelines-on-maintaining-confidentiality-inwards-013.pdf		

6.2.1.1.1.2 A policy or standard operating procedure or procedure or guideline describing how to ensure that user health records are secured in clinical areas is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must address how confidentiality will be maintained. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Aspects
1. Control of access to the health records storage area in user care areas
2. Electronic security measures to prevent unauthorised access to electronic health records Explanatory note: This will include, bu need not be limited to, access screen locks.
3. Backup systems for electronic health records
4. Defining of the frequency of backup processes
5. Regular updating of software for electronic health records Reference: https://www.hst.org.za/publications/NonHST%20Publications/Final%20National%20Guideline%20for%20Filing%20Archiving%20and%20Disposal%20of%20Patient%2

Standard 6.2.1.2 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 6.2.1.2.1 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).

6.2.1.2.1.1 The policy or standard operating procedure or procedure or guideline for confirmation of informed consent is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. The person(s) responsible for confirming the consent form		
2. Confirmation with user that Doctor explained the procedure and possible complications		
3. Details that must be confirmed with the user are documented in the procedure (This includes but not limited to Procedure the user is booked for, user allergies, any mediation taken by the user, information on keeping nil per mouth before surgery, post operation care).		

Sub Domain 6.2.2 7 Clinical management

Standard 6.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 6.2.2.1.1 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.

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

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

Verify whether the unit has the guidelines listed below. Score 1 if the guideline is available and 0 if not available

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. National Tuberculosis Management Guidelines 2014 0r latest		
4. Guidelines for the Treatment of Malaria in South Africa 2018 or latest		
5. Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework 2020 or latest		
6. National Infection Prevention and Control Strategic Framework 2020 or latest		
7. Guidelines on Implementation of the Antimicrobial Strategy in South Africa: One Health Approach & Governance 2017 or latest		

8. National clinical guidelines of PEP in occupational and non-occupational exposures 2020 or latest		
9. Policy Guidelines on 72-hour Assessment of Involuntary Mental Health Care Users, 2012 or latest		
10. Policy Guidelines on Seclusion and Restraint of Mental Health Care Users, March 2012 or latest		
11. Guidelines for Maternity Care in South Africa 2016 or latest		
12. New-born Care Charts: Management of Sick and Small New-borns in Hospital 2014 or latest		
13. National Consolidated Guidelines for the Management of HIV in Adults, Adolescents, Children and Infants and prevention of Mother to child transmission 2020 or latest		

Standard 6.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 6.2.2.2.1 7 Standard operating procedures for the management of complaints must be implemented.

6.2.2.2.1.1 Complaints are logged in a complaint register.

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

The health establishment must log all its complaints in a register, which is a documented record containing information on complaints. The register may be in the form of a book, separate pages filed in a clearly labelled file, or an electronic record. Request the register for complaints and verify whether the aspects listed below are included. Score 1 if the aspect is included and 0 if not included.

Score	Comment

Aspects	Score	Comment
1. Reference number of complaint		
2. Date complaint was received		
3. Surname and name of user		
4. Surname and name of person who lodged complaint on user's behalf (where relevant)		
5. Service area where the incident resulting in the complaint occurred		
6. Short summary describing the essence of the complaint		
7. Category of complaint (assessed when logged and reassessed once resolved)		
8. Severity of complaint (determined when logged and reassessed once resolved)		
9. Escalation of complaints relating to serious patient safety incidents to forum responsible for such incidents(where applicable)		
10. Action taken to resolve complaint		
11. Outcome of complaint (including level of satisfaction of complainant)		
12. Date the complaint was resolved		
13. Number of working days taken to resolve complaint		
14. Action taken to prevent a recurrence of the same incident		

6.2.2.2.1.2 Complaints identified as serious patient safety incidents are referred to the forum reviewing patient safety incidents for further management.

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

All serious patient safety incidents must be reported to the forum responsible for managing them. Review records from the previous quarter. The column indicating the level of risk represented by the complaint must be completed in the complaints register. The register must indicate that these complaints have been escalated to the forum dealing with serious patient safety incidents. In cases where no serious patient safety incidents occurred, zero reporting must be done. Not applicable: Where no complaints in relation to serious patient safety incidents are made and where there is proof that zero reporting was done.

Score	Comment

6.2.2.2.1.3 Complaints are managed in accordance with the timelines documented in the standard operating procedure.

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

Select three records of resolved complaints and assess the summary on the outcome of complaints investigation form (Annexure E in the National Guideline to Manage Complaints, Compliments and Suggestions in the Health Sector of South Africa). Verify that the timelines for acknowledgement of complaints and the timelines for their resolution have been met. Score 1 if the timelines have been met and 0 if not met.

Score	Comment

Unit 1 Complaint 1

Aspects	Score	Comment
1. Timelines for acknowledgement of complaints		
2. Timelines for resolution of complaints		

Unit 2 Complaint 2

Aspects	Score	Comment
1. Timelines for acknowledgement of complaints		
2. Timelines for resolution of complaints		

Unit 3 Complaint 3

Aspects	Score	Comment
1. Timelines for acknowledgement of complaints		
2. Timelines for resolution of complaints		

6.2.2.2.1.4 Information regarding the resolution of the complaint is made available to the complainant.

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

Select three records of resolved complaints from the complaints folder or file. Verify whether a record of the communication of the resolution of the complaint to the complainant is available in the folder or file, including the outcome of the investigation and redress agreed. Where minutes of a meeting are sent as a record of the resolution, the complainant must have been present at the meeting. Redress may include one or more of the following: • An apology, explanation or an acknowledgement of responsibility; and/or • Remedial action that may include: (i) the review or changing of a decision on the service or care provided to an individual user; (ii) revising published material; (iii) revising a procedure to prevent the recurrence of an adverse event or incident; and (iv) the training of health care personnel or strengthening of their supervision; or any combination of the above. Score 1 if the documentation is available in the file and 0 if not available. NB: Telephonic conversations to address redress will only be accepted when witnessed, documented and signed by two colleagues.

Score	Comment

Unit 1 Complaint 1

Aspects	Score	Comment
1. Outcome of the investigation. Explanatory notes: Following an investigation the outcome of the complaint must be recorded as resolved, closed or progress report where the complexity of the investigation requires further investigations. Resolution of complaint can include but not limited to patient satisfied and redress done, Patient Safety Incident, litigation and complainant could not be traced.		
2. Redress. Explanatory notes: Redress may include one or more of the following: An apology, explanation or an acknowledgement of responsibility; and/or Remedial action that may include: (i) the review or changing of a decision on the service or care provided to an individual user; (ii) revising published material; (iii) revising a procedure to prevent the recurrence of an adverse event or incident; and (iv) the training of health care personnel or strengthening of their supervision; or any combination of the above. Not applicable: Where the complainant is not satisfied with investigation outcome or resolution or cannot be traced		

Unit 2 Complaint 2

Aspects	Score	Comment
1. Outcome of the investigation. Explanatory notes: Following an investigation the outcome of the complaint must be recorded as resolved, closed or progress report where the complexity of the investigation requires further investigations. Resolution of complaint can include but not limited to patient satisfied and redress done, Patient Safety Incident, litigation and complainant could not be traced.		
2. Redress. Explanatory notes: Redress may include one or more of the following: An apology, explanation or an acknowledgement of responsibility; and/or Remedial action that may include: (i) the review or changing of a decision on the service or care provided to an individual user; (ii) revising published material; (iii) revising a procedure to prevent the recurrence of an adverse event or incident; and (iv) the training of health care personnel or strengthening of their supervision; or any combination of the above. Not applicable: Where the complainant is not satisfied with investigation outcome or resolution or cannot be traced		

Unit 3 Complaint 3

Aspects	Score	Comment
1. Outcome of the investigation. Explanatory notes: Following an investigation the outcome of the complaint must be recorded as resolved, closed or progress report where the complexity of the investigation requires further investigations. Resolution of complaint can include but not limited to patient satisfied and redress done, Patient Safety Incident, litigation and complainant could not be traced.		
2. Redress. Explanatory notes: Redress may include one or more of the following: An apology, explanation or an acknowledgement of responsibility; and/or Remedial action that may include: (i) the review or changing of a decision on the service or care provided to an individual user; (ii) revising published material; (iii) revising a procedure to prevent the recurrence of an adverse event or incident; and (iv) the training of health care personnel or strengthening of their supervision; or any combination of the above. Not applicable: Where the complainant is not satisfied with investigation outcome or resolution or cannot be traced		

6.2.2.2.1.5 A policy or standard operating procedure or procedure or guideline for the management of complaints is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document

(optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained

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. Timelines 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. Mechanism to enable vulnerable groups to participate in complaints process		

Criterion 6.2.2.2.2 7 The health establishment must have a functional quality management system

6.2.2.2.2.1 Quality improvement plans are developed by health care personnel .

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

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

Score	Comment

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

6.2.2.2.2.2 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 6.2.2.2.3 7 Formal processes are in place to manage clinical risk.

6.2.2.2.3.1 A policy or standard operating procedure or procedure or guideline for the management of clinical risk is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Requirement for clinical risk assessments is conducted in every clinical department.		
2. Identification of clinical hazards		
3. Risk rating of identified clinical hazards		
4. Compilation of the clinical risk register		
5. Standardised approach to clinical risk mitigation		
6. Establishment of the clinical risk management structure		

6.2.2.2.3.2 A functional quality and clinical risk management structure is in place.

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

Request the terms of reference of the quality and clinical risk management structure. Verify whether the documentation complies with the requirements listed below. Score 1 if the aspect is compliant and 0 if not compliant. NB: Any format for the structure will be acceptable, as long as the requirements stipulated in the measures are met. A single structure covering multiple functions will be acceptable, or any other configuration of multiple structures.

Score	Comment

Aspects	Score	Comment
1. Membership of the structure		
2. Term in office		
3. Roles and responsibilities of structure or members		
4. Frequency of meetings		
5. Quorum for the structure		

6.2.2.2.3.3 Clinical risk and quality related matters are discussed by the structure.

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

Request the minutes of the structure from the previous quarter and verify whether the aspects listed below are discussed by the structure, remedial or corrective actions implemented(where applicable). Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

Unit 1 Aspects discussed(Verify if aspects listed below are discussed)

Aspects	Score	Comment
1. Clinical risk		
2. Adverse events and or/adverse drug reactions		
3. Drug utilisation, audit or pharmaceutical and therapeutics matters		
4. Complaints		
5. Review of emergency resuscitations		
6. Infection prevention and control practices		
7. Waste management practices		
8. Occupational Health and Safety		

Unit 2 Remedial or Corrective Action(NB; Verify whether remedial or corrective actions are documented and implemented; NB Score Not applicable if there were no gaps identified)

Aspects	Score	Comment
1. Clinical risk		
2. Adverse events and or/adverse drug reactions		
3. Drug utilisation, audit or pharmaceutical and therapeutics matters		
4. Complaints		
5. Review of emergency resuscitations		
6. Infection prevention and control practices		
7. Waste management practices		
8. Occupational Health and Safety Reference: Promoting Rational Use of Medicines: Core Components - WHO Policy Perspectives on Medicines, No. 005, September 2002; https://apps.who.int/medicinedocs/en/m/abstract/Js21654en/ Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework. March 2020 Promoting Rational Use of Medicines: Core Components - WHO Policy Perspectives on Medicines, No. 005, September 2002. https://apps.who.int/medicinedocs/en/m/abstract/Js21654en/ National Guideline to Manage Complaints, Compliments and Suggestions in the Public Health Sector of South Africa (9.1.3 Designation of members for hospital CCSCs)		

6.2.2.2.3.4 Annual clinical risk assessments are conducted in every clinical department of the health establishment.

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

The purpose of these assessments is to identify risk to users, healthcare workers and visitor's consequent to receiving care. This process will include but not limited to risk assessments related to health care-associated infections. The profile of the health establishment will provide guidance on clinical departments of the health establishment. Not applicable: Never

Score	Comment

Criterion 6.2.2.2.4 7 Standardised procedures to identify and mitigate clinical risk must be implemented during the care of vulnerable users.

6.2.2.2.4.1 A policy or standard operating procedure or procedure or guideline for the care of the terminally ill which addresses the needs of the user and their family is available.

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

Verify whether the aspects listed below are included and explained in the document which must address the needs of the user and his/her family, friends and carers. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
Development and implementation of the plan		
1. Assessment of the user's needs to be made, using a multidisciplinary approach		
2. Development of a multidisciplinary care plan to be tailored to the user's specific needs		
3. The user and his/her family, carers and/or friends to be included in the development of the plan		
4. The care plan to be documented and shared with members of the team.		
5. Care to be provided in accordance with the plan		
Content of the plan		
6. Pain management		
7. Supportive equipment		
8. Personal hygiene		
9. Prevention of bedsores		
10. Prevention of falls		
11. Nutritional requirements		
12. Psychosocial and spiritual requirements References: •https://www.up.ac.za/media/shared/62/Palliative%20Care%20Resources/final-npfspc-august2017.zp166876.pdf •https://sahivsoc.org/Files/HIV%20Palliative%20Care%20Guidelines%2022%20October%202018%20MR%20(003).pdf		

6.2.2.2.4.2 A policy or standard operating procedure or procedure or guideline for conducting and acting on risk assessments is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Criteria for identifying frail and aged users		
2. Criteria for identifying users with reduced mobility		
3. Assessment tools completed for frail and aged users on admission. Explanatory note: This may include, but need not be limited to, the Water low scale to assess the user's risk of developing bedsores, or the Morse fall scale to assess the user's risk of falling.		
4. Assessment to be filed in the user health record		
5. Care plan to be developed in accordance with identified needs		
6. Implementation of care plan to be monitored		

6.2.2.2.4.3 A policy or standard operating procedure or procedure or guideline for conducting risk assessments for mental health users is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained. NB: Score Not applicable if the health establishment does not admit mental healthcare users

Score	Comment

Aspects	Score	Comment
1. Risk assessment to include consideration of: aggression, violence, suicidal ideation, self-harm, substance withdrawal, risk of absconding.		
2. Categorisation of at-risk users to be documented in the user health record		
3. Categorisation of at-risk users to be documented in the relevant unit register		
4. All relevant health care personnel to be informed of the at-risk user		
5. Formal handover of at-risk users to take place at shift changes		
6. User care plan to include specific risk mitigation measures		
7. Delivery of care in accordance with the care plan		

6.2.2.2.4.4 A policy or standard operating procedure or procedure or guideline for the management of high-risk mental health users is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if

the aspect is included and explained and 0 if not included or not explained. NB: Score Not applicable if the health establishment does not admit mental healthcare users.

Score	Comment

Aspects	Score	Comment
1. User to be assessed on admission for factors related to aggression		
2. User to be assessed on admission for factors related to suicidal risk		
3. User to be assessed on admission for factors related to absconding		
4. Chemical sedation to be prescribed in user records		
5. Physical restraint to be prescribed in user records		
6. Prescribed restraint to be documented in unit register		

Criterion 6.2.2.2.5 7 The health establishment must monitor clinical outcomes to improve service delivery.

6.2.2.2.5.1 The health establishment participates in morbidity and mortality meetings.

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

Documented evidence of participation in morbidity and mortality meetings from the previous quarter must be available for the areas listed below, including but not limited to attendance registers and minutes of meetings that include action to be taken to prevent similar incidents from occurring. NB: In smaller health establishments or those with very low mortality/morbidity rates, it is not required for the disciplines listed below to be dealt with in separate meetings – one M & M meeting dealing with all disciplines is acceptable.

Score	Comment

Aspects	Score	Comment
1. Maternal and perinatal		
2. Neonatal (where available)		
3. Paediatric		
4. Medical		
5. Surgical		

6.2.2.2.5.2 Morbidity and mortality statistics at the health establishment are monitored.

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

These statistics must be collected at least quarterly and be made available for discussion at clinical/risk management committee meetings. Not applicable: Never

Score	Comment

6.2.2.2.5.3 Improvement programmes are implemented to address concerns where identified.

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

Where areas of concern are identified, quality improvement plans must be developed and implemented to improve performance. Not applicable: Where no areas of concern are identified.

Score	Comment

Criterion 6.2.2.2.6 7 The health establishment must implement systems to ensure that blood and blood products are available and administered safely.

6.2.2.2.6.1 A policy or standard operating procedure or procedure or guideline for the administration of blood is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Confirmation of informed consent for transfusion		
2. Doctors and/or registered nurses to verify order for transfusion, user, blood product to be transfused, blood group and expiry date of blood product		
3. Correct filters and intravenous administration set to be used according to blood or blood product to be transfused		
4. Criteria for blood warming		
5. Identification of user prior to commencing transfusion		
6. Recording of baseline vital signs prior to commencing transfusion		
7. Aseptic technique to be followed when commencing transfusion		
8. Transfusion rate to be controlled/titrated as per doctor's prescription		
9. Vital signs to be checked every 15 minutes for the first hour, every 30 minutes for the second hour and hourly thereafter, for each unit transfused		
10. Vital signs to be monitored as per health establishment guideline		
11. No medicines or other fluid to be added to blood products before or during a transfusion		
12. Criteria for retaining and returning empty blood product bags to blood bank Reference: •https://sanbs.org.za/wp-content/uploads/2016/09/Clinical_Guidelines_5thEdition_2014.pdf		

Criterion 6.2.2.2.7 7 Systems to mitigate the risk of medicine-related patient safety incidents must be implemented.

6.2.2.2.7.1 A policy or standard operating procedure or procedure or guideline detailing the process to be followed for safe administration of medicines to users is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the

accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained

Score	Comment

Aspects	Score	Comment
1. User identification to be confirmed prior to administration of medicine		
2. The correct medicine to be confirmed prior to administration		
3. The correct dose to be confirmed as per the user medicine chart		
4. Medicine to be administered in accordance with the prescribed frequency and time		
5. Medicine to be administered via the correct route		
6. The validity of the prescription to be verified prior to administration		
7. Administration of parenteral medicine		
8. Administration of Schedule 5 and 6 medicine		
9. Process for recording the administration of medicine		
10. Process for reporting medicine errors and adverse drug reactions		

Criterion 6.2.2.2.8 7 Authorisation must be confirmed for all research projects involving users at the health establishment.

6.2.2.2.8.1 A letter of permission from the head office or management for each research project at the health establishment is available.

Assessment type: Document - **Risk rating:** Vital 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. Not applicable: Where no research projects were conducted in the health establishment in the past 12 months

Score	Comment

Criterion 6.2.2.2.9 7 Systems must be in place to facilitate user identification.

6.2.2.2.9.1 A policy or standard operating procedure or procedure or guideline for identifying users is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. User identity to be confirmed before each clinical intervention to ensure that the correct user is receiving the correct care		
2. User identity to be confirmed by at least two identifiers and may include, but need not be limited to, the user's name and date of birth		
3. Users to be encouraged to participate in the identification process, which may include, but need not be limited to, volunteering personal information for confirmation		
4. Method of identification (may include, but need not be limited to, wristbands or name tags)		
5. Applying the identification band or item		
6. Removal of identification band/item		
7. Specific precautions for managing at-risk users, including, but not limited to, babies and intellectually challenged users.		

Criterion 6.2.2.2.10 7 Communication during user handover must be standardised to advance user safety.

6.2.2.2.10.1 A policy or standard operating procedure or procedure or guideline for the handover of users from emergency medical services (EMS) to health care providers in the health establishment is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Times of arrival and handover to be recorded		
2. Vital signs recorded during the transfer to be communicated		
3. Method of transfer of user from ambulance to consultation room or hospital bed to be recorded, i.e. walking, stretcher or wheelchair		
4. User identity to be confirmed		
5. Clinical status of the user to be recorded (Glasgow coma scale)		
6. Clinical status of the user to be recorded (pain score)		
7. Known medical history to be communicated.		
8. The name and designation of the health care provider receiving the user to be recorded.		
9. Signatures of transferring and receiving health care provider to be recorded		
10. Target time frames for the completion of user handover		

Criterion 6.2.2.2.11 7 The management of emergency resuscitations must be guided and monitored to improve user outcomes.

6.2.2.2.11.1 A policy or standard operating procedure or procedure or guideline for the management of emergency resuscitations is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Procedure for calling out resuscitation team		
2. Composition of resuscitation team		
3. Expertise of members of resuscitation team		
4. Documentation for recording details of the resuscitation		
5. Debriefing sessions held following each resuscitation		
6. Referral protocol for users transferred to another health establishment after the resuscitation		
7. Sensitive management of user's family and/or visitors during a resuscitation		
8. All documentation completed during resuscitations to be audited. Explanatory note: This requirement is for documentation audits, i.e. checking that all required fields have been completed with relevant information. It does not require evaluation of the clinical care provided, which is addressed in aspect j. below.		
9. Where gaps in record keeping are identified, quality improvement plans to be implemented		
10. All actions taken during resuscitations to be audited. Explanatory note: This requirement is for clinical audits, i.e. confirmation that the actions taken are in accordance with the health establishment's resuscitation protocols.		
11. Where gaps in the clinical management of emergency resuscitations are identified, quality improvement plans to be implemented		
12. Resuscitation audit reports to be included as part of the health establishment's clinical reviews.		

Criterion 6.2.2.2.12 7 A system to manage adverse drug reactions must be implemented.

6.2.2.2.12.1 A policy or standard operating procedure or procedure or guideline for the monitoring of adverse drug reactions is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. All adverse events related to the use of drugs to be reported		
2. Immediate care to be provided to the user affected by the incident		
3. Incident to be reported to the unit manager where it occurred		
4. Incident to be reported to the pharmacist responsible		
5. Incidents to be categorised according to severity		
6. Procedure for reporting incidents in accordance with the risk categorisation		
7. Incident to be reported to the relevant forum in a standardised manner, which may include, but need not be limited to, the use of a reporting form.		
8. Procedure to indicate where the reporting form may be obtained. This may include, but need not be limited to, hospital patient safety incident committee or a focal person nominated by the hospital who coordinates patient safety incidents.(Electronic evidence/system is acceptable).		
9. All sections of the reporting form to be completed comprehensively by relevant individuals		
10. A separate form to be used for reporting each incident		
11. Procedure for conducting an investigation of an adverse drug reaction		
12. Procedure for reviewing adverse drug reactions by the forum		
13. Procedure for providing feedback to the affected user		
14. Procedure for sharing lessons learned to prevent future occurrences		
15. Incidents must be reported to South African Health Products Regulatory Authority(SAHPRA) References: •https://www.sahpra.org.za/health-products-vigilance/ •http://www.health.gov.za/index.php/2014-03-17-09-09-38/policies-and-guidelines/category/3272017po?download=2562:national-guideline-for-patient-safety-incident-reporting-and-learning-march2017 •https://apps.who.int/medicinedocs/documents/s18571en/s18571en.pdf •http://apps.who.int/medicinedocs/documents/s22109en/s22109en.pdf		

Sub Domain 6.2.3 21 Adverse events

Standard 6.2.3.1 21(1) The health establishment must have a system to monitor and report all adverse events.

Criterion 6.2.3.1.1 21(2)(a) The health establishment must have a register for all adverse events.

6.2.3.1.1.1 An adverse event reporting register is available in the health establishment.

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

The register must include the following: name of affected person, date of incident, time of incident and nature of incident. This register could be manual or electronic.

Not applicable: Never

Score	Comment

Criterion 6.2.3.1.2 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.

6.2.3.1.2.1 A policy or standard operating procedure or procedure or guideline for management of adverse events and patient safety incidents is available.

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

Verify whether the aspects listed below are included and explained in the document. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Criteria for identification of patient safety incidents		
2. Action taken to mitigate harmful consequences		
3. Criteria for prioritisation of notification of incidents		
4. Recording and analysis of incidents		
5. Methods of investigating incidents		
6. Classification of adverse events		
7. Development of action plans to prevent or avoid recurrences		
8. Implementation of recommendations from investigations and reviews to ensure the development of improved practices Reference: •https://www.idealhealthfacility.org.za/		

6.2.3.1.2.2 A reporting system for adverse events is in place.

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

Examine three adverse reports from the previous 12 months to verify whether the aspects listed below are included. Score 1 if the aspect is compliant and 0 if not.

Score	Comment

Unit 1 Report 1

Aspects	Score	Comment
1. Severity of the incident		
2. Category (type) of the incident		
3. Immediate action taken		
4. Root cause analysis conducted		
5. Action taken to address gaps identified during the investigation process		

Unit 2 Report 2

Aspects	Score	Comment
1. Severity of the incident		
2. Category (type) of the incident		
3. Immediate action taken		
4. Root cause analysis conducted		
5. Action taken to address gaps identified during the investigation process		

Unit 3 Report 3

Aspects	Score	Comment
1. Severity of the incident		
2. Category (type) of the incident		
3. Immediate action taken		
4. Root cause analysis conducted		
5. Action taken to address gaps identified during the investigation process		

Domain 6.3 CLINICAL SUPPORT SERVICES

Sub Domain 6.3.1 10 Medicines and medical supplies

Standard 6.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 6.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

6.3.1.1.1.1 A policy or standard operating procedure or procedure or guideline for management of medical supplies is available.

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

Verify whether the aspects listed below are included and explained in the document. The information may be detailed in a single document or in several separate documents. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment

Aspects	Score	Comment
1. Control of access to stores		
2. Storage of medical supplies		
3. Procurement (ordering) of medical supplies		
4. Calculation of minimum, maximum and reorder stock levels		
5. Receipt of medical supplies into stores		

6. Completion of stock (bin) cards and/or electronic stock monitoring system		
7. Management of stock cards and/or electronic stock monitoring system		
8. Stock taking procedure		
9. Managing return of stock to supplier		
10. Issuing of medical supplies to wards/units		
11. Handling of expired, obsolete, or user-returned medical supplies		

Sub Domain 6.3.2 12 Blood services

Standard 6.3.2.1 12(1) Hospitals and CHCs must ensure that users have access to blood and blood products when required.

Criterion 6.3.2.1.1 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.

6.3.2.1.1.1 All adverse blood reactions are documented and reported monthly.

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

Manual or electronic minutes from the previous quarter must reflect that the forum has been informed of all adverse blood reactions and that it has considered and discussed the reported incidents. If no incidents were reported, zero reporting must be done. Not applicable: Where no adverse blood reactions have occurred

Score	Comment

6.3.2.1.1.2 Root cause analysis was conducted where adverse blood reactions were reported.

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

Documented evidence must be available demonstrating that the cause of adverse blood reactions was investigated. Not applicable: Where no adverse blood reactions were reported

Score	Comment

6.3.2.1.1.3 Action is taken to prevent the recurrence of adverse blood reactions where gaps in management are identified.

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

Documented evidence must be available reflecting action taken where the root cause analysis identified gaps in management of the administration of blood or blood products. Not applicable: Where no adverse blood reactions were reported

Score	Comment

Telephone: 012 942 7700

Email: admin@ohsc.org.za

Website: www.ohsc.org.za

Physical address:
The Office of Health Standards Compliance,
79 Steve Biko Road,
Prinshof,
Pretoria
0084

Postal Address:
Private Bag X21
Arcadia
0007

ISBN:
978-0-620-90157-4