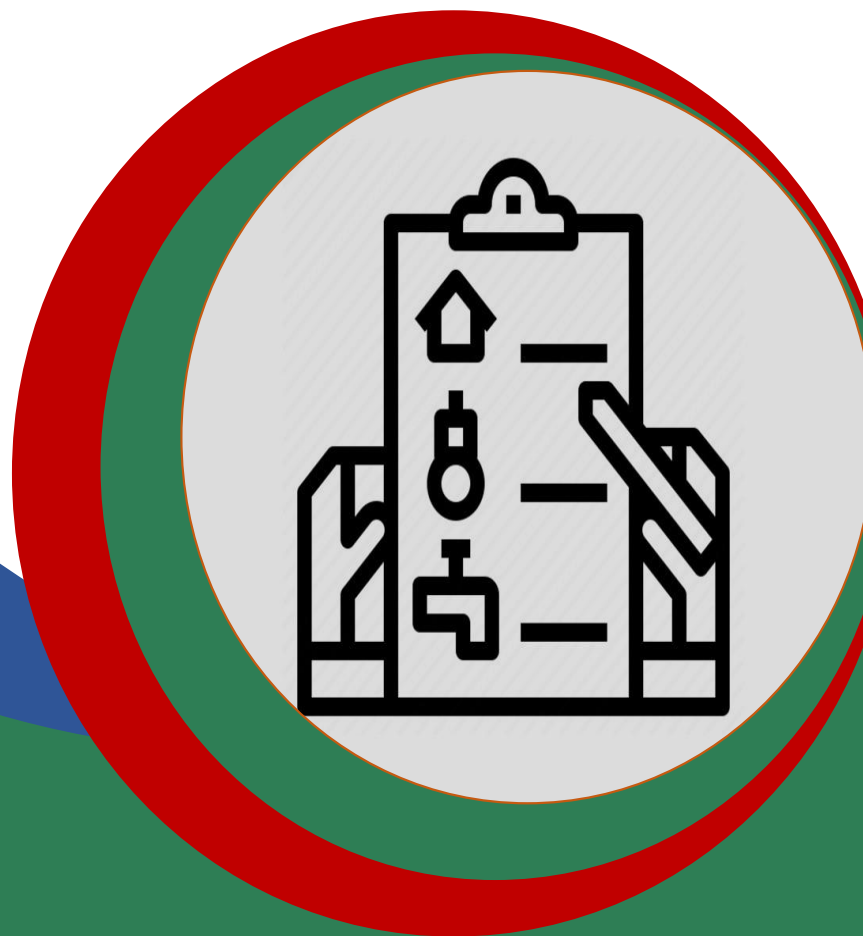




Office of Health Standards Compliance
Ensuring quality and safety in health care

Regulatory Tertiary Hospital Inspection Tool v1.0



CEO Or Hospital Manager



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

1 CEO Or Hospital Manager

Domain 1.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 1.2.1 6 User health records and management

Standard 1.2.1.1 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 1.2.1.1.1 6 The health establishment must ensure that confidential information or user-identifiable data is not divulged without prior consent as per legislation.

1.2.1.1.1.1 A standard operating procedure for obtaining user consent when sharing user-identifiable information with a third party 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. Consent to be obtained from the user prior to disclosure of information requested by third parties.		
2. Data to be anonymised when disclosure is not warranted.		
3. Disclosure to be kept to a minimum, i.e., the health care provider only divulges data as required, not the entire record.		
References: https://www.justice.gov.za/infoereg/docs/InfoRegSAPOPIA-act2013-004.pdf https://www.hpcs.co.za/Uploads/Professional_Practice/Conduct & Ethics/Booklet 5 Confidentiality Protecting and Providing Information September 2016.pdf		

1.2.1.1.1.2 Consent is obtained from a user before user-identifiable information is communicated to the third party.

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

Select three records from the previous twelve months of users who have given consent to release their identifiable information to a third party, including, but not limited to, lawyers, insurance companies and statutory bodies. Score 1 if a signed consent form is available and 0 if not available. Score not applicable where no such requests have been made in the past twelve months.

Score	Comment

Aspects	Score	Comment
1. Record 1		
2. Record 2		
3. Record 3		

Sub Domain 1.2.2 7 Clinical management

Standard 1.2.2.1 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 1.2.2.1.1 7 Authorisation must be confirmed for all research projects involving users at the health establishment.

1.2.2.1.1.1 A letter of permission from the relevant authority for each research project 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 twelve months. In the event that no research projects were conducted the health establishment must document zero reporting

Not applicable: Where no research projects were conducted in the past twelve months,

Score	Comment

Criterion 1.2.2.1.2 7 All local tendering and contracting processes must be in accordance with relevant legislation.

1.2.2.1.2.1 A standard operating procedure on contract management 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. Procedures for contract negotiation		
2. Health care personnel involved in the process.		
3. Management of service level agreements		
4. Contractual obligations		

1.2.2.1.2.2 Compliance with Service level agreements is monitored.

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

Request a list of outsourced services and sample three current outsourced contracts including but not limited to waste, security, cleaning, food services, CSSD or laundry. Request documents from the previous quarter to establish whether the performance of the service provider has been monitored against the service level agreement. Score 1 if compliant and score 0 if non-compliant. Where the health establishment has less than three outsourced services only assess the number of available service level agreement and score not applicable for the other aspects.

Score	Comment	
Aspects	Score	Comment
1. Service level agreement 1		
2. Service level agreement 2		
3. Service level agreement 3		

1.2.2.1.2.3 Non-compliance with the service level agreement is addressed with the service provider for rectification.

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

Documented evidence of action taken must be available. The document must be dated and signed. This will include but is not limited to report or email communication sent to the service provider. **Not applicable:** Where no incidents of non-compliance to service level agreement have occurred.

Score	Comment

Criterion 1.2.2.1.3 7 Infection prevention and control messages must be communicated.

1.2.2.1.3.1 A service level agreement or memorandum of agreement for outsourced laundry services is available

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

This is to ensure effective management of outsourced laundry services. The service level agreement or memorandum of agreement must be valid (not expired). It must be signed by the service provider and the responsible authority.

Not applicable: Where the service is not outsourced.

Score	Comment

Criterion 1.2.2.1.4 7 Standard operating procedures for the management of complaints must be implemented.

1.2.2.1.4.1 A complaints committee is appointed in the health establishment.

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

Verify whether the complaints committee has been appointed as required in section 11 of the National Guideline to Manage Complaints, Compliments and Suggestions - Version 2, 2022. This may be a standalone committee or may form part of other committees or structures that deal with quality improvement. Evidence could include a formal letter of appointment of designation or be included in the job description.

Not applicable: Never

Score	Comment

Sub Domain 1.2.3 9 Waste management

Standard 1.2.3.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 1.2.3.1.1 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

1.2.3.1.1.1 A service level agreement for removal and safe disposal of waste is available.

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

The service level agreement must be valid (not expired), signed by the service provider and the responsible authority and witnessed.
Not applicable: Never

Score	Comment

Domain 1.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 1.4.1 18 Governance

Standard 1.4.1.1 18(1) The health establishment must have a functional governance structure with written Terms of Reference.

Criterion 1.4.1.1.1 18 The health establishment has a functional governance structure.

1.4.1.1.1.1 Terms of reference of the governance structure are available.

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

Verify whether the aspects listed below are included and explained in the terms of the reference. Score 1 if the aspect is included and explained and 0 if not included or not explained.

Score	Comment	
Aspects	Score	Comment
1. The membership of the structure. Explanatory note: Expertise of members in areas such as accounting, financial management, human resource management, information management and legal matters in accordance with section 41(8) of the National Health Act.		
2. Responsibilities and lines of accountability for the structure.		
3. Term of office		
4. Frequency of meetings		
5. Quorum for the structure		

1.4.1.1.1.2 Meetings are held in accordance with the terms of reference

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

Verify whether meetings are held in line with the frequency stipulated in the terms of reference. Request minutes for the past six months. Manual or electronic minutes 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.)

Not applicable: Never

Score	Comment

Criterion 1.4.1.1.2 18 The governance structure must monitor implementation of the strategic plan.

1.4.1.1.2.1 Minutes of meetings of the governance structure indicate that implementation of the Strategic Plan and/ or Annual Performance Plan is monitored.

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 the implementation of the Strategic Plan and/or Annual Performance Plan of health establishment and the monitoring thereof.

Not applicable: Never

Score	Comment

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1.4.1.1.2.2 Remedial action is implemented where Strategic Plan and /or Annual Performance Plan targets have not been met.

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

This can be any evidence of implementation of the action plans which may include but is not limited to recommendations and interventions captured in the minutes or reports.

Not applicable: Where targets have been met.

Score	Comment

Criterion 1.4.1.1.3 18 The governance structure must monitor the quality of care, including user safety.

1.4.1.1.3.1 Minutes of meetings of the governance structure indicate that quality of care is monitored.

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 must reflect discussions on the quality of care including user safety and monitoring thereof.

Not applicable: Never

Score	Comment

1.4.1.1.3.2 Remedial action is implemented where gaps are identified in the quality of care provided.

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

This can be any evidence of implementation of the action plans which may include but is not limited to recommendations and interventions captured in the minutes or reports. Not applicable: Where no gaps or challenges are identified regarding the quality of care.

Score	Comment

Criterion 1.4.1.1.4 18 The governance structure must ensure that organisational risks are identified and mitigated.

1.4.1.1.4.1 Minutes of meetings of the governance structure indicate that organisational risks are managed.

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

Manual or electronic minutes 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 must reflect discussions on organisational risks identification and mitigation strategies.

Not applicable: Never

Score	Comment

1.4.1.1.4.2 Remedial action is implemented where risks are escalating, or mitigation strategies are not effective.

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

This can be any evidence of implementation of the action plans which may include but is not limited to recommendations and interventions captured in the minutes or reports.

Not applicable: Where the identified organisational risks are effectively controlled.

Score	Comment

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Criterion 1.4.1.1.5 18 The governance structure must ensure that the financial sustainability of the health establishment is assured.

1.4.1.1.5.1 The Auditor General report is available.

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

A copy of the audit report for the previous twelve months must be available.

Not applicable: Where the health establishment has not undergone an audit by the Auditor General in the previous twelve months or when awaiting the audit report.

Score	Comment

1.4.1.1.5.2 Auditor General reports are discussed with the governance structure.

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

Manual or electronic minutes 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 must reflect discussions on external audit reports.

Not applicable: Where the health establishment has not undergone an audit by the Auditor General in the previous twelve months or when awaiting the audit report.

Score	Comment

1.4.1.1.5.3 Minutes of meetings of the governance structure indicate that financial reports are monitored.

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 must reflect discussions on financial reports and the monitoring of financial performance.

Not applicable: Never

Score	Comment

1.4.1.1.5.4 Remedial action is taken where gaps are reported.

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

This can be any evidence of implementation of the action plans which may include but is not limited to recommendations and interventions captured in the minutes or reports.

Not applicable: Where no gaps are recorded.

Score	Comment

1.4.1.1.5.5 Minutes of meetings of the governance structure reflect that disclosures of financial interest for managers have been discussed.

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

In terms of the Public Service Regulations, 2016 (PSR, 2016) designated employees are required to disclose their financial interests (Chapter 2, Part 2). The following are categories of designated employees (SMS members, OSD / personal notches (level 13 & above), Level 12 (including OSD/personal notches), Ethics Officers / PSC officials, Level 11 (including OSD / personal notches).

Manual or electronic minutes from the previous twelve 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 must reflect discussions on disclosures of financial interest and the monitoring thereof. Not applicable: Never

Score	Comment

1.4.1.1.5.6 Remedial action is implemented where gaps/challenges are identified.

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

This can be any evidence of implementation of the action plans which may include but is not limited to recommendations and interventions captured in the minutes or reports.

Not applicable: Where no gaps or challenges were identified regarding the financial disclosures.

Score	Comment

1.4.1.1.5.7 A copy of the delegation of authority for the health establishment's manager is available.

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

Verify whether the aspects below are included in the delegation document. Original documents or copies must be available for inspection. Delegations must be signed by the individual delegating the authority and the individual to whom the authority is delegated. Score 1 if the aspect is included and 0 if not included. Score not applicable where no delegations of authority have been made or have been revoked, e.g. where a province is under administration or delegations are centralised at province/district or any other reason. In such cases, documented evidence must be provided.

Score	Comment	
Aspects	Score	Comment
1. Financial management		
2. Supply chain management		
3. Human resources management		

1.4.1.1.5.8 Evidence of compliance with the delegations of authority is available.

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

Request records from the previous twelve months and verify compliance with the delegations of authority in the areas listed below. Score 1 if compliant and 0 if not compliant. Score not applicable for delegation of authority that was not implemented in the previous twelve months or where no delegations of authority have been made or have been revoked, e.g. where a province is under administration, or delegations are centralised at province/district or any other reason.

Score	Comment	
Aspects	Score	Comment
1. Financial management		
2. Supply chain management		
3. Human resources management		

Criterion 1.4.1.1.6 18 The governance structure must ensure effective management and development of human resources.

1.4.1.1.6.1 Minutes of meetings of the governance structure indicate that human resources management and development reports are discussed.

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

Manual or electronic minutes 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 must reflect discussions on human resources management and development reports.

Not applicable: Never

Score	Comment

1.4.1.1.6.2 Remedial action is implemented where gaps are identified.

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

This can be any evidence of implementation of the action plans which may include but is not limited to recommendations and interventions captured in the minutes or reports.

Not applicable: Where no gaps or challenges were identified regarding human resource management and development.

Score	Comment

Official Sign-Off


The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health. To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Tertiary Hospitals.

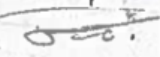
Acknowledgments


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- The Provincial Departments of Health for their input and comments during the consultation phase.

It is hereby certified that the Regulatory Tertiary Hospital Inspection Tools version 1.0 was developed by the Office of Health Standards Compliance.

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