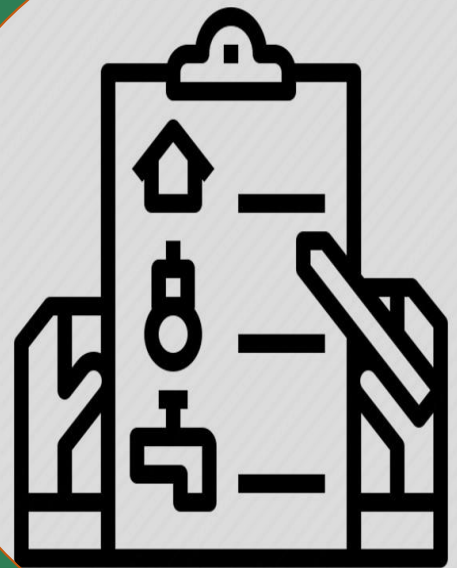




Office of Health Standards Compliance  
Ensuring quality and safety in health care

# Regulatory Tertiary Hospital Inspection Tool v1.0



Laboratory Services

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

## 7 Laboratory Services

### Domain 7.2 CLINICAL GOVERNANCE AND CLINICAL CARE

**Sub Domain 7.2.1 7** Clinical management.

**Standard 7.2.1.1 7(2)** (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

**Criterion 7.2.1.1.1 7 Health care personnel receive ongoing in-service education according to their roles and responsibilities.**

**7.2.1.1.1.1** In-service training is provided on laboratory equipment.

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

Evidence of training which includes amongst others attendance registers, programmes must be available for the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available). Evidence can be manual or electronic.

Not applicable: Where there have been no newly appointed health care personnel or new equipment introduced in the past twelve months.

Score	Comment

**Criterion 7.2.1.1.2 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.**

**7.2.1.1.2.1** A copy of the quality control audit done by the laboratory service provider is available.

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

A signed and dated quality control audit report from the previous twelve months must be available. The report must indicate that test results provided by the laboratory are accurate and reliable.

Not applicable: Never

Score	Comment

**Criterion 7.2.1.1.3 7 Procedures to minimise the risk of health care-associated infections must be implemented.**

**7.2.1.1.3.1** An emergency eyewash station or eyewash kit is available.

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

The emergency eyewash station or eye wash kit must be easily accessible.

Not applicable: Never

Score	Comment

**7.2.1.1.3.2** Sterile sealed eyewash kit is checked.

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

Request documented evidence from the previous month indicating when the eyewash kit was checked for leaks and expiry dates.

Not applicable: Never

Score	Comment

**Sub Domain 7.2.2 8** Infection prevention and control programmes.

**Standard 7.2.2.1 8(1)** The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

**Criterion 7.2.2.1.1 8(2)(a)** The health establishment must ensure that there are hand washing facilities in every service area.

**7.2.2.1.1.1** Hand washing facilities are available.

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

Select an area in the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available) and inspect the handwashing facilities for the items listed below. Score 1 If the item is available and 0 if not available.

Score	Comment

Unit 1 Area 1

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

Unit 2 Area 2

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

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

Unit 3 Area 3

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

7.2.2.1.1.2 Alcohol based hand rub is available.

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

Select an area in the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available) and observe whether alcohol-based hand rub is available. Score 1 if available and 0 if not available.

Score	Comment	
Aspects	Score	Comment
1. Area 1		
2. Area 2		
3. Area 3		

**7.2.2.1.1.3** Posters on hand hygiene are displayed.

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

Select an area in the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available) and observe whether posters on hand hygiene are displayed. This could be a single hand hygiene poster or individual posters for hand washing or correct use of alcohol-based hand rub. Score 1 if available and 0 if not available.

Score	Comment	
Aspects	Score	Comment
1. Area 1		
2. Area 2		
3. Area 3		

**Criterion 7.2.2.1.2 8(2)(d) The health establishment must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.**

**7.2.2.1.2.1** Personal protective equipment is worn.

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

Using the checklist below, verify whether protective clothing and equipment is worn in the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available). Score 1 if the items are worn and 0 if not worn. Score not applicable where at the time of the inspection, personnel are not in a situation in which they are required to wear protective clothing.

Score	Comment

Unit 1 Area 1

Aspects	Score	Comment
1. Non-sterile gloves		
2. Disposable gowns or aprons		
3. Protective face shields or goggles		
4. Face masks or N95 or KN95 or FFP2 respirators or approved equivalent		

Unit 2 Area 2

Aspects	Score	Comment
1. Non-sterile gloves		
2. Disposable gowns or aprons		
3. Protective face shields or goggles		
4. Face masks or N95 or KN95 or FFP2 respirators or approved equivalent		

Unit 3 Area 3

Aspects	Score	Comment
1. Non-sterile gloves		
2. Disposable gowns or aprons		
3. Protective face shields or goggles		
4. Face masks or N95 or KN95 or FFP2 respirators or approved equivalent		

**Sub Domain 7.2.3 9** Waste management.

**Standard 7.2.3.1 9(1)** The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

**Criterion 7.2.3.1.1 9(2)(a)** The health establishment must have appropriate waste containers at the point of waste generation.

**7.2.3.1.1.1** There are appropriate containers for disposal of all types of waste.

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

Verify whether the waste containers listed below are available in the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available). Health care waste containers must have the appropriate international hazard symbol and be marked as prescribed in SANS 10248-1: Management of health care waste, Part 1: Management of health care risk waste from a health facility. Score 1 if the waste container is available and 0 if not available. Where a particular type of waste is not generated in the section/unit, score not applicable.

Score	Comment

Unit 1 Area 1

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

Unit 2 Area 2

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

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

**Criterion 7.2.3.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.**

**7.2.3.1.2.1** There is a temporary healthcare risk waste storage area.

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

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

Score	Comment

Aspects	Score	Comment
1. Space available to store waste containers		
2. Area is well ventilated		
3. Area is well lit		
4. Area has impervious floor surfaces (waterproof or resistant, not cracked)		

### Domain 7.3 CLINICAL SUPPORT SERVICES

**Sub Domain 7.3.1 10** Medicines and medical supplies

**Standard 7.3.1.1 10(1)** The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

**Criterion 7.3.1.1.1 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.**

**7.3.1.1.1.1** Laboratory supplies are available.

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

Request the list of medical supplies/consumables for the unit. Randomly sample fifteen items from the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available) and check whether the sampled items are available and not expired (where applicable). Document the name of the non-compliant items that were sampled. Score 1 if the sampled item is available and not expired (where applicable) or 0 if not available or expired or if there is no list of medical supplies/consumables available.

Score	Comment

Aspects	Score	Comment

1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		
6. Item 6		
7. Item 7		
8. Item 8		
9. Item 9		
10. Item 10		
11. Item 11		
12. Item 12		
13. Item 13		
14. Item 14		
15. Item 15		

**Sub Domain 7.3.3 11** Diagnostic services

**Standard 7.3.3.1 11(1)** Health establishments must ensure that diagnostic services are available and safe for users and for health care personnel involved in delivering these services.

**Criterion 7.3.3.1.1 11** Laboratory services are available, and results provided within agreed timescales.

**7.3.3.1.1.1** Laboratory results are completed within the agreed-upon turnaround times.

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

Request the turn-around times for the unit. Examine the records in the laboratory logging test requests and sample ten turnaround times of tests conducted in the previous three months. Check results from the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available). Verify that the selected results have been completed within the agreed-upon turnaround times. Document the non-compliant tests that were sampled. Score 1 if the results are available within the agreed-upon time frame and 0 if not.

Score	Comment	
Aspects	Score	Comment
<b>Routine tests</b>		
1. Record 1		
2. Record 2		



3. Record 3		
4. Record 4		
5. Record 5		
<b>Emergency tests (Not applicable if there were no emergency test requests)</b>		
6. Record 6		
7. Record 7		
8. Record 8		
9. Record 9		
10. Record 10		

**Sub Domain 7.3.2 13** Medical equipment.

**Standard 7.3.2.1 13(1)** Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

**Criterion 7.3.2.1.1 13(2)(b)** The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

**7.3.2.1.1.1** Functional laboratory equipment is available.

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

Request the list of medical equipment for the unit. Randomly sample twenty equipment from the different sections of the unit (this includes but is not limited to Microbiology, Chemistry, Haematology, Histology/Cytology where the service is available) and check whether the sampled equipment is available and functional. Document the name of the non-compliant equipment that was sampled. Score 1 if equipment is available and functional and 0 if the selected equipment is not available or not functional or if the list is not available.

Score	Comment

Aspects	Score	Comment
1. Equipment 1		
2. Equipment 2		
3. Equipment 3		
4. Equipment 4		
5. Equipment 5		
6. Equipment 6		
7. Equipment 7		
8. Equipment 8		

9. Equipment 9		
10. Equipment 10		
11. Equipment 11		
12. Equipment 12		
13. Equipment 13		
14. Equipment 14		
15. Equipment 15		
16. Equipment 16		
17. Equipment 17		
18. Equipment 18		
19. Equipment 19		
20. Equipment 20		

**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**

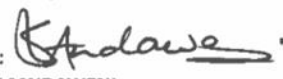
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It is hereby certified that the Regulatory Tertiary Hospital Inspection Tools version 1.0 was developed by the Office of Health Standards Compliance.

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A decorative graphic on the left side of the page, consisting of three curved, overlapping bands. The top band is red, the middle band is blue, and the bottom band is green. The bands curve from the top left towards the bottom right, creating a sense of movement and depth.