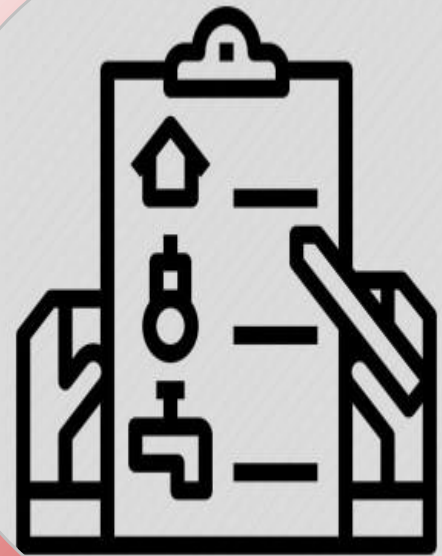


Regulatory Regional Hospital Inspection Tool v1.3



Laboratory Services



Facility:
Date:

- **Tool Name:** Regulatory Regional Hospital Inspection tool v1.3 - Final
- **HEs Type:** Hospitals **Sector:** Public
- **Specialization:** Regional
- **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(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 7.2.1.1.1 7 Healthcare providers are informed on the health establishment and their specific responsibilities.

7.2.1.1.1.1 Health care personnel have been informed about the Standard Operating Procedures of the unit and health establishment.

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

Documented evidence that personnel have been informed about the Standard Operating Procedures of the unit and health establishment must be available. This could include but is not limited to distribution lists which include personnel signatures to indicate they have read and understood the document (which must be dated and signed), proof of attendance at meetings where policies, guidelines and standard operating procedures are discussed, or similar evidence for electronic distribution. Score 1 if such evidence is available and score 0 if it is not available.

Score	Comment	
Aspects	Score	Comment
1. Cleaning of hazardous and biohazardous spills		
2. Management of needlestick and sharps injuries		
3. Use of Personal Protective Equipment (PPE).		

Standard 7.2.1.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 7.2.1.2.1 7 The health establishment implements process to ensure environmental cleanliness.

7.2.1.2.1.1 All work completed is verified by the cleaning supervisor or a delegated health care personnel.

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

Daily inspections will ensure the cleanliness of the building. The person responsible for overseeing the cleaning service must inspect the building daily to confirm that cleaning has been carried out according to the schedule and that all areas attended to have been cleaned thoroughly. Monitoring tools (i.e. tick sheets) listing all cleaning tasks must be completed for each room or area. Not applicable: Never

Score	Comment

7.2.1.2.1.2 The unit is observed to be clean.

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

Inspector to observe general cleanliness of the unit including but not limited to whether the unit is free of dirt and stains. Not applicable: Never

Score	Comment

Criterion 7.2.1.2.2 7 Procedures to minimise the risk of health care-associated infections must be implemented.

7.2.1.2.2.1 An emergency eyewash station or eyewash kit is available.

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

The emergency eyewash station or bottle must be available, functional and easily accessible. An eyewash kit which is moveable is acceptable. Not applicable: Never

Score	Comment

7.2.1.2.2.2 Sterile sealed eyewash bottles are checked for leaks and expiry dates monthly.

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

There must be a documented record for the previous three months of the dates when the eyewash bottles were checked. Not applicable: Never

Score	Comment

Criterion 7.2.1.2.3 7 Communication systems must be available and functional to facilitate adequate user care, and safety of user and health care personnel.

7.2.1.2.3.1 Functional, accessible telephones are available in the laboratory unit.

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

Maintaining and sustaining communication is essential for user safety. This may include, but need not be limited to, communication of urgent test results. Telephones must be functional and available. Not applicable: Never

Score	Comment

Criterion 7.2.1.2.4 7 Health care personnel receive ongoing in-service education according to their roles and responsibilities.

7.2.1.2.4.1 The orientation programme includes training of laboratory personnel in the use of laboratory equipment.

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

The orientation records for the previous 12 months must include training in the use of laboratory equipment. Not applicable: Where no new health care personnel were employed in the past 12 months

Score	Comment

7.2.1.2.4.2 The personnel development and in-service training programme makes provision for training on the correct use of laboratory equipment.

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

The personnel development and in-service training programme for the previous 24 months must include laboratory equipment training. Updates will be necessary if new equipment is purchased or if utilisation, maintenance or cleaning requirements change for equipment already in use. Training might be conducted in selected training laboratories; however, evidence of training must be available in the unit (attendance registers, programmes), this can be manual or electronic. Not applicable: Never

Score	Comment

Criterion 7.2.1.2.5 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.

7.2.1.2.5.1 A copy of the quality control audit done by the laboratory service provider within the past 12 months is available.

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

A signed and dated quality control audit report from the previous 12 months must be available. The report must indicate that test results provided by the laboratory are accurate and reliable. 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

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

Score	Comment

Aspects	Score	Comment

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

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 Health care personnel have access to and use appropriate protective clothing and equipment.

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

Verify whether protective clothing and equipment are available and worn in the areas listed below. Score 1 if the items are available and worn and 0 if they are not available or not worn. Score NA where, at the time of the inspection, health care personnel are not working in a situation where they are required to wear protective clothing. Score NA for service not offered by the health establishment.

Score	Comment

Unit 1 Storage room/area: Available

Aspects	Score	Comment
1. Gloves		
2. Aprons		

3. Masks		
4. Goggles or Visor		
5. FFP2 or KN95 or N95 respirator		

Unit 2 Microbiology section: Worn

Aspects	Score	Comment
1. Gloves		
2. Aprons		
3. Masks		
4. Goggles or Visor		
5. FFP2 or KN95 or N95 respirator		

Unit 3 Chemistry section: Worn

Aspects	Score	Comment
1. Gloves		
2. Aprons		
3. Masks		
4. Goggles or Visor		
5. FFP2 or KN95 or N95 respirator		

Unit 4 Haematology section: Worn

Aspects	Score	Comment
1. Gloves		
2. Aprons		
3. Masks		
4. Goggles or Visor		
5. FFP2 or KN95 or N95 respirator		

Unit 5 Cleaning personnel: Worn

Aspects	Score	Comment
1. Gloves-nonsterile		
2. Domestic gloves		
3. Aprons		

4. Masks		
5. Goggles or Visor		
6. FFP2 or KN95 or N95 respirator		

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. Health care waste containers must have the appropriate international hazard symbol and be marked as prescribed in SANS 10248-1: Management of healthcare waste, Part 1: Management of healthcare risk waste from a health facility. Score 1 if the waste container is available and 0 if not available. Where a particular type of waste is not generated in the unit, score NA

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

Inspect the laboratory store to verify whether each of the listed items is present. Score 1 if the item is present and 0 if not present. Score not applicable for items not used by the laboratory.

Score	Comment	
Aspects	Score	Comment
Laboratory consumables:		
1. Lancets		
2. Blood glucose strips		
3. Urine dipsticks		
4. Urine specimen jar or flask		
5. Malaria rapid test (where applicable in facilities in KwaZulu-Natal, Gauteng, Mpumalanga and Limpopo Province)		
6. Rapid HIV test		
7. Covid-19 test kits		

8. Rh 'D' (Rhesus factor) test		
Required specimen collection materials and stationery:		
9. Vacutainer tube: blue top (sodium citrate)		
10. Vacutainer tube: red or yellow top (serum separator)		
11. Vacutainer tube: grey top (sodium fluoride)		
12. Vacutainer tube: white top (plasma preparation)		
13. Vacutainer tube: purple top (ethylenediaminetetraacetic acid)		
14. Microtainer tube: yellow top (serum separator – paediatric)		
15. Sterile specimen jars		
16. Dry swabs		
17. Swabs with transport medium		
18. Sterile tubes (without additive) for microscopy, culture and sensitivity (MCS)		
19. Venipuncture needles (green or black)		
20. Specimen plastic bag		
Pap smear collection materials:		
21. Liquid-based cytology (LBC) vials (NA if health establishment uses traditional pap smear method)		
22. Combi-brush (NA if health establishment uses traditional pap smear method)		
23. Cervix brush (NA if health establishment uses traditional pap smear method)		
24. Fixative (NA if health establishment uses liquid-based cytology method)		

25. Wooden spatula (NA if health establishment uses liquid-based cytology method)		
26. Slide holder or brown envelope (NA if health establishment uses liquid-based cytology method)		
27. Microscope slides (NA if health establishment uses liquid-based cytology method)		
Early infant diagnosis (EID) collection material:		
28. Dried blood spot (DBS) polymerase chain reaction (PCR) kit or equivalent		
29. National Health Laboratory Services (NHLS) stationery		
30. Request forms		
31. Cytology request form		

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(2) The health establishment must where applicable be accredited by the relevant regulatory body relating to the type of diagnostic service.

7.3.3.1.1.1 The accreditation certificate issued by the relevant regulatory body is available.

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

A valid certificate of accreditation by the South African National Accreditation System (SANAS) must be available. Not applicable: Never

Score	Comment

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

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

Examine the records in the laboratory logging test requests. Verify that the most recently completed results per category have been completed in the laboratory within the agreed-upon turnaround times (as stipulated in the service level agreement) and sent to the requesting ward or unit. Score 1 if the results are available within the agreed-upon time frame and 0 if not. NB: Score Not applicable for tests not conducted in the laboratory.

Score	Comment

Aspects	Score	Comment
1. CD4 count		

2. FBC		
3. U & E		
4. ESR		
5. Malaria		
6. Prothrombin time (PT)		
7. TB sputum GeneXpert		
8. PCR		
9. LFT		
10. RPR		
11. HIV ELISA		
12. Bilharzia Microscopy		
13. Covid PCR		
14. Blood Culture MCS		
15. CSF MCS		
16. Catheter urine MCS		
17. Surgical Wound MCS		

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 with appropriate consumables and reagents is available

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

Verify whether the equipment and consumables listed below are available and functional. Ask laboratory personnel to demonstrate that listed equipment is functional (where applicable). Score 1 if the item is available and functional and 0 if not available or not functional. Score not applicable for items not used by the laboratory.

Score	Comment	
Aspects	Score	Comment
General		
1. Centrifuge different sizes		
2. Cuvette		

3. Electronic balance		
4. Extraction hood (for safety when working with aerosol)		
5. Laboratory cabinet		
6. Laboratory refrigerator (with built-in thermometer or external thermometer)		
7. Paraffin dispenser		
8. Pipette (could be automated or graduated or glass)		
9. Shaker		
10. Sterilising unit		
11. Timer-stopwatch		
12. Water bath serological medium 5–10ℓ		
Microbiology section		
13. Agar Plates		
14. Bunsen Burners		
15. Drugs for sensitivity testing		
16. Incubator(laboratory)		
17. Laboratory scale		
18. Microscopes		
19. Pipettes		
20. Stains- reagents		
21. Urine analyser		
Chemistry section		
22. Clinical chemistry analyser		
23. Laboratory scale		
24. Slide stainers		
25. Urine analyser		
Haematology section		
26. Counting chamber, Fuchs-Rosenthal ruling		

27. Microscopes		
28. Sedimentation rate units or ESR analyser.		
29. Slide stainers		
30. Stains- reagents		
Histology/Cytology section		
31. Stains- reagents		
32. Tissue processors		

Domain 7.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 7.4.1 20 Occupational health and safety

Standard 7.4.1.1 20(1) The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

Criterion 7.4.1.1.1 20(2)(b) Awareness of safety and security issues must be promoted

7.4.1.1.1.1 The emergency evacuation plan is prominently displayed

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

The evacuation plan must include but is not limited to route/directions to be followed during evacuation, emergency exits and assembly point(s). This must be visibly displayed. Not applicable:

Never

Score	Comment

7.4.1.1.1.2 The healthcare personnel are familiar with the emergency evacuation procedure

Assessment type: Staff interview - **Risk rating:** Essential measure

Interview three health care personnel to establish whether they are able to explain the evacuation procedure as illustrated in the evacuation plan. Score 1 if they explain the procedure as illustrated in the evacuation plan and 0 if not. Where no evacuation plan is available, this measure must be scored 0.

Score	Comment	
Aspects	Score	Comment
1. Healthcare personnel 1		
2. Healthcare personnel 2		
3. Healthcare personnel 3		

Domain 7.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 7.5.1 14 Management of buildings and grounds

Standard 7.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 7.5.1.1.1 14(2)(b) The health establishment must as appropriate for the type of buildings and grounds of the establishment have a maintenance plan for buildings and the grounds.

7.5.1.1.1.1 No obvious safety hazards are observed during the visit

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

Inspect the surroundings for maintenance-related safety hazards in the unit. This will include but is not limited to loose electrical wiring, collapsing ceiling, roof or doors and any other type of safety hazards that represent a risk to the health and safety of personnel, users and visitors. Not applicable: Never

Score	Comment

Criterion 7.5.1.1.2 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

7.5.1.1.2.1 Laboratory services has natural ventilation or functional mechanical ventilation.

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

National building regulations stipulate that satisfactory ventilation is only provided by forcing outdoor air into a space mechanically or passively, through either ducting or apertures open to the outside, including, but not limited to, windows or ventilation grilles. Verify that the laboratory services unit has natural ventilation (windows and doors that can be opened) or functional mechanical ventilation (i.e. a ducting system). Not applicable: Never

Score	Comment

Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.

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

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- The Certification and Enforcement Committee of the OHSC Board for reviewing the tools and for recommending to the Board for approval.

It is hereby certified that the Regulatory Regional Hospital Inspection tools version 1.3 was developed by the Office of Health Standards Compliance.

Ms W Moleko

Signature:



**Executive Manager: Health Standards
Development Analysis and Support**

Date:

10/08/2022

Dr Sipiwe Mndaweni

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