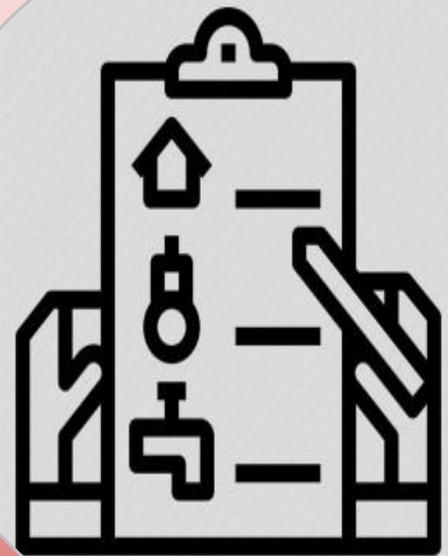


Regulatory Regional Hospital Inspection Tool v1.3



Pharmacy



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

9 Pharmacy

Domain 9.1 USER RIGHTS

Sub Domain 9.1.1 4 User information

Standard 9.1.1.1 4(1) The health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.

Criterion 9.1.1.1.1 4(2)(a)(ii) The health establishment must provide users with information relating to service opening and closing times.

9.1.1.1.1.1 Legible signage at the entrance to the pharmacy indicates the days and times when services are offered.

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

The service opening and closing times must be displayed at the entrance of the pharmacy. The information must be legible. Not applicable: Never

Score	Comment

Criterion 9.1.1.1.2 4(2)(a)(iv) The health establishment must provide users with information relating to the complaints, compliments and suggestions management system.

9.1.1.1.2.1 A complaints toolkit is available at pharmacy.

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

Verify whether the complaint forms, box and poster are available at the pharmacy. Score 1 if compliant and score 0 if not compliant. NB: In small health establishment, the toolkit can be in close proximity to the pharmacy.

Score	Comment

Aspects	Score	Comment
1. Lockable complaints box is visibly placed next to the unit.		
2. Complaints box is fixed to wall or a flat surface.		
3. Official complaint forms in at least two commonly spoken official languages are available next to box or there is an indication on the poster where to obtain the forms.		

4. Standardised poster describing process to follow to lodge a complaint is visibly displayed.		
5. Poster on complaints is available in at least two of the official languages commonly spoken in the area.		

Sub Domain 9.1.2 5 Access to care

Standard 9.1.2.1 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 9.1.2.1.1 5(2)(a) The health establishment must implement a system of triage.

9.1.2.1.1.1 A process to fast-track users with special needs is implemented.

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

Special needs refer to users who are severely immunocompromised, very sick, frail, elderly or postoperative. It must be evident from observing the activities in the waiting area that there is a process of assessing and determining the order in which users should be assisted, based on their need for care. The criteria used for this process must be explicitly stated to users, either in a written or verbal manner or a designated window for dispensing. Evidence of adherence to these criteria must be observed by pharmacy personnel. Not applicable: Where, at the time of the inspection, no very sick, frail or elderly or post-operative care users were attending the pharmacy.

Score	Comment

Sub Domain 9.1.3 22 Waiting times

Standard 9.1.3.1 22 The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

Criterion 9.1.3.1.1 22 Waiting times are monitored and improvement plans are implemented.

9.1.3.1.1.1 The locally agreed target waiting time for the pharmacy is displayed.

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

The aim of this requirement is to give users an indication of how long they should expect to wait in the pharmacy, and to assist pharmacy personnel to work within the scope of the waiting time target. The waiting time must be displayed in an area that is easily visible to waiting users. Not applicable: Never

Score	Comment

9.1.3.1.1.2 Compliance with waiting time target(s) in the unit is monitored.

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

Request the previous six months' tools used for monitoring waiting times at the pharmacy. Not applicable: Never

Score	Comment

Domain 9.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 9.2.1 6 User health records and management

Standard 9.2.1.1 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 9.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

9.2.1.1.1.1 A “No unauthorised entry” sign is displayed on the door of the pharmacy.

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

Verify whether the pharmacy door displays a sign reading “No unauthorised entry.” Any other sign, e.g. “Staff only,” will be scored non-compliant. Not applicable: Never

Score	Comment

9.2.1.1.1.2 Access to the pharmacy is controlled at all times.

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

The pharmacy should have a lockable security gate or access-controlled door to which only pharmacy personnel have access. Pharmacy personnel holding the keys/access cards/access codes must keep them on their person and not leave them lying around. Not applicable: Never

Score	Comment

9.2.1.1.1.3 Confidentiality of health records is maintained.

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

Observe how user health records are managed in the unit and determine whether unauthorised individuals would be able to access the information in the health records. This includes but not limited to health records being used during dispensing, for clinical audits or other administrative purposes. Such records should be kept in a manner that safeguards against unauthorised access to the content of the health record. Not applicable: Never

Score	Comment

Sub Domain 9.2.2 7 Clinical management

Standard 9.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 9.2.2.1.1 7 Healthcare providers are informed on the health establishment and their specific responsibilities.

9.2.2.1.1.1 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. Confidentiality of user health records		
2. Accessing medicines after hours		
3. Reporting of adverse drug reactions		
4. Storage of schedule 5 and 6 medicines		

Standard 9.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 9.2.2.2.1 7 The health establishment implements process to ensure environmental cleanliness.

9.2.2.2.1.1 All work completed is verified by the cleaning supervisor or delegated pharmacy personnel.

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

Daily inspections will ensure the cleanliness of the pharmacy. The person responsible for overseeing the cleaning service must inspect the pharmacy daily to confirm that cleaning has been carried out according to the schedule and that all areas attended to have been effectively cleaned. Monitoring tools (including, but not limited to, checklist/tick sheets) listing all cleaning tasks must be completed for each room or area. Not applicable: Never

Score	Comment

9.2.2.2.1.2 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, dust and stains. Not applicable: Never

Score	Comment

Criterion 9.2.2.2.2 7 The health establishment must have a functional quality management system

9.2.2.2.2.1 Quality improvement plans are developed by health care personnel.

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

Request the quality improvement plan of the unit from the previous six months. Verify whether the aspects listed below are documented. Score if aspect is documented and 0 if not. NB: 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		

9.2.2.2.2 Corrective action has been taken to improve the quality of service provided where gaps are identified.

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

Evidence must be available that the action specified in the quality improvement plan was implemented. Not applicable: Where there were no gaps identified.

Score	Comment

Criterion 9.2.2.2.3 7 Communication systems must be available and functional to facilitate adequate user care, and safety of user and health care personnel.

9.2.2.2.3.1 Functional telephones are available and accessible in the pharmacy.

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

Maintaining and sustaining communication are essential for user safety. Telephones must be functional and available in the pharmacy. Not applicable: Never

Score	Comment

Criterion 9.2.2.2.4 7 Users must be counselled appropriately to ensure adherence to therapy.

9.2.2.2.4.1 Users receiving medicine have a clear understanding of how and when to take their medicine and any other relevant information.

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

Interview three users who have received medicines and ask them the questions below. Score 1 if the answer is 'yes' and 0 if the answer is 'no'.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you the purpose of each medicine?		

2. Did the pharmacist or post-basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you when to take your medicine/s?		
3. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain if you should take the medicine/s with or without food?		
4. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you the most common side-effects you may experience from the medicine/s?		
5. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist give you the opportunity to ask any questions or discuss anything that worries you about your medicine/s?		

Unit 2 User 2

Aspects	Score	Comment
1. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you the purpose of each medicine?		
2. Did the pharmacist or post-basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you when to take your medicine/s?		
3. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain if you should take the medicine/s with or without food?		
4. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you the most common side-effects you may experience from the medicine/s?		
5. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist give you the opportunity to ask any questions or discuss anything that worries you about your medicine/s?		

Unit 3 User 3

Aspects	Score	Comment
1. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you the purpose of each medicine?		

2. Did the pharmacist or post-basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you when to take your medicine/s?		
3. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain if you should take the medicine/s with or without food?		
4. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist explain to you the most common side-effects you may experience from the medicine/s?		
5. Did the pharmacist or post basic pharmacist assistant or learner post basic pharmacist assistant or intern pharmacist give you the opportunity to ask any questions or discuss anything that worries you about your medicine/s?		

Criterion 9.2.2.2.5 7 The pharmacy must be licensed by the Director-General of the National Department of Health.

9.2.2.2.5.1 The licence for the pharmacy issued by the Director-General of the National Department of Health is available.

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

This will promote user safety by ensuring that the pharmacy meets all legal requirements. The licence issued by the Director-General of the National Department of Health must be displayed. Not applicable: Never

Score	Comment

Criterion 9.2.2.2.6 7 The pharmacy must be registered with the South African Pharmacy Council.

9.2.2.2.6.1 The current certificate of recording of a pharmacy with the South African Pharmacy Council or proof of the annual fee payment is available.

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

The current certificate of registration of the health establishment's pharmacy with the South African Pharmacy Council or proof that the annual fee payment is up to date must be visibly displayed in the pharmacy. Not applicable: To pre-May 2003 pharmacies. *Pre-May 2003 Pharmacies refers to all Pharmacies that were registered with SAPC on or before this date and they are deemed to be licensed* Reference: South African Pharmacy Council: Pharmacy Inspections and Guide to Compliance

Score	Comment

Criterion 9.2.2.2.7 7 The designated pharmacist must be registered with the South African Pharmacy Council.

9.2.2.2.7.1 Proof of registration with the South African Pharmacy Council of all pharmacists(s)and pharmacist assistant(s) is available.

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

Definition according to the Pharmacy Act: Pharmacist's assistant means a natural person registered in one of the following categories:(a) pharmacist's assistant (learner basic);(b) pharmacist's assistant (basic);(c) pharmacist's assistant (learner post-basic);(d) pharmacist's assistant (post -basic);(e) pharmacy technician (learner) (f) pharmacy technician (student);(f) pharmacy technician (trainee);(q) pharmacy technician; or(h) pharmacy student; which constitute the various categories of pharmacy

support personnel registered as such in terms of the Act' The current certificate of registration with the South African Pharmacy Council of all pharmacist(s), pharmacist assistant(s) must be visibly displayed in the pharmacy or available in a file. Electronic evidence will be accepted. Not applicable:

Never

Score	Comment

Criterion 9.2.2.2.8 7 Practices for dispensing medicines must comply with the Pharmacy Act 53 of 1974, the Medicines and Related Substances Act 101 of 1965 and relevant regulations.

9.2.2.2.8.1 Medicines dispensed for users are labelled in accordance with applicable legislation.

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

Request permission from three users to assess the medicine that has been dispensed to them on the day of the inspection. Verify whether the medicine dispensed complies with the requirements below. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. Labels of dispensed medicines are clear and legible.		
2. Label affixed to medicine does not obstruct or cover the expiry date.		
3. Label affixed to medicine includes user's name.		
4. Label affixed to medicine includes the name of the medicine.		
5. Label affixed to medicine includes dosage and directions for use.		
6. Label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
7. Label affixed to medicine includes date of dispensing.		
8. Reference number or prescription number (where applicable)		

9. Cautionary or advisory labels and instructions (where appropriate)		
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Unit 2 User 2

Aspects	Score	Comment
1. Labels of dispensed medicines are clear and legible.		
2. Label affixed to medicine does not obstruct or cover the expiry date.		
3. Label affixed to medicine includes user's name.		
4. Label affixed to medicine includes the name of the medicine.		
5. Label affixed to medicine includes dosage and directions for use.		
6. Label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
7. Label affixed to medicine includes date of dispensing.		
8. Reference number or prescription number (where applicable)		
9. Cautionary or advisory labels and instructions (where appropriate)		

Unit 3 User 3

Aspects	Score	Comment
1. Labels of dispensed medicines are clear and legible.		
2. Label affixed to medicine does not obstruct or cover the expiry date.		
3. Label affixed to medicine includes user's name.		
4. Label affixed to medicine includes the name of the medicine.		
5. Label affixed to medicine includes dosage and directions for use.		

6. Label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
7. Label affixed to medicine includes date of dispensing.		
8. Reference number or prescription number (where applicable)		
9. Cautionary or advisory labels and instructions (where appropriate)		

Criterion 9.2.2.2.9 7 Users must obtain their medicines from the pharmacy on the day of their visit.

9.2.2.2.9.1 Scripts in the pharmacy are correlated with the medicines dispensed to confirm that medicines were received as prescribed.

Assessment type: Patient record audit - **Risk rating:** Vital measure

Select three user scripts in the pharmacy and ask the dispensing healthcare provider to show what medicines were dispensed against this script. If all medicines as prescribed were dispensed, score 1. If the user has not received all the medicines as prescribed, score 0. Note: Where prescribed medicines were declined by the user it should be documented in the health record.

Score	Comment	
Aspects	Score	Comment
1. User health record 1		
2. User health record 2		
3. User health record 3		

Criterion 9.2.2.2.10 7 Medicines must be stored and managed in compliance with the Pharmacy Act 53 of 1974, the Medicines and Related Substances Act 101 of 1965 and the relevant rules and regulations.

9.2.2.2.10.1 The pharmacy has functional room thermometer(s).

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

A functional thermometer(s) must be available. Not applicable: Never

Score	Comment

9.2.2.2.10.2 The temperature of the pharmacy is maintained within the safety range.

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

Use the checklist below to verify whether the temperature in the pharmacy is maintained between 15 and 25 degrees Celsius.

Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

Aspects	Score	Comment
1. The temperature of the pharmacy is recorded daily. Explanatory note: This serves to assess whether the health establishment consistently monitors the room temperature. Request temperature monitoring sheets from the previous three months.		
2. The temperature of the pharmacy is maintained between 15 and 25 degrees Celsius.		

9.2.2.2.10.3 Covid 19 vaccines are stored as per manufacturer's instructions.

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

Review the vaccine manufacturer's instructions for the storage of the Covid 19 vaccine and assess whether the vaccines are stored as required. Not applicable: Where Covid 19 vaccines are not kept/stored in the health establishment.

Score	Comment

9.2.2.2.10.4 Procedures to maintain the cold chain for all thermolabile medicines including vaccines are implemented.

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

Use the checklist below to verify whether the cold chain for vaccines is maintained. Score 1 if compliant with the aspect below and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Pharmacy has a vaccine or medicine refrigerator with a thermometer. Explanatory note: The vaccine or medicine refrigerator may be located in any space in the pharmacy. A domestic refrigerator will be scored non-compliant.		
2. Temperature of refrigerator is recorded twice daily, seven hours apart (check three months' records)		
3. Temperature of refrigerator is maintained between 2 and 8 degrees Celsius (check three months' records)		

4. The pharmacy has a cooler box and ice packs for transporting or temporary storage of thermolabile medicines including vaccines.		
5. There is a functional thermometer in the cooler box.		

Criterion 9.2.2.2.11 7 A functional pharmaceutical and therapeutics committee must be appointed in the health establishment to ensure the rational use of medicines.

9.2.2.2.11.1 The terms of reference for the Pharmaceutical and Therapeutics committee, or relevant structure, include the details listed below.

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

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

Score	Comment	
Aspects	Score	Comment
1. Purpose of committee		
2. Multidisciplinary membership required (Composition)		
3. Roles and responsibilities of forum members (Functions)		

9.2.2.2.11.2 The minutes of the Pharmaceutical and Therapeutics committee or relevant structure demonstrate that actions have been taken to ensure rational use of medicine.

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

Minutes of meetings that document discussions relating to the rational use of medicines must be available. The minutes must demonstrate evaluation of the optimal use of medicines, including, but not limited to, protecting users against antibiotic resistance, adherence to evidence-based guidelines and cost-effectiveness of care. The WHO's definition of rational use of medicines is: "Patients receive medicine appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." Not applicable: Never 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/>

Score	Comment

Criterion 9.2.2.2.12 7 A system to manage adverse drug reactions must be implemented.

9.2.2.2.12.1 An adverse drug reaction reporting register is available in the department.

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

The register must include the following: name of affected person, date of incident, time of incident, nature of incident. Not applicable: Never

Score	Comment

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9.2.2.2.12.2 Adverse drug reactions are reported to the national pharmacovigilance centre or agency.

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

Adverse drug reactions must be reported using the correct procedure. Request records from the previous six months, and evidence of reporting (may be manual or electronic). Not applicable: Where no adverse drug reactions were reported.

Score	Comment

9.2.2.2.12.3 Minutes of the forum monitoring adverse drug reactions demonstrate that adverse drug reaction reports are reviewed.

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

These adverse drug reactions could be discussed at Pharmaceutical and Therapeutics committee. Manual or electronic minutes from the previous quarter must be signed and dated and include an attendance register. The content must reflect discussions on the review of reports on adverse drugs reactions. If no incidents were reported, zero reporting must be done. Not applicable: Where no adverse drug reactions were reported.

Score	Comment

9.2.2.2.12.4 The minutes of the forum responsible for the monitoring of adverse drug reactions demonstrate that appropriate action is taken to reduce the likelihood of adverse drug reactions occurring.

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

Manual or electronic minutes from the previous quarter must be signed and dated and include an attendance register. The content must reflect evidence of actions taken to reduce adverse drug reactions. Not applicable: Never

Score	Comment

Criterion 9.2.2.2.13 7 Designated suppliers and delivery systems for medicines must adhere to their contractual obligations for the supply and delivery of medicines.

9.2.2.2.13.1 A document outlining the ordering and delivery schedule for medicine is available.

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

A document detailing when to place orders and when to expect delivery of orders must be available.

Not applicable: Never

Score	Comment

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Criterion 9.2.2.2.14 7 An updated computerised or manual (stock cards) inventory management system for medical supplies must be in place.

9.2.2.2.14.1 The electronic network system for monitoring the availability of medicines is used effectively.

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

Verify whether the electronic network system for monitoring the availability of medicines is used effectively in terms of the list below. Electronic systems may include, but need not be limited to, the Stock Visibility System, RX Solutions and JAC system. To determine whether the health establishment has reported the availability of medicines as required, visit the website used to view captured medicine availability data. Score 1 if the aspect is compliant and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Health establishment has a functional electronic network system for monitoring availability of medicines.		
2. Approved list of medicines to be updated is visible in electronic network system.		
3. Capturing device (this could be a computer, tablet or cellphone) is in good working order.		
4. Accessories are in good working order.		
5. Capturing device is stored in a lockable unit (only applicable to SVS)		
6. Accessories for device, i.e. batteries and charger, are stored in a lockable unit (only applicable to SVS)		
7. Access to keys for unit where capturing device and its accessories are stored is restricted (only applicable to SVS)		
8. In the past seven working days or more this health establishment has not been marked as non-reporting at the point of assessment (SVS cell phone will show last reporting date; only applicable to SVS) Explanatory note: The sources for the information are the website used to view the availability of captured medicine data and the associated primary health care health establishment dashboard.		

Sub Domain 9.2.3 8 Infection prevention and control programmes

Standard 9.2.3.1 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 9.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.
9.2.3.1.1.1 Hand washing facilities are available.

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

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

Criterion 9.2.3.1.2 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.

9.2.3.1.2.1 Personal protective equipment is available and worn.

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

Verify whether the protective clothing and equipment listed below is available and worn. Score 1 if the item is available and worn and score 0 if not available or not worn. Score NA where, at the time of the inspection, pharmacy personnel are not in a situation requiring them to wear protective clothing.

Score	Comment

Unit 1 Storage area/room: Available

Aspects	Score	Comment
1. Gloves non-sterile		
2. Face masks		
3. Protective eyewear (goggles) or face shields		
4. Domestic rubber gloves (for cleaners only)		

Unit 2 Pharmacy health care providers: Worn

Aspects	Score	Comment
1. Gloves non-sterile		
2. Face masks		
3. Protective eyewear (goggles) or face shields		

Unit 3 Cleaning personnel: Worn

Aspects	Score	Comment
1. Domestic rubber gloves		
2. Gloves non-sterile		
3. Face masks		
4. Protective eyewear (goggles) or face shields		

Sub Domain 9.2.4 9 Waste management

Standard 9.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 9.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

9.2.4.1.1.1 The pharmacy has 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 risk 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 healthcare risk waste from a health facility. Where a particular type of waste is not generated in the pharmacy, score NA.

Score	Comment

Aspects	Score	Comment
1. Pharmaceutical waste (dark green)		
2. Chemical waste, including cytotoxic or genotoxic.		
3. General waste		

Criterion 9.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

9.2.4.1.2.1 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)		

9.2.4.1.2.2 Expired or obsolete medicine is discarded according to prescribed procedures.

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

Verify whether the health establishment complies with the procedure for discarding expired or obsolete medicine. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

Aspects	Score	Comment

1. Expired or obsolete medicine is placed in a dark green container marked with the words "Pharmaceutical waste liquid or solid" or similar according to the contract in place.		
2. The required documentation is attached to the container or available on request. Explanatory note: This includes, but is not limited to, name of health establishment, date, expired or obsolete medicine, strength, dosage form, quantity, expiry date for expired items and signature of responsible person.		

Domain 9.3 CLINICAL SUPPORT SERVICES

Sub Domain 9.3.1 10 Medicines and medical supplies

Standard 9.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 9.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

9.3.1.1.1.1 The stock control system for medicines shows minimum and maximum levels and/or reorder levels for medicine.

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

Each item held as stock(medicine) must have documented minimum, maximum and/or reorder levels. These levels must be recorded on bin cards or equivalent. The system may be manual or electronic.

Not applicable: Never

Score	Comment

9.3.1.1.1.2 Stock levels for medicine on the shelves correspond with recorded stock levels in the stock control system.

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

Select five items(medicines) held as stock and verify the number of items available against the balance indicated on the bin cards or equivalent. The system may be manual or electronic.

Score	Comment	
Aspects	Score	Comment
1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		

9.3.1.1.1.3 A stock take of medicine was done in the past 12 months.

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

Documented evidence of a formal stock take will be required, i.e. a report indicating that stock take has been completed in the previous 12 months. Report should include but not limited to expired medicine (if any) and its monetary value. Not applicable: Never

Score	Comment

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Criterion 9.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

9.3.1.1.2.1 Medicines in the unit are stored and managed in accordance with Good Pharmacy Practice.

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

Inspect the aspects listed below in the cupboards or medicine shelves where medicines are kept. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Cupboard or medicine trolley has sufficient space for orderly arrangement of medicines.		
2. Cupboard or medicine trolley is clean (no debris, no dust, no visible dirt in cupboard or trolley, nothing in trolley not directly related to storage, dispensing or administration of medicine, nothing in cupboard or trolley that represents an infection control risk, e.g. food)		
3. Medicines are stored according to a classification system.		
4. No evidence of pests in cupboard or medicine trolley		
5. Access control measures are in place to ensure that only authorised persons have access to medicine.		
6. System is in place to ensure packing and issuing of medicine according to 'first expired, first out' (FEFO) principle.		
7. System is in place to check expiry dates of medicines.		
8. No expired medicines to be observed in area used for medicine storage.		

9.3.1.1.2.2 The name and contact details of the pharmacist on duty for the provision of services after hours are available.

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

A document must be displayed listing the name and contact details of the pharmacist on duty after hours. The document must be signed and dated by the responsible pharmacist. Not applicable: Never

Score	Comment

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9.3.1.1.2.3 A locked emergency cupboard for the supply of medicine after hours is available.

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

The emergency cupboard must be located in an area that can be accessed after hours and it must be kept locked. Not applicable: Where medicines are not obtained from the pharmacy after hours.

Score	Comment

9.3.1.1.2.4 A stock management system is in place for medicines in the emergency cupboard.

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

The stock in the emergency cupboard must be managed in the same way as stock in the wards or in the pharmacy. Minimum, maximum and reorder levels must be determined for all medicines held in the emergency cupboard and bin cards or equivalent must be completed. Not applicable: Where the health establishment does not use an emergency cupboard.

Score	Comment

9.3.1.1.2.5 Medicines issued from the emergency cupboard are documented.

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

All medicines dispensed from the emergency cupboard must be documented, including the date of issue, the health care provider issuing the medicine and the user to whom the medicine is issued. This information must be kept in the emergency cupboard. Not applicable: Where the health establishment does not use an emergency cupboard.

Score	Comment

9.3.1.1.2.6 Stock levels of medicine in the emergency cupboard correspond with recorded stock levels in the stock control system.

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

Select five items held as stock and verify the number of items available against the balance indicated on the bin cards or equivalent. The system may be manual or electronic.

Score	Comment	
Aspects	Score	Comment
1. Item 1		

2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		

9.3.1.1.2.7 Medicines as per the applicable essential medicines list or formulary are available in the pharmacy and/or medicine storage room.

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

All health establishments must hold stock according to the tracer medicine list as a routine. Should medicines be out of stock, substitutes will only be accepted if documented evidence of the recommended substitute from the provincial or district pharmacist is available. Alternatively, where the tracer medicine list recommends several medicines as equivalent for treatment, substitutes from this list of recommended medicines will be acceptable without a letter from the national, provincial or district pharmacy service. Routine use of alternative dosages or formulations will be scored noncompliant. Inspect the pharmacy/dispensary to verify whether the tracer medicines listed below are available. Score 1 if the item is in stock and not expired and 0 if it is not in stock or if it is available but expired.

Score	Comment	
Aspects	Score	Comment
1. Adrenaline injection 1mg/ml		
2. Amikacin 100mg or 250mg or 500mg injection		
3. Amoxicillin suspension 125mg/5ml or 250mg/5ml		
4. Amoxicillin capsules 250mg or 500mg		
5. Artesunate 60mg injection		
6. Atropine 0.5mg or 1mg ampoule		
7. Budesonide or Beclomethasone inhaler		
8. Carbamazepine 200mg tablets or Lamotrigine 25mg tablets		
9. Cefixime capsules 400mg or Azithromycin 250mg or 500mg		
10. Ceftriaxone 250mg or 500mg or 1000mg injection		

11. Co-trimoxazole suspension 50ml or 100ml		
12. Co-trimoxazole tablets 480mg or 960mg		
13. Covid 19 vaccines (Not applicable where health establishment is not designated to keep the vaccine)		
14. Dexamethasone 4mg/ml		
15. Diazepam 5mg/ml 2ml ampoule		
16. DTaP-IPV / Hib vaccine / Hexavalent		
17. Enalapril 2.5 mg or 10mg or 20mg or Perindopril 4mg tablets		
18. Furosemide 20mg or 10mg/2ml ampoule		
19. Gentamicin 80mg/2ml ampoule or Fosfomycin 3g granules		
20. Heparin injection 5000 iu/ml or Enoxaparin sodium		
21. Hydrochlorothiazide tablets 12.5mg or 25mg		
22. Hydrocortisone 100mg/ml or 200mg/2ml vial		
23. Ibuprofen tablets 200mg or 400mg		
24. Insulin short acting soluble 100IU/ml		
25. Insulin medium acting soluble		
26. Ipratropium 0.25mg/2ml or 0.5mg/2ml Unit dose vial for nebulisation		
27. Lidocaine/Lignocaine IM 1% or 2% 20ml vial		
28. Magnesium sulphate injection 40mg/ml or 80mg/ml		
29. Metformin tablets 500mg or Metformin tablets 850mg		
30. Medroxyprogesterone acetate 150mg/ml or Norethisterone 200mg/ml injections		

31. Midazolam (1mg/ml 5ml ampoule or 5mg/ml) 3ml ampoule)		
32. Morphine injection 10mg or 15mg		
33. Naloxone 0.4mg/1ml 1 ml ampoule		
34. Oral rehydration salt (ORS)		
35. Oxytocin 2iu/2ml or 5iu/ml or 10iu/ml or Ergometrine 0.5mg		
36. Paracetamol tablets 500mg		
37. Paracetamol 50ml or 100ml syrup 120mg/5ml		
38. Phenytoin injection 250mg/5ml		
39. Prednisone 5mg tablets or Prednisolone 5mg tablets		
40. Salbutamol inhaler		
41. Simvastatin 10mg or 20mg or 40mg		
42. Streptokinase 1.5 MIU injection		
43. Tetanus Toxoid		
44. Vitamin A 50 000IU capsules or Vitamin A 100 000IU capsules or Vitamin A 200 000IU capsules		
TB treatment		
45. Isoniazid tablets 100mg or 300mg		
46. Pyridoxine 25mg		
47. Rifampicin + Isoniazid + pyrazinamide + ethambutol (RHZE) 150/75/400/275 tablets		
48. Rifampicin + Isoniazid (RH) 300mg/150mg or 150/75mg tablets		
49. Rifampicin + Isoniazid (RH) 60/60 tablets or Rifampicin + Isoniazid (RH) 75/50 tablets or Rifampicin + Isoniazid (RH) +pyrazinamide (RHZ) 75/50/150 tablets		
ANTIRETROVIRAL THERAPY		

50. Abacavir 20mg/ml solution or Abacavir 60 mg dispersible tablets or Abacavir/Lamivudine 120/60 mg dispersible tablets		
51. Abacavir 60mg or 300mg tablets		
52. Dolutegravir (DTG) 50mg tablets		
53. Efavirenz 600mg		
54. Lamivudine 10mg/ml syrup/solution		
55. Lamivudine 150mg tablets or 300mg tablets		
56. Lamivudine 150mg / Zidovudine 300mg tablets		
57. Lopinavir / Ritonavir 80/20mg/ml solution		
58. Lopinavir, Ritonavir 80/20mg/ml solution OR Lopinavir, Ritonavir 40/10mg capsules (pellets) OR sachets (granules)		
59. Lopinavir, Ritonavir 200/50mg tablets or Atazanavir, Ritonavir 300/100mg or Atazanavir 150mg capsules with Ritonavir 100mg capsules		
60. Nevirapine 200mg tablets		
61. Nevirapine 50mg/5ml solution		
62. Ritonavir 80g/ml solution		
63. Ritonavir 100mg tablets		
64. Tenofovir + Emtricitabine + Efavirenz (TEE) 300/200/600mg		
65. Tenofovir 300mg tablets		
66. Tenofovir/Lamivudine/ Dolutegravir (TLD) 300/300/50mg		
67. Zidovudine 50mg/5ml 200 ml suspension/solution		
68. Zidovudine 100mg or 300mg tablets		
Vacolitre		
69. Dextrose 5% solution 200ml		
70. Modified Ringer's lactate or Ringer's lactate 1000ml		
71. Sodium chloride 0.9% 1000ml		
72. Sodium chloride 0.9% 200ml		
73. Sodium chloride 0.45% 1000ml		

Domain 9.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 9.4.1 20 Occupational health and safety

Standard 9.4.1.1 20(1) The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

Criterion 9.4.1.1.1 20(2)(b) Awareness of safety and security issues must be promoted

9.4.1.1.1.1 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

9.4.1.1.1.2 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 9.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 9.5.1 14 Management of buildings and grounds

Standard 9.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 9.5.1.1.1 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.

9.5.1.1.1.1 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, including but not limited to loose electrical wiring, collapsing ceiling or roof, collapsing doors. or 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 9.5.1.1.2 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.

9.5.1.1.2.1 The pharmacy has a functional air conditioner(s).

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

Verify whether the air conditioner(s) switches on and off and provides cold/cool air to the room in accordance with the temperature setting. Not applicable: Never

Score	Comment

9.5.1.1.2.2 Pharmacy waiting area has natural ventilation or functional mechanical ventilation.

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

The 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 such as windows or ventilation grilles. Verify that the pharmacy waiting area has natural ventilation (windows and doors that can be opened or functional mechanical ventilation (i.e. a ducting system). Not applicable: Never

Score	Comment

9.5.1.1.2.3 Pharmacy unit has natural ventilation or functional mechanical ventilation.

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

The 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 such as windows or ventilation grilles. Verify that the pharmacy 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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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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