



OHSC

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



REGULATORY CLINIC INSPECTION TOOL VERSION 1.2

DISPENSARY / MEDICINE CUPBOARD



Facility:
Date:

- **Tool Name:** Regulatory Clinic Inspection tool version 1.2 - Final
- **HEs Type:** Clinics/ PHC
- **Sector:** Public
- **Specialization:** Clinic
- **Created By:** Health Standards Development and Training Unit

3 Dispensary / Medicine Cupboard

Domain 3.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 3.2.1 6 User health records and management

Standard 3.2.1.1 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 3.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

3.2.1.1.1.1 There is a “No unauthorised entry” sign on the door of the Dispensary.

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

Observe if there is a sign that reads “No unauthorised entry” on the Dispensary door. All internal signs must as a minimum be laminated. Text on signs must be typed, no hand written signs must be accepted. Signs do not need to be framed, but laminating must be in good condition, no turned corners or peeling loose at places. If frames are not used- posters must be neatly fasten to the wall. Any other sign, e.g. “Staff only” will be scored not compliant. Measure should not be assessed if the health establishment does not have a dispensary but only has a medicine storage room(no dispensing is done in medicine storage rooms and user records are therefore not found in medicine rooms) Not applicable: Where the health establishment does not have a dispensary but have medicine storage rooms

Score	Comment

Sub Domain 3.2.2 7 Clinical management

Standard 3.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 3.2.2.1.1 7 The health establishment implements process to ensure environmental cleanliness.

3.2.2.1.1.1 A cleaning schedule for the Dispensary/Medicine room is available.

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

Regular cleaning of the health establishment is an important aspect of infection prevention and control. The cleaning schedule should include all areas of the health establishment or the specific areas in that unit that must be cleaned, it should include the tasks to be carried out and the frequency. Not Applicable: Never

Score	Comment

3.2.2.1.1.2 Cleaning is carried out in accordance with the schedule.

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

Request the document indicating when cleaning has been carried out. Check whether the cleaning tasks conducted correlate with the cleaning times and tasks on the schedule. Not applicable: Never

Score	Comment

3.2.2.1.1.3 All work completed is signed off by the cleaners.

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

The document which indicates when cleaning was carried out must be signed by the cleaner who performed the tasks. Not applicable: Never

Score	Comment

3.2.2.1.1.4 All work completed is verified by the clinic manager or a delegated member of personnel.

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

The document indicating when cleaning was carried out must be countersigned by the individual responsible for overseeing the cleaning services. Not applicable: Never

Score	Comment

3.2.2.1.1.5 CHECKLIST: The Dispensary/Medicine room is clean.

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

Use the checklist below to check whether the service areas are clean. Score 1 if the aspect is met and score 0 if it is not met. Score NA (not applicable) if the facility has fewer than the areas indicated, or for any aspects not found in the area.

Score	Comment	
Aspects	Score	Comment
Dispensary/Medicine room		
1. Windows are clean		
2. Window sills are clean		
3. The floor is clean		
4. Skirting boards are free of dust		
5. The countertops are clean		
6. The door handles are clean		

7. Mirrors are clean		
8. Walls are clean		
9. Bins are not overflowing		
10. Bins are clean		
11. The area is odour-free		
12. The area is free of cobwebs		

3.2.2.1.1.6 CHECKLIST: The waiting area for the Dispensary/Medicine room is clean.

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

Use the checklist below to check whether the waiting area(s) are clean. Score 1 if the aspect is met and score 0 if it is not met. Score NA (not applicable) if the health establishment has fewer than the areas indicated or does not have a waiting area for dispensary or for aspects not found in the waiting area.

Score	Comment

Unit 1 Waiting area 1

Aspects	Score	Comment
1. Windows are clean		
2. Window sills are clean		
3. The floor is clean		
4. Skirting boards are free of dust		
5. The countertops are clean		
6. The door handles are clean		
7. Mirrors are clean		
8. Walls are clean		
9. Bins are not overflowing		
10. Bins are clean		
11. The area is odour-free		
12. The area is free of cobwebs		

Unit 2 Waiting area 2

Aspects	Score	Comment
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1. Windows are clean		
2. Window sills are clean		
3. The floor is clean		
4. Skirting boards are free of dust		
5. The countertops are clean		
6. The door handles are clean		
7. Mirrors are clean		
8. Walls are clean		
9. Bins are not overflowing		
10. Bins are clean		
11. The area is odour-free		
12. The area is free of cobwebs		

Sub Domain 3.2.3 8 Infection prevention and control programmes

Standard 3.2.3.1 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 3.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

3.2.3.1.1.1 CHECKLIST: Hand washing facilities are available.

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

Use the checklist below to check whether hand washing facilities and the items listed below are available. The hand washing facilities can be located within the Dispensary/Medicine Room or immediately outside the Dispensary/Medicine Room, e.g. in a passage or an adjacent room. Score 1 if compliant with the aspect listed below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Functional hand wash basin (The basin should not be blocked, broken, or have deep cracks causing leaking of water.)		
2. Taps are functional with running water. Explanatory note: Where the health establishment utilises hand sanitiser during drought episodes, this requirement should be scored NA (not applicable).		

3. Liquid hand wash soap. Explanatory Note: Requirement not applicable when health establishment utilises sanitiser during drought episodes		
4. Disposable hand paper towels (wall mounted dispenser not required in Dispensary/Medicine Room)		
5. A poster on hand hygiene is displayed above or next to the hand wash basin.		

3.2.3.1.1.2 Hand sanitiser is available.

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

To be assessed in areas experiencing drought. Hand sanitiser must be available at the time of inspection. Not applicable: Where health establishment has functional tap and running water.

Score	Comment

Sub Domain 3.2.4 9 Waste management

Standard 3.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 3.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

3.2.4.1.1.1 Appropriate containers for disposal of pharmaceutical waste are available.

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

Dark green container marked with the words "Pharmaceutical waste liquid or solid" must be available. Not applicable: Where the health establishment does not dispose of the medication but packs the medication for removal to a disposing health establishment.

Score	Comment

Criterion 3.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

3.2.4.1.2.1 CHECKLIST: Waste is segregated as required by the waste management practices.

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

Use the checklist below to check if waste is segregated as required by the waste management practices stipulated in the National Environmental Health Norms and Standards. Score 1 if compliant with the aspects below and score 0 if not compliant.

Score	Comment

Aspects	Score	Comment

1. General waste is disposed of separately in a black or beige or white or transparent plastic bag.		
2. Pharmaceutical waste is stored separately in a container or box for removal to the disposing health establishment. (This aspect relates to clinics which transfer their pharmaceutical waste to another health establishment for disposal. Pharmaceutical waste includes obsolete medication and medication returned to the clinic by users.)		

Domain 3.3 CLINICAL SUPPORT SERVICES

Sub Domain 3.3.1 10 Medicines and medical supplies

Standard 3.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 3.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

3.3.1.1.1.1 CHECKLIST: The standard operating procedure for management of medicines is available.

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

Read through the standard operating procedure and confirm whether the aspects listed below are included and explained. Score 1 if the aspect is included and explained and score 0 if it is not included or included but not explained.

Score	Comment	
Aspects	Score	Comment
1. Cleaning of the medicine room/dispensary		
2. Storage and organisation of the medicine room/dispensary		
3. Security and control of access to the medicine room/dispensary (within and outside normal working hours)		
4. Cold chain management		
5. Management of medicines in the consulting room		
6. Pest Control		
7. Calculation and use of minimum, maximum and re-order stock levels		
8. Completion and management of stock (bin) cards		
9. Stock taking procedure		
10. Management of short-dated stock		
11. Procurement (ordering) of medicines		
12. Ordering and delivering schedule for stock		

13. Receipt of medicines into the medicine room/dispensary (ordered or borrowed stock)		
14. Managing return of stock to the depot		
15. Managing stock transfers between health establishments		
16. Medicine availability monitoring procedure/guide		
17. Separation and handling of expired, obsolete, unusable or patient returned medicines (Schedule 0 - 4 medicines)		
18. Disposal of expired, obsolete, unusable and patient-returned medicines (Schedule 0 - 4 medicines)		
19. Managing recall of medicines		
20. Storage and control of Schedule 5 and Schedule 6 medicines		
21. Emergency medicine cupboard or trolley management		

3.3.1.1.1.2 CHECKLIST: The electronic network system for monitoring the availability of medicines is used effectively

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

Use the checklist to check whether the electronic network system for monitoring the availability of medicines is used effectively. The electronic systems can include but are not limited to Stock Visibility System (SVS), RX Solutions and JAC. To determine whether the health establishment has reported the availability of medicines as required, visit the website used to view captured medicine availability data, and the Primary Health Care Health Establishment Dashboard associated with it. Score 1 if the aspect is compliant and score 0 if it is not compliant

Score	Comment	
Aspects	Score	Comment
1. The health establishment has a functional electronic network system for monitoring the availability of medicines		
2. The approved list of medicines to be updated is visible in the electronic network system.		
3. The capturing device is in good working order.		
4. The accessories are in good working order.		
5. The capturing device is stored in a lockable unit (only applicable to SVS)		

6. Accessories, which include batteries and a charger, for the device are stored in a lockable unit (only applicable to SVS)		
7. Access to the keys for the unit where the capturing device and its accessories are stored is restricted (only applicable to SVS)		
8. In the last 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)		

3.3.1.1.1.3 Re-ordering stock levels (min/max and/or re-order levels) are determined for each item on the district/health establishment formulary.

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

Each item held as stock should have documented minimum, maximum and/or re-order levels. These levels should be recorded on the bin cards or equivalent. The system can be manual or electronic. Not applicable: Never

Score	Comment

3.3.1.1.1.4 There is evidence that a stock take of medicine was done in the last 12 months.

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

Documented evidence of a formal stock take will be required, i.e. a certificate or report, indicating that the stock take has been completed in the last 12 months. Report should detail amongst others-expired medicine and its monetary value. Not applicable: Never

Score	Comment

3.3.1.1.1.5 Schedule 5 and 6 medicines in stock correspond with the balance recorded in the register.

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

Select three medicines from the Schedule 5 medicine cupboard and check for correspondence with the register. If the medicines do not correlate this measure will be scored 0. Not applicable: Where Schedule 5 and 6 medicines are not held at the health establishment

Score	Comment

Criterion 3.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

3.3.1.1.2.1 CHECKLIST:90 % of the medicines on the tracer medicine list are available.

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

All clinics must hold stock according to the Tracer Medicine List as a routine. Should medicines be out of stock, substitutions will only be accepted if documented evidence of the recommended substitute from the District pharmacist is available. Alternatively, where tracer medicine list recommends several medicines as equivalent for treatment, substitutions from this list of

recommended medicines will be acceptable without a letter from the District pharmacist. Routine use of alternative dosages or formulations will be scored non-compliant. Check in the pharmacy/dispensary to see if 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
Oral formulations/inhalers		
1. Abacavir 20mg/ml solution or Abacavir 60 mg dispersible tablets		
2. Abacavir 300mg tablets		
3. Amoxicillin 250mg capsules		
4. Amoxicillin 500mg capsules		
5. Amoxicillin 125mg/5ml or 250mg/5ml suspension		
6. Azithromycin 250mg or 500mg tablets		
7. Beclomethasone/Budesonide 100mcg or 200 mcg metered dose inhaler (MDI)		
8. Carbamazepine 200mg tablets or Lamotrigine 25mg tablets		
9. Co-trimoxazole 200/40mg per 5ml suspension		
10. Co-trimoxazole 400/80mg tablets		
11. Efavirenz 200 mg capsules		
12. Efavirenz 50mg capsules		

13. Enalapril 5mg or 10mg tablets		
14. Ferrous lactate/gluconate liquid/syrup		
15. Ferrous sulphate (dried) /fumarate tablets providing ± 55 to 65mg elemental iron		
16. Folic acid 5 mg tablets		
17. Hydrochlorothiazide 12.5mg or 25mg tablets		
18. Ibuprofen 200 mg tablets		
19. Ibuprofen 400mg tablets Explanatory note: This can either be a 400mg tablet or 2 X 200mg tablets.		
20. Isoniazid 100mg tablets		
21. Isoniazid 300mg tablets		
22. Lamivudine 10mg/ml solution		
23. Lamivudine 150mg tablets		
24. Combined oral contraceptive pill containing 30 mcg ethinylestradiol) ethinylestradiol/levonorgestrel or ethinylestradiol/norethisterone or ethinylestradiol/gestodene or ethinylestradiol/norgestimate		
25. Lopinavir, Ritonavir 200/50mg tablets or Atazanavir 150mg capsules WITH Ritonavir 100mg capsules		
26. Lopinavir, Ritonavir 80/20mg/ml solution		
27. Metformin 500mg tablets		
28. Metformin 850mg tablets		
29. Methyldopa 250 mg tablets		
30. Metronidazole 200mg or 400mg tablets		

31. Nevirapine 200mg tablets		
32. Nevirapine 50mg/5ml suspension		
33. Oral rehydration solution		
34. Paracetamol 120mg/5ml syrup		
35. Paracetamol 500mg tablets		
36. Prednisone 5mg tablets		
37. Pyrazinamide 500mg tablets		
38. Pyridoxine 25mg tablets		
39. Rifampicin + Isoniazid (RH) 300mg/150mg or 150/75mg tablets		

40. Rifampicin + Isoniazid (RH) 60/60 tablets		
41. Rifampicin + Isoniazid + pyrazinamide + ethambutol (RHZE) (150/75/400/275) tablets		
42. Salbutamol 100 mcg MDI		
43. Simvastatin 10mg or 20 mg or 40mg tablets		
44. Tenofovir/emtricitabine/efavirenz 300/200/600mg tablets		
45. Tenofovir/emtricitabine 300/200 mg		
46. Vitamin A 50,000U capsules		
47. Vitamin A 100,000U capsules		
48. Vitamin A 200,000U capsules		

49. Zidovudine 50mg/5ml, 200 ml suspension		
Injections		
50. Benzathine benzylpenicillin 1.2MU or 2.4MU vial		
51. Ceftriaxone 500mg or 1g vials		
52. Medroxyprogesterone acetate 150mg/ml injection or norethisterone 200mg/ml		
Topicals		
53. Chloramphenicol 1%, ophthalmic ointment		
Refrigerator		
54. BCG vaccine		
55. Insulin, short acting		
56. Measles vaccine		
57. Hexavalent: DTaP-IPV-HB-Hib vaccine		
58. Oxytocin 5 or 10 IU/ml AND Ergometrine 0.5mg or oxytocin/ergometrine 5U/0.5mg combination		
59. Pneumococcal Conjugated Vaccine (PCV)		
60. Polio vaccine (oral)		
61. Rotavirus vaccine		
62. Tetanus toxoid (TT) vaccine		
Emergency medicine		
63. Activated Charcoal		

64. Adrenaline 1mg/ml (Epinephrine) 1ml ampoule		
65. Amlodipine 5mg or 10mg tablets		
66. Aspirin 100mg or 300mg tablets		
67. Atropine 0.5mg or 1mg ampoule		
68. Calcium Gluconate 10% 10ml ampoule		
69. 50% dextrose (20ml ampoule or 50ml bag) or 10% dextrose 1L solution		
70. Furosemide 20mg or 10mg/2ml ampoule		
71. Hydrocortisone 100mg/ml or 200mg/2ml vial		
72. Prednisone 5 mg tablets		
73. Ipratropium 0.25mg/2ml or 0.5mg/2ml Unit dose vial for nebulisation		
74. Lidocaine/Lignocaine IM 1% or 2% 20ml vial		
75. Magnesium sulphate 50%, 1g/2ml ampoule (minimum of 14 ampoules required for one treatment)		
76. Midazolam (1mg/ml 5ml ampoule or 5mg/ml 3ml ampoule) or Diazepam 5mg/ml 2ml ampoule		
77. Nifedipine 5mg or 10mg capsules		
78. Neonatalyte 200ml solution		
79. Paediatric solution e.g. ½ strength Darrows (200ml or 500ml) solution		
80. Promethazine 25mg/2ml or 25mg/1ml ampoule		

81. Short acting sublingual nitrates e.g. glyceryl trinitrate SL or isosorbide dinitrate sublingual, 5 mg tablets		
82. Salbutamol 0.5% 20ml nebulising solution or 2.5mg/2.5ml or 5mg/2.5ml Unit dose vial for nebulisation		
83. Sodium chloride 0.9% 1L solution		
84. Thiamine 100mg/ml 10ml vial		

3.3.1.1.2.2 CHECKLIST: Three scripts in the Dispensary are correlated with the medicines dispensed to ensure that all medicines were received as prescribed.

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

Select three user scripts in the Dispensary and check whether medicines were dispensed against this script. If all medicines as prescribed were dispensed, then score 1. If a user has not received all the medicines as prescribed, score 0. Score not applicable if dispensing is done exclusively in the consulting rooms.

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

3.3.1.1.2.3 CHECKLIST: The temperature of the Dispensary/Medicine Room is maintained within the safety range.

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

Use the checklist below to check whether the temperature in the Dispensary/Medicine Room is maintained between 15 - 25 degrees Celsius. Score 1 if compliant with the aspect listed below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. There is at least one functional room thermometer		

2. The temperature of the Dispensary/Medicine Room is recorded daily (This is to assess if the health establishment consistently monitors the room temperature. Request temperature monitoring sheets from the previous three months.)		
3. The temperature of the Dispensary/Medicine Room is maintained between 15 - 25 degrees Celsius		

3.3.1.1.2.4 CHECKLIST: Cold chain procedure for vaccines is maintained.

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

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

Score	Comment	
Aspects	Score	Comment
1. The health establishment has a vaccine or medicine refrigerator with a thermometer		
2. The temperature of the refrigerator is recorded twice daily, seven hours apart (check three month's record)		
3. The temperature of the refrigerator is maintained between 2 and 8 degrees Celsius (check three month's record)		
4. There is a cooler box for storage of vaccines if needed.		
5. Ice packs are available for use as needed.		
6. There is a functional thermometer for use in the cooler box		

3.3.1.1.2.5 The register for schedule 5 and 6 medicines is completed correctly.

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

Accurate, comprehensive recording of administration and dispensing of Schedule 5 and 6 medicines is a legal requirement and must be done in accordance with the applicable legislation. All columns in the provided registers must be comprehensively completed. Any omitted information noted during the review of the register will result in a non-compliant score. The inspector must confirm that all sections of the register have been completed correctly. If any of the columns have not been completed, this measure will be scored 0. Not applicable: Where schedule 5 and 6 medicines are not held at the health

Score	Comment

3.3.1.1.2.6 There is no expired medicine on the shelves.

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

Randomly check medicines on the shelves of the Dispensary/Medicine Room. Score 0 if any expired medicines are found on the shelves. Not applicable: Never

Score	Comment

Domain 3.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 3.5.1 14 Management of buildings and grounds

Standard 3.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 3.5.1.1.1 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.

3.5.1.1.1.0 The Dispensary/Medicine Room has a functional air conditioner.

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

Observe if the air conditioner switches on and off and provides cold/cool air to the room in accordance with the temperature setting. 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 Clinics.

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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 these Regulatory Clinic Inspection tools version 1.2 was developed by the Office of Health Standards Compliance.

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Executive Manager
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Date: 28/01/2020

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