



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



**Dispensary Medicine Cupboard/Room**

**v1.3**

**Regulatory Clinic inspection tool**

Facility:
Date:

- **Tool Name:** Regulatory Clinic Inspection tool v1.3 - Final
- **HEs Type:** Clinics/ PHC
- **Sector:** Public
- **Specialization:** Clinic
- **Created By:** Health Standards Development and Training

### 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 handwritten 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** All work completed is verified by the clinic manager or a delegated member of 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 effectively cleaned. Monitoring tools (e.g. checklists/tick sheets) listing all cleaning tasks must be completed for each room or area.

Not applicable: Never

Score	Comment

**3.2.2.1.1.2 CHECKLIST:** The areas listed below are clean.

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

Verify whether the service areas listed below are clean. Inspector to observe general cleanliness of the area including but not limited to whether the area is free of dirt and stains. Score 1 if the area is clean and score 0 if not clean. Score NA (not applicable) if an indicated area does not exist in the health establishment.

Score	Comment

Aspects	Score	Comment
1. Dispensary/Medicine room		
2. Waiting area		

**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 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.		
6. Alcohol based hand rub		

**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:** A 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. NB: The standard operating procedure must as minimum comply with the following requirements: Title of the document, Name of the District or sub-district or health establishment , signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional),date of implementation or approval, date of next review (Documents must be reviewed at a minimum every 5 years),summary of changes made to each version of the document (optional).NB: If signed by a delegated official a delegation letter or document is required, document can manual or electronic.

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

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**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 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** CHECKLIST: 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 and 6 medicine cupboard and verify whether the quantity available corresponds with the balance recorded in the register. Score 1 if there is correspondence 0 if not. Score not applicable where schedule 5 and 6 medicines are not held in the health establishment.

Score	Comment	
Aspects	Score	Comment
1. Medicine 1		
2. Medicine 2		
3. Medicine 3		

**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: 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
<b>Oral formulations/inhalers</b>		

1. Abacavir 20mg/ml solution or Abacavir 60 mg dispersible tablets or Abacavir/Lamivudine 120/60 mg dispersible tablets		
2. Abacavir 300mg tablets		
3. Amoxicillin 250mg or 500mg capsules		
4. Amoxicillin 125mg/5ml or 250mg/5ml suspension		
5. Azithromycin 250mg or 500mg tablets		
6. Beclomethasone/Budesonide 100mcg or 200 mcg metered dose inhaler (MDI)		
7. Carbamazepine 200mg tablets or Lamotrigine 25mg tablets		
8. Co-trimoxazole 200/40mg per 5ml suspension		
9. Co-trimoxazole 400/80mg tablets		
10. Dolutegravir 50 mg capsule		
11. Enalapril 5mg or 10mg tablets		
12. Ethambutol 400mg tablets		
13. Ferrous lactate/gluconate liquid/syrup		
14. Ferrous sulphate (dried) /fumarate tablets providing $\pm$ 55 to 65mg elemental iron		
15. Folic acid 5 mg tablets		
16. Hydrochlorothiazide 12.5mg or 25mg tablets		
17. Ibuprofen 200mg or 400mg tablets		
18. Isoniazid 100mg or 300mg tablets		
19. Lamivudine 10mg/ml syrup/solution		
20. Lamivudine 150mg tablets		

21. Combined oral contraceptive pill containing 30 mcg ethinylestradiol) ethinylestradiol/levonorgestrel or ethinylestradiol/norethisterone or ethinylestradiol/gestodene or ethinylestradiol/norgestimate		
22. Lopinavir, Ritonavir 200/50mg tablets or Atazanavir, Ritonavir 300/100mg or Atazanavir 150mg capsules with Ritonavir 100mg capsules		
23. Lopinavir, Ritonavir 80/20mg/ml solution or Lopinavir, Ritonavir 40/10mg capsules (pellets) or sachets (granules)		
24. Metformin 500mg or 850mg tablets		
25. Methyldopa 250 mg tablets		
26. Metronidazole 200mg or 400mg tablets		
27. Nevirapine 200mg tablets		
28. Nevirapine 50mg/5ml suspension		
29. Oral rehydration solution		
30. Paracetamol 120mg/5ml syrup		
31. Paracetamol 500mg tablets		
32. Prednisone 5mg tablets or Prednisolone 5mg tablets		
33. Pyrazinamide 500mg tablets		
34. Pyridoxine 25mg tablets		
35. Rifampicin + Isoniazid (RH) 300mg/150mg or 150/75mg tablets		
36. Rifampicin + Isoniazid (RH) 60/60 tablets or Rifampicin + Isoniazid (RH) 75/50 tablets or Rifampicin + Isoniazid (RH) + pyrazinamide (RHZ) 75/50/150 tablets		
37. Rifampicin + Isoniazid + pyrazinamide + ethambutol (RHZE) 150/75/400/275 tablets		
38. Salbutamol 100 mcg MDI		

39. Simvastatin 10mg or 20 mg or 40mg tablets		
40. Tenofovir/emtricitabine/efavirenz 300/200/600mg tablets		
41. Tenofovir/ lamivudine /dolutegravir 300/300/50mg tablets		
42. Vitamin A 50,000U or 100,000U or 200,000U capsules		
43. Zidovudine 50mg/5ml, 200 ml suspension		
<b>Injections</b>		
44. Benzathine benzylpenicillin 1.2MU or 2.4MU vial		
45. Ceftriaxone 250mg or 500mg or 1g vials		
46. Medroxyprogesterone acetate 150mg/ml or Norethisterone 200mg/ml injections		
47. Gentamicin 80mg/2ml ampoule or Fosfomycin 3g granules		
<b>Topicals</b>		
48. Chloramphenicol 1%, ophthalmic ointment		
<b>Refrigerator</b>		
49. BCG vaccine		
50. Insulin, short acting		
51. Measles vaccine		
52. Hexavalent: DTaP-IPV-HB-Hib vaccine		
53. Ergometrine 0.5mg or Oxytocin/ ergometrine 5U/0.5mg combination		
54. Pneumococcal Conjugated Vaccine (PCV)		

55. Polio vaccine (oral)		
56. Rotavirus vaccine		
57. Tetanus toxoid (TT) vaccine		
<b>Emergency medicine</b>		
58. Activated Charcoal		
59. Adrenaline 1mg/ml (Epinephrine) 1ml ampoule		
60. Amlodipine 5mg or 10mg tablets		
61. Artesunate 60mg injection*** (Only Malaria endemic areas)		
62. Aspirin 100mg or 300mg tablets		
63. Atropine 0.5mg or 1mg ampoule		
64. Calcium Gluconate 10% 10ml ampoule		
65. 50% dextrose (20ml ampoule or 50ml bag) or 10% dextrose 1L solution		
66. Furosemide 20mg or 10mg/2ml ampoule		
67. Hydrocortisone 100mg/ml or 200mg/2ml vial		
68. Ipratropium 0.25mg/2ml or 0.5mg/2ml Unit dose vial for nebulisation		
69. Lidocaine/Lignocaine IM 1% or 2% 20ml vial		
70. Magnesium sulphate 50%, 1g/2ml ampoule (minimum of 14 ampoules required for one treatment)		
71. Midazolam (1mg/ml 5ml ampoule or 5mg/ml 3ml ampoule) or Diazepam 5mg/ml 2ml ampoule		
72. Naloxone 0.4mg/1ml 1 ml ampoule****(Only required at midwife obstetric units; **)		

73. Nifedipine 5mg or 10mg capsules		
74. Neonatalyte 200ml solution		
75. Paediatric solution e.g. ½ strength Darrows (200ml or 500ml) solution		
76. Prednisone 5 mg tablets or Prednisolone tablets		
77. Promethazine 25mg/2ml or 25mg/1ml ampoule		
78. Short acting sublingual nitrates e.g. glyceryl trinitrate SL or isosorbide dinitrate sublingual, 5 mg tablets		
79. Salbutamol 0.5% 20ml nebulising solution or 2.5mg/2.5ml or 5mg/2.5ml Unit dose vial for nebulisation or Salbutamol 100 mcg MDI		
80. Sodium chloride 0.9% 1L solution		
81. Streptokinase 1.5 MIU injection**( Only required at midwife obstetric units; **)		
82. 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

**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.

**3.5.1.1.1.1** 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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- Provincial Department of Health personnel, Quality Assurance Managers, District Managers, Programme Managers, Facility/Operational Managers for their valuable feedback
- 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 Clinic 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**

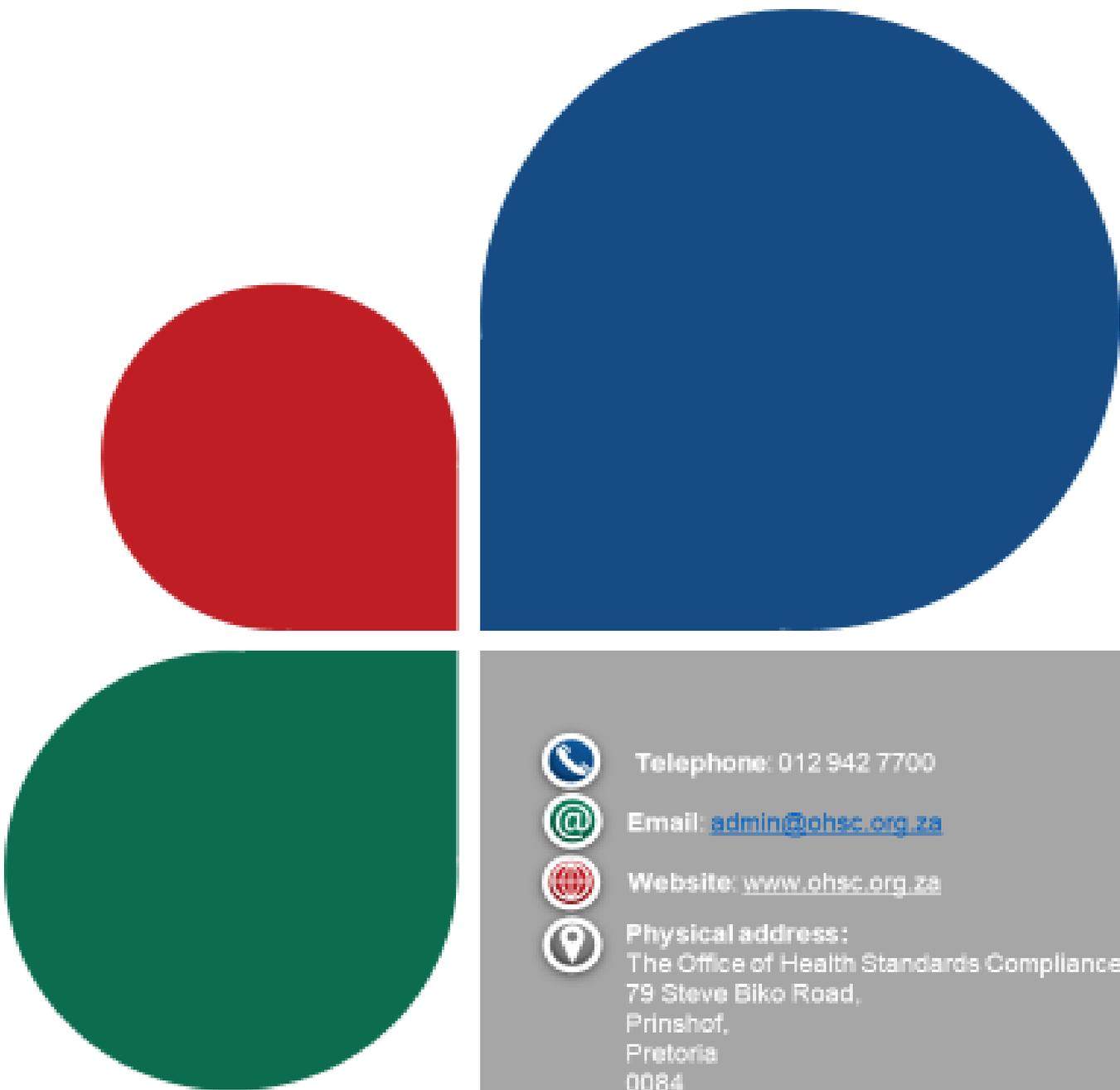
**Signature:**



**Chief Executive Officer: OHSC**

**Date:**

10/08/2022



Telephone: 012 942 7700



Email: [admin@ohsc.org.za](mailto:admin@ohsc.org.za)



Website: [www.ohsc.org.za](http://www.ohsc.org.za)



Physical address:  
The Office of Health Standards Compliance,  
79 Steve Biko Road,  
Prinshof,  
Pretoria  
0084



Postal Address:  
Private Bag X21  
Arcadia  
0007



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