PROGRAMME

ards Compliance
ety in healthcare

NATIONAL TRAINING WORKSHOP PROGRAMME
GENERAL PRACTICES INSPECTION TOOL
31ST MAY 2025
14H00 – 18H30
MS TEAMS WEBINAR

PROGRAMME DIRECTOR: MS I LOOTS

TIME	ITEM	FACILITATOR
14h00 – 14h10	Opening and purpose of the workshop	Ms I Loots
14h10 – 14h20	Introductory Remarks	Dr S Mndaweni
14h20 – 14h35	Background on the development of the General Practices Inspection tool	Mr J Nkambule
14h35 – 15h30	• Introduction of General Practices inspection tool • Administration and Practice Management functional area	Ms B Mashinini
15h30 -16h15	Clinical Support and Care functional area (Domain 1, 3 and 5)	Ms D Hans
16h15 – 16h30	BREAK	All
16h30 – 17h15	Clinical Support and Care functional area (Domain 2)	Ms A Mafilika
17h15 - 17h45	Inspection process	Mr B Khumalo
17h45 - 18h15	Certification and Enforcement	Dr L Rashokeng
18h15 – 18h20	Way Forward	Ms I Loots
18h20 - 18h30	Closing Remarks	Dr Z Mgugudo-Sello SAMA


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NATIONAL TRAINING WORKSHOP
GENERAL PRACTICE INSPECTION TOOL
DATE: 31 MAY 2025
Jabu Nkambule
Our Vision:
Consistent, safe and quality healthcare for all.
Our Mission:
"We monitor and enforce healthcare safety and quality standards in health establishments independently, impartially, fairly, and fearlessly on behalf of healthcare users."
OHSC
Office of Health Standards Compliance
Ensuring quality and safety in health care
Jabu Nkambule

2 PRESENTATION OUTLINE

1. Background on Consultative and development process

2. General Practice Types and Functional Areas

3. Legislation/Guidelines considered during development of inspection tool

3 Background on Consultative and development process

08 December 2020

- OHSC received a request from NDOH to develop the General Practice Inspection tool using the Norms and Standards Applicable to Different Categories of health establishments 2018.

21 July 2021

- Working document developed and reviewed by OHSC panel of expert members (Dr Modi and Dr Maduna).
- Initial consultative meeting to engage with the GP community through the Unity Forum of Family Practitioners (UFFP) leadership.

4 Background on Consultative and development process

21 July 2021

- Provided an overview of the legislative and regulatory framework within which the OHSC operates as a regulatory entity.
- The UFFP was taken through the structure and content of the draft 2 inspection tool to enable the GPs to understand the tool and make inputs.
- OHSC/UFFP/SAMA task team established, several meetings were convened to discuss draft 2 content.

5 Background on Consultative and development process…cont

08 October 2022

- In-person national consultative workshop was held with UFFP/SAMA leadership to agree on the content of GP practitioners draft 3 inspection tool.
- Outstanding standard development processes discussed (this included the validation/piloting of the tool, governance related to approval of the tool, training requirements and implementation for the tool).
- We also agreed to collaborate as we conduct the provincial wider GP community workshops.

January to November 2023

- Provincial consultative workshops were conducted in the following provinces: Gauteng, Limpopo, Mpumalanga, KZN, Western Cape.
- Consultation in other provinces not conducted due to various reasons(including poor/lack of response).

6 Background on Consultative and development process…cont

February-September 2024

- Feedback received during provincial workshops collated and discussed.
- Follow up meetings held with SAMA to discuss input.
- Draft 4 was circulated to following stakeholders: Intercare Group, Netcare Medicross, Solidarity, Netcare, Aurora Medical Group, KZN Natal Doctors Healthcare Coalition, Emerging Market Healthcare(EMC).
- Input received, collated, discussed and some incorporated.

26 October 2024

- National Consultative workshop conducted to adopt the Inspection tool.
- Attended by various GP formations(CPD points allocated).
- Compliance Inspectorate, Certification units, NDOH and Provincial Quality Managers invited.
- Additional feedback received, reviewed and some incorporated.
- Desktop pilot version generated.

7 Background on Consultative and development process…cont

November-December 2024

- Desktop pilot conducted by OHSC Compliance Inspectorate unit.
- Feedback provided, reviewed and processed. Some feedback noted for testing during field pilot.
- Field pilot GP practices identified in consultation with various stakeholders(UFFP/Intercare/CUPS etc).

February 2025

- Field pilot conducted in General Practices in Gauteng and Mpumalanga during the week of 17-21 February 2025.(Compliance Inspectorate and HSDT).

8 Background on Consultative and development process…cont

February-May 2025

- Field pilot feedback received from Compliance Inspectorate was reviewed and processed.
- The post field pilot version was reviewed by OHSC EXCO.
- Inspection tool submitted to the Certification and Enforcement Committee(CEC) for review on 19 March 2025. Minor changes proposed mainly on dispensing requirements, the tool was then recommended to the Board for approval.
- The inspection tool was approved by the Board on 29 April 2025.
- The approved inspection tool was signed off by OHSC EXCO.

9 General Practice Types and Functional Areas

- Solo practices
- Group practices

Functional Areas_ GP inspection tool

- Administration and Practice Management
- Clinical Care and Support

10 Legislation/Guidelines considered during development of inspection tool

- Health Professions Act 56 of 1974
- National Health Amendment Act no. 12 of 2013
- Medicines and Related Substances Act, 1965 (ACT 101 of 1965)
- Pharmacy Act no. 53 of 1974
- General Regulations made in terms of the Medicines and Related Substances Act 101 of 1965
- Occupational Health and Safety Amendment Act no. 181 of 1993
- HPCSA Booklets
- Protection of Personal Information Act 4 of 2013

11 Legislation/Guidelines considered during development of inspection tool….

- Regulations relating to Health Care Waste Management in Health Establishments (No. R. 375)
- Regulations relating to research with human participants, R719, 19 Sept 2014
- Referral Policy for South African Health Services and Referral Implementation Guidelines 2020
- Practical Manual: Implementation of the National Infection Prevention and Control Strategic Framework, October 2021.
- SANS standards (ISO 11607)

NATIONAL TRAINING WORKSHOP

INTRODUCTION TO GENERAL PRACTICE INSPECTION TOOL AND ADMINISTRATION AND PRACTICE MANAGEMENT

31 May 2025

Presenter: Busisiwe Mashinini

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

Our Vision:

Assuring, safe and quality healthcare for all.

Our Mission:

"We monitor and enforce healthcare safety and quality standards in health establishments independently, impartially, fairly, and fearlessly on behalf of healthcare users."

2 Presentation Outline

- Brief recap on Norms and Standards Regulations
- Link between National Health Act, Norms and Standards Regulations and the OHSC General Practice inspection tool.
- Definition of key concepts
- Introduction to General Practice inspection tool (layout)
- Clarification and interpretation of the requirements in the inspection tool

4 Norms and Standards Regulations

❖ **Norms and Standards Regulations Applicable to Different Categories of Health Establishments**

- ❑ **Promulgated on 2nd February 2018**
- ❑ **Came into operation 12 months after promulgation, February 2019**

5 Outline of Norms and Standards Regulations

SEVEN CHAPTERS – 22 REGULATIONS

CHAPTER 1

- **Regulation 1**. Definitions
- **Regulation 2**. Scope and application
- **Regulation 3**. Purpose of the Regulations

Not captured as domain

CHAPTERS 2 – 6

- **Five critical areas of risk for safe healthcare services (5 domains)**
- **Regulations 4 - 20**: Assessed for compliance

CHAPTER 7 – General provisions

- **Regulations 21 – 22:** Do not relate to a clinical environment.
- Therefore **not used as a domain** in the inspection tools.
- Assessed under the relevant domains

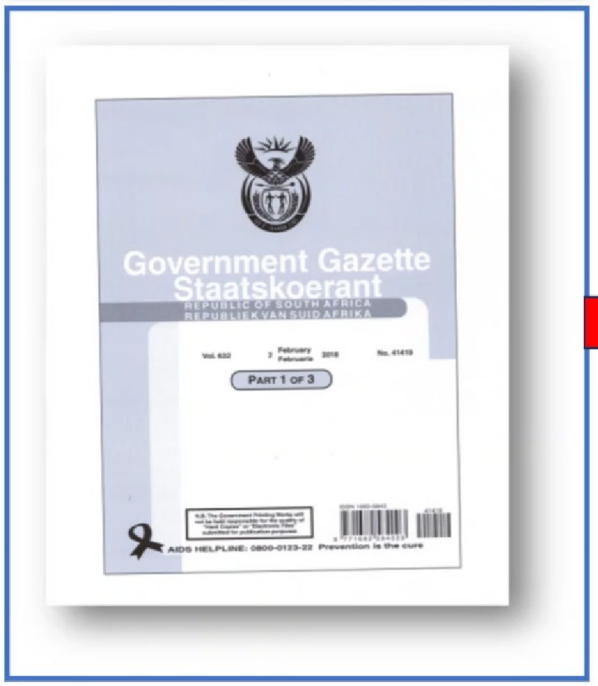
Not captured as domain

6 Summary of Domains

- **Domain 1:** User Rights
- **Domain 2:** Clinical Governance and Clinical Care
- **Domain 3:** Clinical Support Services
- **Domain 4:** Governance and Human Resources
- **Domain 5:** Facilities and Infrastructure

6 Link between NHA, Norms and Standards and OHSC inspection tools

NATIONAL HEALTH ACT,2003 (Act No. 61 of 2003



NORMS AND STANDARDS REGULATIONS – 2018 CAME TO EFFECT - 2019

OHSC INSPECTION TOOLS

8 Definition of Key Concepts (1)

National Health Act, 2003 (Act No.61 of 2003)

- **"user"**- means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service.

- **"health establishment"** means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;

9 Definition of Key Concepts (2)

- **"health care provider"** means a person providing health services in terms of any law, including in terms of the:
  - ***(a) Allied Health Professions Act, 1982 (Act No. 63 of 1982)***
  - ***(b) Health Professions Act, 1974 (Act No. 56 of 1974)***
  - ***(c) Nursing Act, 1978 (Act No. 50 of 1978)***
  - ***(d) Pharmacy Act. 1974 (Act No. 53 of 1974)***
  - ***(e) Dental Technicians Act, 1979 (Act No. 19 of 1979)***
- **"health worker"** means any person who is involved in the provision of health services to a user, **but does not include** a health care provider
- **"health care personnel"** means health care providers and health workers

11 Version No. and Functional Areas

12 Approved inspection tool

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

SIGNATURE:
MS. WINNIE MOLEKO
EXECUTIVE MANAGER: HEALTH STANDARDS, DEVELOPMENT ANALYSIS AND SUPPORT
DATE: 30/04/2025

SIGNATURE:
DR MATHABO MATHEBULA
CHIEF OPERATIONS OFFICER: OHSC
DATE: 06/05/2025

SIGNATURE:
DR SIPHIWE MNDAWENI
CHIEF EXECUTIVE OFFICER: OHSC
DATE: 09/05/2025

13 Inspection tool layout

Domain 1.1 USER RIGHTS

Sub Domain 1.1.1 4 User information

Standard 1.1.1.1 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 1.1.1.1.1 4(2)(a)(iv) The health establishment must provide users with information relating to the complaints, compliments and suggestions management system.

NB: Extracted from Norms and Standards Regulations. Statements may not be altered

14 Types of measures

- **Direct Measure**
  - Measure statement
  - No aspects
- **Checklist Measure**
  - Measure statement
  - Has aspects
    - Single checklist & Multiple Checklist

15 Assessment Methodology

- Document Review
- Patient record audit
- Observation
- Staff interview
- Patient interview

16 Risk rating categories

Non-negotiable measures	Vital measures	Essential measures
• Risk of: ✓ loss of life or ✓ harm requiring prolonged recovery • Cannot be compromised or negotiated	• Extremely important (vital) for direct service delivery and clinical care • Risk of immediate and long-term adverse effects on the health of the population. • Require immediate and full correction. • Critical to ensure the safety of users and healthcare personnel.	• Very necessary (essential) • Require resolution within a given time period. • Indirectly affect the quality and safety of clinical care given to users.

Adapted from the Australian risk rating methodology

17 Explanatory notes or Instructions

- **Provide additional clarity on the requirements to facilitate common understanding and interpretation for common application**
- **Describe the evidence required for compliance with the measure and guides how the requirements will be scored**
- **Indicate when these requirements are not be applicable**

18 SOPs - 11

1.1.1.1.1.1 A standard operating procedure for the management of complaints is available

1.1.2.1.1.1 A standard operating procedure to prioritise users requiring urgent care is available.

1.2.1.1.1.1 A standard operating procedure for health records management is available.

1.2.1.2.1.1 A standard operating procedure for obtaining informed consent is available.

1.2.2.2.1.1 A standard operating procedure for safe injection practices is available.

1.2.2.2.1.2 A standard operating procedure for invasive procedures is available.

1.2.2.2.2.1 Standard operating procedures for conducting research in the practice is available.

1.2.3.1.4.1 A standard operating procedure for decontamination processes is available.

1.2.4.1.1.1 A standard operating procedure for waste management is available.

1.2.5.1.1.1 A standard operating procedure for managing adverse drug reactions is available.

1.3.1.1.1.1 A standard operating procedure for management of medicines is available.

19 SOP measure

1.1.1.1.1.1 A standard operating procedure for the management of complaints is available

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

The aspects listed below must be **included and explained** in the standard operating procedure. **Score 1** if the aspect is included and explained and **score 0** if it is not included or included but not explained. **The document must as a minimum comply with the following requirements: (1)Title of the document, (2) name of the practice owner or group, signed and dated by the relevant authority responsible for approving the document in a group practice or the practice owner, (3) designation of the approver, (4) date of implementation or approval, (5) date of next review.** Documents must be reviewed regularly up to a **maximum of every 5 years.** The document can be **manual or electronic.** The information may be detailed in a single document or in several documents.

Aspects:

1. ***The mechanism(s) by which users can report a complaint.***
2. ***The information to be collected to document the complaint.***
3. ***The procedure for investigating complaints.***
4. ***The procedure for redress of complainants***

20 Same instruction for all SOP measures in the tool

The aspects listed below must be included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and score 0 if it is not included or included but not explained. The document must as a minimum comply with the following requirements: Title of the document, name of the practice owner or group, signed and dated by the relevant authority responsible for approving the document in a group practice or the practice owner, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to a maximum of every 5 years. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

SCORE NOT APPLICABLE:

- ***for practices not performing invasive procedures.***
- ***where research is not conducted in the practice.***
- ***where decontamination is not done in the practice or in a practice that utilises single use disposable equipment/devices.***

31 Domain 1: User Rights

Criterion 1.1.1.1.1 4(2)(a)(iv) The health establishment must provide users with information relating to the complaints, compliments and suggestions management system.

1.1.1.1.1.3 Complainants are informed about the complaint's resolution

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

Select three records of resolved complaints from the **previous twelve months.** Verify whether a record of the communication of the resolution of the complaint to the complainant is available. This could include but is not limited to a **written letter** or **email** or **report on the outcome of the investigation**. Score 1 if the documentation is available and 0 if not available. Score not applicable if there were no complaints received in the previous twelve months.

Aspects

Complaint 1

Complaint 2

Complaint 3

33 Domain 2: Clinical Governance and Clinical Care

Sub Domain 1.2.1 6 User health records and management
Standard 1.2.1.1 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 1.2.1.1.1 6(2)(a) The health establishment must have a health record filing, archiving, disposing, storage and retrieval system which complies with the law.

1.2.1.1.1.3 Health records are archived and disposed of in line with HPCSA guidelines

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

Archiving or disposal of health records in the practice must comply with requirements of HPCSA Booklet 9; section 9 (Duration for the retention of health records). Use the checklist below to determine whether the health establishment adheres to the requirements listed below. Score 1 if compliant and score 0 if not compliant. **Score not applicable where electronic records are used or where the practice has been operational for less than six (6) years.**

Aspects

1. A register of archived records is available.
2. A register of disposed records is available
3. A copy of the disposal certificates is available

34 Domain 2: Clinical Governance and Clinical Care

Criterion 1.2.2.1.1 7(2)(a) The health establishment must ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel.

1.2.2.1.1.1 Healthcare providers are informed about clinical policies and guidelines.

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

Documented evidence that health care providers have been informed about the clinical policies and guidelines must be available. This could include but is not limited to **distribution lists,** which include **health care provider signatures** to indicate they have read and understood the document (which must be **dated and signed**), proof of attendance at meetings where policies and guidelines are discussed or similar evidence for electronic distribution. **Request records from the previous twelve months.**

Not applicable: In a practice where no new health care provider was appointed in the previous twelve months; in a solo practice where the General Practitioner is the only health care provider.

35 Domain 2: Clinical Governance and Clinical Care

Criterion 1.2.3.1.1 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

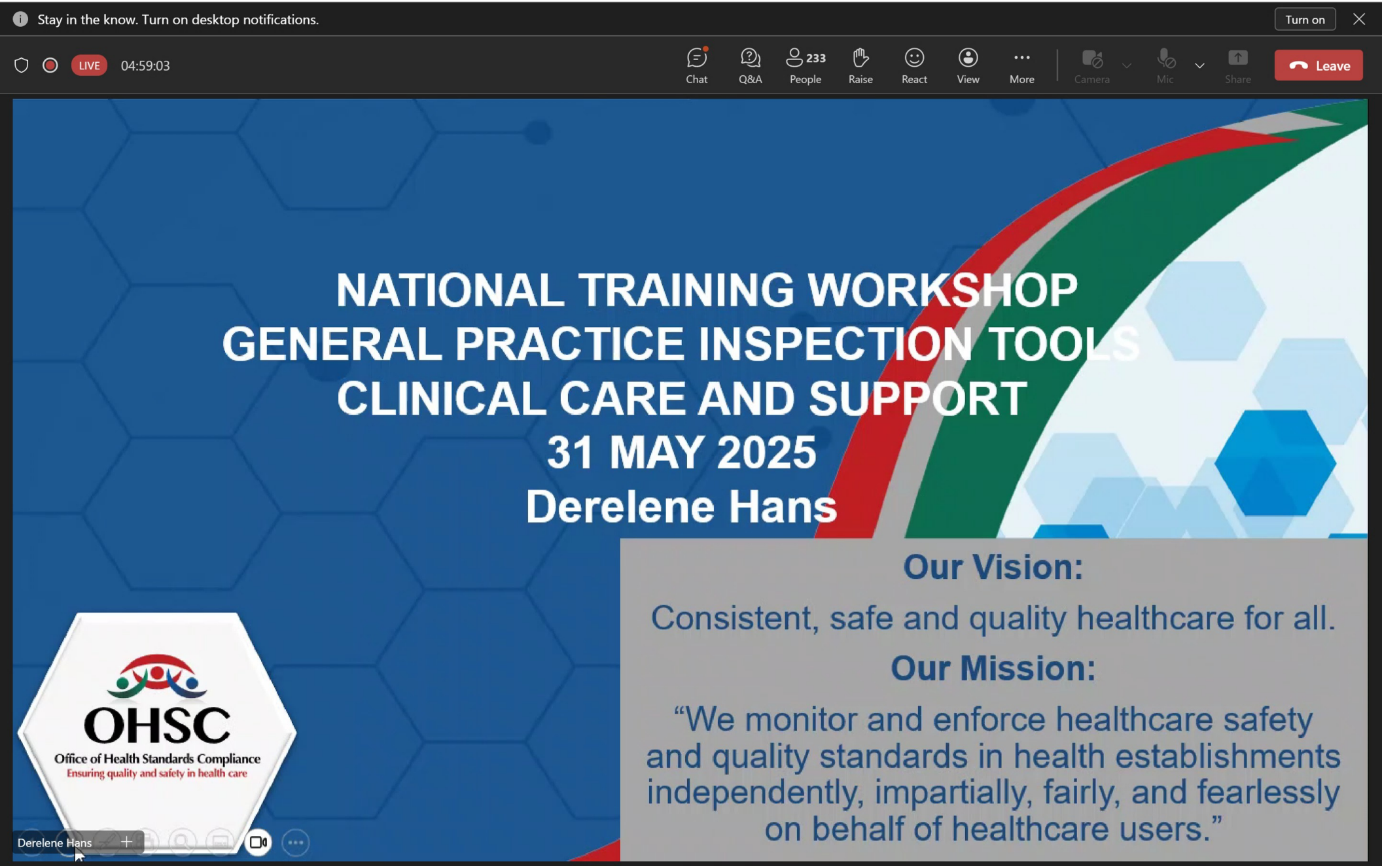
1.2.3.1.1.1 The practice has determined the linen requirements.

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

It is necessary to determine the linen requirements for the practice to ensure sufficient linen is available. The linen requirements

must be documented for the type of linen used in the practice, which can be **cloth** or **disposable linen**. The document must include but is not limited to the type of linen used, the minimum and maximum number for each type of linen. The document can be available manual or electronical.

Not applicable: Never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Derelene Hans

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PRESENTATION OUTLINE

Presentation will cover the following:

- DOMAIN 1: **User Rights**
- DOMAIN 3: **Clinical Support Services**
- DOMAIN 5: **Facilities and Infrastructure**

3

DOMAIN 1: USER RIGHTS

Sub Domain 2.1.1 4 User information

Standard 2.1.1.1 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 2.1.1.1.1 4(2)(a)(i) The health establishment must provide users with information relating to the health care services provided by the health establishment.

2.1.1.1.1.1 Users are informed about services offered in the practice.

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

Information on services provided to users must be available. Services could include but is not limited to management of minor ailments, minor surgical procedures, chronic disease management, travel health, reproductive health and provision of SONARs. The information may be available or displayed at the entrance of a practice which is the sole occupant of a building, or in the foyer or waiting room of a practice that shares a building with other businesses. The information can be on a poster, manual or electronic notice board, booklets or pamphlets or a notice indicating that the information is available on the practice's website.

Not applicable: Never

5 USER INFORMATION CONT…

Criterion 2.1.1.1.3 4(2)(a)(iv) The health establishment must provide users with information relating to the complaints, compliments and suggestions management system.

2.1.1.1.3.1 A system to provide users with information on the complaints management procedure is available.

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

HPCSA Booklet 3 (2.12) Complaints about health services. Everyone has the right to complain about health care services, to have such complaints investigated and to receive a full response on such investigation". There must be a system in place to inform users on the procedure for lodging complaints in the practice. The system could include but is not limited to information displayed (posters or pamphlets or notice) within the practice informing users about the complaints procedure or where to access information about complaints procedure. This can be a manual or electronic system.

Not applicable: Never

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USER INFORMATION CONT...

Criterion 2.1.1.1.5 4(2)(c) The health establishment must display the results of user experience of care surveys conducted within the past twelve months.

2.1.1.1.5.1 Results of the user experience of care survey are displayed.

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

The results from the most recent user experience of care survey for the practice must be visibly displayed. Alternatively, there must be a notice informing users on how to access the user experience of care survey results for the practice. The survey must have been conducted within the previous twelve months.

Not applicable: Never

DOMAIN 1: ACCESS TO CARE

Sub Domain 2.1.2 5 Access to care

Standard 2.1.2.1 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 2.1.2.1.1 5(2)(a) The health establishment must implement a system of triage.

2.1.2.1.1.2 The system to prioritise users requiring urgent care is implemented.

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

Observe whether the system to prioritise users is implemented. This system could include the availability of a health care personnel (such as a doctor or a nurse or a receptionist) to identify users that require urgent care, or a notice displayed in waiting areas or an electronic display or any other system.

Not applicable: Where there are no users requiring prioritisation at the time of inspection.

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ACCESS TO CARE CONT ....

2.1.2.1.1.1 CHECKLIST: Health care personnel are familiar with the system to prioritise users.

Assessment type: Staff interview **Risk rating:** Vital measure

Interview three health care personnel to establish understanding of the system to prioritise users that require urgent care in the practice. This system could include the availability of a health care personnel (such as a doctor or a nurse or a receptionist) to identify users that require urgent care, or a notice displayed in waiting areas or an electronic display or any other system. Score 1 if compliant and score 0 if compliant. **Where the practice has less than three health care personnel score not applicable for the other aspects**

1. Health care personnel 1
2. Health care personnel 2
3. Health care personnel 3

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ACCESS TO CARE CONT....

Criterion 2.1.2.1.2 5(2)(b) The health establishment must ensure access to emergency medical transport for users requiring urgent transfer to another health establishment, and that they are accompanied by a health care provider.

2.1.2.1.2.1 Emergency Medical Service contact number(s) are available.

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

Check whether public and private emergency medical services contact numbers are available.

Not applicable: Never

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ACCESS TO CARE CONT....

Standard 2.1.2.2 ***5(3)*** The health establishment must maintain a system of referral as established by the responsible authority.

Criterion 2.1.2.2.1 5(4)(b) The health establishment must ensure that a copy of the referral document is kept in the user's health record.

2.1.2.2.1.1 CHECKLIST : Copies of referral documents are available at the practice making the referral.

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

Request the copies of referral document (this could be a letter or form) of the **three users** referred out of the practice in the previous three months. The document can be manual or electronic. Score 1 if the referral document contains the aspect listed below and score 0 if the aspect listed below is not documented. Score not applicable if there were no users referred out in the previous three months. (Referral Policy for South African Health Services and Referral Implementation Guidelines, August 2020.pg 16). **Multiple checklist**

Aspects

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Q&A

DOMAIN 3: CLINICAL SUPPORT SERVICES

Sub Domain 2.3.1 *10* Medicines and medical supplies

Standard 2.3.1.1 *10(1)* The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 2.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

2.3.1.1.1.1 CHECKLIST: The practice has a system to order **medicines and medical supplies.**

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

Observe if there is a manual or electronic system to order **medicine and medical supplies** in place.

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MEDICINES AND MEDICAL SUPPLIES CONT…

2.3.1.1.1.3 CHECKLIST: The practice monitors stock levels of **medicine.**

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

Randomly sample **three medicines** held as stock and verify whether minimum, maximum and/or reorder levels are documented. The levels must be recorded on the bin cards, or any other system used by the practice. **In non-dispensing practices, this will be the emergency medicines held as stock.** The system may be manual or electronic. Score 1 if compliant and 0 if not compliant.

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MEDICINES AND MEDICAL SUPPLIES CONT....

2.3.1.1.2.3 CHECKLIST: Cold chain for thermolabile medicines is maintained.

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

Use the checklist below to verify whether the cold chain for thermolabile medicines are maintained. Score 1 if compliant with the aspect below and 0 if not compliant. **Score not applicable where the practice does not keep thermolabile medicine.**

1. Medicine refrigerator is available.

Explanatory note: *The medicine fridge must not contain any food items or beverages.*

2. The temperature of the refrigerator is monitored.

Explanatory note: *The temperature of the refrigerator must be monitored twice a day, 7-12 hours apart, and maintained between 2 and 8 degrees Celsius. The temperature monitoring could be done manually or using an electronic device and should be recorded. Check records from the previous three months, for electronic monitoring historic readings must be made available for review.*

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Busisiwe Mashinini
Thank you for the question. There are requirements across the inspection to...

MEDICINES AND MEDICAL SUPPLIES CONT....

12. Scalpel blades
13. Disposable eye patches
14. Pregnancy test
15. Blood glucose strips
16. Spatula
17. Gauze swabs
18. Cotton wool balls
19. Bandage crepe
20. Needles
21. Alcohol swabs
22. Syringes
23. Urine dipsticks
24. Urine specimen jar or flask
25. Lancets

Not applicable: Where phlebotomy is not done

26. Venepuncture needles
27. Vacutainer needle holder
28. Vacutainer blood collection tubes
29. Pregnancy tests
30. Pap smear collection materials.

Not applicable: where pap smear is not done at the practice

22 MEDICINES AND MEDICAL SUPPLIES CONT....

Criterion 2.3.1.1.3 10 The practice must implement controls for the management, recording and distribution of medicines listed in Schedules 5 and 6 of the Medicines and Related Substances Act.

2.3.1.1.3.1 Schedule 5 and 6 medication storage area is kept locked.

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

Observe whether the schedule 5 and 6 medication storage area is kept locked.

Not applicable: Where the practice does not keep schedule 5 or schedule 6 medicine.

2.3.1.1.3.2 The entries in the schedule 5 and 6 drug register are complete.

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

All columns in the registers must be completed comprehensively. Any omitted information noted during the review of the register will result in a non-compliant score. Verify whether all sections of the register have been completed. In a solo practice there might not be another health care provider to counter sign the entries.

Not applicable: Where the practice does not keep schedule 5 or schedule 6 medicine.

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MEDICINES AND MEDICAL SUPPLIES CONT....

2.3.1.1.3.3 CHECKLIST: Schedule 5 and 6 medicines in stock correspond with the balance recorded in the register.

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

Randomly sample 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 the practice does not keep schedule 5 or schedule 6 medicine**.

1. Medicine 1
2. Medicine 2
3. Medicine 3

24 MEDICINES AND MEDICAL SUPPLIES CONT....

Criterion 2.3.1.1.4 10 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.

2.3.1.1.4.1 CHECKLIST: Medicines in the practice are stored and managed in accordance with Good Pharmacy Practice in South Africa.

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

Check whether the practice complies with the requirements listed below. Score 1 if the aspect is compliant and 0 if not compliant.

1. Shelves or cupboards or medicine trolley allows for rotation of medicines.

2. Shelves or cupboards or medicine trolley are clean.

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MEDICINES AND MEDICAL SUPPLIES CONT....

3. Medicines are stored according to a classification system.
Explanatory note: Verify the classification system used by the practice, including but not limited to storage by formulation, physiological system, alphabetical order, or another method, and confirm that the selected system is followed.

4. There are security and access control measures in the medicine storage area.
Explanatory note: The medicine storage area will include but is not limited to a medicine trolley, medicine room, or medicine cupboard.

5. System is in place to prevent the expiry of medicines.
Explanatory note: Observe whether there is a system to check expiry dates. This will include but is not limited to a colour-coded system for items that expire in a certain month, documentation of expiry dates in a book, First expired First out (FEFO) or any other system.

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MEDICINES AND MEDICAL SUPPLIES CONT....

Criterion 2.3.1.1.5 10 The practice must ensure that medication is prescribed in accordance with legislation and best practice guidelines.

2.3.1.1.5.1 Users are informed about their medicines.

Assessment type: Patient interview **Risk rating:** Vital measure

Interview **three users** who have received medicines and verify whether they have been informed about the aspects listed below. Score 1 if user was informed and 0 if not informed. Score not applicable if the practice does not dispense medicine.

1. The user is informed about what each medicine is for.
2. The user is informed when to take the medicine.

MEDICINES AND MEDICAL SUPPLIES CONT....

Criterion 2.3.1.1.6 *10* The practice ensures that medication is dispensed in accordance with legislation, and to minimise the risk of user harm.

2.3.1.1.6.1 Medicines dispensed for users are labelled as per 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 listed below. Score 1 if the aspect is compliant and 0 if not compliant. **Score not applicable if the practice does not dispense medicine.**

1. The label includes the name of the user
2. The label includes the name of the medicine.

30 MEDICINES AND MEDICAL SUPPLIES CONT....

3. The label includes the strength of the medicine.
4. The label includes the dosage of the medicine.
5. The label includes the route of administration for the medicine.
6. The label includes the frequency with which the medicine should be taken.
7. The label includes the duration for which the medicine should be taken **(where applicable)**
8. The expiry date of the medicine is visible.

MEDICINES AND MEDICAL SUPPLIES CONT....

2.3.1.1.6.2 Medicines are dispensed by licensed health care providers.

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

Observe whether medicine is dispensed to users by a licensed health care provider in terms of Medicines and Related Substances Act, 1965 General Regulations section 14(4).

Not applicable: Where the practice does not dispense medication.

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MEDICAL EQUIPMENT

Sub Domain 2.3.2 *13* Medical equipment

Standard 2.3.2.1 *13(1)* Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

Criterion 2.3.2.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

2.3.2.1.1.1 CHECKLIST: Functional medical equipment is available.

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

Use the checklist below to check whether medical equipment is available and functional in the practice. Score 1 if the item listed is available and functional and score 0 if it is not available or functional.

MEDICAL EQUIPMENT CONT....

Essential basic equipment: Explanatory note: The basic equipment listed in this section must be available in the practice.

1. Stethoscope
2. Stadiometer (to measure height)
3. Tape measure
4. Thermometer
5. Adult weighing scale
6. Baby weighing scale
7. Patella hammer
8. Tuning fork
9. Blood pressure machine (manual or electronic/digital)
10. Diagnostic sets, including ophthalmic pieces (wall-mounted or portable)
11. Gestation calculator (Manual or electronic)
12. Foetal stethoscope/handheld Doppler or Sonar
13. Eye chart (Snellen or equivalent)

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MEDICAL EQUIPMENT CONT....

Equipment for minor surgical procedures. Explanatory note: Score not applicable for equipment not utilised or required in the practice.

21. Ceiling or wall mounted or portable examination light.
22. Suture pack
23. Dressing cart/trolley
24. Electrocautery machine
25. Forceps
26. Suture holder
27. Swab holder
28. Scalpel handle

DOMAIN 5

FACILITIES AND INFRASTRUCTURE

DOMAIN 5: FACILITIES AND INFRASTRUCTURE

Sub Domain 2.5.2 *14* Management of buildings and grounds

Standard 2.5.2.1 *14(1)* The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 2.5.2.1.1 14(2)(a) The health establishment must as appropriate for the type of buildings and grounds of the establishment have all the required compliance certificates in terms of the building regulations.

2.5.2.1.1.1 Fire extinguishing devices are serviced.

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

Each fire extinguishing device must be serviced annually and should have a label indicating the date that it was serviced and the date that the next service is due.

Not applicable: Never

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MANAGEMENT OF BUILDINGS AND GROUNDS

Criterion 2.5.2.1.2 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.

2.5.2.1.2.1 CHECKLIST: The practice building is maintained.

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

Observe the condition of the various areas of the building(s) using the aspects listed below. Score 1 if compliant and score 0 if not compliant. **Score not applicable if the health establishment does not have the listed areas or the aspects.**

1. Walls are intact and not damaged
2. The ceiling is intact and not damaged.
3. The doors are in working condition and not damaged
4. Lights are functional and not broken
5. The floor is intact and not damaged
6. The toilets are functional and not broken
7. Gutters or PVC pipes are intact and not damaged
8. Windows are in working condition (Glass or handles are not broken).

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ENGINERING SERVICES

Sub Domain 2.5.3 *15* Engineering services

Standard 2.5.3.1 *15(1)* The health establishment must ensure that engineering services are in place.

Criterion 2.5.3.1.1 15(2) The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

2.5.3.1.1.1 The practice has a functional piped water supply system.

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

The water supply for the practice must be connected to the reticulation system.

2.5.3.1.1.2 Emergency water supply is available.

Emergency water supply must always be available in case of water supply interruptions. Water can be made available through but not limited to containers with lids or water tanks e.g. JoJo tank, Roto tank or water supplied by service providers). **Not applicable: Never**

ENGINERING SERVICES CONT…

2.5.3.1.1.4 An oxygen cylinder is available in the practice.

Assessment type: Observation **Risk rating:** Non-negotiable measure

Verify whether an oxygen cylinder with a functional gauge is available, oxygen levels must not be below the minimum level indicated in the gauge.

Not applicable: Where an oxygen concentrator is used

2.5.3.1.1.5 Oxygen concentrator is available and functional.

Assessment type: Observation **Risk rating:** Non-negotiable measure

Please note that where an oxygen concentrator is used, a backup electricity supply must be available to ensure that the unit will be functional during interruptions in electricity supply.

Not applicable: Where oxygen cylinders are used.

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SECURITY SERVICES

Sub Domain 2.5.1 *17* Security services

Standard 2.5.1.1 *17(1)* The health establishment must have systems to protect users, health care personnel and property from security threats and risks.

Criterion 2.5.1.1.1 17(2)(a) The health establishment must ensure that security staff are capacitated to deal with security incidents, threats and risks.

2.5.1.1.1.1 Systems are in place to ensure safety in the practice.

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

Verify whether a security system is in place. Security systems could include but are not limited to physical security personnel or systems (security gate with controlled access, boom gates, biometrics, contracted armed response).

Not applicable: Never


Stay in the know. Turn on desktop notifications.
Turn on
LIVE
06:02:01
Chat
Q&A
225
People
Raise
React
View
More
Camera
Mic
Share
Leave
GENERAL PRACTITIONER WORKSHOP
31 MAY 2025
CLINICAL CARE AND SUPPORT
Clinical Governance and Clinical Care
Domain 2
OHSC
Office of Health Standards Compliance
Ensuring quality and safety in health care
Presenter:
Andiswa Mafilika
Andiswa Mafilika

2 CLINICAL GOVERNANCE AND CLINICAL CARE

Presentation Outline

Sub- Domains:

- ❖User health records and Management
- ❖Clinical Management
- ❖Infection Prevention and Control
- ❖Waste Management

4 User health records and Management

DIRECT MEASURE:

Criterion 2.2.1.1.2 6(2)(b) The health establishment must ensure confidentiality of health records.

2.2.1.1.2.1 The Protection of Personal Information Act (POPI Act) is displayed.

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

- Observe whether the Protection of Personal Information Act (POPI Act) is displayed in the practice.

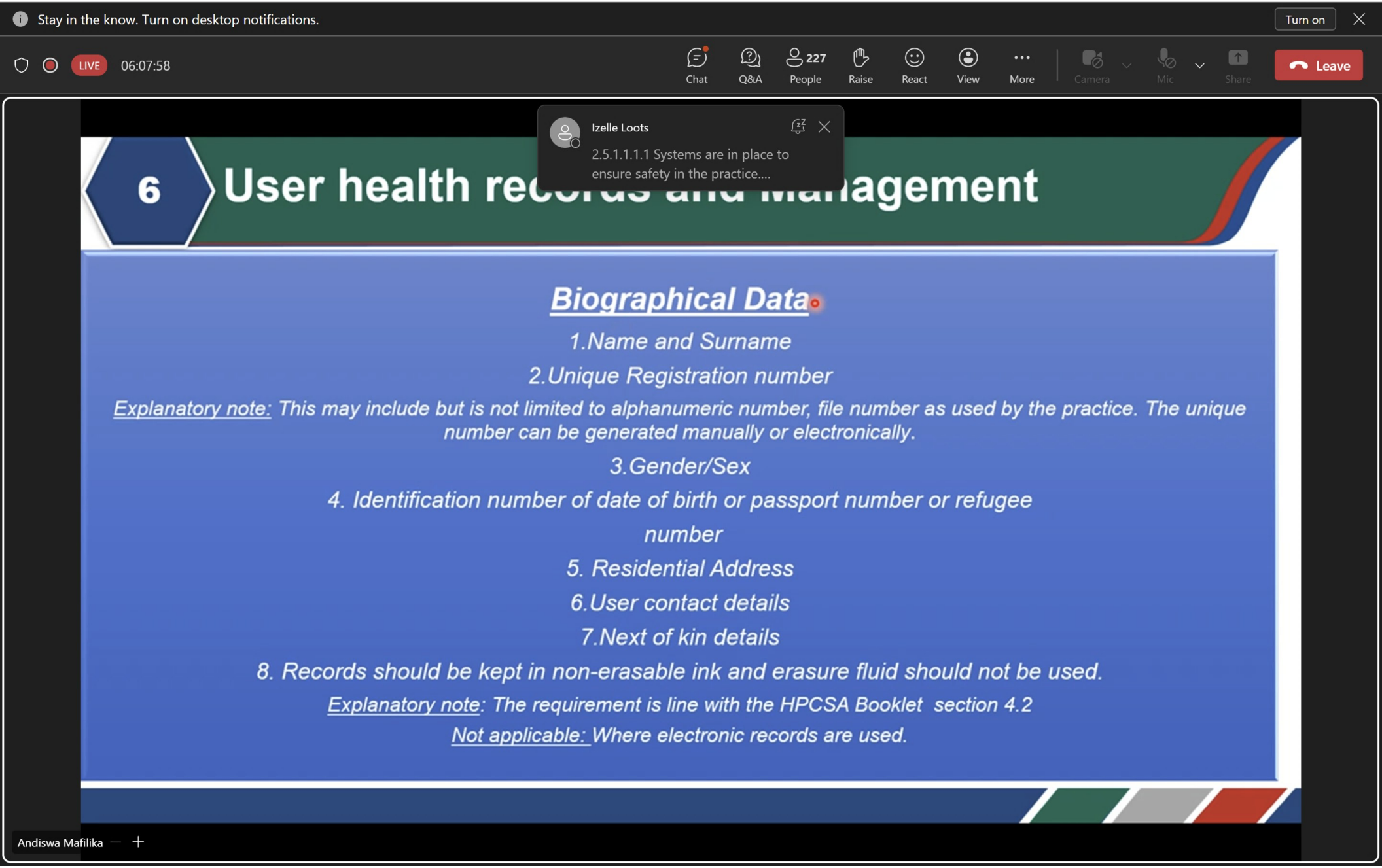
Not applicable: Never

CHECKLIST MEASURE:

2.2.1.1.2.2 *Confidentiality of health records is maintained.*

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

- In line with section 14 of the National Health Act.
- Observe how user health records are managed in various areas within the practice and determine whether unauthorised individuals would be able to access the information in the health records.
- This will include the health records of users waiting to be seen, users who have already been seen but whose records have not yet been returned to the records storage area/room.


Stay in the know. Turn on desktop notifications.
Turn on
LIVE
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Chat
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227
People
Raise
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More
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Izelle Loots
2.5.1.1.1.1 Systems are in place to ensure safety in the practice....
6
User health records and management
Biographical Data
1.Name and Surname
2.Unique Registration number
Explanatory note: This may include but is not limited to alphanumeric number, file number as used by the practice. The unique number can be generated manually or electronically.
3.Gender/Sex
4. Identification number of date of birth or passport number or refugee number
5. Residential Address
6.User contact details
7.Next of kin details
8. Records should be kept in non-erasable ink and erasure fluid should not be used.
Explanatory note: The requirement is line with the HPCSA Booklet section 4.2
Not applicable: Where electronic records are used.
Andiswa Mafilika

7 User health records and Management

CHECKLIST MEASURE:

Criterion 2.2.1.2.2 6(4)(b) The health establishment must record information relating to the examination and health care interventions of users.

2.2.1.2.2.1 *The clinical assessment and management plan for the user is recorded in the user health record.*

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

- Select three health records of users who were seen at the time of inspection or records from the previous months and verify if the aspects listed below have been recorded.
- Score 1 if compliant and 0 if not compliant.
- Score not applicable for any aspects not applicable to the user. The requirement is in line with HPCSA Booklet 9 section 4.1 and section 4.2

8 User health records and Management

Aspects

1. Date of consultation
2. Time of consultation
3. Allergies (where applicable)
4. Assessment of the user's condition
5. Clinical management plan of the user
6. Medication prescribed (where applicable)
7. Details of referrals *(where applicable)*
8. Adverse effects to treatment or medication *(where applicable)*

Aspects cont...

9. *Results of investigations requested*
10. *Follow-up requirements are agreed with users and documented in the user record (where applicable)*
11. Records should be kept in non-erasable ink and erasable fluid should not be used

Explanatory note: ***The requirement is in line with HPCSA***

Not applicable ***Where electronic records are used***

12. Each entry signed by health care provider

9 User health records and Management

CHECKLIST MEASURES:

2.2.1.2.2.2 Diagnostic investigation results are available in the user's health record.

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

- Select health records of three users who have had investigations done in the previous three months and assess whether the results are available in the user's health record.
- Score 1 if the results are available and 0 if not available.
- Manual or electronic health records are acceptable.

2.2.1.2.2.3 Diagnostic investigation results are reviewed by the doctor

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

- Select health records of three users who were seen at the practice in the previous three months and verify whether the results were reviewed by the doctor.
- This will include but is not limited to signing the results or using a stamp or making notes in the record acknowledging the results. If using electronic systems, notes can be made indicating results have been reviewed.

12 User health records and Management

CHECKLIST MEASURE:

Standard 2.2.1.3 6(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 2.2.1.3.1 6 A documented procedure which describes the information to be collected and discussed during the process to obtain informed consent is implemented, in accordance with Chapter 2 of the National Health Act(Section 7).

2.2.1.3.1.1 Informed consent forms are completed correctly.

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

- Select three health records of users who were seen at the time of inspection or health records from the previous three months.
- Verify whether an informed consent was signed for each invasive procedure or treatment.
- Check whether the details listed below are recorded on the consent forms. Score 1 if is recorded and 0 if it is not recorded.

13 User health records and Management

Informed Consent

1. User full name(s) and surname
2. The user's age, date of birth or identity number
3. *The consent form is dated*
4. *The exact nature of the procedure or treatment*

5. *A consent form is signed by the user, the legal guardian or any person legally responsible for the user.*

Explanatory note: Signatory providing informed consent is legally entitled to give informed consent in accordance With section 7 of the National Health Act 62 of 2003,HPCSA Booklet 4 and Section 129 of the Children's Act 38 of 2005

6. The consent form is signed by the health care provider.

Explanatory note: Where this is not practicable, health care provider may delegate the function to another health care provider.

14 Sub domain-Clinical Management

DIRECT MEASURE:

Standard 2.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 2.2.2.1.1 7(2)(a) The health establishment must ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel.

2.2.2.1.1.1 Clinical guidelines are available in consultation rooms.

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

- This includes but is not limited to National Department of Health clinical guidelines or other evidence-based clinical guidelines.
- Check the consulting room(s) for the availability of the latest clinical guidelines.
- Guidelines can also be available electronically or via electronic application.
- *Not applicable*: Never

15 Clinical Management

CHECKLIST MEASURE:

Standard 2.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 2.2.2.2.1 7 The health establishment implements process to ensure environmental cleanliness.

2.2.2.2.1.1 Disinfectants, cleaning materials and equipment are available.

Assessment type: Observation - Risk rating: Essential measure

- ❖Check the available cleaning materials.
- ❖Score 1 if the item is available and 0 if it is not available.
- ❖ Score not applicable if the item is not part of the routine supplies of the practice.

16 User health records and Management

Disinfectant and Cleaning Material

1. Chlorine releasing agent-hypochlorite (e.g Biocide D or Clorox)
2. Alcohol based agent (70%-90%)
3. Detergent-neutral Ph
4. Cleaning solutions are labelled

Cleaning equipment

5.Colour labelled mop- Red for toilets and bathrooms
6.Colour labelled mop-Blue Clinical and non-clinical services
7. Mop labelled for cleaning exterior areas (where applicable)
8.Green bucket and cloths for bathroom and consulting room handwashing basins
9.Red bucket and cloths for toilet
10.White cloths for kitchen
11.Blue bucket and cloths for clinical areas and non-clinical service area

17 Clinical Management

CHECKLIST MEASURE:

Criterion 2.2.2.2.3 7 The practice must have systems in place to ensure users requiring resuscitation receive an immediate response by health care providers trained in resuscitation .

2.2.2.2.3.1 Emergency bag or trolley is stocked with medicines, medical supplies and equipment.

Assessment type: Observation - **Risk rating**: Non-negotiable measure

- Inspect the contents of the emergency bag or emergency trolley against the aspects listed below.
- Score 1 if the aspect listed is available, functional and not expired (where applicable)
- Score 0 if the aspect is not available, not functional or expired (where applicable).

18 Clinical Management

Devices to open and protect airway

1. Oropharyngeal airway (a minimum of two different sizes one for adult and one for paediatric users)

Devices to deliver oxygen/ventilate users

2. Oxygen cylinder or oxygen concentrator x1
3. Manual resuscitator device or bag and valve mask (adult) x1
4. Manual resuscitator device or bag and valve mask (paediatric) x1
5. Oxygen Masks - re-breather (adult) x1
6. Oxygen Mask - re-breather (paediatric) x1
7. Nebulising mask (Paediatric) x1
8. Pulse oximeter (must be available in the vicinity not necessarily on the trolley) x1

19 Clinical Management

Devices to gain intravascular access and administer intravenous fluids

10. Intravenous administration sets x2 sets
11. Intravenous cannulae (a minimum of three different sizes that accommodate both adult and paediatric users)
12. NaCl 0,9% IV solution 1000ml (a minimum of x1 vaculiter)
13. Ringers or Balsol IV solution 1000ml (a minimum of x1 vaculiter)
14. Half Darrows solution 200ml or 500 ml (a minimum of x1 vaculiter)

Equipment to provide cardiac compressions

15. Cardiac resuscitation board x1

Medicine: Emergency treatment for anaphylaxis/initiating resuscitation

16. Adrenaline 1mg ampoule (a minimum of x1 ampoule)
17. Water for injection 10ml (a minimum of x1 ampoule)
18. Hydrocortisone 100mg/2ml (a minimum of x1 ampoule)
19. Promethazine 25mg/ml or 2ml ampoule.

Explanatory note: This can be stored in a schedule 5 lockable cupboard or Doctors bag (a minimum of x1 ampoule)

20 Clinical Management

Medicine: Emergency treatment for anaphylaxis/initiating resuscitation

20. Aspirin 300mg tablet (a minimum of x1 tablet)
21. Salbutamol inhalation ampules (a minimum of x1 ampoule)
22. Diazepam 10 mg ampoule or other suitable Benzodiazepine.

Explanatory note: This can be stored in a schedule 5 lockable cupboard or Doctors bag) (a minimum of x1 ampoule)

23. Dextrose 5% 50ml or 100ml or 200ml (a minimum of x1 vaculiter)
24. Naloxone 0,4mg ampoule(a minimum of x1 ampoule)

21 Clinical Management

CHECKLIST

2.2.2.2.3.2 Medical supplies and equipment for emergency care are available.

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

Inspect whether medical supplies and equipment used for emergency care are available. The items may be available in the emergency bag or trolley or vicinity of the bag or trolley. Score 1 if the aspect listed is available and not expired

•(where applicable) and score 0 if the aspect is not available or expired (where applicable).

Medical Supplies

1. Gloves
2. Syringes (a minimum of two syringes of any size,2ml or 5ml or 10ml or 20ml)
3. Needles (a minimum of three different sizes that accommodate both adult and paediatric users)
4. Alcohol swab
5. Plaster to secure IV
6. Resuscitation protocol or Resuscitation Algorithm

Equipment to diagnose and treat cardiac dysrhythmias and cardiac arrest

7. Automated External Defibrillator (AED) or defibrillator with pads, paddles and electrodes

22 Clinical Management

CHECKLIST MEASURE:

2.2.2.2.3.3 The emergency bag or emergency trolley and emergency equipment are checked.

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

- Request a documented practice for checking the emergency bag or emergency trolley and emergency equipment.
- Verify whether it is checked in line with the documented practice.
- This must also include checking of the defibrillator/Automated External Defibrillator. Request records from the previous month.
- In the event that the Automated External Defibrillator is locked and serviced by an online service centre ,the documentation from the service centre must be requested for the previous month.

Not applicable: Never

23 Sub domain : Infection Prevention and Control

CHECKLIST MEASURE:

Standard 2.2.3.1 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 2.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

2.2.3.1.1.1 Hand washing facilities are available.

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

- Select three different service areas in the practice and use the checklist below to check whether the hand washing facilities and items listed below are available. Score 1 if the aspect is available and score 0 if the aspect is not available.
- Score not applicable if the health establishment has fewer areas than those listed for review.

24 Clinical Management

Hand washing-Aspects

1. Functional hand wash basin

Explanatory note: The basin should not be blocked, broken or have cracks

2. Taps are functional and not broken

3.Plain liquid soap or wall- mounted soap dispenser

4. Paper towel dispenser with disposable hand and paper towels

5.General waste container

Explanatory note: This could be disposable or reusable vessels or bins in which waste is placed and must have an appropriate liner.

25 Infection Prevention and Control

CHECKLIST MEASURES:

2.2.3.1.1.2 An alcohol-based hand rub is available.

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

- Select three user care areas and observe whether alcohol-based hand rub is available.
- Score 1 if available and 0 if not available.
- Where the practice has less than three areas only assess the number of available areas and score not applicable for the other aspects.

2.2.3.1.1.3 Posters on hand hygiene are displayed.

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

- Select three user care areas and observe whether posters on hand hygiene are displayed.
- This could be a single hand hygiene poster or individual posters for hand washing or correct use of alcohol-based hand rub. The posters must be laminated or framed.
- Score 1 if available and 0 if not available.
- Where the practice has less than three areas only assess the number of available areas and score not applicable for the other aspects.

Infection Prevention and Control

Criterion 2.2.3.1.2 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

2.2.3.1.2.1 Clean linen is available in the practice.

Assessment type: Observation - Risk rating: Essential measure

- Check whether clean linen is available as determined by the practice requirements. This can be cloth or disposable linen.

Not applicable: Never

2.2.3.1.2.2 There is a designated area or cupboard for storage of clean linen.

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

- Observe if there is a dedicated area for storage of clean linen.

Not applicable: *Never*

27 Infection Prevention and Control

DIRECT MEASURE:

2.2.3.1.2.3 The practice has a designated area for the temporary storage of dirty linen.

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

This is only required where the practice uses cloth linen.

Not applicable: Where only disposable linen is used.

CHECKLIST MEASURE:

Criterion 2.2.3.1.3 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.

2.2.3.1.3.1 ***Health care personnel are informed about prophylactic immunisations for high-risk infections***.

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

- Interview three health care personnel to establish their awareness of the procedure to follow for accessing prophylactic immunisations for high-risk infections.
- Where the practice has less than three health care personnel available score not applicable for the other aspects.

28 Infection Prevention and Control

CHECKLIST MEASURE:

Criterion 2.2.3.1.4 8 Decontamination processes provide safe, effective decontamination of medical devices.

2.2.3.1.4.1 Health care personnel responsible for decontamination can explain the procedure.

Assessment type: Staff interview - Risk rating: Essential measure

- Interview three health care personnel responsible for decontamination
- Ask them to describe how they perform decontamination of instruments from start to finish. Score 1 if the aspect is described and 0 if not described.
- Score not applicable where decontamination is outsourced or in practices that utilise single use disposable instruments.

29 Infection Prevention and Control

1.Personal protective equipment to be worn.

2. Clean sink or bowel to be filled with water and detergent

3. Detergent solution to be constituted and replaced in accordance with manufacturer's instructions.

Explanatory note: Detergent to disinfect instruments should be used .

4.Instruments to be fully immersed in solution.

5.Instruments to be brushed to remove all visible material

6.Instruments to be rinsed

7.Instruments to be dried before disinfecting

8.Sterile packaging to be done according to procedure.

9.In-pack chemical indicator to be placed in all sets and towels

10.Tracking system indicators to be marked on packs and sets

11.Packing is done in wraps or containers according to the manufactures' instructions and SANS standards(ISO 11607)

12. Storage to ensure the integrity of medicines

Explanatory note: The manner in which sterile packs are stored must prevent physical damage to packages, avoid exposure of packages to moisture.

30 Waste Management

CHECKLIST MEASURE:

Standard 2.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 2.2.4.1.1 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

2.2.4.1.1.1 Health care waste is managed in line with waste management practices.

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

- Use the checklist below to check whether health care risk waste is managed as required.
- Score 1 if the aspect is compliant and score 0 if it is not compliant.

31 Clinical Management

Waste Management – Aspects (Consulting/Procedure/waiting area and Bathroom)

1. Health care risk waste disposal bins with functional lid or health care risk waste box.
2. Health care risk waste disposal bins or boxes lined with red colour plastic bags
3. Health care risk waste disposal bins or boxes contain only health care waste
4. Sharps container.

Explanatory note: Sharps are disposed of in impenetrable, tamperproof containers that is not overflowing.

5. Expired or obsolete medicine is placed in a dark green container marked with the words "Pharmaceutical waste liquid or solid.

Explanatory note: The container can also be located in the Medicine storage or dispensing area.

6. General waste container.

Explanatory note: This could be disposable or reusable vessels or bins in which waste is placed and must have an appropriate liner (black, beige, white, or transparent packaging can be used)

19 Clinical Management

Devices to gain intravascular access and administer intravenous fluids

10. Intravenous administration sets x2 sets
11. Intravenous cannulae (a minimum of three different sizes that accommodate both adult and paediatric users)
12. NaCl 0,9% IV solution 1000ml (a minimum of x1 vaculiter)
13. Ringers or Balsol IV solution 1000ml (a minimum of x1 vaculiter)
14. Half Darrows solution 200ml or 500 ml (a minimum of x1 vaculiter)

Equipment to provide cardiac compressions

15. Cardiac resuscitation board x1

Medicine: Emergency treatment for anaphylaxis/initiating resuscitation

16. Adrenaline 1mg ampoule (a minimum of x1 ampoule)
17. Water for injection 10ml (a minimum of x1 ampoule)
18. Hydrocortisone 100mg/2ml (a minimum of x1 ampoule)
19. Promethazine 25mg/ml or 2ml ampoule.

Explanatory note: This can be stored in a schedule 5 lockable cupboard or Doctors bag (a minimum of x1 ampoule)

20 Clinical Management

Medicine: Emergency treatment for anaphylaxis/initiating resuscitation

20. Aspirin 300mg tablet (a minimum of x1 tablet)
21. Salbutamol inhalation ampules (a minimum of x1 ampoule)
22. Diazepam 10 mg ampoule or other suitable Benzodiazepine.

Explanatory note: This can be stored in a schedule 5 lockable cupboard or Doctors bag) (a minimum of x1 ampoule)

23. Dextrose 5% 50ml or 100ml or 200ml (a minimum of x1 vaculiter)
24. Naloxone 0,4mg ampoule(a minimum of x1 ampoule)


Stay in the know. Turn on desktop notifications.
Turn on
LIVE
06:39:51
Chat
Q&A
230
People
Raise
React
View
More
Camera
Mic
Share
Leave
AutoSave
GP training Compliance Inspectorate - Read-Only — Saved to my Mac
Search (Cmd + Ctrl + U)
Home
Insert
Draw
Design
Transitions
Animations
Slide Show
Record
Review
View
Record
Comments
Share
Paste
Cut
Copy
Format
New Slide
Layout
Reset
Section
Convert to SmartArt
Picture
Shapes
Text Box
Arrange
Quick Styles
Shape Fill
Shape Outline
Sensitivity
Add-ins
Designer
General Practitioner's Training
COMPLIANCE INSPECTORATE
May 2025
Welcome back!
OHSC
Office of Health Standards Compliance
Ensuring quality and safety in health care
Presenter Mr B Khumalo
SPECIFIC MANDATE OF THE PROGRAMME/ CI UNIT
PURPOSE OF THE PROGRAMME/UNIT
Inspection Duration and Types
OHSC Inspectors
Dr. Lesiba Rashokeng
Accessibility: Good to go
Notes
Comments
127%

2 SPECIFIC MANDATE OF THE PROGRAMME/ CI UNIT

- Specific mandate for the unit
- Purpose of the unit
- Inspection duration and types
- The inspectors
- The inspection process

3 SPECIFIC MANDATE OF THE PROGRAMME/ CI UNIT

- The Office of Standards Compliance is mandated by the national health Act 12 of 2013 (79)1(b) which provides that the office must ***inspect and certify*** health establishment as ***compliant or noncompliant*** with prescribed norms and standards or where appropriate and necessary withdraw such certification.

- Sec 82. (1) also provides that a health officer (Inspector) may ***enter any premises***, excluding a private dwelling, at any reasonable time and

(a) inspect such premises establishments, ensure compliance with this Act.

- Procedural regulations pertaining to the functioning of the Office of Health Standard Compliance and handling of complaints by the Ombud, 2016. ***12 (Inspection Strategy, procedures and plan), 13 (Notice of inspection to the health establishment), 14 (Inspection process) and 15 (Additional inspection)***

- Norms and Standards Regulations Applicable to Different Categories of Health Establishments, 2018. These regulations came into effect in February 2019 and are used to ***inspect*** and certify health establishments as compliant. The purpose of these regulations is ***to promote and protect the health and safety of users and healthcare personnel.***

Compliance Decision (Compliance Status Framework – CSF)

RISK RATING

STEP 1

Determine the risk rating for:

STEP 2

- Non-Negotiable Measures (NNMs)
- Essential Measures
- Vital Measures

FACILITY GRADING

STEP 3

Determine the Essential & Vital Grading using the risk rating scores threshold (Step 2)

All Three measures determine the **compliance decision**

Risk Rating Threshold

Grading	Risk- Rating
Excellent	V≥80% E≥70%
Good	V=70-79% E=60-69%
Satisfactory	V=60-69% E=50-59%
Unsatisfactory	V<60% E<50%
V=Vital, E=Essential	

STEP 4

Final Grading for the facility
Determined by selecting the lowest obtained grading for the Essential & Vital measure

STEP 5

To attain a **compliance status** for a facility, a facility must obtain a grading of satisfactory, good or excellent and attain 100% score on NNMs

Stay in the know. Turn on desktop notifications. Turn on

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ngiyathokoza! ro livhuwa!
dankie! ke a leboga! enkosi!
thank you! ndo livhuwa!
inkomu!
ke a leboha! ngiyabonga!
siyabonga!

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

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bkhumalo@ohsc.org.za
support@ohsc.org.za

Dr. Lesiba Rashokeng

Unknown User
Who pays for the inspections

Co...on (Compliance Status Framework – CSF)

RISK RATING

STEP 1

Determine the risk rating for:

STEP 2

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STEP 4

Final Grading for the facility
Determined by selecting the lowest obtained grading for the Essential & Vital measure

STEP 5

To attain a **compliance status** for a facility, a facility must obtain a grading of satisfactory, good or excellent and attain 100% score on NNMs


Stay in the know. Turn on desktop notifications.
Turn on
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National Training Workshop on the General Practice Inspection Tool
Certification and Enforcement
OHSC
Office of Health Standards Compliance
Ensuring quality and safety in health care
31 May 2025
Dr. Lesiba Rashokeng

2 FUNCTIONS OF THE UNIT/PROGRAMME

Certification of Health Establishments (HE's)

Certify all (100%) compliant HE's that are recommended for certification following recommendation by the inspector.

Enforcement Actions taken against non-compliant HEs

Take appropriate and suitable enforcement action against all (100%) persistent non-compliant HEs that are recommended for enforcement action.

Publishing of Bi-Annual Report - on OHSC website and other relevant publications, detailing the inspections done, certificates issued, recommendations made to relevant authorities, appeals tribunals held and complaints received in the previous six (6) months.

CERTIFICATION OVERVIEW

Section 79 (1)(b) of the Act prescribes one of the mandatory functions of the Office is to:

- Inspect and **certify** health establishments as compliant or non-compliant with the prescribed norms and standards, or where necessary, withdraw such certification.
- All health establishments compliant with the prescribed norms and standards, post the inspection process, issued with a certificate of compliance (CoC);
- The issued Certificate of Compliance valid for a period of not more than **four (4) years,** subject to a possible renewal period of not more than **twelve (12) months**;
- The Certificate of Compliance can be suspended or revoked by the OHSC if:
  - ✓ A Compliance Notice is issued against a certified health establishment,
  - ✓ Conditions set out in the compliance notice are not fulfilled;
  - ✓ Recommendation by the Health Ombud following an investigation,
  - ✓ For enforcement purposes.

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

Certificate of Compliance

This Certificate of Compliance is issued by the Office of Health Standards Compliance in terms of section 82(7) of the National Health Act, 2003 (Act No. 61 of 2003) as read with regulation 18 (1) of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations).

A Certificate of Compliance is valid for a period of not more than 4 years, before which time the health establishment must apply for renewal. The Office may, however, in terms of regulation 15(1) of the Regulations, conduct an additional inspection at any time if it has reason to believe that the establishment is failing to comply with the provisions of the Act.

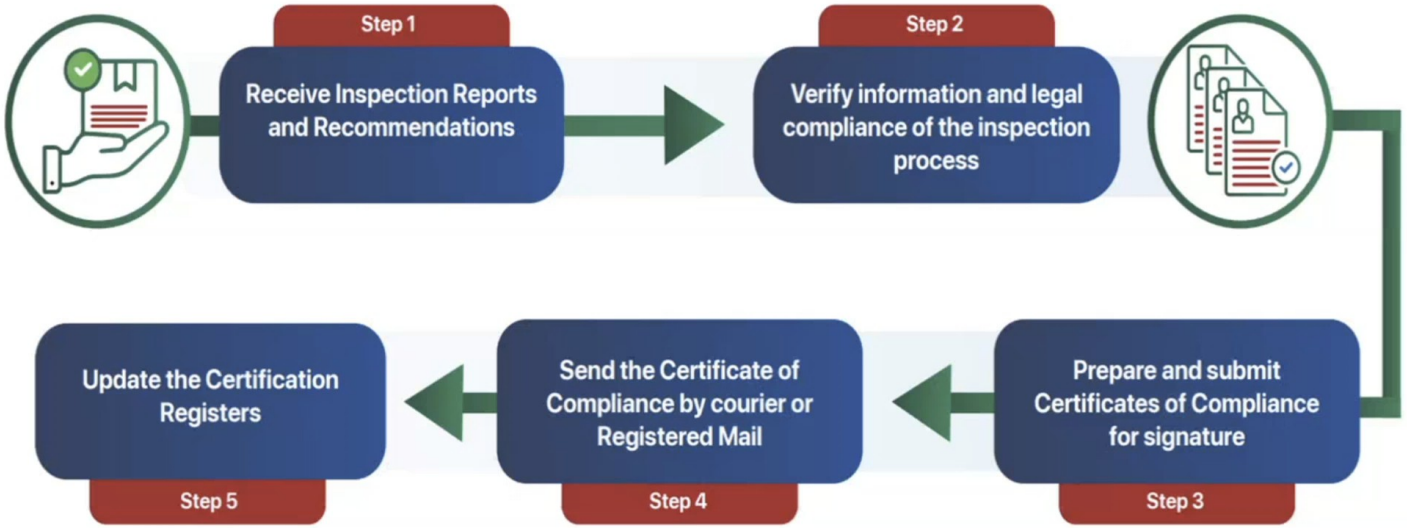
Name of Health Establishment:	Mediclinic Nelspruit Hospital
Category of Health Establishment:	Hospital
Physical address	1 Louise Street Southeuwel Mbombela 1201
Date of inspection	20 May 2024
Compliance Status	Compliant
Grading	Excellent

Chief Executive Officer

12 - August - 2024
Date of certification

11 - August - 2028
Date of expiry of certification

5 CERTIFICATION PROCESS FLOW



6 COMPLIANCE ENFORCEMENT PROCESS

Reg. 22(3) progressive application of compliance enforcement actions.

7 PERSON IN CHARGE ROLES

Inspection & Investigation Support

- Assist Inspectors during inspections
- Respond to Preliminary inspection reports
- Support Ombud investigations
- Maintain updated inspection records

Internal Compliance Leadership

- Display Certificate of Compliance
- Conduct annual Self Assessment for HE
- Assign Person in charge if not self/owner
- Develop and monitor QIP
- Apply for renewal/extension

Information & Communication

- Report on EWS indicators
- File annual return by 31 March every year
- Respond to enforcement actions
- Disseminate OHSC information to staff & users

8

KEY DOCUMENTS

Primary Legislative Framework

- National Health Act 2003(61 of 2003)
- National Health Amendment Act 2013(12 of 2013)
- Procedural Regulations (Government Gazette No. 40350, 13 October 2016)
- Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000)

Operational Documents

- Norms and Standards Regulations
- OHSC Publications
  - Annual inspection strategy
  - Enforcement policy
  - Code of conduct for inspectors
  - Self-assessment tools/frameworks
  - Bi-Annual Reports
- Internal Documents
  - Self-assessment reports
  - QIPs
  - Compliance correspondence with OHSC/Ombud

17 OHSC CONTACT PERSON

Should you wish to communicate with the office regarding certification or enforcement matters, please feel free to contact the office:

Mr Patrick Chauke / Dr LJ Rashokeng

OHSC Certification and Enforcement Unit

Email: pchauke@ohsc.org.za / lrashokeng@ohsc.org.za

Tel: (012) 942-7804 / 082 650 9855 / 060 546 4534

2 Way forward

CPD points will be sent to HPCSA two weeks after the workshop, and no late information will be accepted there after.

- The training video will be shared with the GP groups for distribution
- General Practitioners are required to register on the link
- Inspections will commence end of June 2025
- Guidance and Support workshops will commence in the near future

Inspection tools will be available on the website, with a QR code provided for quick access. Scan the QR code to be taken directly to the inspection tool for convenient use.