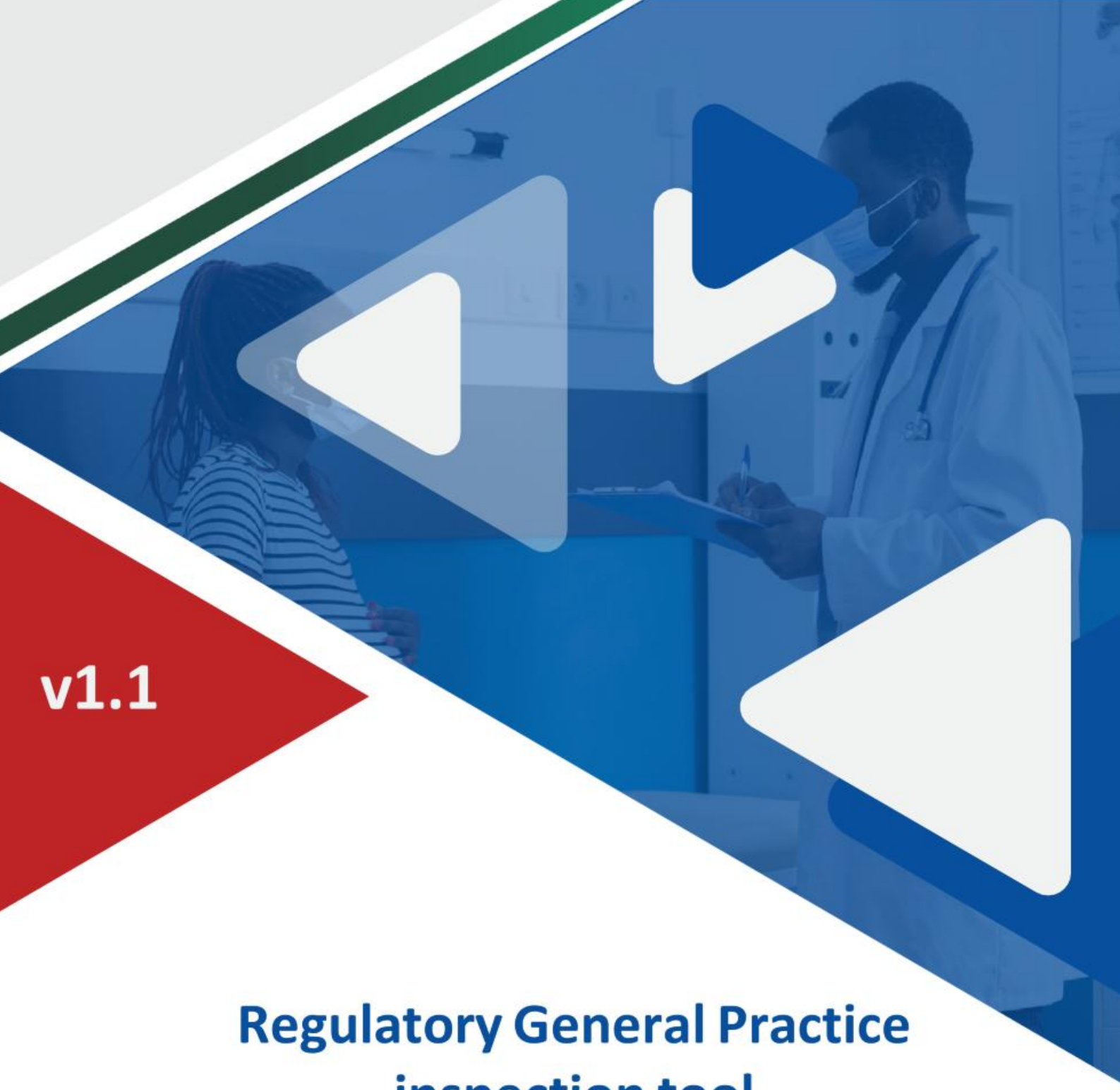

v1.1

Regulatory General Practice inspection tool

Administration and Practice Management

OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

Facility: Date:

- **Tool Name:** Regulatory General Practice Inspection Tool v1.1
- **HEs Type:** General Practice
- **Sector:** Private
- **Specialization:** Group practice and Single/Solo practice

Created By: Health Standards Development and Training

1 Administration And Practice Management

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.**

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: 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	Comment

Aspects	Score	Comment
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.		

1.1.1.1.1.2 Complaints are logged in a register

Assessment type: Document - **Risk rating:** Vital measure
Request the register where complaints are recorded and check if entries were documented in the previous twelve months. The register must include but is not limited to Name and Surname of the complainant, Reference or file number, date of complaint, summary or details of complaint. The register may be a manual or an electronic record. Score 1 if compliant and 0 if not. Not applicable where no complaints have been received in the twelve months before the inspection. Zero reporting must be documented if there were no complaints lodged.

Score	Comment

Aspects	Score	Comment
1. Complaint 1		
2. Complaint 2		
3. Complaint 3		

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.

Score	Comment

Aspects	Score	Comment
1. Complaint 1		
2. Complaint 2		
3. Complaint 3		

Sub Domain 1.1.2 ***5*** Access to care

Standard 1.1.2.1 ***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 1.1.2.1.1 ***5(2)(a)*** **The health establishment must implement a system of triage.**

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

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

Users requiring urgent care could include but is not limited to users with life - threatening conditions, frail users, infants and acutely unwell users. The aspects listed below must be included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, 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	Comment

Aspects	Score	Comment
1. The prioritisation procedure is described.		

2. The manner of communication of the prioritisation procedure to users is described. Explanatory note: The manner of communication could include amongst others: a notice displayed in waiting areas or on notice boards informing users; an electronic display or it can be any other process.		

Domain 1.2 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.**

1.2.1.1.1.1 A standard operating procedure for health records management 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: 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	**Comment**

Aspects	**Score**	**Comment**
1. Filing of the health record.		
2. Maintaining confidentiality and security of user health records. Explanatory note: This requirement must comply with legislative prescripts, where these are available, and minimum standards specified in government policies and guidelines. Please note this will apply to all IT systems where user information is stored and not only the electronic health record. Electronic records must be safeguarded with passwords or any other security measures.		
3. Duration of retention of health records. Explanatory note: This requirement must comply with legislative prescripts e.g. The HPCSA Booklet 9, National Health Act section 13, and Protection of Personal Information Act Section 14. In addition, further guidance is given in Medical Records in South Africa: An MPS Guide Appendix 1: Retention and Destruction of Records. S Anthony June 2016 MPS.		
4. User access to their health records.		
5. The preparation and release of health record documentation to third parties. Explanatory note: This section must include signed consent by the user for the information to be released to the requesting third party, prior to the release of the information.		
6. The archiving of health records.		

7. The disposal of health records. Explanatory note: Confidentiality of the records must be maintained, whether the disposal or destruction is done internally or by a contracted service provider. Reference: Medical Records in South Africa: An MPS Guide Appendix 1: Retention and Destruction of Records. S Anthony June 2016 MPS. Not applicable where no manual records are in use.		

1.2.1.1.1.2 Healthcare personnel responsible for records management have received training or orientation in the management of health records.

Assessment type: Document - **Risk rating:** Essential measure
Request training or orientation records for the previous twelve months and verify if training or refresher training or orientation on health records management has been conducted for health care personnel. Evidence must include an attendance register. This can be manual or electronic. Score 1 if compliant and 0 if not compliant. Score not applicable where there has been no new/revised records management guidelines or newly appointed health care personnel in the previous twelve months.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Health care personnel 1		
2. Health care personnel 2		
3. Health care personnel 3		

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 the medical practice has been operational for less than six (6) years.

Score	**Comment**

Aspects	**Score**	**Comment**
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		

Standard 1.2.1.2 ***6(5)*** The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 1.2.1.2.1 ***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).**

1.2.1.2.1.1 A standard operating procedure for obtaining informed consent 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, 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. The requirement is in line with HPCSA Booklet 4 section 3. Score not applicable If no surgical procedures are performed in the practice.

Score	Comment

Aspects	Score	Comment
1. Procedure for obtaining consent (this will include obtaining consent during an emergency).		
2. Information to be provided to the user. Explanatory note: This will include but is not limited to nature of the procedure, risks, benefits, probability of success, costs, consequences and follow up care.		
3. Legal standing to give informed consent. Explanatory note: Legal standing refers to the user's mental capacity to provide consent or the legal authority of the person providing consent on behalf of the user where the user does not have the mental capacity to provide consent, as defined in HPCSA Booklet 9.		
4. Procedure to review consent.		

Sub Domain 1.2.2 *7* Clinical management

Standard 1.2.2.1 *7(1)* The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 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 guidelines for priority conditions.

Assessment type: Document - **Risk rating:** Essential measure
Documented evidence that health care providers have been informed about the clinical guidelines for priority conditions 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. Score non-compliant if there are no clinical guidelines for priority conditions available in the practice.
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.

Score	Comment

Standard 1.2.2.2 *7(2)* (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 1.2.2.2.1 *7* The practice must implement measures and processes to protect users undergoing invasive procedures.

1.2.2.2.1.1 A standard operating procedure for safe injection practices 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, 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 information may be detailed in a single document or in several documents. The document can be manual or electronic. (www.who.int/infection-prevention).

Score	Comment

Aspects	Score	Comment
1. Clean workspace.		
2. Hand hygiene.		
3. Sterile syringe and needle. Explanatory note: This could be a sterile syringe and needle with re-use prevention and/or injury protection feature whenever possible.		
4. Sterile vial of medication.		
5. Sterile diluent (where applicable)		
6. Skin disinfectant.		
7. Aseptic technique.		
8. Collection of sharps.		
9. Management of multi dose vials.		
10. Waste management.		
11. Recording of administered injection. Explanatory note: This could include but is not limited to name of administrator, time, site of injection, batch number, name of medicine, dosage and route.		

1.2.2.2.1.2 A standard operating procedure for surgical procedures 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, 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 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 If no surgical procedures are performed in the practice.

Score	Comment

Aspects	Score	Comment
1. Consent for procedure obtained.		
2. Identified area for performing surgical procedures.		

3. Management of users receiving local anaesthetics.		
4. Infection prevention and control measures.		
5. Surgical care. Explanatory note: This will include but is not limited to use of diathermy, estimated blood loss, suturing, wound dressing, and histology. These examples do not apply to all procedures.		
6. Monitoring of users before, during and after the procedure.		
7. Documentation of procedure.		

Criterion 1.2.2.2.2 *7* There are mechanisms in place to ensure the safety of users enrolled into research programmes via the practice.

1.2.2.2.2.1 Standard operating procedures for conducting research in the practice 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, score 0 if it is not included or included but not explained. The document must as 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 where research is not conducted in the practice.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Research conducted at the practice must be approved. Explanatory note: All research conducted on human subjects in the Republic of South Africa must be approved by a Health Research Ethics Council registered with the National Health Ethics Research Council, as per Regulation 6(a) of the Regulations relating to research with human participants, R719, 19 Sept 2014. The practice has the required documents, or a copy thereof, that indicate permission was granted for the researcher to conduct the research at that practice.		
2. Researchers declare any potential conflict of interest in relation to the research to be conducted.		
3. The research participants are informed of insurance cover. Explanatory note: Regulation 5(m) of the Regulations relating to research with human participants, R719, 19 Sept 2014 stipulates that users must be informed of insurance for compensation in the event of a research-related injury.		
4. Participants must be provided with comprehensive and understandable information about the aim of the research.		
5. Participants must be provided with comprehensive and understandable information about the risks and benefits of participating in the research.		

6. Participants must be provided with comprehensive and understandable information about their rights.		
7. Participants must sign an informed consent form to participate in the research projects.		
8. The signed informed consent form must be filed.		

Sub Domain 1.2.3 ***8*** Infection prevention and control programmes

Standard 1.2.3.1 ***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 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 manually or electronically.

Not applicable: Never

Score	Comment

Criterion 1.2.3.1.2 ***8*** **The health establishment must report information on health care associated infections and notifiable diseases to the appropriate public health agencies.**

1.2.3.1.2.1 Notifiable medical conditions are reported to the relevant authority.

Assessment type: Document - **Risk rating:** Vital measure
View submissions from the previous six months. Notifiable medical conditions can be reported manually or entered electronically in the web-based system. To register on the platform: https://nmc.nicd.ac.za/Account/Login To report notifiable conditions: https://www.nicd.ac.za/nmc-overview/notification-process/
Not applicable: Where no notifiable medical conditions were diagnosed in the previous twelve months.

Score	Comment

Criterion 1.2.3.1.3 ***8*** **The practice must train health care personnel and users on infection prevention and control practices.**

1.2.3.1.3.1 In-service training on infection prevention and control is conducted for health care personnel.

Assessment type: Document - **Risk rating:** Essential measure
Request the in-service training records for the previous twelve months. Verify whether in-service training on infection prevention and control-related topics has been conducted. Score 1 if there is evidence of in-service training and 0 if not.
Not applicable: Where there have been no new health care personnel appointed in the previous twelve months or if no new or revised infection prevention and control-related guidelines published in the previous twelve months.

Score	Comment

Aspects	Score	Comment

1. Standard precautions. Explanatory note: This will include but is not limited to hand hygiene, use of PPE, and health care waste management.		
2. Transmission-based precautions. Explanatory note: This will include but is not limited to airborne, contact, and droplet precautions.		

Criterion 1.2.3.1.4 *8* Decontamination processes provide safe, effective decontamination of medical devices.

1.2.3.1.4.1 A standard operating procedure for decontamination processes 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, score 0 if it is not included or included but not explained. The document must as 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. Not applicable: Where decontamination is not done in the practice or in practices that utilise single use disposable instruments.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Use of personal protective equipment.		
2. Segregation of clean and dirty areas in the decontamination area.		
3. Manual cleaning and drying of instruments.		
4. Decontamination process.		
5. Maintenance and testing of decontamination equipment.		
6. Sterile packaging to be done according to procedure.		
7. In-pack chemical indicator to be placed in all sets and towels.		
8. Tracking system indicators to be marked on packs and sets.		
9. Packing is done in wraps or containers according to the manufacturer's instructions and SANS standards (ISO 11607).		
10. System for investigating sterilisation failures.		
11. Storage to ensure the integrity of materials.		

1.2.3.1.4.2 Health care personnel responsible for decontamination of instruments have been trained.

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

Request the in-service training records for the previous twelve months. Verify whether in-service training on decontamination of instruments has been conducted. Decontamination is a general term used to describe processes that include cleaning, disinfection and sterilisation (Practical Manual: Implementation of the National Infection Prevention and Control Strategic Framework, October 2021. Page 63.

Not applicable: Where decontamination is outsourced (done outside the practice) or in practices that utilise single use disposable devices/instruments. Where there have been no newly appointed health care personnel responsible for decontamination in the previous twelve months.

Score	Comment

1.2.3.1.4.3 A service level agreement or memorandum of agreement for decontamination services is available.

Assessment type: Document - **Risk rating:** Vital measure
Where decontamination is (outsourced) done outside the practice, a copy of the service level agreement or memorandum of agreement must be available at the practice. The service level agreement or memorandum of agreement must be valid (not expired). It must be signed by the service provider and the responsible authority.
Not applicable: Where service is not outsourced.

Score	Comment

1.2.3.1.4.4 Compliance with service level agreements or memorandum of agreement is monitored.

Assessment type: Document - **Risk rating:** Vital measure
Request records from the previous six months and check whether the service level agreement or memorandum of agreement is monitored. Evidence could include but is not limited to signed monitoring checklists, minutes of meetings, emails, and reports.
Not applicable: Where service is not outsourced.

Score	Comment

1.2.3.1.4.5 Remedial action is taken to rectify the breaches identified.

Assessment type: Document - **Risk rating:** Vital measure
A document reflecting actions taken to rectify identified breaches in the terms of the service level agreement or memorandum of agreement is available.
Not applicable: Where breaches were not identified or where the service is not outsourced.

Score	Comment

Criterion 1.2.3.1.5 *8* The practice must manage and maintain the equipment used for decontamination to ensure sustainability of decontamination services.

1.2.3.1.5.1 Decontamination equipment is tested.

Assessment type: Document - **Risk rating:** Vital measure
Decontamination equipment is tested for functionality in accordance with the manufacturer's instructions. The manufacturer's instructions must be available, as well as the register or logbook indicating that testing is done in accordance with the manufacturer's instructions. In cases where the manufacturer’s instructions are not available, a guiding document developed by the practice must be available. Check records from the previous three months. Score 1 if compliant and 0 if not compliant.
Not applicable Where decontamination is not done at the practice.

Score	Comment

Aspects	Score	Comment
1. Equipment 1		
2. Equipment 2		
3. Equipment 3		

Criterion 1.2.3.1.6 *8* The practice must have systems in place to keep the environment clean by implementing pest control measures in all areas.

1.2.3.1.6.1 The practice has a pest control programme.

Assessment type: Document - **Risk rating:** Vital measure
The practice has a documented pest control program available. If the practice is a tenant of a building, the building manager/owner must provide the practice with the pest control program. Reference: Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework March 2021, page 124.
Not applicable: Never

Score	Comment

Sub Domain 1.2.4 *9* Waste management

Standard 1.2.4.1 *9(1)* The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 1.2.4.1.1 *9(2)(b)* The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

1.2.4.1.1.1 A standard operating procedure for waste management is available.

Assessment type: Document - **Risk rating:** Vital measure
The aspects listed below must be included and explained in the standard operating procedure. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The document must as 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	Comment

Aspects	Score	Comment
1. Segregation of waste.		
2. Handling of waste.		
3. Storage of waste.		
4. Collection of waste.		
5. Disposal of waste.		

1.2.4.1.1.2 A copy of service level agreement or memorandum of agreement for waste removal is available.

Assessment type: Document - **Risk rating:** Essential measure
The service level agreement or memorandum of agreement must be valid (not expired) and signed by the service provider and the practice.
Not applicable: Never

Score	Comment

1.2.4.1.1.3 Compliance with Service level agreements or memorandum of agreement is monitored.

Assessment type: Document - **Risk rating:** Essential measure
Request records from the previous six months and check whether the service level agreement or memorandum of agreement is monitored. Evidence could include but is not limited to signed monitoring checklists, minutes of meetings and reports.
Not applicable: Never.

Score	Comment

1.2.4.1.1.4 Remedial action is taken to rectify the breaches identified.

Assessment type: Document - **Risk rating:** Vital measure
A document reflecting actions taken to rectify identified breaches in the terms of the service level agreement or memorandum of agreement is available.
Not applicable: Where breaches were not identified

Score	Comment

Sub Domain 1.2.5 ***21*** Adverse events

Standard 1.2.5.1 ***21(1)*** The health establishment must have a system to monitor and report all adverse events.

Criterion 1.2.5.1.1 ***21(2)(b)*** **The health establishment must have systems in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events.**

1.2.5.1.1.1 A standard operating procedure for managing adverse drug reactions 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, 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	Comment

Aspects	Score	Comment
1. Immediate action to be taken to manage the user.		
2. Identification of the drug that caused the reaction.		

3. Documentation of reaction in the user health record.		
4. Reporting of adverse drug reaction to relevant authority.		
5. Providing feedback to user.		

1.2.5.1.1.2 Adverse drug reactions are reported.

Assessment type: Document - **Risk rating:** Vital measure
Documented records of reporting of adverse drug reactions to the relevant regulator is available. Request records from the previous three months.
Not applicable: In cases where no adverse drug reactions occurred in the past three months.
Reference: https://www.sahpra.org.za/health-productsvigilance/

Score	Comment

Domain 1.3 CLINICAL SUPPORT SERVICES

Sub Domain 1.3.1 ***10*** Medicines and medical supplies

Standard 1.3.1.1 ***10(1)*** The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 1.3.1.1.1 ***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.**

1.3.1.1.1.1 A standard operating procedure for management of medicines 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, 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	Comment

Aspects	Score	Comment
1. Storage and control of medicines		
2. Ordering of medicines		
3. Security and control of access to the medicine storage area		
4. Cold chain management		
5. Management of expired, obsolete, unusable medicine		

Criterion 1.3.1.1.2 ***10*** **The practice ensures that medication is dispensed in accordance with legislation, and to minimise the risk of user harm.**

1.3.1.1.2.1 The health care providers have valid dispensing license.

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

Where a practice dispenses medication, the current dispensing license obtained in accordance with Regulation 11(a) of the General Regulations made in terms of the Medicines and Related Substances Act, 1965(Act no. 101 of 1965):
Amendment must be available.
Not applicable: Where the practice does not dispense medicine.

Score	Comment

Sub Domain 1.3.2 ***13*** Medical equipment

Standard 1.3.2.1 ***13(1)*** Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

Criterion 1.3.2.1.1 ***13*** **The health establishment must adhere to a planned schedule for maintaining medical equipment.**

1.3.2.1.1.1 Maintenance plan for medical equipment is available.

Assessment type: Document - **Risk rating:** Vital measure
Request the medical equipment maintenance plan for the previous twelve months, the maintenance plan must be aligned to the manufacturer's instructions of each equipment. In cases where the original manufacturer's instructions are not available, a guiding document developed by the practice must be available. The maintenance plan would include all the prescribed maintenance by the Original Equipment Manufacturer, which includes but is not limited to calibration, checks, cleaning, and replacement of parts. The medical equipment that requires maintenance may include but is not limited to Autoclave, ECG machine, Lung function machine, Electronic Blood pressure machine, Diathermy, Sonar.
Not applicable: Never.

Score	Comment

1.3.2.1.1.2 Equipment is maintained per the maintenance schedule.

Assessment type: Document - **Risk rating:** Vital measure
Medical equipment must be maintained as documented in the maintenance plan which is aligned to manufacturer's instructions. Request maintenance records from the previous twelve months and verify whether equipment has been maintained in line with maintenance plan.
Not applicable: Never

Score	Comment

Criterion 1.3.2.1.2 ***13*** **Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.**

1.3.2.1.2.1 Healthcare providers have received training on the use of medical equipment.

Assessment type: Document - **Risk rating:** Essential measure
Request training or orientation records from the previous twelve months. This includes but is not limited to orientation records demonstrating that in-service training or training by the supplier of new equipment has been conducted. Score not applicable where there was no new equipment introduced or where there were no new health care provider appointed in the past twelve months or where the health establishment has less than three health care providers available score not applicable for the other aspects.

Score	Comment

Aspects	Score	Comment
1. Health care provider 1		
2. Health care provider 2		
3. Health care provider 3		

Domain 1.4 GOVERNANCE AND HUMAN RESOURCES

Sub Domain 1.4.1 ***19*** Human resources management

Standard 1.4.1.1 ***19(1)*** The health establishment must ensure that they have systems in place to manage health care personnel in line with relevant legislation, policies and guidelines.

Criterion 1.4.1.1.1 ***19(2)(a)*** **The health establishment must, as appropriate to the type and size of the establishment, have and implement a human resource plan that meet the needs of the health establishment.**

1.4.1.1.1.2 The practice provides induction to newly appointed health care personnel.

Assessment type: Document - **Risk rating:** Essential measure
Request records from the previous twelve months and verify whether induction has been conducted for newly appointed health care personnel. Evidence should include proof of attendance; additional evidence may comprise of an induction programme, presentations and induction report.
Not applicable: Where no new health care personnel were appointed in the previous twelve months, in solo practice where there are no employees

Score	Comment

1.4.1.1.1.3 Health care providers are trained in Basic Life Support (BLS) or Cardiopulmonary resuscitation (CPR) training for professionals.

Assessment type: Document - **Risk rating:** Vital measure
Request documented evidence of Basic Life Support (BLS) or Cardiopulmonary resuscitation (CPR) training for professionals and select three records of health care providers for review. A certificate from an accredited BLS or CPR training for professionals service provider issued within the previous two years must be available. Proof of attendance whilst waiting for a certificate will not be accepted. Score 1 if compliant and 0 if not. Please note, where a health care provider maintains a valid Advanced Cardiovascular Life Support (ACLS) or Paediatric Advanced Life Support PALS) without letting it expire, Basic Life Support (BLS) is not required

Score	Comment

Aspects	Score	Comment
1. Health care provider 1		
2. Health care provider 2		
3. Health care provider 3		

Criterion 1.4.1.1.2 ***19(2)(c)*** **The health establishment must, as appropriate to the type and size of the establishment, have a system to monitor that health care personnel maintain their professional registration with the relevant councils on an annual basis.**

1.4.1.1.2.1 Health care providers have a current registration with relevant health professional bodies.

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

Select records of three health care providers and verify whether current registration with the relevant professional/statutory bodies is available. A copy of the registration certificate or card issued by the professional/statutory body must be available or can be viewed in an online platform of the statutory council. Score 1 if compliant and 0 if not. Where the health establishment has less than three health care providers available score not applicable for the other aspects.

Score	Comment

Aspects	Score	Comment
1. Health care provider 1		
2. Health care provider 2		
3. Health care provider 3		

Sub Domain 1.4.2 *20* Occupational health and safety

Standard 1.4.2.1 *20(1)* The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

Criterion 1.4.2.1.1 *20* The practice protects the health and safety of employees by implementing the requirements of the Occupational Health and Safety Act, 1993 (Act No.85 of 1993).

1.4.2.1.1.1 An occupational health and safety risk assessment has been conducted in the practice.

Assessment type: Document - **Risk rating:** Essential measure
A risk assessment is the process or method of identifying hazards and risk factors that have the potential to cause harm to users and personnel. Request the health and safety risk assessment, which must be conducted at intervals not exceeding two years. This responsibility is required in terms of Sections 8 and 9 of the Occupational Health and Safety Act, 101 of 1992 and the related Regulations. The identification of risks can be done by the practice owner or delegated person or service provider.
Not applicable: Never

Score	Comment

1.4.2.1.1.2 Mitigation plans are implemented for identified risks.

Assessment type: Document - **Risk rating:** Essential measure
Documented evidence of identified risks and the implementation of mitigating actions must be available. The documented evidence may include, but need not be limited to, reports such as hazard identification and risk assessment reports, a quality improvement plan or minutes of meetings in which risk management is discussed, which must be signed and dated. Where the practice is situated in leased premises, the landlord must provide the required document to the tenant.
Not applicable: Where no risks were identified.

Score	Comment

1.4.2.1.1.3 A system to manage occupational injuries and diseases is available.

Assessment type: Document - **Risk rating:** Vital measure
The system must outline the process or procedure to follow including registers, reports or specific forms used. This includes but is not limited to incidents such as exposure to bodily fluids. The documents may be manual or electronic.
Not applicable: Never

Score	Comment

1.4.2.1.1.4 Health care personnel who experienced exposure to bodily fluids receive post-exposure prophylaxis

Assessment type: Document - **Risk rating:** Vital measure
Documented evidence must be available to demonstrate that health care personnel who were exposed to bodily fluids received post- exposure prophylaxis in accordance with national guidelines.
Not applicable: Where no exposure to bodily fluids have been reported or where health care personnel refused post- exposure prophylaxis or where no post exposure prophylaxis was required.

Score	Comment

Domain 1.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 1.5.1 ***14*** Management of buildings and grounds

Standard 1.5.1.1 ***14(1)*** The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 1.5.1.1.1 ***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.**

1.5.1.1.1.1 The building(s) complies with safety regulations.

Assessment type: Document - **Risk rating:** Vital measure
Use the checklist below to check whether the building(s) is (are) compliant with safety regulations. Score 1 if compliant and score 0 if not compliant.

Score	Comment

Aspects	Score	Comment
1. Fire safety compliance certificates. Explanatory note: The certificate is issued when the building is commissioned or when there have been major renovations done in the building. This refers to the certificate issued by the municipality. Where the practice is situated in leased premises, the tenant must request the required document from the landlord		
2. Electrical compliance certificates. Explanatory note: Electrical Certificates of Compliance (C.O.C) are documents issued by a qualified and registered electrician. These certificates provide a guarantee that all work carried out in a building conforms to the regulations set out by the Electrical Contracting Board of South Africa (ECB). Where the practice is situated in leased premises, the tenant must request the required document from the landlord.		

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 General Practices.

Acknowledgments

The Office of Health Standards Compliance wishes to extend heartfelt acknowledgment and gratitude to the following stakeholders who have contributed to the development of the Regulatory General Practice Inspection Tools version 1.1.

- Health Standards Development and Training unit team (Ms. Izelle Loots, Mr. Jabu Nkambule, Ms. Busisiwe Mashinini, Ms. Derelene Hans, and Ms Andiswa Mafilika) for the development of the General Practice inspection tools.
- Dr Thabiso Makola, the former Director: Health Systems, Data Analysis and Research at OHSC, for providing technical support and guidance during the development of the General Practice Inspection tools.
- The Executive Manager Health Standards Design, Analysis and Support (HSDAS), Ms Winnie Moleko; the Chief Operations Officer (COO), Dr Mathabo Mathebula, and the Chief Executive Officer (CEO), Dr Siphiwe Mndaweni, for their guidance and strategic support during the development of the General Practice Inspection tools.
- The internal OHSC teams (Compliance Inspectorate, for their contribution during the development and piloting of the General Practice inspection tools).
- Dr Grace Labadarios, Dr Aquina Thulare and Mr Moremi Nkosi from the National Department of Health for their support, input and comments on the inspection tools during the consultation phase.
- The Unity Forum of Family Practitioners (UFFP) and South African Medical Association (SAMA) leadership Dr Norman Mabasa, Dr Claude Ndlovu, Dr Unben Pillay, Dr Neven Pillay, Dr Mvuyisi Mzukwa, Dr Angelique Coetzee, Dr Ziyanda Mgugudo-Sello and the entire leadership at provincial/regional level for the robust and fruitful engagements during the development of the General Practice Inspection tool.
- Thank you to the following organisations for reviewing and providing feedback during the consultation process: Intercare Group, Solidarity, Netcare Medicross, Aurora Medical Group, KZN Natal Doctors Healthcare Coalition, Emerging Market Healthcare (EMC).

It is hereby certified that the Regulatory General Practice Inspection Tools version 1.1 was developed by the Office of Health Standards Compliance.

MS. WINNIE MOLEKO
EXECUTIVE MANAGER: HEALTH STANDARDS, DEVELOPMENT ANALYSIS AND SUPPORT
DATE: 09/10/2025

SIGNATURE:
DR MATHABO MATHEBULA
CHIEF OPERATIONS OFFICER: OHSC
DATE: 13/10/2025

SIGNATURE:
DR SIPHIWE MNDAWENI
CHIEF EXECUTIVE OFFICER: OHSC
DATE: 13/10/2025

012 942 7700

stddevqueries@ohsc.org.za

www.ohsc.org.za

The Office of Health Standards Compliance Eco
Glades Office Park 1
Block B, 70 Ribbon Grass Road, Highveld,
Centurion Gauteng
0157

Postal Address:
Private Bag X21
Arcadia
0007