



# OHSC

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



## REGULATORY CLINIC INSPECTION TOOL VERSION 1.2

# CLINIC MANAGER



Facility:
Date:

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

# 1 Clinic Manager

## 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 CHECKLIST:** Complaints records reflect compliance with the National Guideline to Manage Complaints, Compliments and Suggestions in the Public Health Sector in South Africa

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

Use the checklist below to check the availability of records required for effective complaints management. Check complaints records for the past three months for statistical data. For complaints letters and redress letters and/or minutes, check the last five resolved complaints for evidence. Note: • The evidence requested below can be available manually or electronically. Score 1 if the evidence is available and score 0 if it is not available. • In cases where no complaints were received in the past three months: The Complaints Compliance Report for the health establishment as generated from the national web-based information system must show 100% compliance for “Null” reporting for the health establishment for the past three months. Where a “Null” report is available, score NA (not applicable) for measures marked with an asterisk '\*'.

Score	Comment	
Aspects	Score	Comment
1. The health establishment/District standard operating procedure to Manage Complaints, Compliments and Suggestions is available		
2. The statistical report for indicators and classifications for complaints is available Explanatory Note: This will be scored not applicable if there were no complaints logged		
3. Complaints register for logging complaints is available		
<b>If complaints letters are available in the complaints file (check the last 5 complaints resolved)</b>		
4. Complaints file 1*		
5. Complaints file 2*		
6. Complaints file 3*		
7. Complaints file 4*		

8. Complaints file 5*		
<p>Complaints redress letters and/or minutes are available in the complaints file (check the last 5 complaints resolved). Explanatory note: A written letter or report on the outcome of the investigation should be provided to the user, families or supporting persons who lodged the complaint. Redress refers to a range of appropriate responses that can be provided to a user or families/supporting persons by a health establishment. Such responses or remedies can include but are not limited to an apology, an explanation or an acknowledgement of responsibility. NB: Telephonic conversations will be accepted as a form of redress when the user or complainant cannot be contacted using the normal redress procedure. This could include but is not limited to users in rural areas, users who have relocated, users who do not have postal addresses, users in informal settlements and users who cannot come to the health establishment for any other reason.</p>		
9. Complaints file 1*		
10. Complaints file 2*		
11. Complaints file 3*		
12. Complaints file 4*		
13. Complaints file 5*		

**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 CHECKLIST:** The standard operating procedure (SOP) to prioritise very sick, frail and elderly health care users is available.

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

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

Score	Comment	
Aspects	Score	Comment

1. The prioritization procedure for the health establishment is described. Explanatory Note: This could include amongst others: availability of a dedicated person at waiting areas to identify these users and inform others users of the prioritisation process; a notice put in waiting areas and in notice boards informing users that the above mentioned users will be prioritised; an electronic display at waiting areas indicating that the users mentioned above will be prioritised or it can be any other process		
2. The procedure is displayed in at least two official local languages in the waiting area indicating the prioritisation process for very sick, frail and elderly patients.		
3. In-service training for ALL staff on prioritisation process		
4. Delegate the function of prioritisation process to a designated staff member on a daily basis		
5. Conducting random spot checks during the day to determine if the very sick, frail, and elderly patients are prioritised.		

**Criterion 1.1.2.1.2 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.**

**1.1.2.1.2.1** There is a pre-determined Emergency Medical Services response time to the health establishment.

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

There are currently no specified Norms for EMS response time. Inspector to accept the pre-determined EMS response times provided by the health establishment. The pre-determined EMS response times from the previous quarter are documented and available. Not Applicable: Never

Score	Comment

**1.1.2.1.2.2** The health establishment monitors the Emergency Medical Service response times.

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

A register or records documenting the following will be required for evidence of compliance: Name of the user for whom the ambulance is requested, the time the request was made and the time the ambulance arrived. For Gateway clinics, this will be monitoring of the response time for the team responsible for transferring the user to the Emergency Unit. Not applicable: Never

Score	Comment

**1.1.2.1.2.3** The health establishment reports delays in Emergency Medical Service response times to the relevant authority.

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

Evidence of reporting to District Office will be required. For Gateway clinics, this will be reporting to the relevant hospital Committee. A report or an email sent to the relevant authority will be required. Not applicable: Where there have been no delays in EMS response times, or user transfers in Gateway Clinics

Score	Comment

**Criterion 1.1.2.1.3 5(2)(c) The health establishment must adhere to clinical guidelines on stabilizing users presenting in an emergency before referring them to another health establishment.**

**1.1.2.1.3.1** Professional nurses have received training in Basic Life Support (BLS).

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

Training should be provided by an accredited service provider. A Basic Life Support certificate from an accredited service provider issued within the previous two years will be required. In clinics with five or more professional nurses, at least 80% must have a certificate (round up from 75% where necessary). In clinics with four professional nurses, at least three must be trained. In clinics with three or fewer professional nurses, all of them must be trained. Proof of attendance whilst waiting for a certificate will not be accepted. Not applicable: Never

Score	Comment

**Standard 1.1.2.2 5(3)** The health establishment must maintain a system of referral as established by the responsible authority.

**Criterion 1.1.2.2.1 5(4)(a) The health establishment must ensure that users are provided with information relating to their referral to another health establishment.**

**1.1.2.2.1.1 CHECKLIST:** The standard operating procedure for the referral system is available.

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

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

Score	Comment	
Aspects	Score	Comment
1. District referral network		
2. Referral register		
3. Standardised user referral form		
4. Standardised user referral feedback form		

**Sub Domain 1.1.3 22** Waiting times

**Standard 1.1.3.1 22** The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

**Criterion 1.1.3.1.2 22** Waiting times are monitored by the health establishment.

**1.1.3.1.2.1** Compliance with waiting time target(s) is monitored by the health establishment.

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

Request the tools used for the previous six months for monitoring waiting times and assess if the health establishment monitors waiting times. Not applicable: Never

Score	Comment

**1.1.3.1.2.2** The waiting time survey report is available.

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

The report from the previous six months must be available. Not applicable: Never

Score	Comment

**Criterion 1.1.3.1.1 22 Waiting times are monitored and improvement plans are implemented.**

**1.1.3.1.1.1** A quality improvement plan indicates corrective measures taken where waiting time targets are not met.

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

There must be documented evidence of action taken to reduce waiting times at the health establishment, aiming towards achievement of the waiting times targets. This could be a Quality Improvement plan(QIP). This does not need to be a stand-alone QIP, the information could be in a consolidated QIP addressing other gaps in the health establishment. Not applicable: Where waiting time targets are met

Score	Comment

**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 CHECKLIST:** The standard operating procedure for key functions of health records management is available.

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

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

Score	Comment	
Aspects	Score	Comment
1. Accessing of user records		
2. Tracking of user records		

3. Filing of user records		
4. Storage of user records		
5. Archiving of records		
6. Disposal of records		

**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 HPCSA requirements.**

**1.2.1.2.1.1 CHECKLIST:** The standard operating procedure for informed consent is available which includes the aspects listed below.

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

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

Score	Comment	
Aspects	Score	Comment
1. The signatory providing consent must be legally entitled to give informed consent Explanatory note: As described in the National Health Act, this can be a person authorised by the court (e.g. a curator), or in order of priority, the user's spouse, partner, parent, grandparent, major child or brother or sister. In an emergency, lifesaving procedures can be authorised by the health care provider, if "the treatment is limited to what is immediately necessary to save life or avoid significant deterioration in the user's health" HPCSA, Booklet 4. In case of a child, the age to give consent is over 12 years in accordance with sections 129(2)(a)(b) and 129(3)(a)(b)(c) of the Children's Act 38 of 2005.		
2. The exact nature of the operation/procedure or treatment, including the site and side where relevant, must be communicated to the user		
3. The user's full names must appear on the consent form		
4. The age or date of birth or identity number of users must be reflected on the consent form		
5. The consent form must be signed by the user, their legal guardian (for minors) or the person legally responsible for the user (adults with diminished mental capacity)		
6. The consent form must be signed by the health care provider who will perform the procedure		
7. The consent form must be dated		
8. All entries on the form must be legible		

**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 CHECKLIST:** National guidelines on priority health conditions are available.

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

Use the checklist below to check whether a copy of the guidelines is available. Guidelines can also be available electronically or via an application programme (app). Check that the most current guidelines are being used. Score 1 if available and score 0 if not available.

Score	Comment	
Aspects	Score	Comment
1. National Consolidated Guidelines for the Prevention of Mother-to-Child Transmission of HIV and the Management of HIV in Children, Adolescents and Adults, 2015 or latest		
2. National Tuberculosis Management Guidelines, 2014 or latest		
3. National Guidelines for the Management of Tuberculosis in Children, 2013 or 2014 or latest		
4. National Management of Drug-Resistant Tuberculosis. Policy Guidelines, 2013 or latest		
5. Infection Prevention and Control Guidelines for TB, MDR-TB and XDR- TB, 2015 or latest		
6. Guidelines for Maternity Care in South Africa, 2016 or latest		
7. Sexually Transmitted Infections Management Guidelines, 2015 or latest		
8. National Management of Type 2 Diabetes at Primary Care Level, 2014 or latest		
9. National Clinical Guidelines for the management of hypertension, 2006 or latest		

**1.2.2.1.1.2 CHECKLIST:** There is evidence that healthcare personnel have been informed about national guidelines on priority health conditions.

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

Documented evidence that personnel have been informed about the clinical policies and guidelines must be available, this could include but is not limited to distribution lists which include personnel signatures to indicate they have read and understood the



document (which must be dated and signed), proof of attendance of meeting where policies and guidelines are discussed or similar evidence for electronic distribution. Score 1 if such evidence is available and score 0 if it is not available.

Score	Comment	
Aspects	Score	Comment
1. National Consolidated Guidelines for the Prevention of Mother-to-Child Transmission of HIV and the Management of HIV in Children, Adolescents and Adults, 2015 or latest		
2. National Tuberculosis Management Guidelines, 2014 or latest		
3. National Guidelines for the Management of Tuberculosis in Children, 2013 or 2014 or latest		
4. National Management of Drug-Resistant Tuberculosis. Policy Guidelines, 2013 or latest		
5. Infection Prevention and Control Guidelines for TB, MDR-TB and XDR- TB, 2015 or latest		
6. Guidelines for Maternity Care in South Africa, 2016 or latest		
7. Sexually Transmitted Infections Management Guidelines, 2015 or latest		
8. National Management of Type 2 Diabetes at Primary Care Level, 2014 or latest		
9. National Clinical Guidelines for the management of hypertension, 2006 or latest		

**Criterion 1.2.2.1.3 7 The health establishment monitors indicators of clinical risk and implements actions to mitigate risk when necessary.**

**1.2.2.1.3.1 CHECKLIST:** The clinical risk aspects listed below are addressed in the Quality Improvement Plan.

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

Request the quality improvement plan from the previous six months and assess if the aspects listed below are addressed. The plan should contain the gaps identified and the interventions to be implemented. Score 1 if compliant and score 0 if not compliant. Score not applicable (NA) where gaps have not been identified for a specific aspect.

Score	Comment

Aspects	Score	Comment
1. Complaints statistical data - relating to clinical care		
2. Patient safety incident reported(incidents related to clinical care)		
3. Clinical record audit		
4. Annual risk assessment for infection prevention and control		
5. Loss to follow-up of HIV and TB users		
6. Tracer list medicine stock-out		
7. Laboratory specimen collection material stock-out		

**1.2.2.1.3.2 CHECKLIST:** Training is provided to professional nurses on clinical guidelines.

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

Use the checklist below to determine whether the training on clinical guidelines is provided to professional nurses. Score 1 if compliant and score 0 if not compliant. Note: For aspects one and two below: In clinics with five or more professional nurses, at least 80% must have a certificate (round up from 75% where necessary). In clinics with four professional nurses, at least three must be trained. In clinics with three or less professional nurses, all of them must be trained.

Score	Comment

  

Aspects	Score	Comment
1. 80% of professional nurses have been trained on Adult Primary Care or Practical Approach to Care Kit		
2. 80% of professional nurses have been trained on Integrated Management of Childhood Illness		
3. 50% of professional nurses at the health establishment are trained on BANC Plus		

**1.2.2.1.3.3 CHECKLIST:** The health establishment conducts clinical audits of each priority programme at least annually.

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

Request the clinical audit reports/documents and assess if the health establishment has conducted clinical audits for the conditions/programmes listed below. Score 1 if compliant and score 0 if not compliant.

Score	Comment

Aspects	Score	Comment
1. HIV/TB		
2. NCD (diabetes and hypertension)		
3. Maternal health (ANC & PNC)		
4. Well baby		
5. Sick child (IMCI)		

**1.2.2.1.3.4 CHECKLIST:**80% of the user records audited for clinical audits are compliant.

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

Request the Summary of Results Table for clinical record audits performed by the health establishment in the previous 12 months. (Please note that this may be the incomplete table for the current financial year and the completed table for the previous financial year. Assess the audit results for the 12 months prior to the inspection only.) Check whether 80% of records audited have achieved 100% compliance with the clinical audit checklists provided by the NDoH, as determined using the LQAS method described in the National Clinical Record Audit Guideline for Primary Healthcare Facilities. This will be indicated in the Summary of Results Table. Score 1 if the Table indicates that the target of 80% compliance has been achieved and score 0 the target has not been achieved.

NB: Inspectors should not calculate the percentage themselves.

Score	Comment	
Aspects	Score	Comment
1. HIV/TB		
2. NCD (diabetes and hypertension)		
3. Maternal health (ANC & PNC)		
4. Well baby		
5. Sick child (IMCI)		

**1.2.2.1.3.5 CHECKLIST:** National guidelines are followed for all notifiable medical conditions.

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

Assess if the health establishment complies with the requirements for recording and reporting of notifiable diseases listed below. The evidence could be obtained electronically or manually. Score 1 if compliant; score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment

1. Notifiable medical conditions are recorded in the notification booklet or entered electronically in a web-based system Explanatory note: The health establishment should be aware of the number of cases of different notifiable diseases presenting in order to identify emerging trends as early as possible and report these to the relevant authority. Look at the GW17 register to see if all diagnosed notifiable diseases have been recorded.		
2. All notifiable diseases are reported using the prescribed form or electronically in a web-based system		
3. View submissions from the previous six months. The health establishment should produce evidence that the report has been sent to the public agency. This could be via a fax, email, post or a messenger. How to report NMC? Reporting can be done either via a paper based or an electronic notification. Paper based notification o Complete the NMC Case Notification Form. Send the NMC Case Notification Form to NMCsurveillanceReport@nicd.ac.za or fax to 086 639 1638 or NMC hotline 072 621 3805. Form(s) can be sent via SMS, WhatsApp, email, fax. Send a copy to the NMC focal person at Sub District/District (details given on the NMC Notification booklet cover page).o The NMC Focal Person at health facility level or Sub-District must ensure that the forms are captured electronically. or Electronic notification via the NMC APP; Download the NMC APP from <a href="http://www.nicd.ac.za/notifiable-medical-conditions/">http://www.nicd.ac.za/notifiable-medical-conditions/</a> or via your cell phone app store		

**1.2.2.1.3.6 CHECKLIST:** The targets for proxy indicators for clinical risk are met.

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

Request records from the previous quarter to determine whether the targets set for proxy indicators of clinical risk are met. Score 1 if the targets are met and score 0 if the targets are not met. NB: The indicators for TB do not include MDR and XDR TB. For the indicator on Immunisation coverage request annualised records.

Score	Comment	
Aspects	Score	Comment
1. TB treatment success rate is at least 87% (Excluding MDR and XDR patients)		
2. TB (new pulmonary) defaulter rate is less than 5%		
3. Antenatal visit rate before 20 weeks gestation is at least 70%		
4. Antenatal user initiated on ART rate is at least 97%		
5. Immunisation coverage under one year (annualised) is at least 86%		

**1.2.2.1.3.7 CHECKLIST:** There is an improvement in proxy indicators for clinical risk.

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

Request records from the previous quarter relative to the inspection, and records from the same quarter of the previous financial year. For example, if the inspection is conducted in the third quarter of the 18/19 financial year, request the records for the second quarter of the 18/19 financial year, and the second quarter of the 17/18 financial year. Compare the rates from the two quarters (second quarter of 17/18 vs 18/19) to check whether there has been an improvement for proxy indicators for clinical risk. Score 1 if there is an improvement of 5% or more and score 0 if the improvement is less than 5%. Score NA (not applicable) if the targets for proxy indicators for clinical risk have been met. NB: For the indicator on Immunisation coverage request annualised records.

Score	Comment	
Aspects	Score	Comment
1. TB treatment success rate has increased by at least 5% from the previous year		
2. TB (new pulmonary) defaulter rate has improved by at least 5%		
3. Antenatal visit rate before 20 weeks gestation has increased by at least 5% from the previous year		
4. Antenatal users initiated on ART rate has increased by at least 5% from the previous year		
5. Immunisation coverage under one year (annualised) has increased by at least 5% from the previous year		

**Criterion 1.2.2.1.2 7 The health establishment implements process to ensure environmental cleanliness.**

**1.2.2.1.2.1** All cleaners have been trained in cleaning procedures.

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

Request the training records for cleaning staff. Review the records to determine whether all cleaners at the health establishment have attended training in the cleaning procedures to be followed. Not applicable: Never

Score	Comment

**1.2.2.1.2.2** Records show that pest control is done according to schedule.

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

Regular pest control will ensure that infestations of the building are prevented. The health establishment must have a documented schedule for pest control. Services must be delivered according to schedule. In cases where the service provider has found evidence of pests, fumigation or other relevant treatment is done as required; where there is no evidence of pests documented confirmation of the visit and inspection must be available. For health establishments that are not provided with an invoice, evidence of pest control can include signatures in the visitor's book or similar proof. Not applicable: Never

Score	Comment

**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)(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.

**1.2.3.1.1.1 CHECKLIST:** The standard operating procedure for the management of users with highly infectious diseases is available.

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

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

Score	Comment	
Aspects	Score	Comment
1. Users with highly infectious diseases are accommodated in a designated room or area in the clinic		
2. Cleaning and disinfection of the designated room or area is conducted immediately after the user leaves the area or room		
3. Availability of personal protective equipment		

**1.2.3.1.1.2 CHECKLIST:** The standard operating procedure for standard precautions is available.

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

Read through the standard operating procedure and confirm whether the aspects listed below are included and explained. The information can be detailed in a single document or several separate documents. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained.

Score	Comment	
Aspects	Score	Comment
1. Hand hygiene		
2. Personal Protective Equipment		
3. Patient placement		

4. Appropriate use of antiseptics, disinfectants and detergents		
5. Respiratory hygiene and cough etiquette		
6. Injection safety, prevention of injuries from sharp instruments.		
7. Environmental cleanliness		
8. Decontamination of medical devices		
9. Handling of linen and laundry		
10. Principles of asepsis		
11. Post-exposure prophylaxis		

**1.2.3.1.1.3 CHECKLIST:** All healthcare workers have been trained on standard precautions in the past two years.

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

Use the checklist below to check whether health care workers have received in-service training in standard precautions in the past two years. Select two health care providers and two cleaners from the health establishment's personnel. Request the training records (attendance registers). Score 1 if the health care workers have been trained and score 0 if they have not been trained.

Score	Comment

Unit 1 Healthcare Provider 1

Aspects	Score	Comment
1. Hand hygiene		
2. Personal Protective Equipment		
3. Prevention of respiratory infections		
4. Safe injection practices		
5. Sharps safety		
6. Environmental cleanliness		
7. User Care equipment		
8. Handling of linen		

Unit 2 Healthcare Provider 2

Aspects	Score	Comment
1. Hand hygiene		

2. Personal Protective Equipment		
3. Prevention of respiratory infections		
4. Safe injection practices		
5. Sharps safety		
6. Environmental cleanliness		
7. User Care equipment		
8. Handling of linen		

Unit 3 Cleaner 1

Aspects	Score	Comment
1. Hand hygiene		
2. Personal Protective Equipment		
3. Prevention of respiratory infections		
4. Environmental cleanliness		
5. Handling of linen		
6. Waste management and disposal		

Unit 4 Cleaner 2

Aspects	Score	Comment
1. Hand hygiene		
2. Personal Protective Equipment		
3. Prevention of respiratory infections		
4. Environmental cleanliness		
5. Handling of linen		
6. Waste management and disposal		

**1.2.3.1.1.4 CHECKLIST:** All healthcare workers are made aware of the provincial letter or memo or circular or policy that inform personnel of the procedure to follow for prophylactic vaccinations.

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

Use the checklist below to check whether health care providers are made aware of and know the contents of the communication from the province informing them about the procedure on accessing prophylactic vaccinations for high- risk infections. Score 1 if compliant and score 0 if not compliant.

Score	Comment



Aspects	Score	Comment
1. Letter or memo or circular or policy from the provincial head of health or the delegated personnel member at the provincial office that informs personnel of the procedure to follow for prophylactic vaccinations is available. Explanatory note: Request the letter or memo or circular or policy addressing the aspect listed above.		
2. Letter or memo or circular or policy from the provincial head of health or the delegated personnel member at the provincial office indicating the recommended vaccinations as determined by the disease profile of the health establishment or region is available Explanatory note: Request the letter or memo or circular or policy addressing the aspect listed above.		
3. Letter or memo or circular or policy from the provincial head of health or the delegated personnel member at the provincial office indicating the procedure to follow to obtain prophylactic vaccinations, including who will bear the cost of vaccinations, is available Explanatory note: Request the letter or memo or circular or policy addressing the aspect listed above.		
4. Personnel have signed an acknowledgment indicating that they are aware of and know the contents of the letter or memo or circular or policy and its application Explanatory note: The documented evidence could include distribution lists, in-service training records or meeting sessions; personnel signatures should be in the record (dated and signed).		

**1.2.3.1.1.5** Personnel who experience needle stick injuries receive post-exposure prophylaxis.

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

Proactive management of needlestick injuries is necessary to prevent the development of blood borne diseases. Documented evidence must be available to demonstrate that personnel who have had a needle stick injury receive prophylaxis in accordance with nationally approved guidelines. Not applicable: Where no needle stick injuries have been reported

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 CHECKLIST:** The standard operating procedures for handling, storage and safe disposal of waste are available, which include the aspects listed below .

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

Request a copy of the standard operating procedure(s) for general and health care risk waste. Read through the standard operating procedure and confirm whether the aspects listed below are included and explained. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained.

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

**1.2.4.1.1.2** A copy of the signed waste removal service level agreement between the health department and the service provider is available.

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

This is to ensure proper management of waste. The service level agreement must be valid (not expired) and signed by the service provider and the responsible accounting officer. Not applicable: In Gateway clinics where waste is removed to the central store of the hospital.

Score	Comment

**1.2.4.1.1.3** Waste is removed in line with the service level agreement.

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

Request a copy of the service level agreement and records used to document the removal of waste by the service provider. This could be a register. Assess records from the last three months to see if waste is collected as indicated in the service level agreement. Not applicable: In Gateway Clinics where waste is stored in a central location which accommodates both hospital and clinic waste, as the hospital will be responsible for this function.

Score	Comment

**1.2.4.1.1.4** The service level agreements (SLAs) for waste removal and disposal of waste is monitored.

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

Monitoring compliance with the service level agreement will ensure that breaches in service delivery are identified. This could include a monitoring checklist, minutes of meetings, reports, receipts and disposal certificates. Not applicable: In Gateway Clinics where waste is stored in a central location which accommodates both hospital and clinic waste, as the hospital will be responsible for this function.

Score	Comment

**1.2.4.1.1.5** Identified breaches in the service level agreement are escalated to the relevant authority.

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

This will ensure that the service level agreement is honoured and actions are taken to rectify any breaches identified. Evidence reflecting escalation of the breaches to the relevant authority must be available. This must be recorded in a document (evidence of submission to relevant authority must be available) or sent electronically via email. Not applicable: Where there are no breaches of contract or in Gateway clinics where waste is removed to the central store of the hospital

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)(a)** The health establishment must have a register for all adverse events.

**1.2.5.1.1.1** An adverse event reporting register available in the health establishment.

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

Harmful incident (adverse event): An incident that results in harm to a health care user that is related to medical management, in contrast to disease complications or underlying disease. The register can be manual or electronic. The following columns in the register must be completed. Name and Surname of affected person, date of incident, time of incident, summary of incident, findings and recommendations(if available),user outcome(if available). In cases where there are no incidents, zero reporting should be done. Not applicable: Never

Score	Comment

**Criterion 1.2.5.1.2 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.

**1.2.5.1.2.1 CHECKLIST:** The standard operating procedure for Patient Safety Incident Reporting and Learning is available.

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

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

Score	Comment	
Aspects	Score	Comment
<b>MANAGEMENT OF PATIENT SAFETY INCIDENTS Patient Safety Committee</b>		
1. Terms of reference		

2. Designation of members of the committee		
<b>Process to manage patient safety incidents</b>		
3. Identifying patient safety incidents		
4. Immediate action		
5. Prioritisation		
6. Notification		
7. Investigation		
8. Classification		
9. Analysis		
10. Implementation of recommendations		
11. Learning		

**1.2.5.1.2.2 CHECKLIST:** The standard operating procedure for Patient Safety Incident Reporting and Learning is adhered to.

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

Use the checklist below to check that the standard operating procedure is adhered to. Check health care user safety records for the past three months. Note: • Annual statistical reports for categories and indicator must be available even if no incidents were reported in the past three months, indicating a '0' in the months where no incidents were reported. Score 1 if available and score 0 if not available. • In cases where no incidents occurred in the past three months, the Patient Safety Incident Compliance report for the health establishment as generated from the national web-based information system must show 100% compliance for "Null" reporting for the health establishment for the past three months. In this case, score Not Applicable for the relevant aspects as indicated below.

Score	Comment	
Aspects	Score	Comment
1. Completed Patient safety incident form with investigation report is available for all patient safety incident cases that have been closed on the Patient Safety Incident Register		
2. Statistical report for classifications of agents involved		
3. Statistical report for classifications of incident type		
4. Statistical report for classifications of incident outcome		

5. Statistical report for indicators of patient safety incidents		
--	--	--

**1.2.5.1.2.3** All Severity Assessment Code (SAC) 1 adverse events are reported to the next level of management within 24 hours.

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

Severity Assessment Code 1 adverse events are events which cause serious harm or death (specifically caused by health care rather than the health care user's underlying condition or illness). The relevant columns in the patient safety incident register should be completed. It should be indicated in the register that this event has been escalated to the structure dealing with serious patient safety incidents. In cases where there were no serious patient safety incidents, zero reporting should be done. Not applicable: Where there are no serious patient safety incidents

Score	Comment

**Domain 1.4 GOVERNANCE AND HUMAN RESOURCES**

**Sub Domain 1.4.1 18** Governance

**Standard 1.4.1.1 18(1)** The health establishment must have a functional governance structure with written Terms of Reference.

**Criterion 1.4.1.1.1 18** The health establishment has a functional governance structure.

**1.4.1.1.1.1 CHECKLIST:** There is a functional Clinic Committee.

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

Use the checklist below to check whether the documents are available as evidence that the Clinic Committee is functional. Score 1 if they are available and score 0 if they are not available.

Score	Comment	
Aspects	Score	Comment
<b>Formal Appointment</b>		
1. Signed appointment or acknowledgement letters from the Office of the MEC delegated person		
2. Adopted and signed constitution or terms of reference as per provincial guidelines. Explanatory note: It must be stipulated in this document-who is authorised to open the complaints box.		
3. Code of conduct for Clinic Committee		
<b>Training</b>		

4. Attendance register for orientation and training conducted within the first 12 months of appointment. Explanatory Note: Evidence to be requested/obtained from districts or sub-districts)		
<b>Services Planning, Monitoring, Evaluation and meetings</b>		
5. List of community needs as discussed by the Clinic Committee in the past 12 months Explanatory note: This information could be from the health establishment profile, operational plan or minutes of Clinic Committee meetings held with community meetings with action plans.		
6. Agendas indicate that community needs and progress against the operational plan was discussed at least twice in the past 12 months		
7. Signed minutes indicate that progress against the operational plan was discussed at least twice in the past 12 months		
8. The current year plan indicates scheduled meetings (at least two within the next 12 months)		
9. Attendance registers show that meetings held formed a quorum		
10. Minutes of Clinic Committee meetings indicate that statistical data on population health indicators are discussed		
11. Minutes of Clinic Committee meetings indicate that the clinic's human resources situation is discussed		
12. Minutes of Clinic Committee meetings indicate that the situation relating to equipment and supplies is discussed		
<b>Complaints, Compliments and Suggestion Management (check record of the past 6 months)</b>		
13. Proof that the Clinic Committee took part in opening complaints boxes according to the stipulated schedule (signed register)		
14. Minutes indicate that the management of complaints are discussed at Clinic Committee meetings		
<b>Accountability and Communication</b>		
15. Contact details of Clinic Committee members are clearly displayed in the reception area		

**Sub Domain 1.4.2 19 Human resources management**

**Standard 1.4.2.1 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 1.4.2.1.1 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.**

**1.4.2.1.1.1** Staffing needs have been determined in line with workload requirements.

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

Personnel allocation will ensure that areas of the health establishment are adequately staffed to enhance safe service delivery to health care users. A needs analysis must be done in relation to the workload. Request a document detailing staffing needs for the health establishment. This could be amongst others the approved staff establishment for the clinic or WISN. Not applicable: Never

Score	Comment

**1.4.2.1.1.2** Personnel are appointed in line with the determined requirements.

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

Check if the numbers of personnel appointed in each area are in accordance with the approved posts in that service area. Not applicable: Never

Score	Comment

**Criterion 1.4.2.1.2 19(2)(b) The health establishment must, as appropriate to the type and size of the establishment, have a performance management and development system in place.**

**1.4.2.1.2.1 CHECKLIST:** The Performance Management system is adhered to.

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

Request five performance management files which have been finalised for the following categories of health care personnel: two professional nurses, one enrolled nurse, one nursing assistant and one cleaner. Assess if these comply with the aspects listed below. Score 1 if the aspect is compliant and score 0 if it is not compliant. Score NA for categories of staff not appointed at the health establishment. NB: For aspect 4 refer to DPSA guideline using this link:[http://www.dpsa.gov.za/dpsa2g/documents/ep/2017/14\\_4\\_1\\_p\\_15\\_09\\_2017%20directive.pdf](http://www.dpsa.gov.za/dpsa2g/documents/ep/2017/14_4_1_p_15_09_2017%20directive.pdf)

Score	Comment

Unit 1 Professional Nurse 1

Aspects	Score	Comment
1. Performance Management Agreement is signed by the supervisor and employee		
2. Annual work plan activities are aligned to the operational plan of the health establishment		

3. Completed Personal Development Plan (PDP) or equivalent is available		
4. Objectives and targets are formally reviewed every six monthly as per DPSA guidelines		
5. Annual (final) assessment report (PMDS)		

Unit 2 Professional Nurse 2

Aspects	Score	Comment
1. Performance Management Agreement is signed by the supervisor and employee		
2. Annual work plan activities are aligned to the operational plan of the health establishment		
3. Completed Personal Development Plan (PDP) or equivalent is available		
4. Objectives and targets are formally reviewed every six monthly as per DPSA guidelines		
5. Annual (final) assessment report (PMDS)		

Unit 3 Enrolled nurse

Aspects	Score	Comment
1. Performance Management Agreement is signed by the supervisor and employee		
2. Annual work plan activities are aligned to the operational plan of the health establishment		
3. Completed Personal Development Plan (PDP) or equivalent is available		
4. Objectives and targets are formally reviewed every six monthly as per DPSA guidelines		
5. Annual (final) assessment report (PMDS)		

Unit 4 Nursing Assistant



Aspects	Score	Comment
1. Performance Management Agreement is signed by the supervisor and employee		
2. Annual work plan activities are aligned to the operational plan of the health establishment		
3. Completed Personal Development Plan (PDP) or equivalent is available		
4. Objectives and targets are formally reviewed every six monthly as per DPSA guidelines		
5. Annual (final) assessment report (PMDS)		

Unit 5 Cleaner

Aspects	Score	Comment
1. Performance Management Agreement is signed by the supervisor and employee		
2. Annual work plan activities are aligned to the operational plan of the health establishment		
3. Completed Personal Development Plan (PDP) or equivalent is available		
4. Objectives and targets are formally reviewed every six monthly as per DPSA guidelines		
5. Annual (final) assessment report (PMDS)		

**Criterion 1.4.2.1.3 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.**

**1.4.2.1.3.1 CHECKLIST:** All healthcare providers have current registration with relevant health professional bodies.

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

Use the checklist below to check whether personnel working at the health establishment are registered with relevant professional bodies. A copy of registration certificate or card issued by professional bodies must be available .Score 1 if they have current registration and score 0 if they do not have current registration. Score NA (not applicable) for categories of personnel not appointed at the health establishment. Receipts of payment for registration will not be accepted as evidence of compliance

Score	Comment

Aspects	Score	Comment
1. Clinical Nurse Practitioner		
2. Professional nurse		
3. Enrolled nurse		
4. Nursing assistant		
5. Medical Officer - full time		
6. Medical officer- sessional		
7. Medical officer- sessional - private GP		
8. Pharmacist (where applicable)		
9. Pharmacist assistant (where applicable)		

**Sub Domain 1.4.3 20** Occupational health and safety

**Standard 1.4.3.1 20(1)** The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

**Criterion 1.4.3.1.1 20(2)(a)** An active Health and Safety Committee ensures a safe working environment

**1.4.3.1.1.1 CHECKLIST:** The standard operating procedure for management of occupational health and safety incidents is available.

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

Read through the standard operating procedure and confirm whether the aspects listed below are included and explained. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. Note: An occupational health and safety incident is any injury that staff has sustained while being on duty. In cases where there is not clarity on whether the injury will qualify as an occupational health and safety incident, the incident must still be reported. The determining body will evaluate the case and make a finding.

Score	Comment	
Aspects	Score	Comment
1. Forms to be completed to report occupational health and safety incidents		
2. Process for submitting completed forms		

3. Format for register to record occupational health and safety incidents.		
4. Analysis of incidents to establish trends.		

**1.4.3.1.1.2** An occupational health and safety risk assessment has been conducted in the past two years.

**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 the users and personnel. The occupational health and safety risk assessment conducted in the previous two years must be available. The reports must be signed and dated. Not applicable: Never

Score	Comment

**1.4.3.1.1.3** Risk mitigation interventions are implemented for identified risks.

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

There must be documented evidence of identified risks and the implementation of mitigating actions. The documented evidence could include reports, such as hazard identification and risk assessment (HIRA) reports, or minutes of meetings in which risk management is discussed, which must be signed and dated. Not applicable: Never

Score	Comment

**1.4.3.1.1.4** CHECKLIST: Occupational Health and Safety incidents are recorded in a register.

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

Request the register and check if it complies with the aspects listed below. Closed cases/incidents logged in the register must contain the details as indicated below. The register can be manual or electronic. All columns in the register must be completed. Zero reporting will be required if no incidents have occurred. Score 1 if complaint and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Summary of description of incident		
2. Summary of investigation conducted		
3. Outcome of investigation		
4. Recommendation/s		
5. Date recommendations implemented		

**1.4.3.1.1.5** Occupational Health and Safety incident investigations are recorded.

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

The register should contain details of the investigation conducted for each health and safety incident. Not applicable: Where there are no health and safety incidents

Score	Comment

**1.4.3.1.1.6** Remedial actions to address identified occupational Health and Safety incidents are implemented.

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

The register should contain details about the interventions implemented for each health and safety incident. Not Applicable: Where there are no health and safety incidents

Score	Comment

**Domain 1.5 FACILITIES AND INFRASTRUCTURE**

**Sub Domain 1.5.1 17** Security services

**Standard 1.5.1.1 17(1)** The health establishment must have systems to protect users, health care personnel and property from security threats and risks.

**Criterion 1.5.1.1.1 17(2)(a)** The health establishment must ensure that security staff are capacitated to deal with security incidents, threats and risks.

**1.5.1.1.1.1 CHECKLIST:** The standard operating procedure for safety and security is available.

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

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

Score	Comment	
Aspects	Score	Comment
1. High risk areas and the specific security needs for these areas		
2. Access control within the health establishment		
3. Reporting of security incidents (format for register for security breaches)		
4. Training of personnel on the management of alarms (where applicable)		

5. Provision of guarding services(where this service is provided)		
6. Patrolling of the health establishment		
7. Equipment for personnel		
8. Documentation of response time for security breaches/incidents		

**1.5.1.1.1.2** A signed copy of the service level agreement between the security company and the provincial department of health is available.

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

This is to ensure the safety and security of users and personnel in the health establishment. The service level agreement must be valid (not expired) and signed by the service provider and the responsible accounting officer. Not applicable: Where the service is not outsourced

Score	Comment

**1.5.1.1.1.3** A designated person monitors the service level agreement for security services.

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

Monitoring compliance with the service level agreement will ensure that breaches in service delivery are identified. This could include a monitoring checklist, minutes of meetings or reports. Not applicable: Where the service is not outsourced

Score	Comment

**1.5.1.1.1.4** Security breaches are recorded in a register.

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

The register can be manual or electronic. All columns in the register must be completed. The register must include the following: name of affected person (if applicable), date of incident, time of incident and nature of incident. In cases where there are no incidents, zero reporting should be done. Not applicable: Where there were no security breaches in the past three months

Score	Comment

**1.5.1.1.1.5** Remedial actions to address security breaches identified are implemented.

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

There must be documented evidence of action taken to address security breaches. This could be a quality improvement plan or a report. Not Applicable: Where there were no security breaches.

Score	Comment

--	--

**1.5.1.1.1.6 CHECKLIST:** Security services are rendered according to service level agreement or standard operating procedure.

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

Use the checklist below to check whether the security services are rendered according to the service level agreement or standard operating procedure. Score 1 if compliant and score 0 if not compliant. Score NA (not applicable) for whichever option is not in operation at the clinic.

Score	Comment	
Aspects	Score	Comment
<b>If armed response is available</b>		
1. Response time is indicated in the register for security breaches		
2. Response to security breaches is within the response time indicated in the register		
<b>If security guards are available</b>		
3. Duty patrol register updated (Occurrence book - OB book)		
4. There is access control system in the health establishment		

**1.5.1.1.1.7** Security guards have received training.

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

For outsourced services, request records from the service provider. For security guards employed by the health establishment, request training records. If the security guards are PSIRA-accredited, it can be accepted that they will have received training. In this case, the security guards on site must wear a valid PSIRA badge. NB: All PSIRA Certificates must be renewed every 12 months for security businesses and every 24 months for security officers. Not applicable: Where armed response services are in place

Score	Comment

**Official Sign-Off**

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.

To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Clinics.

### **Acknowledgements**

There are many people who have contributed to the development of the Regulatory Clinic Inspection Tools Version 1.2. The Office of Health Standards Compliance wishes to extend most heartfelt acknowledgement and gratitude to the following:

- The WHO technical team for providing guidance on the very first draft inspection tools database
- Health Standards Development and Training unit team (Dr Grace Labadarios, Mr Jabu Nkambule, Ms Florina Mokoena) for the development of the clinic inspection tools.
- The internal OHSC teams (Compliance Inspectorate, Certification and Enforcement, Complaints and Assessment, Complaints and Investigation, Systems, Data Analysis and Research), for their contribution during the development of the clinic inspection tools and (Information Technology and Communication and Stakeholder Relations) for providing support.
- National Department of Health, Ms Ronel Steinhobel, Dr Shaidah Asmall, Mr Kgwiti Mahlako for reviewing and commenting on the inspection tools
- Provincial Department of Health personnel, Quality Assurance Managers, District Managers, Programme Managers, Facility/Operational Managers for their valuable feedback
- The Certification and Enforcement Committee of the OHSC Board for reviewing the tools and for recommending to the Board for approval.

**It is hereby certified that these Regulatory Clinic Inspection tools version 1.2 was developed by the Office of Health Standards Compliance.**

**Ms. W Moleko**  
**Executive Manager**  
**Health Standards Development Analysis and Support**  
**Date: 28/01/2020**

**Signature:**



**Dr Sipiwe Mndaweni**  
**Chief Executive Officer**  
**Date: 28/01/2020**

**Signature:**



**Telephone:** 012 942 7700  
**Email :** [admin@ohsc.org.za](mailto:admin@ohsc.org.za)  
**Website :** [www.ohsc.org.za](http://www.ohsc.org.za)

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

**Postal Address:**  
Private Bag X21  
Arcadia  
0007

**ISBN:**  
978-0-620-90157-4

