



OFFICE OF THE HEALTH STANDARDS COMPLIANCE (OHSC)

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CERTIFICATION AND ENFORCEMENT MANUAL

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CERTIFICATION AND ENFORCEMENT MANUAL

Administrator

Approval date

Chief Executive Officer
(signature)

**Certification and
Enforcement Unit**

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1. DEFINITIONS

- 1.1. **“Board”** means the Board of the Office of Health Standards Compliance appointed in terms of Section 79A of the Act;
- 1.2. **“Chief Executive Officer/CEO”** means the person appointed as Chief Executive Officer of the OHSC in terms of Section 79H (1) of the Act;
- 1.3. **“Constitution”** means the Constitution of the Republic of South Africa, 1996;
- 1.4. **“Compliance Enforcement Committee”** means an administrative body established by the OHSC to adjudicate on formal hearings relating to breaches or non-compliance with the prescribed norms and standards;
- 1.5. **“early warning system”** means the surveillance systems that collect information of serious user-related incidents that prompt interventions by the health establishment, the Office or relevant authority;
- 1.6. **“health establishment”** means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;
- 1.7. **“Inspector”** means a person appointed as an inspector in terms of Section 80(2) of the Act;
- 1.8. **“Minister”** means the Minister responsible for Health;
- 1.9. **“norms and standards”** means the norms and standards prescribed by the Minister in terms of Section 90(1)(b) and (c) of the Act;
- 1.10. **“Office”** means the Office of Health Standards Compliance established by Section 77(1) of the Act;
- 1.11. **“Ombud”** means a person appointed as an Ombud in terms of Section 81(1) of the Act;
- 1.12. **“person-in charge”** means a person designated by the relevant authority, as a person in charge of a health establishment;
- 1.13. **“Policy”** means this Enforcement Policy of the Office;
- 1.14. **“Regulations”** means the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud;
- 1.15. **“Relevant Authority”** refers to provincial department of health, district health authority, municipal authority or equivalent authority in the private sector;
- 1.16. **“the Act”** means the National Health Act, 2003 (Act No. 61 of 2003);

- 1.17. **“User”** means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is—
- (a) below the age contemplated in Section 39 (4) of the Child Care Act, 1983 (Act No. 74 of 1983), **“user”** includes the person’s parent or guardian or another person authorised by law to act on the first mentioned person’s behalf; or
 - (b) incapable of taking decisions, **“user”** includes the person’s spouse or partner or, in the absence of such spouse or partner, the person’s parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the first mentioned person’s behalf.

2. INTRODUCTION

This Certification and Enforcement Manual (manual) for the Office of Health Standards Compliance (OHSC) comprises of the Certification and Enforcement Framework, Standard Operating Procedures for Certification, Standard Operating Procedures for Enforcement, Enforcement Policy and annexures.

The main role of health establishment inspection is the promotion of compliance with the norms and standards prescribed by the Minister of Health in relation to the national health system.

3. PREAMBLE

The Office of Health Standards Compliance (OHSC) is charged with a responsibility to monitor compliance with the prescribed norms and standards through inspections, early warning system, complaints, enforcement and other suitable measures. Where applicable certify health establishments found to be compliant with the prescribed norms and standards, withdraw or even suspend certification.

For this purpose the OHSC has the Compliance Inspectorate, Certification and Enforcement Division which monitors compliance with the prescribed norms and standards.

4. VISION

Safe and Quality Healthcare for all.

5. MISSION

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

6. VALUES

Our values are informed by the South African Constitution: Human dignity; accountability, transparency and integrity.

7. OBJECTS OF THE OHSC

7.1 The Objects of the OHSC as reflected in the National Health Act, 2003 (Act No. 61 of 2003) (“the Act”) are to protect and promote the health and safety of users of health services by:

7.1.1 “Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system; and

7.1.2 Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner”.

7.2 In terms of the Act, the OHSC is entrusted with the following mandatory functions: -

7.2.1 **Advise the Minister** on matters relating to the determination of norms and standards to be prescribed for the national health system and the review of such norms;

7.2.2 **Inspect and certify** health establishments as compliant or non-compliant with prescribed norms and standards, or where appropriate and necessary, withdraw such certification;

7.2.3 **Investigate complaints** relating to the national health system;

7.2.4 **Monitor indicators of risk** as an early warning system relating to serious breaches of norms and standards and report any breaches to the Minister without delay;

- 7.2.5 **Identify areas and make recommendations for intervention** by a national or provincial department of health or a health department of a municipality, where it is necessary, to ensure compliance with prescribed norms and standards;
- 7.2.6 **Recommend quality assurance and management systems** for the national health system to the Minister for approval;
- 7.2.7 **Keep records** of all its activities; and
- 7.2.8 **Advise the Minister** on any matter referred to it by the Minister.

8. CERTIFICATION AND ENFORCEMENT FRAMEWORK

The aim of this framework is to outline the guiding principles and important elements relating to certification and enforcement and provides the Office with guidance about the way certification and enforcement activities are to be undertaken. This framework does not override or limit the discretion of the Office to act as it deems fit under legislation.

9. LEGISLATIVE AND OTHER MANDATES

9.1 Legislative Mandates

- 9.1.1 The Constitution of the Republic of South Africa.
- 9.1.2 The National Health Act, 2003.

9.2 Policy Mandates

- 9.2.1 National Development Plan.
- 9.2.2 National Health Insurance Bill.
- 9.2.3 Norms and standards for different categories of health establishments.
- 9.2.4 Procedural Regulations pertaining to the functioning of the Office of Health Standards Compliance and handling of complaints by the Ombud.

9.3 Other Applicable Documents

- 9.3.1 The OHSC's Inspection Strategy.
- 9.3.2 Promotion of Access to Information Act, 2000 (Act No. 2 of 2000) (PAIA).
- 9.3.3 The Protection of Personal Information Act, 2013 (Act No. 4 of 2013).
- 9.3.4 Promotion of Administrative Justice Act, 2003 (Act No. 3 of 2000).
- 9.3.5 Criminal Procedure Act, 1977 (Act No. 51 of 1977).

10. OHSC INSPECTORS

- 10.1 Inspectors appointed by the OHSC shall act within their legal remit of statutory power when undertaking inspection activities.
- 10.2 Only inspectors who are appointed in terms of the Act shall be authorised to conduct inspections.
- 10.3 Inspectors shall have sufficient understanding of the OHSC policies and procedures to ensure a consistent approach to inspections.
- 10.4 Inspectors shall present their certificate of appointment to management of on arrival at a health establishment for an inspection.

11. INSPECTIONS

The function of the inspectorate unit is to protect and promote the health and safety of users of health services by monitoring compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system. There following types of inspections will be conducted by the OHSC: -

12.1 ROUTINE INSPECTIONS

Every health establishment will be inspected by the OHSC once every four (4) years.

12.2 ADDITIONAL INSPECTIONS

The OHSC may conduct an additional inspection, if there are reasonable grounds to believe that: -

- 12.2.1 Such an inspection is needed to establish whether non-compliance has been remedied within the health establishment;
- 12.2.2 The health establishment is contravening the act or any relevant regulations;
- 12.2.3 There are serious breaches of norms and standards, based on the indicators of risk; or
- 12.2.4 The Ombud's findings demonstrate that continued exposure to the health care services provided by health establishment may pose a severe risk to users or health care personnel.

12.3 RISK-BASED INSPECTIONS

Risk based inspections shall be triggered by Early Warning System (EWS).

12. THE INSPECTION PROCESS

- 13.1 The OHSC will issue a notice of inspection (OHSC Form 3) to the health establishment containing, at a minimum, the following information:
- 12.1.1 the purpose of the inspection;
 - 12.1.2 the date of the inspection;
 - 12.1.3 the estimated duration;
 - 12.1.4 the inspection plan referred to in sub-regulation 12(4);
 - 12.1.5 the number of authorised personnel expected to take part in the inspection;
 - 12.1.6 the contact details of the inspector primarily responsible for the inspection;
and
 - 12.1.7 the responsibilities of the health establishment.

13. CERTIFICATION OF HEALTH ESTABLISHMENTS

- 13.1 The OHSC shall issue any health establishment that meets all the compliance requirements with a certificate of compliance within fifteen (15) working days from the date of confirmation of compliance.
- 13.2 The certificate of compliance shall contain the full details of the relevant health establishment.
- 13.3 The certificate of compliance issued by the Office shall be valid for a period of four (4) years and is subject to renewal. Health establishments shall apply six (6) months before the expiry date however inspection must be conducted to determine compliance with the norms and standards.
- 13.4 The certificate of compliance issued by the OHSC shall contain the full details and address of the health establishment to whom it is issued.
- 13.5 Certification status of a health establishment which has applied for renewal may be extended for a period not more than one (1) year from the date of the expiry, to afford the OHSC an opportunity to schedule and conduct an inspection for renewal purposes.
- 13.6 Any compliance notice issued against a health establishment suspend the compliance certificate until the conditions set out in the compliance notice are fulfilled.

14. FRAUD PREVENTION MEASURES AND CONTROL

The OHSC shall ensure the integrity, security and control to prevent the issue of fraudulent certificates by putting in place the following security measures and controls: -

- 14.1 All certificates shall be printed in accordance to the recommendations, conditions and specifications of the Act as well as the Regulations.
- 14.2 All certificates issued by the OHSC shall be in the format prescribed in the Regulations and submitted to the CEO for approval.
- 14.3 All certificates shall be issued on a special kind of paper whose specification shall be approved by the Board and shall bear the OHSC's name, logo, a watermark and corporate colours.
- 14.4 All certificates shall be issued on the following control measures to ensure the security of the certificates:
 - 14.4.1 Copies of certificates shall be kept in a secure room with limited access.
 - 14.4.2 Sequential certificate numbers shall be assigned to all certificates to assist with filing and auditing.
- 14.5 A register shall be kept every time a certificate is printed and shall include the following information:
 - 14.5.1 Date of Issue;
 - 14.5.2 Name of the person that printed the certificates;
 - 14.5.3 Number of certificates printed and the serial numbers; and
 - 14.5.4 Number of certificates cancelled and destroyed, and their serial numbers.

15. COMPLIANCE NOTICES

- 15.1 Compliance notices are a mechanism for the OHSC and inspectors to impose an immediate form of reprimand for certain types of breaches sending a clear message that there are consequences for non-compliance.

15.2 Compliance notice will generally be issued where there is some sanction warranted for the breach, however, the nature of the breach is not serious enough to warrant enforcement action.

15.3 Compliance notice issued against a health establishment suspends the compliance status of a health establishment, until the conditions in the compliance notice are fulfilled.

16. DEFINING ENFORCEMENT AND COMPLIANCE

16.1 The OHSC hereby adopts a broad definition of enforcement which combines the provision of advice with formal action where necessary. This is intended to encourage higher levels of voluntary compliance with the prescribed norms and standards by health establishments as well as the employees thereof. Notwithstanding this, the OHSC shall take immediate action against anyone who act unlawfully when circumstances warrant it.

16.2 For the purposes of the enforcement framework, **Enforcement** is distinguished from compliance as the possible actions the OHSC can take after breaches of the prescribed norms and standards have been identified. **Compliance** can be defined as the ability of a health establishment, facility or the employees thereof to fulfil the requirements of legislation.

16.3 Enforcement ensures that persons in charge of health establishments: -

16.3.1 deal immediately with breaches of the prescribed norms and standards;

16.3.2 ensures compliance with the prescribed norms and standards; and

16.3.3 are held to account for failure to comply with the prescribed norms and standards.

17. APPROACH TO ENFORCEMENT

The OHSC's approach of achieving compliance is progressive and therefore can be separated into four (4) different stages: -

17.1 Monitor compliance with the prescribed norms and standards;

17.2 Identification of areas non-compliance;

17.3 The enforce compliance with the prescribed norms and standards; and

17.4 The outcome of enforcement action.

18. PRINCIPLES OF ENFORCEMENT

Enforcement action is taken within the context of both a legislative and policy framework. The OHSC will carry out its enforcement related work with due regard to the following principles:

19.1 TARGETING

Enforcement targets of those regulated health establishments and/or part thereof which pose the greatest risk and whose levels and persistence of non-compliance with the prescribed norms and standards reflect ongoing actual risks to patient health and safety and potential poor outcomes.

19.2 PROPORTIONALITY

19.2.1 Decisions about a graduated response must be balanced by the potential threat to public health. A proportionate response means that the OHSC's actions will be scaled to the seriousness of the breach. A serious risk to public health needs immediate action to ensure compliance.

19.2.2 Attention will be focused on those activities that give rise to the most serious risks, or where potential hazards are well controlled.

19.3 CONSISTENCY

The OHSC shall take a similar approach, in similar cases, to achieve similar outcomes. While enforcement decisions require the use of professional judgement and discretion to assess varying circumstances, the OHSC shall: -

- 19.3.1 follow the inspection strategy and the standard operating procedures for inspections;
- 19.3.2 ensure fair, equitable and non-discriminatory treatment during inspections; and
- 19.3.3 record any deviation from standard operating procedures and the reasons for such deviation.

19.4 TRANSPARENCY

The OHSC shall be open and transparent about the manner in which it undertakes enforcement activities and the laws it enforces. When educating the persons in charge of health establishments, employees as well as health services users at large, the OHSC shall

make a clear distinction between what is legally required and what is desirable but not compulsory.

19.5 ACCOUNTABILITY

The prescribed norms and standards set explicit quality standards against which health establishments will be objectively assessed and held accountable for compliance. The Office itself is accountable through its published reports on its activities and decisions.

19. DELEGATION OF POWERS

- 19.1 A delegation transfers a specific power or duty under any legislation from a person identified in the legislation to a person holding a position in the OHSC so that position can exercise those functions.
- 19.2 The delegation of powers will be based on the requirements of the relevant legislation, legal advice and operational factors such as the frequency the power needs to be exercised, the potential impact of the power and the amount of discretion required in exercising the power.
- 19.3 Employees of the OHSC must know and understand the powers delegated to their position in their instrument of delegation and must not act beyond the delegated powers.

20. DECISION MAKING RELATING TO ENFORCEMENT

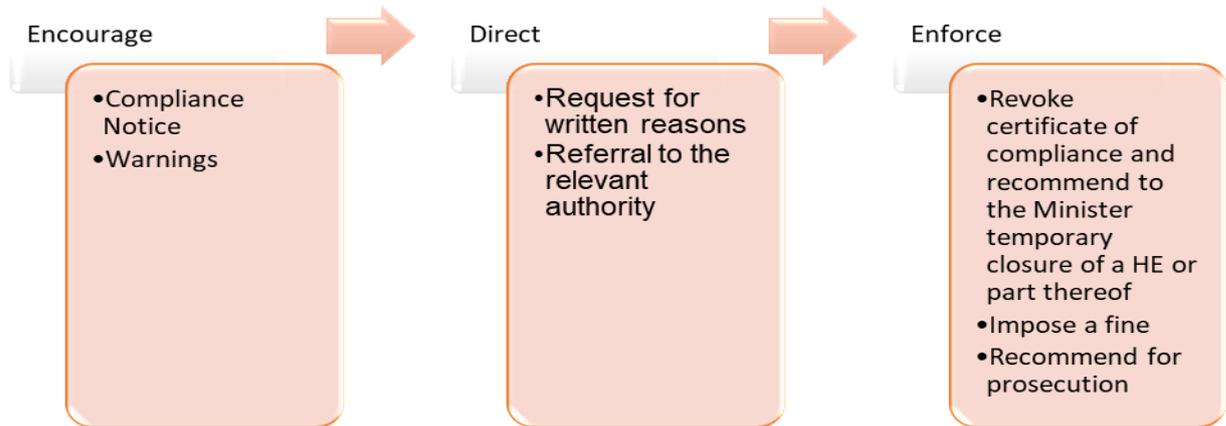
- 20.1 Enforcement decisions must always demonstrate just and fair treatment for all and consistency with the applicable legislation. All matters should be approached and considered on their merits and the evidence available. The implementation of enforcement actions ultimately seeks to achieve the following outcomes: -
 - 20.1.1 Protection of healthcare service users;
 - 20.1.2 long term compliance is achieved through a change of management and behaviour;
 - 20.1.3 breaches are eliminated, controlled or prevented;
 - 20.1.4 persons who fail to comply are held accountable; and
 - 20.1.5 non-compliance across the health sector is deterred.

- 20.2 In coming to a decision on the most appropriate means of enforcement, the OHSC shall consider, amongst others, the following relevant factors: -
- 21.2.1 the seriousness of the non-compliance or breach;
 - 21.2.2 the consequences of non-compliance;
 - 21.2.3 the compliance history of the health establishment;
 - 21.2.4 frequency of breaches / non-compliances to norms and standards; and
 - 21.2.5 any offences outlined in Section 89 (1) (a) to (c) of the Act, by a health establishment, a person in charge or any employee; or
 - 21.2.6 any mitigating or aggravating factors.
- 20.3 The following factors shall not influence enforcement decisions: -
- 20.3.1 any element of discrimination or bias against the person in charge of a health establishment based on ethnicity, nationality, political association, religion, gender, sexuality or beliefs; or
 - 20.3.2 possible political advantage or disadvantage to a government, person holding (or a candidate for) public office, or any political group or party.
- 20.4 Where a personal association or relationship with the person in charge of a health establishment or any other person involved exists: -
- 20.4.1 an alternative person will make decisions where possible; and
 - 20.4.2 the facts about any conflict/relationship shall be recorded accordingly.
- 20.5 Written documentation relating to enforcement shall: -
- 20.5.1 provide a record of all actions taken relevant to the breach / non-compliance to ensure decision making is auditable and withstands scrutiny;
 - 20.5.2 include all the information necessary to make clear what needs to be done to comply with the legal requirements, the reasons for these actions and the required time frame;
 - 20.5.3 state the contravention, measures necessary to ensure compliance and the consequences of non-compliance, such as the potential action for failing to comply; and

18.5.4 clearly differentiate between legal requirements and recommendations of good practice.

21. STAGES OF ENFORCEMENT

Diagram 1 below indicates the stages of enforcement and the applicable and/or appropriate enforcement actions:



22. MULTIPLE ENFORCEMENT ACTIONS

Under no circumstances shall the Office use multiple enforcement actions. Only one enforcement action shall be imposed on a health establishment for a specific breach of the norms and standards and/or persistent non-compliance.

23. RISK BASED COMPLIANCE AND ENFORCEMENT

This enforcement framework shall be risk-based¹. Health establishments shall, in relation to compliance, be put into a risk category, as per **table 1 below**:

¹ A risk-based framework is one that identifies risk and target the specific risk/breach of the norms and standards.

| Grading model | | |
|-----------------------|--------------------|-------------------------------------|
| Grading | Risk rating | Number of Measures compliant |
| Excellent | V ≥80% | 51/64 |
| | E ≥ 70% | 46/65 |
| Good | V = 70 - 79% | 45/64 |
| | E = 60 - 69% | 39/65 |
| Satisfactory | V = 60 - 69% | 38/64 |
| | E = 50 - 59% | 33/65 |
| Unsatisfactory | V <60% | <38/64 |
| | E <50% | <33/65 |

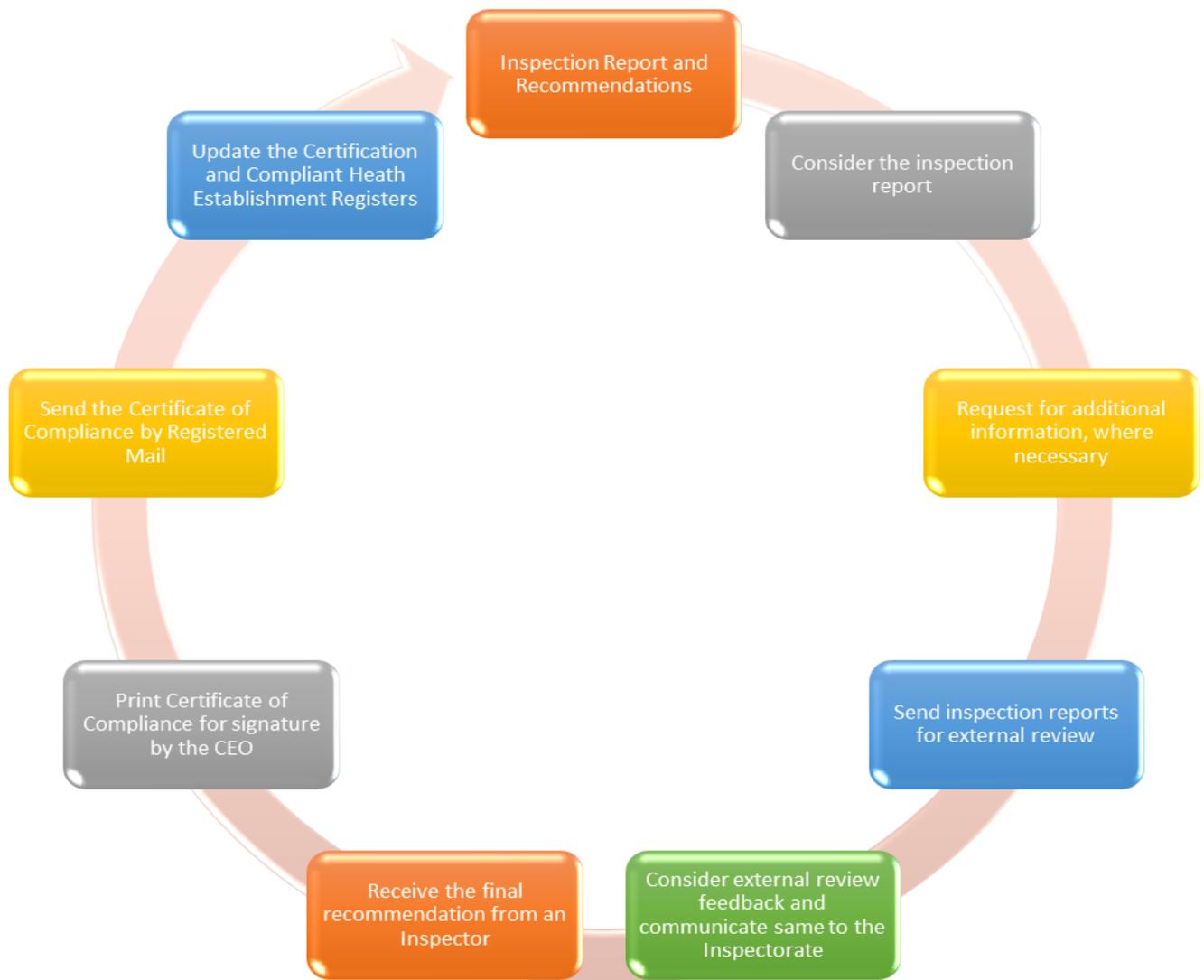
24. STANDARD OPERATING PROCEDURE FOR CERTIFICATION

24.1 CERTIFICATION PROCESS

The OHSC has since developed Standard Operating Procedure (SOP) to provide uniformity and guidance in the process of certifying health establishments and enforcing compliance with the prescribed norms and standards in accordance with the relevant and/or applicable legislation. Upon receipt of a recommendation, from an Inspector, to certify a health establishment, the following procedure shall be followed: -

- a) Update a list of inspection reports received (list the health establishments);
- b) Consider the inspection report for each health establishment;
- c) Request additional information from the Inspector, where necessary,;
- d) Send inspection reports for external review;
- e) Consider external review feedback and communicate same to the Inspectorate;
- f) Receive the final recommendation from an Inspector;
- g) Print the Certificate of Compliance for signature by the CEO;
- h) Send the Certificate of Compliance to a health establishment, by registered mail;
- i) Update the certification and compliant health establishments register.

Diagram 2 below outlines the process for certification.



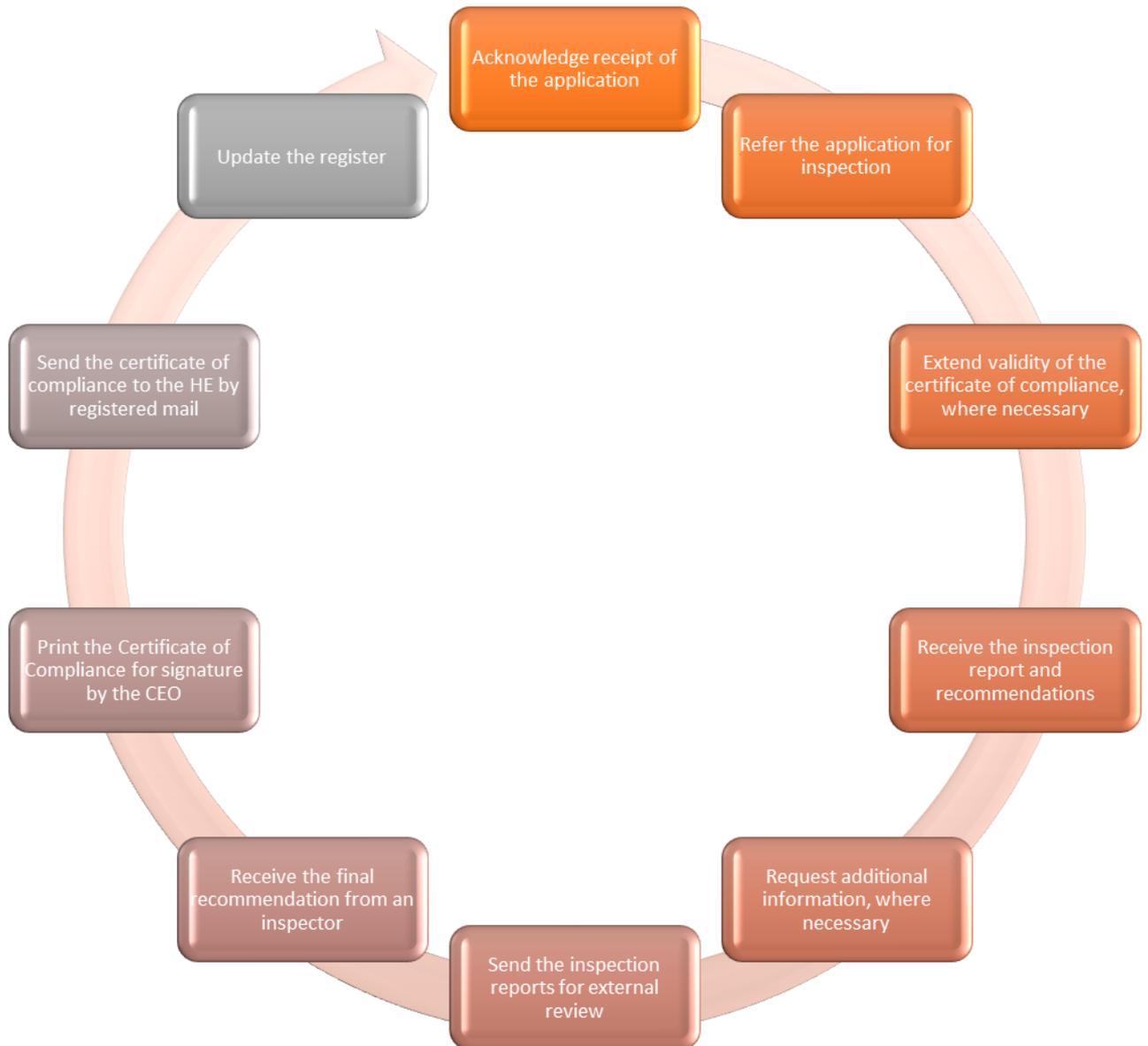
24.2 PROCEDURE FOR RENEWAL OF CERTIFICATE OF COMPLIANCE

Upon receipt of an application for renewal of a certificate of compliance from a health establishment, the Office shall: -

- a) acknowledge receipt of the application for renewal of a certificate of compliance;
- b) refer the renewal application for inspection as prescribed by the procedural regulations;
- c) extend the validity of a certificate of compliance, where necessary;
- d) receive the inspection report and recommendations;
- e) request additional information, where necessary;
- f) send inspection reports for external review;
- g) consider external review feedback and communicate same to the Inspectorate;
- h) receive the final recommendation from an Inspector;

- i) print the Certificate of Compliance for signature by the CEO;
- j) send the Certificate of Compliance to the health establishment, by registered mail;
- k) update the certification register.

Diagram 3 below outlines the process for renewal of a compliance certificate.



24.3 SUSPENSION OF A CERTIFICATE OF COMPLIANCE

Upon receipt of an early warning indicator and inspection report confirming breach of the prescribed norms and standards by a certified health establishment, the OHSC shall: -

- 24.3.1 issue a notice of suspension of a certificate of compliance within twenty-four (24) hours of receipt of the inspection report;
- 24.3.2 allow a health establishment an opportunity to remedy the identified breaches;
- 24.3.3 reconfirm the compliance status of a health establishment within fifteen (15) days from the date of fulfilment of the compliance requirements.

25. STANDARD OPERATING PROCEDURE FOR ENFORCEMENT

The purpose of the Standard Operating Procedure for Enforcement is to provide uniformity and guidance in the process of enforcing compliance with the prescribed norms and standards.

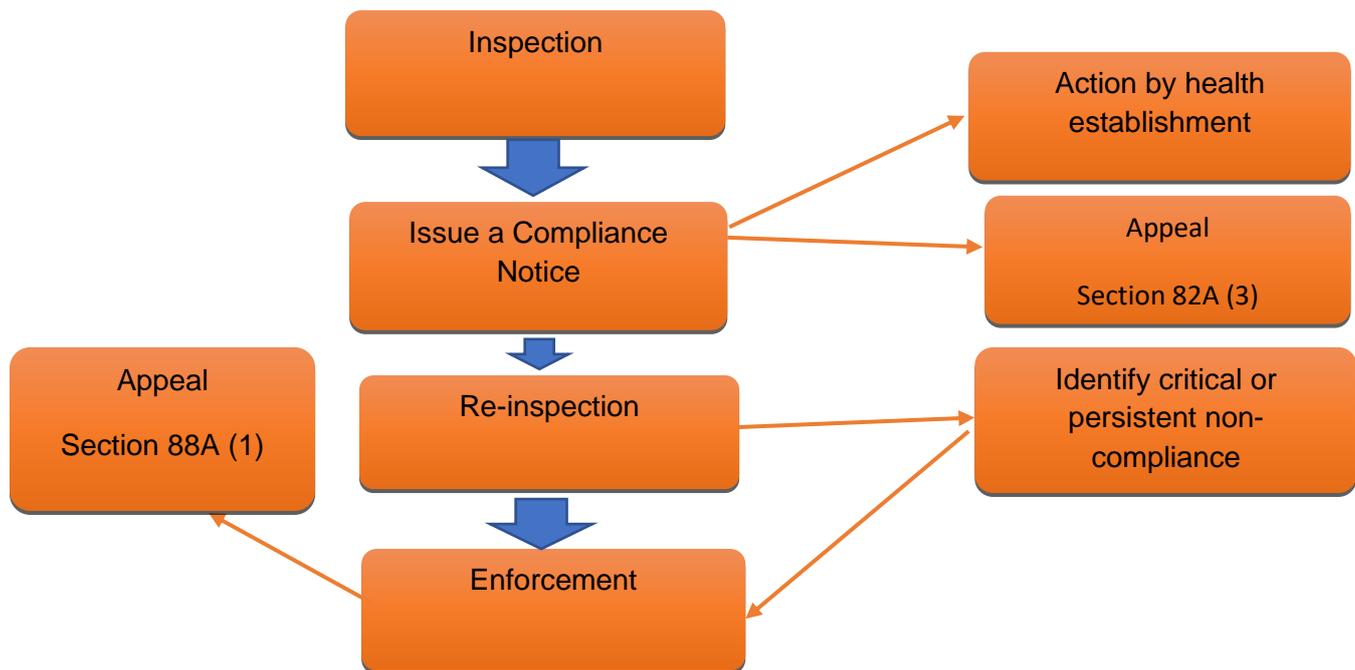
25.1 CRITERIA FOR ENFORCEMENT

In deciding the most appropriate action to take, the Office will be guided by the following considerations: -

- 25.1.1 The adverse effect, that is the extent of the risk, the seriousness of the breach and the actual or potential consequences;
- 25.1.2 The extent to which the person in charge of a health establishment, any employee or health establishment contributed to the breach;
- 25.1.3 The compliance history of the health establishment;
- 25.1.4 Any mitigating or aggravating factors, including efforts undertaken by the person in charge of the premises or health establishment to control the risks;
- 25.1.5 Whether the breach is imminent.

25.2 PROCESS FOR ENFORCEMENT

The process in **Diagram 4** below shall be followed for enforcement to come into effect: -



25.3 PROCEDURE FOR ENFORCEMENT

It is the legislative mandate of the OHSC to monitor compliance with the prescribed norms and standards, where breach is identified, the following enforcement procedure shall be followed: -

- 26.3.1 Make a *prima facie* determination that the report as well as evidence is sufficient to support the findings that more likely than not, the health establishment is in breach of the prescribed norms and standards;
- 26.3.2 Ask the Inspectorate to supplement the report and/or provide further information to assist in making a determination thereof;
- 26.3.3 The OHSC shall facilitate the constitution of the enforcement *ad hoc* committee to convene a hearing;
- 26.3.4 The appropriate enforcement action shall be determined;
- 26.3.5 Where a fine is recommended, the appropriate amount shall also be determined;
- 26.3.6 Where prosecution is recommended, the matter shall be referred to the National Prosecuting Authority (NPA) for determination thereof; and

26.3.7 The OHSC shall prepare a report of all recommendations by the enforcement *ad hoc* committee.

25.4 APPEAL

26.4.1 Any person aggrieved by the decision of the Office shall appeal the decision, in writing, within thirty (30) days from the date of gaining knowledge of the decision.

26.4.2 An *ad hoc* tribunal shall be appointed by the Minister to hear the appeal in terms of Section 88 A (3) of the Amendment Act. The procedure and conduct of the appeal shall be determined by the *ad hoc* tribunal.

26.4.3 The appeal proceedings shall be open to the public, so that any member of the public who wishes to be part of the proceedings can attend.

26.4.4 There is no right of appeal to the *ad hoc* tribunal in relation to conviction for an offence, if prosecuted.

OHSC ENFORCEMENT POLICY

26. PURPOSE OF THE ENFORCEMENT POLICY

26.1 The purpose of the Enforcement Policy is to set out the approach to be followed by the Office in enforcing compliance by health establishments with the prescribed norms and standards to guide its employees, the Board as well as the categories of health establishments to whom the prescribed norms and standards apply.

26.2 The Enforcement Policy also sets out the roles and responsibilities of the stakeholders.

27. APPLICABLE LEGISLATION

27.1 The Constitution of the Republic of South Africa, Act 108 of 1996;

27.2 The National Health Act, 2003 (Act No. 61 of 2003), as amended;

27.3 Promotion of Access to Information Act, 2000 (Act No. 2 of 2000);

27.4 The Protection of Personal Information Act, 2013 (Act No. 4 of 2013);

27.5 Promotion of Administrative Justice Act, 2003 (Act No. 3 of 2000);

27.6 Criminal Procedure Act, 1977 (Act No. 51 of 1977);

27.7 Norms and Standards Regulations applicable to different categories of health establishments, 2016; and

27.8 Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, 2016.

28. PRINCIPLES OF ENFORCEMENT

In exercising its enforcement powers and to promote the statutory objective of promoting and protecting the health and safety of users, the Office has adopted the following five (5) principles in its daily operations and regulatory decisions—

| PRINCIPLE | DEFINITION |
|---------------------|---|
| 28.1 Accountability | The prescribed norms and standards set explicit benchmarks for health establishments that are objectively assessed and held accountable for compliance. |

| | |
|-----------------------------|--|
| 28.2 Transparency | Clear, specific, and explicit obligations are placed on health establishments through the norms and standards, assessment tools and procedures. Furthermore, regulatory findings and decisions are published, as required by the Regulations. |
| 28.3 Targeting | Enforcement shall target health establishments and part thereof which poses a risk to users of health care services. |
| 28.4 Proportionality | The response as well as the use of enforcement powers must be assessed by the Office to be proportionate to the circumstances of an individual case. Where the health establishment can remedy the breach and the risk to users is not immediate, the Office shall give the health establishment an opportunity to remedy the breach before taking enforcement action. |
| 28.5 Consistency | The Office must take a similar approach, in similar cases, to achieve similar outcomes, and ensure that regulatory enforcement processes are consistent, and decisions are reliable and fair (similar action in similar circumstances to achieve similar results). |

29. SCOPE AND APPLICATION

29.1 This policy shall be applicable to—

- a) The OHSC Board;
- b) Employees of the OHSC;
- c) Health establishments; and
- d) Relevant authorities.

30. COMPLIANCE MONITORING

30.1 The Office monitors compliance with the norms and standards in several ways including, but not limited to—

- 30.1.1 Inspections;
- 30.1.2 Complaints investigations; and
- 30.1.3 Early warning system.

31. EDUCATION, ADVICE AND GUIDANCE ON COMPLIANCE

31.1 The purpose of education, advice and guidance is to—

- a) raise awareness of all stakeholders' rights and obligations in relation to the prescribed norms and standards;
- b) support the person in charge of the health establishments on how to comply with the norms and standards and other applicable legislation; and
- c) empower and capacitate health establishments to address breaches of norms and standards within a reasonable time and achieve compliance.

32. INSPECTIONS

32.1 The purpose of inspections is to assess the extent of compliance by health establishments with the prescribed norms and standards and to provide support where necessary.

32.2 Inspectors appointed by the Office may—

- a) Inspect health establishments in accordance with the Inspection Strategy of the Office;
- b) Question any person who is believed to have in her or his possession any relevant information;
- c) Request documents from the person in charge of a health establishment;
- d) Take samples of any substance or relevant photographs; and
- e) Issue a compliance notice to the person in charge of a health establishment if the health establishment is found to have breached any norms and standards.

33. RESPONSE TO NON-COMPLIANCE

The health establishment is responsible to take reasonable time and appropriate action to remedy any identified breaches of norms and standards. If a health establishment fails to correct any identified breaches of norms and standards, a compliance notice will be issued to a health establishment.

34. COMPLIANCE NOTICE

34.1 A compliance notice shall be issued by an inspector to a health establishment that is found to have breached the prescribed norms and standards.

34.2 The health establishment will be expected to comply with the conditions set out in the compliance notice prior to the Office taking any enforcement action.

34.3 A compliance notice shall stipulate the time frame within which remedial action must be taken to correct the identified breaches to the norms and standards.

35. ENFORCEMENT

35.1 PURPOSE OF ENFORCEMENT

35.1.1 The primary purpose of enforcement is to—

- a) enforce compliance by health establishments with the prescribed norms and standards;
- b) protect users and health care personnel from harm and the risk of harm caused by non-compliance by health establishments with prescribed norms and standards;
- c) ensure that users receive health services of acceptable standard and that health care personnel work in a safe environment.

35.1 CRITERIA FOR ENFORCEMENT

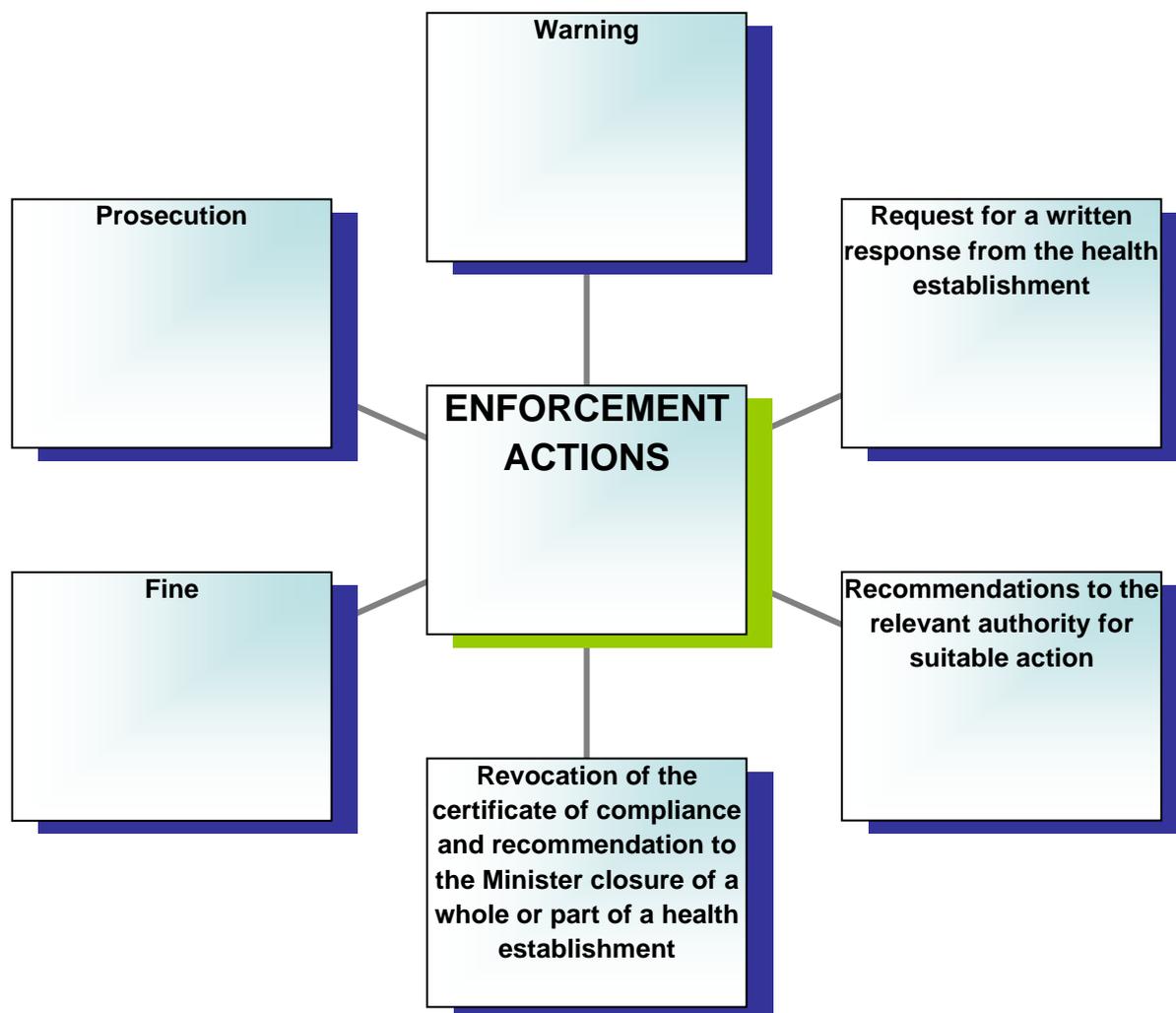
35.1.1 In deciding the most appropriate action to take, the Office may be guided by the following considerations—

- a) The impact of the breach on the provision of health care service delivery;
- b) Any injury, loss, damage or death resulting from the breach;
- c) The health establishment or person in charge blameworthiness or the degree within which they should be held accountable for the breach;
- d) The compliance history of the health establishment;
- e) Any mitigating or aggravating factors, including efforts undertaken by the person in charge of the health establishment to prevent / control the risk;
- f) Whether the breach is imminent.

36. ENFORCEMENT ACTIONS

The below diagram outlines the enforcement actions enjoined on the OHSC by the National Health Act, 2003 (Act No. 61 of 2003) —

Diagram 1 - Enforcement actions



36.1 WRITTEN WARNING

36.1.1 If a health establishment fails to comply with a Compliance Notice issued by an inspector, the Office shall issue a written warning to the person in charge of the health establishment.

36.1.2 The written warning shall include a time frame within which compliance must be achieved.

36.1.2 Failure by the person in charge to respond to a written warning within the reasonable time would lead to the matter being referred for other enforcement processes.

36.2 REQUEST FOR A WRITTEN RESPONSE FROM A HEALTH ESTABLISHMENT

36.2.1 Where appropriate, the Office shall request for a written response from the health establishment, providing reasons for the continued non-compliance.

36.2.2 The request for a written response from the Office will also set out the consequences of failure to respond.

36.3 RECOMMENDATION TO THE RELEVANT AUTHORITY FOR SUITABLE ACTION

36.3.1 The Office shall recommend, to the relevant authority, any appropriate or suitable action to be taken against the person in charge of a health establishment or the health establishment.

36.3.2 The Office shall monitor all recommendations sent to the relevant authority and report to the Minister on the implementation thereof.

36.4 REVOCATION OF A COMPLIANCE CERTIFICATE AND RECOMMENDATION FOR TEMPORARY OR PERMANENT CLOSURE OF A HEALTH ESTABLISHMENT OR PART THEREOF.

36.4.1 Where a health establishment fails to comply with a Compliance Notice issued by an Inspector, the Office may revoke the certificate of compliance issued to a health establishment and recommend to the Minister to temporarily or permanently close a health establishment or a part thereof that constitutes a serious risk to the users.

36.4.2 Health establishments shall be afforded an opportunity to be heard prior to revocation of a compliance certificate or recommendation to the Minister for temporary or permanent closure of a health establishment or part thereof, that poses a risk to the users.

36.4.3 The recommendation to the Minister shall include all the information contained in regulation 27(2) of the Regulations, to enable the Minister to make a decision.

36.5 FINE

36.5.1 Prior to imposing a fine, the Office shall afford the health establishment an opportunity to submit a request for leniency.

36.5.2 The fine, if imposed, will be subject to the thresholds determined by the Minister by notice in the *Government Gazette*.

36.5.3 The health establishment shall pay the imposed fine into a designated account within twenty (20) working days of the decision.

36.5.4 Banking details for payment of fines shall be provided by the Office.

36.6 PROSECUTION

36.6.1 Where an alleged breach of prescribed norms and standards is considered to amount to a criminal offence, the Office shall refer the matter to the National Prosecuting Authority for consideration and possible criminal prosecution.

36.6.2 The Office shall also refer for prosecution any offences in terms of the Act.

36.6.3 The decision to prosecute lies solely with the National Prosecuting Authority after considering all the relevant factors relating to the alleged offence or offences.

37. FORMAL HEARING

37.1 The Office shall notify the health establishment of its intention to revoke the certificate of compliance or to impose a fine, as the case may be, and initiate a hearing which must be presided by a suitable person appointed by the Chief Executive Officer, to allow the health establishment an opportunity to make representations before taking a final decision.

37.1.1 The person appointed as a presiding officer for the hearings shall not have a personal interest in the matter or be in any way associated with any of the parties.

37.1.2 The hearings shall be open to the public, subject to the determination of the presiding officer.

37.1.3 The presiding officer shall communicate the decision on the hearing to the Office, person in charge of a health establishment as well as the relevant authority within the prescribed timeframe.

37.1.4 Notice of hearing—

- a) Notice of hearing shall be given to both the Office and the health establishment to prepare for the hearing.
- b) Notice of hearing or notice of the Office's intention to revoke a certificate of compliance or to impose a fine would be deemed to have been received by the party or parties, as the case may be, if such notice was—
 - i. sent to the registered postal or physical address of either party and there is sufficient proof thereof;
 - ii. sent to either party's official fax number and there is a fax transmission as proof that the fax was sent or received;
 - iii. hand-delivered and signed for at either party's registered business address; or
 - iv. sent by e-mail to either party's official email address.
- c) Where there is proof that the notice of hearing was delivered late, the receiving party may request extension of time or postponement of the hearing, which may not be unreasonably denied.

38. APPEAL

38.1 An appeal against any decision of the Office must be in writing and lodged, with the Minister, within thirty (30) days from the date of gaining knowledge of the decision.

38.2 The Minister shall, upon receipt of the notice of appeal, appoint an *ad hoc* tribunal to hear the appeal.

38.3 The procedure and conduct of the appeal must be determined by the *ad hoc* tribunal.

38.4 There is no right of appeal to the Minister in relation to a conviction for an offence, if prosecuted.

39. PUBLICATION OF TRIBUNAL DECISIONS AND REPORTS

39.1 The Office shall publish the decisions of the *ad hoc* tribunal in the *gazette* within twenty-five (25) working days from the date of the decision.

39.2 All other reports relating to the outcome of the hearings conducted and recommendations made to the Minister or other relevant authorities shall be published on the Office's website every six months.

40. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

| | |
|--|--|
| 40.1 Health establishments, person-in-charge, and employees | <ul style="list-style-type: none">• Familiarise themselves with prescribed norms and standards.• Comply with the prescribed norms and standards.• Cooperate with the Office and its employees. |
| 40.2 Relevant Authorities | <ul style="list-style-type: none">• Ensure that breaches of the prescribed norms and standards are dealt with as and when referred by the Office. |
| 40.3 Users | <ul style="list-style-type: none">• Provide inspectors with required information.• Report breaches of norms and standards / non-compliance by health establishments. |
| 40.4 The Office | <ul style="list-style-type: none">• Inspect compliance with the norms and standards.• Guide health establishment on compliance with the norms and standards.• Enforce compliance with the norms and standards.• Issue certificate of compliance to compliant health establishments. |

41. REVIEW OF THE ENFORCEMENT POLICY

This Policy shall be reviewed as and when necessary.

ANNEXURE A

INSPECTOR'S CODE OF CONDUCT

1. DEFINITIONS

- 1.1. **“Code of Conduct”** means the Code of Conduct for Inspectors of the Office;
- 1.2. **“Office”** means the Office of Health Standards Compliance established by section 77(1) of the Act; and
- 1.3. **“the Act”** means the National Health Act, 2003 (Act No. 61 of 2003).

2. BACKGROUND

- 2.1 The Chief Executive Officer of the Office is required to develop and enforce a Code of Conduct for Inspectors, which must be signed by all the inspectors prior to the commencement of their duties.
- 2.2 This document sets out the standards of professional and ethical conduct expected of all the Inspectors.

3. PURPOSE

- 3.1 The primary purpose of the Code of Conduct is to promote exemplary conduct.
- 3.2 In carrying out their statutory functions, inspectors are required to adhere to certain standards of professional and ethical conduct. It sets the standard on actions, appearance, conduct and demeanor.

4. VALUES AND PRINCIPLES

- 4.1 The Code of Conduct underpins the following set of values and principles which govern the functioning of Inspectors:
 - 4.1.1 Act as the champion of the public and of health users to restore credibility and trust, by protecting the public interests.

- 4.1.2 Protect and promote the health and safety of users of health services in the Republic.
- 4.1.3 Respect healthcare users and their families as well as healthcare staff.
- 4.1.4 Strive for effectiveness in achieving health system change and social impact.
- 4.1.5 Promote excellence, innovation and efficiency in healthcare operations.
- 4.1.6 Promote fairness and commitment to intellectual honesty, displayed through competency.
- 4.1.7 Promote transparency while respecting the right to confidentiality, through objectivity.
- 4.1.8 Achieve the highest standards of ethical behavior, teamwork and collaboration.
- 4.1.9 Promote professionalism, ethics, compassion, diversity, and social responsibility through exemplary personal conduct and skillfulness.

5. SCOPE

The Code of Conduct applies to all Inspectors of the Office appointed in terms of section 80(2) of the Act, when conducting their official duties.

6. COMPLIANCE WITH LAWS AND REGULATIONS

6.1 An Inspector must—

- 6.1.1 commit to ensuring that she or he has a sound understanding of all relevant laws, regulations, norms and standards and policies in order to carry out her or his duties professionally.
- 6.1.2 exercise her or his powers within the ambit of the law and other regulatory prescripts.
- 6.1.3 evaluate health establishments in accordance with the prescribed norms and standards.
- 6.1.3 abide by the Constitution and other relevant laws, regulations, norms and standards, policies and guidelines, in the performance of her or his duties.

7. CONDUCT TOWARDS HEALTH USERS AND THE PUBLIC

7.1 An Inspector must—

- 7.1.1 respect and protect the dignity and rights of health users.

- 7.1.2 not unfairly discriminate against any person based on race, gender, ethnic or social origin, colour, sexual orientation, age, disability, religion, political persuasion, conscience, belief, culture, language, or geographical location.
- 7.1.3 respect the rights of all health users to freedom and security of the person.
- 7.1.4 respect the rights of all health users to privacy, including confidentiality.
- 7.1.5 be polite and accessible to health users, the public and healthcare staff.
- 7.1.6 put the interests of health users and the public first in the execution of her or his duties.

8. CONDUCT TOWARDS THE OFFICE

8.1 An Inspector must—

- 8.1.1 protect and uphold the integrity of the Office.
- 8.1.2 co-operate with other employees to advance the interest of the Office.
- 8.1.3 execute all lawful instructions issued by persons who are officially authorised to give them.
- 8.1.4 deal fairly, professionally and equitably with other employees, irrespective of race, gender, ethnic or social origin, colour, sexual orientation, age, disability, religion, political persuasion, conscience, belief, culture or language.
- 8.1.5 not use her or his influence or abuse her or his authority when dealing with colleagues.
- 8.1.6 not conduct herself or himself in a manner that could jeopardize or harm the name or image of the Office.

9. CONDUCT TOWARDS HEALTH ESTABLISHMENTS AND HEALTHCARE STAFF

9.1 An Inspector must—

- 9.1.1 carry out her or his duties in a courteous and non-discriminatory manner, with a minimum level of disruption necessary.
- 9.1.2 maintain a mutually respectful and collegial relationship with healthcare staff in health establishments.
- 9.1.3 apply her or his knowledge, skills and experience in a competent and professional manner, to the best of her or his ability.
- 9.1.4 gather, interpret and report on evidence concerning health establishment with

the highest levels of professionalism.

9.1.5 objectivity perform her or his duties with the highest degree of reasonableness, fairness and accuracy to make a balanced assessment of a health establishment's compliance with the law.

9.1.6 provide the health establishments with timely, accessible and accurate information regarding compliance or non-compliance and steps to be taken to comply with the prescribed norms and standards.

9.1.7 be unbiased and impartial, not allowing her or his evaluations to be unduly influenced by predetermined views, values or attitudes, instead be guided by the evidence gained during inspections in her or his decision-making.

9.1.8 consider all evidence against a set of predefined principles to ensure that she or he is consistent and fair in her or his judgement.

9.1.9 give honest, impartial and constructive feedback to health establishments after inspections.

10. PERSONAL CONDUCT

10.1 An inspector must—

10.1.1 behave and dress in a manner that enhances the reputation of the Office.

10.1.2 be punctual at all times.

10.1.3 present herself or himself in a professional wear and behave in a professional manner.

10.1.4 uphold highest professional standards in her or his work.

10.1.5 maintain and develop own professional competence.

10.1.6 not make use of any substance having an intoxicating effect while performing her or his duties, except prescribed medication.

10.1.7 refrain from party political activities during the execution of duties.

10.1.8 use appropriate channels to communicate her or his grievances or to direct representations.

10.1.9 Delete any evidence, including photos and other images that were captured on any electronic devices while conducting formal duties, once such evidence is stored as part of inspections record.

10.1.10 maintain confidentiality in relation to all classified information or documents or information or documents that are considered as confidential or secret.

- 10.1.11 constantly seek to enhance her or his efficiency and effectiveness in the carrying out of her or his duties.
- 10.1.12 maintain satisfactory levels of competence and constantly seek to improve her or his proficiency through ongoing training and self-development as determined by the Office.
- 10.1.13 perform her or his work with honesty, integrity, diligence and responsibility.
- 10.1.14 apply her or his decisions, methods, principles and outcomes based on clear and consistent norms and values.
- 10.1.15 not knowingly be part of any illegal activity or engage in any act that may put the Office into disrepute.
- 10.1.16 not make any false or misleading representation or engage in deceptive or unconscionable conduct in relation to her or his functions.
- 10.1.17 maintain utmost privacy in the use, handling, storage and protection of information acquired during her or his duties.
- 10.1.18 not be involved in any act of intimidation or violence during inspections.
- 10.1.19 only use her or his title in relation to official business.
- 10.1.20 not use her or his position to benefit herself or himself or others.
- 10.1.21 avoid situations that could give an impression of impropriety during inspections.
- 10.1.22 not give preferential treatment to any health establishment and avoid situations that would raise the suspicion of preferential treatment.

11. CONFLICT OF INTEREST

11.1 An inspector must—

- 11.1.1 declare any personal or other interest in any matter that is the subject of an inspection or investigation, which could compromise, or appear to compromise, her or his professional judgement, objectivity or independence.
- 11.1.2 not use any information gained through inspections for personal gain or for the gain of others.
- 11.1.3 be honest and accountable in dealing with allocated funds and use the Office's property and other resources effectively, efficiently, and only for authorised purposes.

- 11.1.4 not, without approval, undertake remunerative work outside his or her official duties or use office equipment for such work.
- 11.1.5 guard against activities or relationships which may create a conflict of interest in the performance of her or his duties and disclose any financial or personal conflicts of interest.
- 11.1.6 not permit herself or himself to be exploited in any manner.
- 11.1.7 observe all relevant laws, regulations, policies and norms and standards in the execution of her or his functions or performance of her or his powers.
- 11.1.8 not use a cell phone or access any social media platform during inspection other than for work related or emergency purposes.

12. ACCEPTANCE OF GIFTS, HOSPITALITY AND SERVICES

- 12.1 An inspector may not accept personal gifts, hospitality or services which would, or might appear to place him or her under any obligation.
- 12.2 An Inspector must declare any gift by a health establishment and return any inappropriate gift or gifts that are not generally made available to the public at social events or promotions.

13. REPORTING OF UNPROFESSIONAL, ILLEGAL OR UNETHICAL CONDUCT

- 13.1 An inspector must—
 - 13.1.1 report to the appropriate authorities, fraud, corruption, nepotism, mal-administration or any other act which constitutes an offence, or which is prejudicial to the public interests.
 - 13.1.2 report to the Office any conduct of a colleague, which she or he considers to be unsafe, illegal, unethical or in conflict with the provisions of this Code of Conduct.

14. CONFIDENTIALITY

- 14.1 An Inspector must—
 - 14.1.1 respect the confidentiality of information obtained during the performance of her or his duties.

14.1.2 not disclose such information to any person unless required to do so by law or by an order of Court.

15. REPORTING

15.1 An inspector must—

15.1.1 report her or his findings in an objective and transparent manner.

15.1.2 not knowingly understate or overstate the significance of any reported condition.

16. RECORD KEEPING

An inspector must maintain clear and accurate records in an accessible and secure manner.

17. CONTRAVENTION OF THE CODE OF CONDUCT

An inspector will be guilty of misconduct if she or he contravenes any provision of this Code of Conduct or fails to comply with any provision thereof.

ANNEXURE B

COMPLIANCE STATUS FRAMEWORK FOR CLINICS

1. WHAT IS A COMPLIANCE STATUS FRAMEWORK?

A Compliance Status framework (CSF) is a tool used by the OHSC to determine the status of compliance by a health establishment to regulated norms and standards.

2. PURPOSE OF COMPLIANCE STATUS FRAMEWORK

To guide the OHSC in making compliance decisions in a transparent, fair, and consistent manner.

3. COMPLIANCE

In general, compliance means conforming to a rule, such as a specification, policy, standard or law. For a health establishment to become compliant, steps must be taken to comply with regulated norms and standards.

4. RISK RATING

Risk rating is a methodology used to categorise the level or extent of risk as being minimal, low, medium or high on the basis of the potential consequences of a risk and the level of potential impact the non-compliance may have on users. Risk is measured in the area where it occurs. In the context of OHSC risk will be measured at a functional area level. The OHSC adapted the Australian risk rating methodology¹ to assign the risk level for each measure.

5. RISK RATINGS FOR PRIMARY HEALTH CARE CLINICS (PHCs)

- a. Vital
- b. Essential

6. DEFINITION OF RISK RATINGS

6.1 VITAL

Vital risk rated measures are those which are critical to ensure the safety of staff and users so as not to result in harm or irreversible ill health. Within the vital measures, there are measures that have been identified as non-negotiable, as failure to comply with these measures is highly likely to result in severe harm or death. These measures are categorised as non-negotiable vital (NNV) measures. Health establishments must comply

with these measures to be eligible for certification. The following are the three NNV measures in the clinic tool, all of which are in the Clinical Service area:

- a. Emergency trolley is stocked with the medicines and equipment.
- b. An oxygen cylinder with pressure gauge is available.
- c. The oxygen available in the cylinder is above the minimum level.

6.2 ESSENTIAL

Essential risk rated measures are those which are fundamental to the provision of safe, quality care and are designed to provide an in-depth view of what is expected within available resources.

7. CLINIC INSPECTION TOOL

The inspections are conducted in the functional area. A functional area (FA) is a department, ward, or area within a health establishment where the services are provided. The clinic assessment tool consists of 4 Functional Areas namely:

- a. Clinic Management
- b. Dispensary/Medicines Room
- c. Clinical Services
- d. Maintenance Support

Table 1: Number of measures by risk rating contained in the inspection tools

| Risk Rating | | |
|--------------------|-------|-----------|
| Number of measures | Vital | Essential |
| Total | 76 | 73 |

Table 2: Number of measures by risk rating per functional area.

| Functional Area | Number of measures | Risk Rating | |
|---------------------------|--------------------|-------------|----|
| | | V | E |
| Clinic Management | 55 | 17 | 38 |
| Clinical Services | 54 | 32(*3NNVs) | 22 |
| Dispensary/Medicines Room | 23 | 16 | 7 |
| Maintenance Support | 17 | 11 | 6 |

| | | | |
|--------------|------------|-----------|-----------|
| | | | |
| Total | 149 | 76 | 73 |

8. GRADING

The OHSC will grade health establishments performance into one of four categories, according to the level of compliance achieved with the measures in each category. The grading levels will be as follows:

- a. Excellent
- b. Good
- c. Satisfactory
- d. Unsatisfactory

8.1 EXCELLENT

The minimum risk rating for this category is met as outlined in the matrix (V ≥80% and E ≥70%).

8.2 GOOD

Most services are better than the set norms and standards. The minimum risk rating for this category is met as outlined in the matrix. (V = 70 – 79% and E = 60 – 69 %).

8.3 SATISFACTORY

Services meet the set norms and standards. The minimum risk rating for this category is met as outlined in the matrix (V = 60 – 69% and E = 50 - 59%).

8.4 UNSATISFACTORY

The services are at a risk of avoidable harm and do not meet the set minimum norms and standards. There is limited assurance about safety. The risk rating for this category is below satisfactory limits as outlined in the matrix (V < 60% and E <50%).

The requirements for achievement described above are summarised in **Table 3 below**:

| Grading model | | |
|-----------------------|--------------------|-------------------------------------|
| Grading | Risk rating | Number of Measures compliant |
| Excellent | V ≥80% | 51/64 |
| | E ≥ 70% | 46/65 |
| Good | V = 70 - 79% | 45/64 |
| | E = 60 - 69% | 39/65 |
| Satisfactory | V = 60 - 69% | 38/64 |
| | E = 50 - 59% | 33/65 |
| Unsatisfactory | V <60% | <38/64 |
| | E <50% | <33/65 |

According to this model, risk will be measured in clusters of measures in a functional area. The risk rating cut-offs are determined for each grade to establish the level of grading to be awarded to the health establishment.

Example 1: Unsatisfactory performing clinic (based on the pilot inspection conducted in May 2019)

Compliance Status Framework

Application of CSF

| Grading | Model 3 | Measures | Grading level Outcome | Risk Ratings | Clinic Manager | Medicine Room | Clinical Services | Maintenance Support Services | Overall Risk Grading Outcome |
|----------------|--------------|----------|-----------------------|--------------|----------------|---------------|-------------------|------------------------------|--------------------------------|
| Excellent | NNV – 100% | 4/4 | 76-100% | Vitals | *NNV | | 2/3=66.66% | | 33/64=51.56% Unsatisfactory |
| | V ≥ 80% | 51/63 | | | V | 4/24=17% | 4/7=57% | 21/29=72% | |
| | E ≥ 70% | 44/63 | | Essentials | 6/27=22% | 2/7=24% | 5/8=64% | 2/5=35% | 15/47=31.9% Unsatisfactory |
| Good | NNV – 100% | 4/4 | 66-75% | | | | | Grading | Unsatisfactory |
| | V = 70 -79% | 44/63 | | | | | | | |
| | E = 60 -69% | 38/63 | | | | | | | |
| Satisfactory | NNV – 100% | 4/4 | 56-65% | | | | | | |
| | V = 60 - 69% | 38/63 | | | | | | | |
| | E – 50 - 59% | 32/63 | | | | | | | |
| Unsatisfactory | NNV > 100% | >4/4 | 0-55% | | | | | | |
| | V > 60% | >38/63 | | | | | | | |
| | E > 50% | >32/63 | | | | | | | |

9.1 INTERPRETATION OF THE RATING

Overall health establishment grading:

- Proportion of Vital measures = 50% which falls in the **Unsatisfactory** grading
- Proportion of Essential measures= 32.9% which falls in the **Unsatisfactory** grading
- Therefore, the overall grading of the clinic = **Unsatisfactory**

Compliance Decision: Non-compliant.

Example 2: Good performing clinic (based on pilot conducted in May 2019)

Compliance Status Framework

Application of CSF

| Grading | Model 3 | Measures | Grading level Outcome | Risk Ratings | Clinic Manager | Medicine Room | Clinical Services | Maintenance Support Services | Overall Risk Rating Outcome |
|----------------|-------------|----------|-----------------------|--------------|----------------|---------------|-------------------|------------------------------|-----------------------------|
| Excellent | NNV – 100% | 4/4 | 76-100% | Vitals | *NNV | | 2.97/3= 98.92% | | 53.87/64=88.81% |
| | V – 80% | 51/63 | | | V | 11/13=84.62% | 11.99/13=92.22% | 22.38/13=97.32% | |
| | E – 70% | 44/63 | | Essentials | 35.8/40=89.5% | 4/4=100% | 18.3/19=96.29% | 1.9/2=94.83% | 60/65=92% |
| Good | NNV – 100% | 4/4 | 66-75% | | | | | Grading | Excellent |
| | V – 70% | 44/63 | | | | | | | |
| | E – 60% | 38/63 | | | | | | | |
| Satisfactory | NNV – 100% | 4/4 | 56-65% | | | | | | |
| | V – 60% | 38/63 | | | | | | | |
| | E – 50% | 32/63 | | | | | | | |
| Unsatisfactory | NNV – <100% | <4/4 | 0-55% | | | | | | |
| | V – <60% | <38/63 | | | | | | | |
| | E – <50% | <32/63 | | | | | | | |

9.2 INTERPRETATION OF THE RATING

Overall health establishment grading:

- a. Vitals measures=91% which falls in the **Excellent grading**
- b. Essential measures=92% which falls in the **Excellent grading**
- c. Therefore, the overall grading of the clinic = **Excellent grading**

Compliance decision: Non-Compliant

* The health establishment is **Non-compliant** as the non-negotiable vital measures are < 100%. Should the health establishment correct the deficiencies identified in relation to the non-negotiable measures it will be eligible for certification.

9. DECISION MAKING REGARDING COMPLIANCE

9.1 Each functional area is assessed separately according to the measures appropriate to the functional area. The functional areas will be graded according to how they performed on the Vitals and Essential measures. The overall (all functional areas) performance for the vitals and essentials will be used to determine the health establishment grading level.

9.2 Compliance status will be determined by the performance outcomes of the Vitals and Essential risk rated measures meeting the minimum requirements of the set ranges of the grades, provided the outcomes of NNV's is 100%. The Unsatisfactory grading will automatically be deemed Non-Compliant.

10. COMPLIANCE AND CERTIFICATION

10.1 The decision as to whether a health establishment is eligible for certification depends on two levels of achievement.

- a. Grading of the health establishment.
- b. Performance in relation to the NNV measures.

10.2 The application of the Compliance Status Framework to the inspection findings of health establishment result in the categorisation of the health establishment as Excellent; Good; Satisfactory or Unsatisfactory.

10.3 To be eligible for certification, health establishment must achieve 100% of the NNV measures.

10.4 Health establishments graded as Excellent, Good or Satisfactory and in addition have achieved 100% compliance with the NNV measures will be eligible for certification

11. RULES GOVERNING APPLICATION OF THE COMPLIANCE STATUS FRAMEWORK

11.1 A health establishment must achieve 100% of measures designated as non-negotiable within the Vital measures.

11.2 Failure to achieve 100% of non-negotiable vital measures within vitals on any grading level will result in health establishment being **non-compliant** irrespective of the **vitals and essentials measures performance**.

11.3 Health establishments will be graded at the lowest achieved grading when the outcome of the risk ratings is not on the same grade e.g. When **vitals achieve 70% (Good)** and **essentials achieve 50% (Satisfactory)**, the overall grading awarded to the health establishment will be **satisfactory**.

12. CERTIFICATION

OHSC will certify health establishments as compliant when they attain Excellent, Good & Satisfactory grading, provided they have met all the non-negotiable measures designated within vitals. The three grading levels for certification will have conditions that health establishments must adhere to for the duration of certificate as shown in the Table below.

Table 4: Conditions for Certification

| GRADING | CONDITIONS | DURATION |
|------------------|--|--------------------------------|
| Excellent | 1. Grading level of 75-100% 2. Compliance Certificate 3. Submission of progress report (approved by Person in Charge /District Manager /CEO) with related evidence 4. Specific steps including time frames to remedy areas of non-compliance. | 4 years and as per regulations |
| Good | 1. Grading level of 65-74% 2. Compliance Certificate 3. Submission of progress report (approved by Person in | 4 years and as per regulations |

| | | |
|-----------------------|---|--|
| | Charge/District Manager /CEO) with related evidence 4. Specific steps including time frames to remedy areas of non-compliance. | |
| Satisfactory | 1. Grading level of 55-64% 2. Compliance Certificate 3. Submission of progress report (approved by Person in Charge /District Manager/CEO) with related evidence 4. Specific steps including time frames to remedy areas of non-compliance | 4 years and as per regulations |
| Unsatisfactory | 1. Grading level of <55% 2. Compliance Notice (Non-compliant) 3. Submission of progress report (approved by Person in Charge/District Manager/CEO) with related evidence 4. Specific steps including time frames to remedy areas of non-compliance | Additional inspection within 12 Months |

13. GENERAL CONDITIONS

As part of the ongoing monitoring of health establishments, all health establishments are required to furnish the following to the OHSC:

- a. Submission of **Annual Self-Assessment Reports.**
- b. Submission of **Annual Returns.**
- c. Reporting on **Early Warning System indicators.**

ANNEXURE C

CONTACT DETAILS

| | |
|---|--|
| Director: Certification and Enforcement | Adv Makhwedi Makgopa-Madisa |
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| | |
|---|--|
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