OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

# GUIDANCE MANUAL

## Implementation of Norms and Standards Regulations

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# 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 in terms of Section 79(2)(a) a Guidance Manual for the implementation of norms and standards regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 has been developed by the Office of Health Standards Compliance (OHSC) for the benefit of health establishments.

Date: 18/02/2020

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# 1 ACKNOWLEDGEMENT

There are many people who have contributed to the development of the Guidance Manual for the implementation of norms and standards regulations applicable to different categories of health establishments. The OHSC wishes to extend most heartfelt acknowledgement and gratitude to the following:

- Health Standards Development Analysis and Support unit team (Ms Winnie Moleko, Dr Grace Labadarios, Ms Nonduku Mobadi, Ms Busisiwe Mashinini) for the development of the Guidance Manual for the implementation of norms and standards regulations applicable to different categories of health establishments

- The internal OHSC teams (Compliance Inspectorate, Certification and Enforcement, Complaints Centre and Assessment, Complaints Investigation, Systems, Data Analysis and Research), for their contribution during the development of the Guidance Manual for the implementation of norms and standards regulations applicable to different categories of health establishments and (Information Technology and Communication and Stakeholder Relations) for providing support.

- The Certification and Enforcement Committee of the OHSC Board for reviewing the Guidance Manual and for recommending to the Board for approval.

It is hereby certified that the Guidance Manual for the implementation of norms and standards regulations applicable to different categories of health establishments was developed by the Office of Health Standards Compliance.

# 2 ABBREVIATIONS

| | |
|---|---|
| CHC | Community health centres |
| CSF | Compliance status framework |
| EMS | Emergency medical services |
| GDP | Gross domestic product |
| HCRW | Health care risk waste |
| HPCSA | Health Professions Council of South Africa |
| HR | Human resources |
| IPC | Infection prevention and control |
| MEC | Member of the Executive Council |
| NDoH | National Department of Health |
| NHI | National Health Insurance |
| OHSC | Office of Health Standards Compliance |
| PHC | Primary health care |
| SLA | Service level agreement |
| SOP/s | Standard operating procedure/s |
| TOR | Terms of reference |
| WHO | World Health Organization |

# 3 BACKGROUND AND INTRODUCTION

The Office of Health Standards Compliance (OHSC), as a Schedule 3A public entity, was established in terms of the National Health Amendment Act No.12 of 2013.

## 3.1. Mandate

The OHSC's mandate is to protect and promote the health and safety of users of health services in South Africa by:

- Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to national health systems
- Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

## 3.2. Vision

The OHSC's vision is 'Consistent, safe and quality healthcare for all'.

## 3.3. Mission

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

## 3.4. Values

The OHSC's values are informed by the South African Constitution and Batho Pele principles, which promote the preservation of human dignity, freedom and equality.
In carrying out our mandate, we:

- Champion the cause of the public and of health care users to restore credibility and trust in the health care system
- Respect health care users and their families as well as health care staff
- Strive to achieve health system change
- Strive for excellence, innovation and efficiency in our operations
- Are truthful, fair and committed to intellectual honesty
- Practice transparency but respect confidentiality
- Achieve the highest standards of ethical behaviour, teamwork and collaboration
- Promote professionalism, compassion, diversity and social responsibility.

## 3.5. Regulatory Principles of the Office of Health Standards Compliance

Five principles guide the OHSC's daily operations and decisions in line with good regulatory practice, which enable the evaluation of its performance as a regulator.

- Principle 1: Regulations must foster greater accountability
  Regulations must set explicit benchmarks for regulated entities against which they can be measured objectively and their leadership held accountable for compliance. The OHSC shall be responsible for regulatory decisions and the achievement of regulatory outcomes.

- Principle 2: Regulations must be clear and transparent
  Regulations should state clearly the obligations placed on regulated entities and provide reasons for these obligations. The OHSC shall be transparent in executing its legislative mandate (i.e. the publication of decisions) and allow the public to attend hearings.

- Principle 3: Regulations should target problems or risks to safety
  Regulations should target the problem or risk to users' safety within the health system and identify clearly the outcome of the intervention. Enforcement shall apply to a health establishment or part of a health establishment posing a high risk to users or displaying persistent non-compliance.

- Principle 4: Regulatory interventions should be appropriate
  The enforcement action taken against the health establishment must be proportionate to the problem or risk requiring attention. It should specify the minimum necessary requirements to achieve the desired outcomes of safety, while avoiding an overly punitive approach.

- Principle 5: Regulations should be applied consistently
  Regulatory and enforcement processes and procedures should be consistent to ensure reliable outcomes. Similar actions should be applied to similar breaches.

### 3.6. Legislative Mandate and Policy Consideration

Improving quality and addressing health service delivery are fundamental to strengthening South Africa's current poor health outcomes and its overall health system. Safe health care will restore patients' and employees' confidence in the public and private health care system.

Quality in the health system may be defined as obtaining the best possible results with the resources available. Several governing acts, regulations and policies influence the quality of health care in South Africa, including the following:

#### 3.6.1. Constitution of the Republic of South Africa, Act No. 108 of 1996

Underpinning the entire health system are the constitutional imperatives enshrined in the Bill of Rights in Chapter 2 of the Constitution of the Republic of South Africa, Act No. 108 of 1996 (hereinafter referred to as "the Constitution"). Section 27, in particular, grants right of access to health care services, including reproductive health services and emergency medical treatment. The Constitution requires the state to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.

The realisation of socio-economic rights has been tested multiple times by the Constitutional Court in relation to housing, social assistance and health rights. In most decisions, the Constitutional Court considered the reasonableness of government's measures in attaining these socio-economic rights (James, 2012). The Courts focused on whether government had sufficient plans and policies in place to fulfil the obligations set out in the Bill of Rights.

Regulation of the quality of health services charts a path for all health establishments to comply with policy priorities and minimum standards of care. In this manner, the regulation of quality contributes directly to government's progressive realisation of its constitutional obligations.

The constitutional imperatives set out in the Bill of Rights cannot be achieved without the collective efforts of all spheres of government. Hence, section 41 of the Constitution requires all three spheres of government to work cooperatively to secure the wellbeing of the people of South Africa, and to preserve the peace, national unity and indivisibility of the country. This principle of cooperative government is particularly important in health services, which are a functional area of concurrent competence across national and provincial governments, as defined in Schedule 4 of the Constitution.

National government is responsible for developing and monitoring policies, legislation, and norms and standards for the health sector. Provincial government can discharge its constitutional obligations by passing provincial legislation in the area of health services but remains responsible for the implementation of national policy and legislation, while local government is responsible for municipal and environmental health functions. Section 44 of the Constitution gives the National Assembly the authority to pass legislation about functional areas of concurrent competence and to prescribe minimum norms and standards.

### 3.6.2. The National Health Act, No. 61 of 2003

The Act reaffirms the constitutional rights of users to access health services and just administrative action. Section 18 allows any user of health services to lay a complaint about the manner in which he/she was treated at a health establishment and have the complaint investigated. Complaints provide useful feedback on the areas within health establishments that do not comply with prescribed standards or that pose a threat to the lives of users and employees. The Act obliges MECs to establish procedures for addressing complaints within their area of jurisdiction.

The Act provides the overarching legislative framework for a structured and uniform national health care system. It highlights the rights and responsibilities of health care providers and health care users and ensures broader community participation in health care delivery from a health facility level up to national level. With respect to sections that have been amended, although never promulgated, the Act provided for the creation, within the National Department of Health, of an Office of Standards Compliance with provincial Inspectorate units. The Office of Standards Compliance, as then envisaged, would advise on health standards, carry out inspections and monitor compliance, report on non-compliance, issue or withdraw a certificate of compliance, and advise on strategies to improve quality. The Office would include an Ombudsperson to address

complaints.

### 3.6.3. National Health Amendment Act, No. 12 of 2013

Chapter 10 of the National Health Act relating to the Office of Standards Compliance was repealed in its entirety (and other minor changes were enacted) through the promulgation of the National Health Amendment Act No 12 of 2013, which replaced the previous provisions (that had never been brought into effect) with a new independent entity, the Office of Health Standards Compliance.

The Objectives of the Office are reflected in the Act as being to protect and promote the health and safety of users of health services by:

- Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system
- Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

### 3.6.4. The Protection of Personal Information (PoPI) Act, No. 4 of 2013

The purpose of the PoPI Act is to ensure that all South African institutions conduct themselves in a responsible manner when collecting, processing, storing and sharing another entity's personal information, by holding them accountable should they abuse or compromise personal information in any way.

The PoPI legislation considers personal information to be "precious goods", and aims to bestow upon owners of personal information certain rights of protection and the ability to exercise control over:

- When and how to share information (requires individual consent)
- The type and extent of information individuals choose to share (must be collected for valid reasons)
- Transparency and accountability on how data will be used (limited to the purpose) and notification if/when data is compromised
- Providing individuals with access to personal information as well as the right to have personal data removed and/or destroyed should individuals so wish
- Who has access to personal information i.e. there must be adequate measures and controls in place to track access and prevent unauthorised people, even within the same company, from accessing an individual's information
- How and where personal information is stored. i.e. there must be adequate measures and controls in place to safeguard personal information to protect it from theft
- The integrity and continued accuracy of personal information. i.e. personal information must be captured correctly and once collected, the institution is responsible for maintaining it.

### 3.6.5. Promotion of Access to Information Act (PAIA), No. 2 of 2000

Section 32(1)(a) of the Constitution provides that everyone has right of access to any information held by the state and any information held by another person that is required for the exercise or protection of any rights. Therefore, PAIA gives all South Africans the right to have access to records held by the state, government institutions and private bodies.

The following are the objectives that PAIA seeks to achieve:

- To ensure that the state takes part in promoting a human rights culture and social justice
- To encourage openness and to establish voluntary and mandatory mechanisms or procedures that give effect to the right of access to information in a speedy, inexpensive and effortless manner as reasonably possible
- To promote transparency, accountability and effective governance of all public and private bodies, by empowering and educating everyone to understand their rights in terms of PAIA so that they can exercise their rights in relation to public and private bodies
- To understand the functions and operation of public bodies
- To effectively scrutinise and participate in decision making by public bodies that affects their rights.

### 3.6.6. Other statutes and provisions relevant to the delivery of health services

- Medical Schemes Act, No. 131 of 1998
- Medicines and Related Substances Act, No. 101 of 1965
- Mental Health Act, No. 17 of 2002
- Health Professions Act. No. 56 of 1974
- Pharmacy Act, No. 53 of 1974
- Nursing Act, No. 33 of 2005
- Hazardous Substances Act, No. 15 of 1973
- Human Tissue Act, No. 65 of 1983
- Occupational Diseases in Mines and Works Act, No. 78 of 1973
- Batho Pele Principles
- Patients' Rights Charter
- National Core Standards for Health Establishments in South Africa
- National Health Insurance (NHI)
- National Development Plan (NDP)
- National Health Act: Regulations: Norms and standards applicable to certain categories of health establishments
- Occupational Health and Safety Act, No. 85 of 1993

### 3.6.7. National Policy on Quality (2007)

The policy identifies mechanisms for improving the quality of health care in the public and private sectors. It highlights the need to focus capacity-building efforts and quality initiatives on health professionals, communities, patients and the broader health care delivery system (National Department of Health).

The objectives of the policy on quality are to:

- Improve access to quality health care
- Increase patients' participation and the dignity afforded to them
- Reduce underlying causes of illness, injury and disability
- Expand research on treatments specific to South Africans' needs and on evidence of effectiveness
- Ensure appropriate use of services
- Reduce errors in health care.

### 3.6.8. Procedural regulations pertaining to the functioning of the Office of Health Standards Compliance

The procedural regulations of the Amendment Act, that have been promulgated by the Minister and published in the Gazette on 13 October 2016, guide the exercise of powers conferred on the OHSC, its board, its Chief Executive Officer, the Ombud and the Inspectors. The regulations elaborate on the form of details, procedures and processes to be followed by the Office.

Areas covered in these regulations are:

- Collection of information from health establishments and the designation and duties of the person in charge
- Inspectors and inspections, including their appointment, training, experience and conduct, and the inspection approach and process, including notice and additional inspections
- Entry and search of premises, including procedures to obtain prior consent or the application for a warrant, if required
- Processes of certification, renewal and suspension
- Compliance notice and enforcement process, including formal hearings, revocation of certificates, fines or referrals to prosecuting authority, appeals and reporting
- Lodging, screening, investigation and reporting of complaints, including time frames; complaints handling, investigation and resolution procedures
- General provisions regarding the prescribed forms to be used (listed in schedule 1).
- The procedural regulations are applicable to all categories of health establishments as per the National Health Act.

# 4 OBJECTIVES

The norms and standards regulations for different categories of health establishments are aligned with the regulatory mandate of the Office of Health Standards Compliance (OHSC). Consequently, the regulations guide, monitor and enforce the control of critical risks to the health and safety of users through the relevant systems and support structures.

These regulations articulate the minimum requirements expected of health establishments for improving users' safety and specify benchmarks against which health establishments are measured. The regulations are consistent with the powers given to the Office to monitor, certify and enforce compliance, and to monitor early warning indicators of risk that signal a breach of norms and standards. "Improved users' safety is demonstrated by improved user satisfaction with the health services, reduction of avoidable mortality, harm encountered during care, litigations and reduced healthcare costs".

## 4.1. Purpose of the Guidance Manual

Section 79(2)(a) of the National Health Amendment Act, No.12 of 2013 states that the OHSC may issue guidelines for the benefit of health establishments on the implementation of prescribed norms and standards. This guidance manual has been prepared to meet the requirements of the legislation.

This document is designed to help health care personnel to comply, during the course of their day-do-day work, with the norms and standards regulations for different categories of health establishment. The regulations describe the essential standards of safety that users of health services have a right to receive.

The guide will assist health care personnel to understand the intended benefits to users and health care personnel of complying with the norms and standards regulations applicable to different categories of health establishment as set out in the National Health Act, No 61 of 2003 and the National Health Amendment Act; Act No 12 of 2013. It will also make it easier for health establishments to achieve greater consistency between self-assessment and inspection scores by improving their understanding of what is required.

The guidance manual does not seek to cover the standards that individual health care professionals' must achieve in their day-to-day practice. Such standards have already been determined and enforced by the relevant professional bodies and councils such as the Health Professions Council of South Africa, the South African Pharmacy Council and the South African Nursing Council.

## 4.2. Purpose of Regulations

The purpose of the regulations is to promote and protect the health and safety of users and health care personnel to change people's behaviour and the manner in which systems operate, in accordance with set standards, to achieve defined outcomes.

### 4.3. Scope of Application for Regulations

The norms and standards regulations apply to the following categories of health establishment:

- Public hospitals – central, tertiary, regional, district
- Public community health centres (CHCs)
- Public and private clinics
- Private hospitals
- Private CHCs and day hospitals

# 5 THE STRUCTURE OF THE NORMS AND STANDARDS REGULATIONS

The norms and standards regulations were promulgated on February 2, 2018 and came into operation 12 months after promulgation.

The norms and standards regulations have been grouped into seven chapters:

- **Chapter 1** comprises definitions, and the purpose and scope of the application of the norms and standards.
- **Chapters 2–6** define five areas of risk that are critical to the delivery of safe health care services:

    - **Chapter 2:** User rights
    - **Chapter 3:** Clinical governance and clinical care
    - **Chapter 4:** Clinical support services
    - **Chapter 5:** Facilities and infrastructure
    - **Chapter 6:** Governance and human resources

These chapters translate into domains in terms of the inspection tools as described in section 7.1 of this guidance manual. The chapters have regulations titles that are used to create sub-domains in the inspection tools, e.g. user information, access to care, etc.,

- **Chapter 7** presents the general provisions but does not relate to the clinical environment and does not form its own domain in the inspection tools. Regulations within this chapter are incorporated in other domains in the inspection tools, e.g. adverse Events are monitored under the Clinical Governance and Clinical Care and the Governance and Human Resources chapters; Waiting Times are monitored under User Rights: Access to Care.

The inspection tools are grouped by domains. As illustrated in Figure 5.1, the structure of the inspection tools retains the hierarchy of the National Core Standards. These domains depict areas that are critical to the delivery of health services and the priority risk areas within a health establishment.

Each domain is broken down into sub-domains comprising focus areas of the regulation, or targeted behavioural or activity changes that should bring about better, safer user care. Each domain contains regulated standards that describe the expected performance of the health establishment and the intent of the standard.
The standards are broken down further into criteria, which divide the legal obligation into discrete outputs or activities required of the health establishment to comply with the standards. These criteria should guide the development of compliance strategies and help to interpret the requirements of the standards in terms of the minimum expected activity. The criteria provide guidance on the type of evidence or the standard or proof needed to measure compliance.

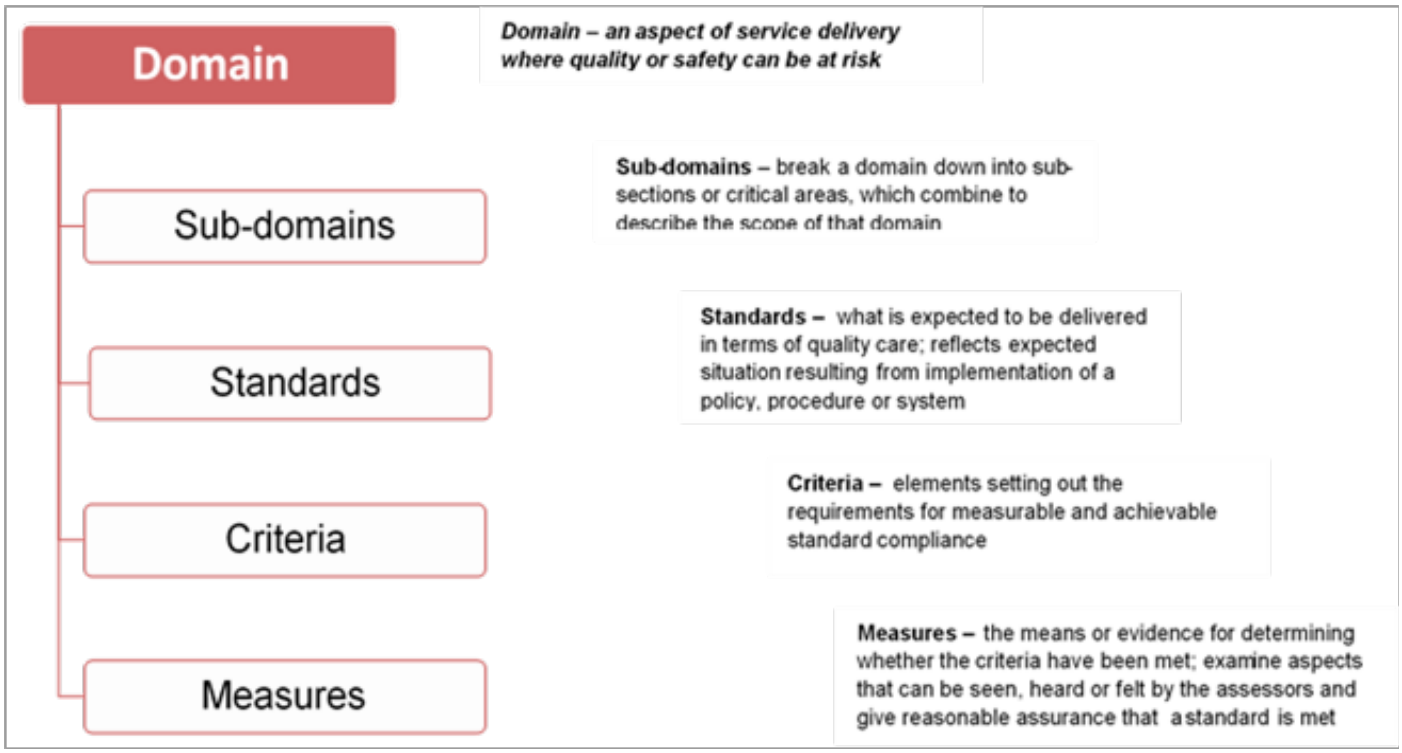


Figure 5.1: Structure of the norms and standards regulations

# 6 INSPECTIONS

Inspections are on-site visits to health establishments for the purposes of gathering information and evidence to assess the health establishment's compliance and/or investigate breaches in norms and standards regulations.

## 6.1. Inspection Strategy, Procedure and Plan

The inspection strategy applies to all categories of health establishments referred to in section 3 of the National Health Act, subject to sub-section (2).

The purpose of the inspection strategy is to guide the inspection activities of the OHSC, as approved by its board and published on its website, and includes the following:

- An approach to prioritising, scheduling and conducting inspections
- Resources and costs for the implementation of the inspection strategy.

The Office shall, within two weeks of the beginning of each financial year, inform the head of the national or provincial department of health or the municipal manager of its approach to carry out inspections. In the case of a private health establishment, the head of the health establishment or the executive management of the private hospital group to which the establishment belongs shall be informed. The Office shall also submit to any of these parties an annual inspection strategy containing information on such approach to inspections.

## 6.2. Types of Inspections

### 6.2.1. Routine inspections

Routine inspections are conducted in accordance with Section 82 of the National Health Amendment Act (Act 12 of 2013), which states:

I. A health officer may enter any premises, excluding a private dwelling, at any reasonable time and —

a. inspect such premises in order to ensure compliance with the Act.
b. question any person who he or she believes may have information relevant to the inspection.
c. require the person in charge of such premises to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document that such person is required to maintain in terms of any law; and
d. take samples of any substance that is relevant to the inspection.

II. A health officer may be accompanied by an interpreter and any other person reasonably required to assist him/her in conducting the inspection.

III. A health officer may issue a compliance notice to the person in charge of the premises if a provision of this Act has not been complied with.

IV. A compliance notice remains in force until the relevant provision of the Act has been complied with and the health officer has issued a compliance certificate in respect of that notice.

V. A health officer who removes any item other than that contemplated in subsection (1) (d) must—

a. issue a receipt for it to the person in charge of the premises; and
b. subject to the Criminal Procedure Act, 1977 (Act 51 of 1977), return it as soon as practicable after achieving the purpose for which it was removed.

### 6.2.2. Additional inspections

An inspector may, at any time, subject to section 82(1) of the Act, conduct an additional inspection, if he/she has reasonable grounds to believe that:

Such an inspection is needed to establish whether non-compliance has been remedied within the health establishment

- The health establishment is contravening the Act or any relevant regulations
- There are serious breaches of norms and standards, based on the indicators of risk
- The ombudsman'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.

### 6.2.3. Risk-based inspections

An inspector may conduct a risk-based assessment triggered by the early warning system for persistent or critical noncompliance or from the Ombudsman's findings

## 6.3. Inspection Process

### 6.3.1. Scheduling of inspections

Distribution and circulation of the inspection schedule
The Executive Manager inspectorate will schedule inspections and distribute the inspection schedule to the Director inspectorate unit, which will redistribute the schedule to inspection team leaders.

The role of the inspectorate team leaders is to:

- Arrange the pre-inspection planning meeting
- Delegate an inspector to assist with inspection planning
- Allocate tasks to team members to fulfil the pre-inspection planning
- Identify the areas to be inspected
- Note distances to be travelled
- Identify suitable modes of transport

- Collect other indicators and facility-related information as part of background checks
- Assign functional areas to be inspected to each inspector
- Prepare all assessment tools in order of functional areas on the relevant checklist and pass on to the respective inspectors.

### 6.3.2. Notice of inspection to health establishment

The inspectors will prepare a notice of inspection to the health establishment (Form 3), which must include, at a minimum, the following information:

- the purpose of the inspection
- the date of the inspection
- the estimated duration
- the inspection plan referred to in sub-regulation 12(4)
- the number of authorised personnel expected to conduct the inspection
- the contact details of the inspector primarily responsible for the inspection
- the responsibilities of the health establishment.

In terms of section 82 of the Act, before commencing with an inspection, an inspector must issue reasonable notice of inspection to the health establishment.

The notice of inspection must be signed by the CEO, or an authorised employee, of the Office of Health Standards Compliance.

The Office may, if it has reasonable grounds to believe that compliance with these notification requirements may jeopardise user safety or quality of care, conduct an unannounced inspection of the health establishment.

### 6.3.3. Conducting the inspection

Upon arrival at the premises of the health establishment, the inspector will clearly identify himself/herself to the person in charge and will:

- Present a certificate of appointment as an inspector, issued in terms of section 80(3) of the Act
- Present a letter of consent referred to in regulation 16(3), or an entry and search warrant issued in terms of section 84(5) of the Act, if applicable.
- Explain that during the inspection, the health establishment must make available the necessary staff, resources and space to allow inspectors to complete the inspection in an efficient manner
- Explain the purpose of the inspection to the managers in relation to the National Health Act as Amended (Act 12 of 2013) and its procedural regulations
- Describe the inspection methodology and process to be followed and allow the health establishment to present an overview of the facility.

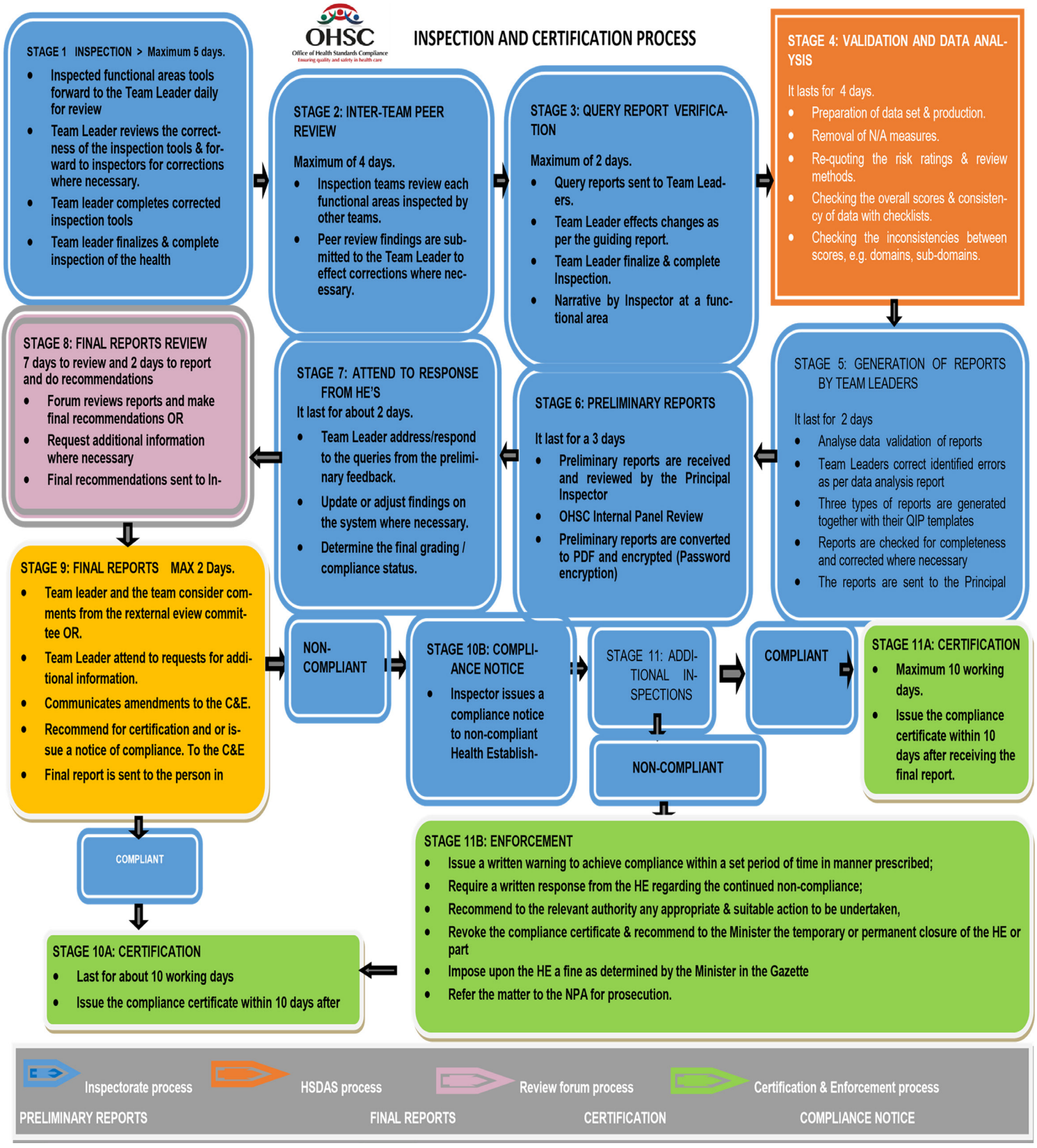


Figure 6.1: Inspection process flow diagram

# 7 INSPECTION TOOLS

Assessment tools are questionnaires with related measures and checklists that are used to assess the health establishment, by collecting information and calculating scores that reflect the health establishment's compliance with norms and standards regulations. The assessment tools are directly linked to the domains, standards and criteria. They are also divided into functional areas that represent different service delivery and operational areas within different types of health establishment.
Assessment tools are grouped according to the different levels of care. The number and size of the tools are directly linked to the different functional areas of the health establishment.

Assessment tools are designed to:

- Help inspectors to measure compliance objectively
- Provide a logical and efficient way of conducting inspections
- Guide inspectors with the most appropriate methodology to use in assessing compliance
- Provide a guidance statement and/or explanatory notes that ensure consistency in understanding and interpreting the requirements of the measure.

## 7.1. Structure of Inspection Tools

**1. DOMAIN 1 User Rights** ← Chapter

**2. SUB-DOMAIN Access to care** ← Regulation heading

**3. Standard** ← Sub-regulation / standard statement

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.

**4. Criterion** ← Sub-regulation / criterion statement

5.(2)(a) A health establishment must implement a system of triage.

**5. Measure** ← Measure statement with methodology and risk rating

The guideline or standard operating procedure for triaging is available.

**6. Explanatory Note:** ← Explanatory notes to clarify evidence required

The document implemented must be approved by a relevant national body, such as the Emergency Medical Services of South Africa. Not Applicable: Never

### 7.2. Assessment Methodology

- The assessment methodology should include:
- Documentation review (Doc)
- Observation (OBS)
- Patient interview (PI)
- Patient record analysis (PRA)
- Staff interview (SI)

Evidence is collected for both compliant and non-compliant measures.

### 7.3. Risk Rating Process Applied to Measures

Health care risk management comprises the systems and processes employed to uncover, mitigate, and prevent risks in health care institutions

Clinical risk management specifically is concerned with improving the quality and safety of health-care services by identifying the circumstances and opportunities that put patients at risk of harm and acting to prevent or control those risks.

The measures in the OHSC inspection tools look for evidence that systems are in place to control risks, i.e. identify hazards (a potential source of harm), prevent harm resulting from the hazard and mitigate the severity of harm should it occur. Each measure is then risk rated according to the level of risk represented by non-compliance with the measure.

The risk rating process implemented by the OHSC is in alignment with global risk rating practice, which considers a hazard in terms of the potential severity of harm should it occur (insignificant, minor, moderate, major, catastrophic), and the likelihood that harm will happen (rare, sometimes, frequent). In addition, the OHSC considers the number of people likely to be affected should an event occur.

Three dimensions (types) of risk are considered in the risk rating process:

- User care and safety
- Processes and systems within health care establishments
- Reputation of establishment

#### 7.3.1. Severity of harm

The severity of harm is determined by answering the question: How severe would the consequence of harm be due to non-compliance with the measure in relation to the dimension of risk? e.g. lack of adequate lighting (hazard) can result in assault of staff or users, misdiagnosis or falls (harm). The consequences of these harm events, should they occur, can be fatal (rarely), cause serious harm (sometimes) or result in less serious harm (mostly).

Table 7.1: Three dimensions of risk and severity

| DIMENSION | SEVERITY | | | | |
|---|---|---|---|---|---|
| | **Insignificant 1** | **Minor 2** | **Moderate 3** | **Major 4** | **Catastrophic 5** |
| **User care and safety** | Little or no impact on user care and safety | Has minor impacts on the quality of care offered to users. Results in increased number of complaints | Leads to adverse outcomes in user care and longer recovery periods | Life threatening situation | Death of user |
| **Processes and systems within health care establishments** | Systems and processes in place and operational. Existence of minor errors in information systems. Processes may be implemented inconsistently. | Systems and processes in place but implemented in an ad-hoc manner. Minor negative impact on quality of care of users and staff morale. | Systems and process are not operational and have a significant negative impact on quality of care | Absence of processes and systems is life threatening. May be detrimental to staff welfare. | Leads to serious injury of staff and places users in life threatening situations or results in death of user. |
| **Reputation of establishment** | No reputational impact | Minor reputational loss | Increasing complaints about quality of care in establishment | Impacts on user confidence in establishment | Significant negative impact on reputation of establishment. Entire health care system user intake volumes drop. |

After application of the above risk rating criteria (see Table 7.2), each measure is classified into one of four categories:

- **Extreme (X)**

Extreme measures are those that are likely to cause serious harm (including death and permanent loss of function) to both users and staff.

- **Vital (V)**

Vital measures are those conditions, practices or processes that might adversely affect the rights, safety or well-being of users and staff.

- **Essential (E)**

Essential measures are considered fundamental to the provision of safe, decent and quality care, and are designed to provide an in-depth view of what is expected from the available resources.

- **Developmental (D)**

Developmental standards are elements of quality of care to which health management should aspire to achieve optimal care. Non-compliance with these measures does not necessarily constitute a risk to patients. However, developmental standards form an integral part of a quality health care system and enhance a health establishment's ability to provide optimal care.

Table 7.2: Risk matrix for classification of risk category of measures

| LIKELIHOOD | DESCRIPTION | SEVERITY | | | | |
|---|---|---|---|---|---|---|
| | | Insignificant (1) | Minor (2) | Moderate (3) | Moderate (3) | Catastrophic (5) |
| **Most (3)** | Most patients in the health establishment will be affected | Medium (Essential) | Medium (Essential) | High (Vital) | Extreme | Extreme |
| **Some (2)** | Some patients in the health establishment will be affected | Low (Developmental) | Medium (Essential) | Medium (Essential) | High (Vital) | Extreme |
| **Rare (1)** | Very few patients will be affected | Low (Developmental) | Low (Developmental) | Medium (Essential) | Medium (Essential) | High (Vital) |

### 7.4. Certificate of Compliance

In terms of Section 79(1)(b) of the National Health Amendment Act, No. 12 of 2013, the Office must inspect and certify a health establishment as compliant or non-compliant with the prescribed norms and standards. Where necessary, it may withdraw such certification

### 7.5. Monitoring Compliance

The office monitors compliance with the norms and standards through:

- Inspections and investigations
- Incident notifications and complaints
- Early warning systems.

All health establishments found to be compliant with the prescribed norms and standards will be issued with a certificate of compliance. The certificate of compliance issued by the Office will be valid for a period of four years and is subject to renewal. Should there be any violation of any act during this period, an additional inspection will be conducted as per the procedural regulations.

A compliance notice issued against a certified health establishment suspends the compliance status until the conditions set out in the compliance notice are fulfilled.

### 7.6. Enforcement of Compliance

In terms of Section 78 of the National Health Act, No 61 of 2003, the mandate of the Office is to protect and promote the health and safety of users by:

- Monitoring and enforcing compliance by health establishments with norms and standards as prescribed by the Minister of Health in relation to the national health system
- Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

The Office is required by the procedural regulations to develop an enforcement policy outlining the approach to be followed in the exercise of its enforcement powers. The enforcement policy adopted by the OHSC is progressive in nature.

# 8 SELF ASSESSMENTS

All health establishments are expected to perform self-assessments to monitor their performance in relation to the regulated norms and standards. The results of these self-assessments must be made available to the OHSC at least once a year and must be conducted against the inspection tools prepared by the NDoH as part of its Ideal Clinic programme.. The OHSC will review these results as part of its system to monitor the health establishment's compliance with the regulated norms and standards between formal inspections.

The content of the Ideal Clinic framework is aligned with the OHSC's regulatory inspection tools. Self-assessments submitted by health establishments to the NDOH as part of the Ideal Clinic programme will be made available to the OHSC for our monitoring purposes.

It is not necessary for health establishments to submit two self-assessments per year – only the self-assessment against the Ideal Clinic framework is required. Copies of the regulatory inspection tools used by the OHSC during inspections are available on the OHSC website should health establishments wish to access them.

# 9 STANDARDS DEVELOPMENT PROCESS

The Office's mandate includes advising the Minister of Health on matters relating to the determination of norms and standards to ensure the delivery of safe, effective health services to the citizens of South Africa, and the review of such norms and standards.

## 9.1. Process flow for standards development

9.1.1. Establish the need for the set of standards to be developed.
9.1.2. Clearly define the scope of standards.
9.1.3. Identify currently available standards for similar health establishments.
9.1.4. Conduct a literature search to determine current benchmarks regarding standards of health care service delivery.
9.1.5. Conduct a review of relevant legislation and policies regarding the services for which the standards are to be developed or reviewed.
9.1.6. Identify key stakeholders who are integral to the delivery and/or use of services.
9.1.7. Identify and utilise the services of legal drafters and specialists in the development of norms and standards regulations.
9.1.8. Draft a set of standards to serve as a point of departure for discussions with stakeholders.
9.1.9. Visit the minimum required number of health establishments to ensure that the standards measure all relevant aspects of service delivery, and are suitable as regulatory requirements.
9.1.10. Circulate the document to be reviewed by participants and collate their feedback.
9.1.11. Edit the document and submit it to the OHSC Certification and Enforcement Committee for approval
9.1.12. Submit the document to the OHSC board for approval.
9.1.13. Submit the proposed standards to the NDoH for circulation and comments.
9.1.14. Collate comments and submit to the CEO and OHSC board for approval.
9.1.15. The OHSC board will submit the standards to the Minister of Health for consideration and publication for public comment

# 10 GUIDANCE BY DOMAINS

## 10.1. User Rights

This chapter details the requirements of health establishments in ensuring that users' rights are upheld and respected when seeking health services. It examines their rights as experienced from the users' point of view, in accordance with the Batho Pele principles and the National Patients' Rights Charter. Therefore, the chapter emphasises user information concerning the availability of health care services and access to care, and health services as experienced by users in the care survey and complaints reports. It includes a discussion of how health establishments should ensure that users are given adequate information about the health care services available to them and that they have access to care in a manner consistent with the nature and severity of their health condition.

- People who use health care services have the right to:
- Have access to information about the services provided by the health establishment
- Access health services that are hygienic, healthy, safe, clean and secure
- Understand the care, treatment and ongoing support choices available to them, and be involved in making decisions about their care, treatment and support.
- Be made aware of waiting times to access services and be attended to in an emergency in accordance to the nature and severity of their condition.

### 10.1.1. User information

| Regulation number | Standard |
|---|---|
| 4(1) | Health establishments must ensure that users are given adequate information about the health care services available and about accessing those services. |
| Guidance | Adequate signage promotes access to care. To access the services provided by the health establishment, users must be able to find their way to the correct service area. Signage should be available in the two most commonly understood local languages and should be easy to read and understand. In designing signage, consideration should be given to users who may be illiterate, e.g. the use of pictograms, or colour coding of signage to designate different service areas (where applicable). |

| Regulation number | Standard |
|---|---|
| | When entering the building, users should have easy access to assistance if needed to determine:<br><br>• Whether the services they require are provided by the health establishment<br>• How and where to access the services if they are provided<br>• Where they can access the required services if they are not provided by the health establishment.<br><br>The person designated to offer this assistance should be well informed in such matters, easily identifiable within the health establishment and available to users. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 4(2)(a)(i) | Health establishments must display the health care services it provides, | The services provided should be clearly displayed outside the health establishment, including the times that services can be accessed and the days that services are provided. This will assist users in identifying a health establishment that can meet their health needs. |
| 4(2)(a)(ii) | Display service opening and closing times. | The information will assist users in accessing the services they need and inform them of the times that these services can be accessed. Where health establishments do not provide a 24-hour service, the contact details for the local emergency health care provider must be displayed, to avoid unnecessary delays in accessing care for users requiring urgent treatment. This can be the number for the nearest health establishment providing out of hours care, the national emergency number, the local ambulance number, or any other emergency number by which users can access emergency services locally. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 4(2)(a)(iii) | Display visiting hours where relevant. | Visiting hours must be clearly displayed at the entrance of the health establishment and units. |

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| 4(2)(a)(iv) | Ensure the complaints, compliments and suggestions management system is in place and clearly displayed. | It is important that users understand how to make a complaint and what to expect should it be necessary for them to complain. The information should be made available to them in a language and format they are able to understand.<br><br>The health establishment must implement systems to ensure that complaints are managed efficiently and in a manner that meets the complainant's needs.<br><br>The health establishment should use the opportunity provided by a complaint to improve its service provision by identifying gaps and taking steps to close gaps, thereby reducing the risk of recurrence of incidents resulting in complaints. This will ensure that both the health establishment and future users benefit from the clinic's response to the complaint. |
| | | The health establishment must provide information of the complaints officer with contact details.<br><br>The complaints in the register must be logged comprehensively, in line with the headings in the register (there should not be gaps, except where a resolution is pending). Complaints must be acknowledged in writing. |
| 4(2)(b) | Provide users with information on any fees payable for health care services, insofar as it is practical to do so before the commencement of health care services. | Health care users should be informed about the cost of care for which they will be responsible and should acknowledge receipt of such information. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 4(2)(c) | Display the results of user experiences from care surveys conducted within the past 12 months. | Surveys of users' experiences must be conducted at least annually. Information obtained should be collated, categorised and analysed, and included in the results of patients' experience of care.<br><br>Affording users the opportunity to share their experiences of care allows them to contribute to the shaping of services. Their feedback can provide valuable information on how to improve the quality of care and may highlight near misses or minor incidents that could prompt investigations and system changes, which, in turn, may prevent serious adverse incidents from happening. Users who are satisfied with the services provided are less likely to complain or take legal action should an adverse incident occur. Eliciting feedback, analysing the feedback and acting on the information provided can therefore contribute to an improved working environment for personnel as well as an improved experience for users. |

### 10.1.2. Access to care

| Regulation Number | Standard |
|---|---|
| 5(1) | The health establishment must ensure that users are attended to in a manner consistent with the nature and severity of their health condition. |
| Guidance | As has been demonstrated in the six priority areas of National Core Standards, excessive waiting times are a source of frustration to users, many of whom may be losing income, or be unable to attend to their personal responsibilities while waiting to receive services. This disruption to users' lives could be minimised by ensuring that waiting times are kept to a minimum by increasing the efficiency of service delivery. |
| | The expected waiting time should be in line with local targets or benchmarks and be calculated based on the average waiting time for a particular functional area from the most recent analysis for the preceding 12-month period. On days when the waiting time is significantly longer than expected, users should be informed and advised of the expected waiting time for that day. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 5(2)(a) | Health establishments must implement a system of triage. | All users should be informed of the health establishment's practice in relation to the prioritisation of sick, frail and elderly users to avoid any ill feeling when these users do not wait as long as others. This can be achieved by means of a poster or information leaflet.<br>The health establishment should have a protocol for the stabilisation of emergency patients who require referral out to other health establishments.<br><br>The most appropriately trained health care professional should perform the initial assessment on the patient. This is contained in the protocol for assessment in the emergency room or admissions wards and will depend on the level of health care facility and the triage status of the patient. |
| 5(2)(b) | Ensure access to emergency medical transport for users requiring urgent transfer to another health establishment and arrange for them to be accompanied by a health care provider. | The health establishment should have a protocol for accessing emergency patient transport which includes providers' contact numbers. The response time for emergency calls and practice trends should be monitored and analysed, and reports submitted to the relevant authority or forum reviewing emergency patient transport. Health care personnel should be aware of the protocol for accessing emergency transport. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 5(2)(c) | Adhere to guidelines on stabilising users presenting in an emergency before referring them to another health establishment. | |

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| 5 (3) | Maintain a system of referral as established by the responsible authority. | Where the health establishment is not able to provide the services required by a user, systems must be in place to ensure the efficient transfer of the user to a health establishment that is able to meet the user's needs. This will require the identification of local establishments providing services not offered at the health establishment, the clearly defined referral pathways, documentation of the contact details of establishments to which users will be referred, documentation of contact details for transport services, the development of standardised forms to record user details both for the referral and for transport required, and documentation of the information to be provided to users regarding the referral. The health establishment of these systems will require collaboration between the health establishments within the district. All aspects of the system should be documented to ensure continuity of service provision. The documentation should be available to all personnel involved in the referral process. |
| 5 (4) (a) | Ensure that users are given information relating to their referral to another health establishment. | Health care users who have been referred out must be given the necessary details of where to go, why they are being referred and what to do after they have been seen by the referral health establishment or health care provider. |

| **Regulation Number** | **Criteria** | **Guidance** |
|---|---|---|
| 5 (4) (b) | Ensure that a copy of the referral document is kept in the user's health record. | The referral protocol describes the criteria for referral in terms of emergency or planned patient transport, where in the network they are being referred and what documentation is required to accompany the patient. A complete referral form should be retained in the user's health records and contain at least the following information:<br><br>• The user's details<br>• Reason for referral<br>• The user's health status |

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| | | • The medication or treatment they have received and medication they are currently on<br>• Results of laboratory or radiology investigations<br>• Any risk factors or infections that may be of concern. |

### 10.2. Clinical Governance and Clinical Care

The clinical governance and clinical care domain focus on the requirements of the health establishment for delivering safe, quality clinical care to users. It is the core domain of the standards and has been designed to highlight clinical risks to patient safety and reliability of care. The domain describes the importance of maintaining patients' health records with the necessary patient identifying information, history and clinical assessment content, care plans and the execution of these plans. It also highlights the legislative requirements in terms of the recording of information in patients' health records, eligibility and health professionals' signatures and details. The domain expands on how patients are to receive quality care by monitoring the consistency and reliability of care delivered against best practice and approved guidelines, including care for priority health conditions.

The pivotal functions of the clinical leadership team are to drive quality and patient safety and provide a supervisory role, which are part of the clinical leadership and clinical risk sub-domain. The health establishment has an obligation to identify and establish quality and safety programmes to protect patients from reasonably foreseeable clinical risks, reduce or prevent adverse events, identify, assess and treat high-risk and vulnerable users, protect patients undergoing high-risk procedures and implement an infection prevention and control programme to reduce health care associated infections.

As part of the infection prevention and control programme, the health establishment must ensure that respiratory risks are identified and reduce the transmission of airborne infections, ensure effective decontamination and sterilisation processes, provide a hygienic and clean clinical environment and handle, store and dispose of health care risk waste safely and effectively.

People who use health care services have the right to:

- Be protected from unsafe and inappropriate care by having comprehensive and complete health records
- Receive care that promotes optimal clinical outcomes through the provision of consistent and reliable care for their condition, including the priority health conditions
- Be protected from clinical risks and hazards through quality and safety programmes
- Be assessed and treated with additional safety precautions if they are high-risk or vulnerable patients, or are undergoing a high-risk procedure

- Be protected from acquiring a health care associated infection through sound infection prevention and control systems, airborne transmission reduction mechanisms, effective decontamination and sterilisation processes, and a hygienic and clean clinical environment.

### 10.2.1. User health records and management

| Regulation Number | Standard |
|---|---|
| 6(1) | The health establishment must ensure that health records of health care users are protected, managed and kept in line with sections 14, 15 and 17 of the Act. |
| | This measure addresses the confidentiality of health records in user care areas where they are being used by health care providers during consultations. User records must be managed in the unit or area in a manner that ensures that confidentiality of the information is maintained. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 6(2)(a) | A health establishment must have a record filing, archiving, disposing, storage and retrieval system that complies with the law. | The health establishment should have a standard operating procedure on the management of health records: the retrieval, filing, classifying, pre-retrieval and refiling of health records.<br><br>Health records' storage area/s must have sufficient space for all records to ensure that records are stored in a systematic way that allows for easy and rapid identification and retrieval when required.<br><br>Staff working in the health records storage and archive department should be trained in the management of records. |
| 6(2)(b) | Ensure confidentiality of health records. | To prevent easy and unauthorised access to information, confidentiality of user records should be maintained in all areas, especially in the clinical area. This includes health records of users waiting to be seen, users who have already been seen, and health records being used for clinical audits that have not yet been returned to the records storage area.<br><br>Such records should be kept in a manner that safeguards against unauthorised access to their content. |

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| 6(2)(c) | Secure health records, using appropriate security control measures, in the records storage area and in the clinical service area. in accordance with the Protection of Personal Information Act, No.4 of 2013. | The health records storage areas should have a lockable security gate, strong room door, access-controlled door, or CCTV- that is functional and monitored.<br><br>The storage area should be fire-proof, such that should there be fire outside the records room, the fire-proofing measures would delay the fire gaining access to the records room. |
| 6(4)(a) | Create and maintain a system of user health records in accordance with the requirements of section 13 of the Act.<br><br>Record the biographic data of the user and the identification and contact information of the user and his/her next of kin. | The user's health records must comply with statutory requirements for record keeping. All entries must be dated and include the health practitioner's credentials. |
| 6(4)(b) | Record information relating to their examination of and health care interventions for users. | Patients' files should comply with statutory requirements for record keeping.<br><br>Results of investigations done must be retained in users' files.<br><br>Users' discharge records should be audited for completion and the identification of gaps. |
| 6(5) | Have a formal process for obtaining informed consent from users. | The health establishment should have a policy and/or guideline for health care personnel for obtaining informed consent from users as per the HPCSA guidelines. This includes the procedures for users with guardians and/or mental health care users, minor procedures in a clinic setting and HIV counselling and testing.<br><br>The guidelines should include:<br><br>• The procedure that the patient is to undergo or the testing (in the case of HIV testing)<br>• An explanation of the risks and alternative procedures<br>• Signatures of the health care provid- |

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| | | er performing the procedure, as per the requirements of section 7 of the National Health Act.<br><br>All relevant areas must be filled in; where they are not applicable, it must be indicated as such. |
| 6(6) | The health establishment must issue a discharge report to users, in accordance with section 10 of the Act. | Upon discharge from the health establishment, a comprehensive discharge report should be completed for all users and a copy kept in their health record.<br><br>Discharge forms for mental health care users must follow the requirements of the Mental Health Care Act, including:<br><br>• Details of the patient's prognosis<br>• Provisional and final diagnosis or legal classification<br>• Treatment given. |

### 10.2.2. Clinical management

| Regulation Number | Standard |
|---|---|
| 7(1) | The health establishment must set up and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines. |
| | Clinical guidelines are aids to providing safe user care and summarise the best available evidence regarding the management of clinical conditions. They are not intended as rigid instructions to health care professionals, but rather as a reference document to give health care professionals all the information they require in a readily accessible format, to assist them in making the best possible decisions for individual users. In addition, they act as a reminder to ensure that no essential steps in investigation and treatment are omitted during the customisation of a care package for an individual user.<br><br>When implemented correctly, clinical guidelines assist in reducing variations in care which, in turn, leads to improved user outcomes. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 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. | The national guidelines for priority health conditions must be available at the health establishment. Personnel should receive training on the content of the guidelines, and clinical audits should be done to ensure that users are managed in accordance with the guidelines. |
| 7(2)(b) | The health establishment must establish and maintain systems, structures and programmes to manage clinical risk. | Clinical audits must be conducted on all priority programmes provided at the health establishment. The audits should focus on ensuring that the clinical guidelines for the national priority programmes are implemented. Clinical audits should be conducted in accordance with any guidance available from the relevant authority. The indicators selected for the audit should deliver benefit to user care services and can include indicators related to inputs, processes or outcomes.<br><br>Clinical auditing is about measuring the quality of care provided to users against relevant standards. Where these standards are not met, the audit should assist in understanding the factors contributing to this situation. This information can then be used to set priorities and make improvements. Care provided in each priority programme should be audited by clinic personnel at least once a year.<br><br>The health establishment must design, implement and monitor safety programmes in the clinical areas to protect and promote the health and safety of users.<br><br>The health establishment must have a clinical risk management SOP. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| | | A multidisciplinary clinical risk assessment committee must be set up with established terms of reference.<br><br>The committee must have a documented clinical risk management strategy.<br>Minutes of the committee must be made available and reflect the mitigation of risks above predetermined threshold, and the identification of gaps.<br><br>Documented evidence must be provided showing how identified problems have been addressed, including the quality improvement plans with time frames. |
| | | The health establishment must audit its delivery of care through internal audits conducted on health records against the clinical guidelines as published by the NDoH.<br><br>Findings must be recorded and reported to staff in the unit. Quality improvement initiatives should be developed to address any gaps found on audit.<br><br>The health establishment should participate in mortality and morbidity meetings to identify gaps in clinical care and determine ways to address them. |

### 10.2.3. Infection prevention and control programmes

| Regulation Number | Standard |
|---|---|
| 8(1) | The health establishment must maintain an environment that minimises the risk of disease outbreak, and the transmission of infection to users, health care personnel and visitors. |
| | Infection rates must be monitored and analysed to track performance and improvements in quality of care. The health establishment has a functional infection prevention and control (IPC) forum with health care professionals participating as active members. Personnel from the units participate in the forum, either directly or via a representative of a group of units, depending on the size of the facility. The IPC forum has terms of reference describing its interdisciplinary membership, roles and responsibilities and strategy for managing infections in the health establishment. There should |

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| | be evidence that the IPC forum receives reports from the various clinical units on infection rates, which are used to identify gaps in quality of care for the implementation of quality improvement initiatives.<br><br>Clinics should have access to an IPC forum at district level. They should participate actively and provide reports to this forum and receive feedback. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 8(2)(a) | A health establishment must ensure that hand washing facilities are available in every service area. | |
| 8(2)(b) | The health establishment must provide isolation units or cubicles for users with contagious infections, use personal protective equipment and administer prophylactic immunisations to staff where relevant. | The health establishment should have a protocol for the management of patients who require isolation, which specifies the criteria for isolation, the isolation facilities to be used and the procedure to be followed for isolation.<br><br>The protocol should include guidelines for a referral system for access to isolation accommodation and must meet the criteria for a formidable epidemic disease isolation facility. |

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| 8(2)(c) | The establishment must ensure clean linen is provided to meet users' needs. | The health establishment must ensure that users are provided with sufficient clean and decent linen that protects them from infections Torn linen must not be used but sent for mending.<br><br>An SOP for the management of laundry services should be detailed.<br>A service level agreement (SLA) should be in place for outsourced linen service providers. The health establishment should monitor the service and take action in the event of failure to deliver or other SLA breaches.<br><br>Linen requirements, such as mattresses and bedding, should meet the needs of the units and sufficient stocks should be maintained.<br>Linen and mattresses should be stored in lockable storage areas.<br><br>Inventory of linen must be taken with regular reconciliation of linen going in and out of the units.<br><br>Shortages of linen should be reported to executive senior management and corrective action taken.<br><br>All laundry machines should be in working order to ensure optimal and efficient service delivery. |
| 8(2)(d) | Ensure that health care personnel are protected from acquiring infection through the use of personal protective equipment and prophylactic immunisations. | Health personnel are provided with personal protective equipment and trained in the use thereof.<br><br>Health care workers are protected against high-risk infectious diseases and offered prophylactic immunisation. |
| | | There is evidence of the record of administered immunisations and refusal thereof.<br><br>Nationally approved respirators for health care personnel at risk of contracting TB or exposed to serious respiratory infections. The respirators are fit tested or have a seal check performed to determine the |

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| | | correct size for each personnel required to wear them. The personnel follow the correct procedures for donning, use and doffing the respirators. |

### 10.2.4. Waste management

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

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 9(2)(a) | The health establishment must have appropriate waste containers at the point of waste generation. | The SOP for obtaining additional health care risk waste (HCRW) containers should be available and communicated to all personnel.<br>Suitable waste containers must be available in the service units where waste is generated. Storage areas for HCRW contain suitable containers, or freezers and fridges in the case of human tissue waste. Records must be kept of waste being stored and removed from the health establishment, including registers for human tissue waste which contain all the patient's relevant details. |
| 9(2)(b) | Implement procedures for the collection, handling, storage and disposal of waste. | The health establishment has policies that guide the safe management of HCRW including:<br>• Safe collection and handling<br>• Segregation<br>• Storage<br>• Disposal.<br>The health establishment must have an agreement with an outsourced provider to transport and the handle HCRW. Their service levels must be monitored, and any breaches investigated and reported to the executive management of the health establishment and the relevant authority. |

### 10.3. Clinical Support Services

The domain on clinical support services includes all services that support clinical care, including timely availability of medicines, efficient provision of diagnostic and therapeutic services, and provision of medical equipment that is functional and appropriate for the care being provided.

Pharmaceutical services must oversee operations of medicine prescribing, acquisition, storage, dispensing and administration. They must ensure the availability of medicines and medical supplies, to promote clinical outcomes and protect patients from harmful medicines.
Diagnostic and blood services must be available and efficient to provide timely and accurate diagnoses or blood products.

Therapeutic services must be accessible and provide multidisciplinary care that follows best practices and safety guidelines and promotes clinical outcomes for patients.

Medical equipment must be available and functional and safe for use by being maintained according to the manufacturer's specifications.

Mortuary services must store, release and transport deceased bodies safely, with respect for human dignity and rights.

People who use health care services have the right to:

- Receive medicines and medical supplies on the day they access the services, or while in the care of the services, in a timely manner that promotes their clinical outcomes and treatment goals
- Be protected from unsafe medicines through the effective storage, prescribing and administration of medicines according to pharmaceutical best practice
- Have access to accurate and timely results of diagnostic procedures
- Have access to safe blood products that are available to promote their clinical outcomes
- Be cared for in a multidisciplinary manner by therapeutic support services that follow best practice and are accessible
- Come into contact with medical equipment that has been maintained, and is safe and functional
- Be treated with dignity and respect when they die.

#### 10.3.1. Medicine and medical supplies

| Regulation Number | Standard |
|---|---|
| 10(1) | The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, No. 101 of 1965. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 10(2)(a) | The health establishment must implement and maintain a stock control system. | A document outlining the terms of agreement for the supply of all stock according to different functional areas must be available and signed by two parties, dated, and specify the ordering procedure and delivery date.<br><br>A document reflecting the monitoring of medicine delivery compliance with the SLA must be available.<br><br>A stock management system must be in place, either electronic or manual, outlining procedures that:<br><br>• Guide how stock orders are placed<br>• Specify how stock is issued<br>• Check expiry dates<br>• Ensure stock is rotated.<br><br>Stocktakes must be conducted at least yearly and the physical stock must correlate with that on the stock management system. |
| 10(2)(b) | Ensure the availability of medicines and medical supplies for the delivery of services. | Tracer medicines, as per the tracer medicines list, must be available in the pharmacy or medicine room.<br><br>Medicine availability must be monitored and reported at least weekly or daily in the event of a critical shortage.<br><br>The operating hours of the pharmacy must be displayed with duty rosters to show that a pharmacist is available to provide access to medicines during these operating hours. A procedure must be in place for accessing medicines when the pharmacy is closed, including an emergency cupboard with controlled access. In clinics, contact details must be provided for pharmacy staff to give access to medicines during an emergency.<br><br>The health establishment must have procedures for ordering, following up orders and receiving medicines from suppliers or |

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| | | the depot. An SLA with suppliers of medicines must be in place and receipt of orders must be monitored against these service levels. Any evidence of discrepancies in orders received must be reported to the executive management of the health establishment and the relevant authority. Feedback from the authority must be obtained of corrective actions to be taken with the supplier or changes to the SLA terms. The health establishment must have protocols for the management of medicines in each unit which describes the ordering, prescribing, storage, preparation, dispensing and administration of medicines. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| | | A roster must be set up scheduling monthly visits by the pharmacist to the unit to assess compliance with these protocols.<br><br>The health establishment must ensure that in all areas where medicines are stored (pharmacy, medicine rooms, unit stock rooms) good pharmacy practice guidelines are followed in terms of:<br><br>• Secure storage<br>• Space<br>• Classification systems<br>• Cleanliness of the environment<br>• Temperature control.<br><br>Thermo-labile medicines must be stored in the following manner to maintain the cold chain:<br><br>• In a fridge suitable for medicines only<br>• Temperature monitored and controlled<br>• Having a backup system in the event of power failure.<br><br>The health establishment must have a protocol for the management of schedule 5 and 6 medicines, which include the way |

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| | | in which these medicines are controlled, recorded and administered. |

### 10.3.2. Diagnostic services

| Regulation Number | Standard |
|---|---|
| 11(1) | The health establishment must ensure that diagnostic services are available and safe for users and health care personnel involved in delivering these services. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 11(2) | A health establishment must, where applicable, be accredited by the relevant regulatory body relating to the type of diagnostic services. | A valid accreditation certificate issued by the South African National Accreditation System must be obtained for laboratory and diagnostic imaging services. |

### 10.3.3. Blood services

| Regulation Number | Standard |
|---|---|
| 12(1) | Hospitals and CHCs must ensure that users have access to blood and blood products when required. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 12(2)(a) | Health establishments must ensure that blood and blood products are stored, handled and delivered in accordance with their cold chain procedures. | Cold chain procedures and equipment must be in place to ensure that the integrity of blood products is maintained at all times, including during transportation.<br><br>The health establishment must have an SOP for the maintenance of cold chain procedures for blood and blood products. Health care professionals should be able to describe the cold chain procedure. |
| 12(2)(b) | Health care personnel involved in the delivery of blood services must protect users and other health care personnel from exposure to hazardous waste. | Blood services personnel must have access to personal protective equipment to perform their duties. Patients must be protected from exposure to hazards through warning notices and the provision of personal protective equipment. |

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| 12(2)(c) | Adverse blood reactions must be reported to a committee in the health establishment that monitors adverse incidents. | Adverse blood reactions must be reported to the forum on adverse events and classified according to severity.<br><br>Zero reports must also be noted. |

### 10.3.4. Medical equipment

| Regulation Number | Standard |
|---|---|
| 13(1) | The health establishment must ensure that medical equipment is available and functional in compliance with the law. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 13(2)(a) | The health establishment must ensure that equipment is licensed where required from the relevant licensing body. | All units in the health establishment must have the required minimum functional essential medical equipment, which must be included in a preventative maintenance plan. |
| 13(2)(b) | Ensure that available equipment is consistent with the essential equipment list in all clinical services areas. | The health establishment must provide the units with general specifications and guidance on equipment that may be requested. The equipment needs of each unit must be evaluated against the specifications and approved by the committee reviewing medical equipment procurement or the relevant authority. |

## 10.4. Facilities and Infrastructure

The facilities and infrastructure domain cover the requirements for a clean, safe and secure physical infrastructure (buildings, plant and machinery) and functional, well managed hotel services and waste disposal systems. It contains the requirements for the buildings and infrastructure to be sufficient, fit for purpose and fit for the services that need to be delivered, including that the facility meets all occupational health and safety laws, and building and environmental standards. The domain also addresses the functionality and maintenance of building engineering services (plans and machinery) that support the safety of users and protect them from harm by ensuring uninterrupted supply of electricity, water, sewerage, gas and suction services. The safety and security of patients in the health establishment is dealt with through the provision of security systems, especially at vulnerable patient points, in order to protect patients, health care personnel, equipment and property.

Part of this domain requires that public areas of the health establishment are kept clean to maximise patients' safety and comfort.

People who use health care services have the right to:

- Be cared for in a building and grounds that are fit for purpose and fit for service, to protect them from safety risks and allow effective care to be provided
- Have their safety and security taken care of, especially if they are vulnerable patients
- Be protected from service disruptions or safety incidents when there is a power, water or other service interruption
- Be able to communicate with the health establishment in cases of emergency or when information is required
- Clean buildings and grounds from which waste is safely removed to reduce potential health risks.

### 10.4.1. Management of buildings and grounds

| Regulation Number | Standard |
|---|---|
| 14(1) | The health establishment and its grounds must meet the requirements of the building regulations. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 14(2)(a) | A health establishment must, as appropriate for its type of buildings and grounds, have all the required compliance certificates in terms of the building regulations. | Valid certificates, approvals or authorisations for the health establishment's buildings and facilities, electricity installations, fire extinguishers and water reticulation systems must be available.<br><br>The fire certificate must indicate the location and number of inspected fire extinguishers, date of inspection and date of expiry. The fire certificate should be checked to determine its validity, e.g. if there have been any alterations to the building since the certificate was issued. |

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| 14(2)(b) | A health establishment must, as appropriate for its type of buildings and grounds, have a maintenance plan. | The health establishment must determine what its building and infrastructure needs are to meet compliance and legislative requirements, and it must document these in a plan. The plan must identify what maintenance and renovations, or new buildings are required, including their costs.<br><br>The plan is to be approved by the relevant authority and included in an approved budget. Delegation of authority for implementing the infrastructure plan should be clearly defined in the approved plan.<br><br>Where planned maintenance cannot be carried out according to schedule, a report must be submitted to the executive management describing the mitigation steps taken. |
| 14(2)(c) | A health establishment must, as appropriate for its type of buildings and grounds, ensure emergency exit and entrance points are provided in all service areas and kept clear at all times. | Emergency access points must be kept clear and open both for vehicles and ambulances as well as patients, stretchers and beds. Entrances must be accessible, allowing patients in wheelchairs, stretchers or patient beds to pass freely without hindrance. |
| 14(2)(d) | A health establishment must, as appropriate for its type of buildings and grounds, have a ventilation system that maintains the inflow of fresh air, temperature, humidity and purity of air within specified limits set for different services areas such as theatres, kitchens and isolation units | Ventilation systems must comply with regulations and be provided according to the specifications in the IUSS guidelines in all critical areas used by users and health care personnel.<br><br>Natural or mechanical ventilation must be present in areas where infection control risk assessments have identified the need for these interventions.<br><br>All users' areas and theatres must have functional ventilation systems that are maintained and serviced as per the preventative maintenance plan. Particle counts must be performed in theatres only when they have been renovated, or newly built, or in the case of outbreaks. |

### 10.4.2. Engineering services

| Regulation Number | Standard |
|---|---|
| 15(1) | The health establishment must ensure that engineering services are in place. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 15(2) | A health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal systems. | The location of the main building engineering services must be indicated in a document; building engineering services include electrical, mechanical, water and sewage connections.<br><br>To ensure uninterrupted services to users, routine inspections must be conducted and documented to ensure availability of services such as electrical power, emergency medical gas, vacuum systems, water and sewage disposal.<br><br>Records of monitoring the availability of emergency power during electrical downtimes must be available. |

### 10.4.3. Transport management

| Regulation Number | Standard |
|---|---|
| 16(1) | The health establishment must ensure that vehicles for transporting users and health care personnel are safe and well maintained. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 16(2)(a) | Health establishments must ensure that vehicles, owned or used, are licensed and maintained. | All vehicles must be properly registered, licensed and serviced according to their maintenance and service plans.<br><br>Records of all maintenance carried out for all vehicles must be available, including invoices from the service provider.<br>Valid copies of all vehicle licenses must be available.<br><br>The health establishment must monitor the performance and usage of vehicles including keeping drivers' log sheets, recording kilometres travelled and submit |

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| | | ting statements in the event of an accident. |
| 16(2)(b) | Ensure that drivers have valid driver's license and/or public transport driving permit. | Drivers must be qualified to drive and have a valid driver's license and, where applicable, a public service certificate. The health establishment must have valid copies of all drivers' documents. |

### 10.4.4. Security services

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

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 17(2) | The health establishment must ensure that security staff are capacitated to deal with security incidents, threats and risks. | The health establishment must have a designated or appointed safety and security manager who is appropriately qualified and experienced, with clear roles and responsibilities as documented in a job description<br><br>A security protocol outlining the security systems must be in place and linked to a safety and security plan detailing high-risk areas.<br>An in-service training plan on risk identification in vulnerable patients, reporting and interventions must be available to all health care personnel. |

## 10.5. Governance and Human Resources

Clinical governance is an integrated component of corporate governance of health services. It ensures that everyone, from clinicians, to managers and members of the governing body, is accountable to health care users and to the community for assuring the delivery of health services that are safe, effective, integrated, of high quality and continuously improving. Health establishments need to put in place strategies that consider their local circumstances.

An effective governance system in health services is characterised by leadership that influences the safety of care by supporting the workforce, shaping the culture, setting the direction and monitoring progress in safety and quality performance. Engaging managers and clinicians in quality improvement activities is important for aligning clinical and managerial priorities .

The leadership and governance domain cover the strategic direction provided by the governance structures and the executive management of the health establishment in improving patient safety and the quality and acceptability of services in the health establishment. It includes the proactive leadership, planning and risk management role that the governance structures and executive management must provide to health care personnel, and the resources and workforce required to deliver services against the health establishment's strategic direction.

The domain also talks to the general quality improvement of systems and processes within the health establishment (over and above the clinical quality improvement from domain 2) in order to ensure that acceptable, quality and safe services are delivered. It covers the responsibilities required daily to support and ensure the delivery of safe and effective patient care, including management of human resources (HR) and finances. It requires that the health establishment manage its health personnel to ensure their capacity to provide efficient and quality health care services. Health personnel must be protected from workplace hazards through an occupational health and safety system and their health and wellbeing promoted through lifestyle modification programmes. Satisfaction levels of health care personnel with their working environment must be measured annually.

People who use health care services have the right to:

- Help guide the health establishment's strategic direction and operations by being part of its governance structures, or providing inputs into the quality improvement of processes and systems by making suggestions or having their complaints addressed
- Be cared for by health care personnel who are adequate in number and have the necessary skills and experience to perform their respective duties of care
- Be cared for by health care personnel who have been protected from occupational health risks and workplace hazards and who have taken care of their health and psychosocial wellbeing
- Know who the executive managers are, what the organogram of the health establishment looks like and what posts are vacant
- Know what the vision, mission and values of the health establishment are and how it plans to meet its strategic direction.

### 10.5.1. Governance

| Regulation Number | Standard |
|---|---|
| 18(1) | The health establishment must have a functional governance structure with written terms of reference. |
| | Leaders at all levels of the organisation must set up and use clinical governance systems to improve the safety and quality of health care for health care users. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 18(2) | The health establishment must ensure that it has a representative board that meets at least twice a year. | Letters of appointment for the members of the governance structure must be available.<br>The health establishment must have terms of reference for its governance structure. |
| | Provide the representative board or committee with the necessary information regarding the clinical governance, operational management, and financial and quality performance of the health establishment. | The health establishment must give the representative board or committee the necessary reports, statistics and information about its:<br><br>• Clinical governance activities<br>• Safe and quality of care<br>• Operational management<br>• Financials and quality performance including strategic plans<br>• Operational plans<br>• Budgets<br>• Operational review reports<br>• Quality of care statistics complaints and patient satisfaction levels |
| | Request guidance and implement recommendations from the representative board or committee to improve service delivery. | The representative board or committee must offer guidance and recommendations to the health establishment on its:<br><br>• Strategic plan<br>• Policies and procedures<br>• Mission and vision<br>• Quality improvement plans<br>• Quality of care indicators and reports<br>• Clinical risks<br>• Organisational risks<br>• Finances<br>• Human resource management<br>• Performance management of executive managers.<br><br>The representative board or committee documents any corrective actions to improve service delivery based on its review of the health establishment's operations. These are monitored for implementation over time. |

### 10.5.2. HR management

| Regulation Number | Standard |
|---|---|
| 19(1) | The health establishment must ensure that it has systems in place to manage health care personnel in line with relevant legislation, policies and guidelines. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 19 (2) (a) | The health establishment must, as appropriate to its type and size, have and implement a human resource plan that meet its needs. | The operational plan must take into account the services the health establishment has to offer, which is reflected in the HR and financial plans (staffing and budgets). |
| 19 (2) (b) | The health establishment must, as appropriate to its type and size, have a performance management and development system in place. | As required by the recruitment policy, all health personnel files must be comprehensive and complete and contain their necessary qualifications and human resource development and performance management information.<br><br>Each health care employee must have a performance management agreement containing his/her performance targets. These performance agreements are monitored at least annually with remedial action being documented if necessary.<br><br>All executive managers in the health establishment must have signed performance management agreements with their manager and the relevant authority. Quarterly performance reviews must be conducted, and documented plans of remedial action be taken to address any gaps in performance. |
| 19 (2) (c) | Have a system to monitor that health care personnel maintains their professional registration with the relevant council on an annual basis. | Records must demonstrate that health care providers' registrations with the relevant professional body or council are current and are verified yearly. This includes employed as well as sessional or independent health care providers. |

### 10.5.3. Occupational health and safety

| Regulation Number | Standard |
|---|---|
| 20 | The health establishment must comply with the requirements of the Occupational Health and Safety Act, No. 85 of 1993. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| | The programme for the prevention and control of respiratory infections must be in place. | To prevent respiratory infections:<br>• All masks must be NIOSH -approved with a particle filtration efficiency of 95%<br>• Fit test must be performed on all employees. |
| | Awareness of safety and security issues must be promoted. | Signs must be displayed at the entrance and at strategic points within the health establishment, e.g. waiting areas, where oxygen cylinders are kept, or where flammable cleaning materials are stored. |

### 10.6. Adverse Events

| Regulation Number | Standard |
|---|---|
| 21 | The health establishment must always have a system to monitor and report adverse events |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 21(2)(a) | The health establishment must have a register for all adverse events. | A systematic way to collect adverse events should be in place including a reporting format and a system, consistently applied by each unit, to classify events in terms of severity.<br><br>The forms used to report adverse events should be available in all units and contain, as a minimum:<br><br>• Information about the type of event<br>• Circumstances surrounding the event<br>• Response by health care personnel immediately after the event<br>• Classification of the severity of the event |

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|---|---|---|
| | | There is a process for identifying adverse events when addressing complaints, so they can be immediately investigated, or mitigating actions put in place to prevent further harm to patients. |
| 21(2)(b) | Have a system in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events. | The health establishment must have an adverse events policy which details its approach to the management of adverse events, including how to identify, classify, report, escalate, communicate, perform a root cause analysis and communicate with patients and their families.<br><br>Personnel must demonstrate that the health establishment encourages the reporting of adverse events through their understanding of what adverse events are, knowing how to report them, and having access to easy-to-use adverse events reporting forms or systems. The health establishment must report adverse events to the relevant authority (as prescribed as an early warning system in section 79(1) d and 79(2)b of the National Health Act).<br><br>Adverse events are investigated to establish the root cause to determine future corrective action to be taken, and to identify trends.<br>A protocol must be in place for informing patients if they have experienced an adverse event.<br><br>The forum reviewing adverse events must analyse all adverse events to determine action to be taken as part of a quality improvement plan to reduce adverse events. There should be evidence that adverse events are reducing over time. |

### 10.7. Waiting Times

| Regulation Number | Standard |
|---|---|
| 22 | The health establishment must monitor waiting times against the National Core Standards for health establishments in South Africa |

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|---|---|
| Guidance | As has been demonstrated in the six priority areas of National Core Standards, excessive waiting times are a source of frustration to users, many of whom may be losing income, or be unable to attend to their personal responsibilities while waiting to receive services. This disruption of users' lives could be minimised by ensuring that waiting times are kept to a minimum by increasing the efficiency of service delivery.<br><br>The expected waiting time should be in line with local targets or benchmarks and be calculated based on the average waiting time from the most recent waiting time analysis, within the preceding 12-month period. |
| | On days when the waiting time is significantly longer than expected, users should be informed and advised of the expected waiting time for that day. |

| Regulation Number | Criteria | Guidance |
|---|---|---|
| 22 | Waiting times must be monitored, and improvement plans implemented. | The health establishment must have a policy on its targets and benchmarks for waiting times and a plan on how it plans to achieve them. Waiting times surveys should be conducted yearly by waiting area section and improvements from the previous year should be determined.<br><br>The health establishment must assign a person to manage queues in the waiting areas. Patients should be provided with information about how long they will wait in a queue at every station in the waiting area and at the consulting rooms. A benchmark or targeted waiting time, that is easily visible to waiting users, should be displayed in the waiting area.<br><br>There must be action plans in place to meet the waiting time targets for each waiting area section and these must be implemented. |

# 11 COMPLIANCE REQUIREMENTS FOR DOCUMENTATION EVALUATED DURING INSPECTIONS

The purpose of this chapter is to clarify the requirements for the interpretation and scoring of evidence. While there is some flexibility about the form it can take, in addressing the measure, the documented evidence should include the following:

- Source (developed or published by)
- Date (valid for 5 years or updated within the 5 years)
- Signed by relevant authority
- Evidence that it has been read by or communicated to the relevant staff.

## 11.1. Policy

A policy is a written document that outlines a government's authority or organisational position on a given subject. The content varies, and policies can include references to legislative and regulatory frameworks guiding the policy, values, strategic objectives, line of authority, delegation, communication, responsibility and accountability, and processes and procedures.

| Assessment Criteria | Responsible Authority |
|---|---|
| **Acknowledgment as an officially approved document**<br><br>National – preamble and foreword with logo but no signature accepted as valid until MOU concluded; MOU to include this issue.<br><br>**Comments:**<br><br>Documents to be signed by the designated person (title stated).<br><br>The document will be accepted only when the delegated person has written pp before signing and the delegated person has written his/her title.<br><br>Note that policies are only from national or provincial sphere of government. | National policy – Minister or Director General of Health |
| | Provincial policy – MEC or HOD of Health |
| | Organisational policy (private sector only) – organisational board or executive management of the organisation |

| Assessment Criteria | Requirements |
|---|---|
| **Date of acceptance/approval/implementation** | Date the policy comes into effect must be indicated in the document. |

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| **Duration of validity**<br><br>Score the health establishments according to their validity period as per their set standard, i.e. according to their document and not according to 5-year period as set by OHSC.<br><br>Note: The principle of scoring health establishments according to their standards should apply to all measures, | National policies – no currently agreed review date (however, documents older than 5 years will be scored non-compliant). |
| | Provincial policies – in accordance with provincial policy (however, documents older than 5 years will be scored non-compliant). |
| | Organisational policies – in accordance with organisational policy (5 years is the maximum duration of validity). |

### 11.2. Standard Operating Procedures

A standard operating procedure (SOP) is a set of written instructions or steps to follow when performing certain functions, tasks or actions. Procedures may be part of a policy, or may be a separate document, usually referring to and aligned with existing, approved policy or research.

| Assessment Criteria | Responsible Authority |
|---|---|
| **Acknowledgment as an officially approved document**<br><br>Documents to be accepted if they have only the signature of the accounting officer; if having both signatures, they score positively. | 1. Signature of compiler or chairperson of the committee responsible for compiling the document.<br>2. Signature of the accounting officer.<br><br>**Specific circumstances:**<br><br>**Pharmacy:**<br><br>SOPs for management of medicines compiled by the District Pharmacist must be signed by the District Manager as the accounting officer. SOPs for management of medicines compiled by any other pharmacist can be signed by the District Pharmacist as the accounting officer.<br><br>**Primary health care (PHC):**<br><br>SOPs developed within clinics must be signed by the accounting officer for the district, i.e. the District Manager or the sub-district manager, who has been delegated to do so.<br><br>**Hospital:**<br><br>SOPs developed at hospitals can be signed |

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| | by the CEO as the accounting officer, or an individual with appropriate qualifications and experience who has been delegated to do so. “Appropriate” refers to the requirement for the delegated individual to have qualifications and experience related to the field of practice or discipline to which the SOP applies e.g. head of clinical services. |

| Assessment Criteria | Requirements |
|---|---|
| **Date of effectiveness/approval/acceptance/ inception** | Date from which the standard operating procedure must be implemented. |
| **Duration of validity** | Review date must be stated; maximum duration of validity 5 years.<br>Where standard operating procedures have not been reviewed in accordance with the stated review date, the document will be scored non-compliant, even if the review date is less than 5 years. |
| **Indication of changes made to the document through time** | The cover page must include a section that summarises changes made to the document over time. The cover page is expected to be in line with guidance from the DPSA on the development of SOPs. |
| | All SOPs developed from 2018 will be expected to include a cover page. SOPs developed prior to 2018 will be accepted without a cover page. However, all relevant information as listed here must still be included in the document. |
| **Standardised format and cover page** | This must be done in accordance with the organisational or provincial policy.<br><br>Ownership and applicability must be indicated on the front page, i.e. the hospital for which the SOP was developed and where it is to be implemented. |
| **Name of the health establishment** | Where documents have been developed centrally and disseminated to different clinics, the document would not be expected state the name of the individual clinic; the name of district office or hospital developing the SOP will be accepted. However, the content of the SOP must be specific for the clinic and not reflect the hospital environment. |

### 11.3. Clinical Guidelines

Guidelines provide a practical description of recommended practice for use in specific circumstances. Guidelines are usually guided by the regulatory, legislative or existing policy framework and are underpinned by international/local evidence/best practice/ research. Guidelines provide a framework for the implementation of policy.

| Assessment Criteria | Responsible Authority |
|---|---|
| Acknowledgment as an officially approved document | Signature of senior member of national department of health; logo of the National Department of Health for documents developed jointly with other organisations; official endorsement from recognised academic institution |
| Date of acceptance/approval/implementation | Date when the guideline is implemented |
| Duration of validity | Ideally, a review date should be stated, but this is not always included. Guidelines older than 5 years will be scored non-compliant |

### 11.4. Protocol

A protocol provides detailed plans/steps/procedures for medical treatment emanating from a special interest or professional group or body.

### 11.5. Terms of Reference

Terms of reference (TOR) refer to the purpose and structure/s of a project, committee, meeting, negotiation, or any similar collection of people who have agreed to work together to accomplish a shared goal. The TOR:

- Explains membership, roles and responsibilities, frequency of meetings, and lines and mechanisms of reporting/accountability
- Needs to be signed
- Can be found in a separate TOR document, or within a broader document, e.g. a constitution.

### 11.6. Service Level Agreement (SLA)

An SLA is a contract between a service provider and their client that specifies mutual obligations for the service provided, plus the performance criteria undertaken by the provider, usually in measurable terms.

# 12 GENERAL DOCUMENTATION REQUIREMENTS

Documentation requested, including but not limited to minutes of meetings, delegations, ordering forms, delivery notes, reports and official communications such as memos, letters and emails must, at the very least, be signed and dated. All signatures must be accompanied by a designation to indicate the level of authority of the individual providing authorisation for the document and to allow for auditing where required.

## 12.1. Electronic documentation

It is acceptable for documents to be made available electronically, as long as anyone who requires access to the documents in the course of their duties can retrieve them at all times. This means that, wherever documentation is made available electronically rather than in hard copy, the following conditions must be met:

- Software and hardware required to access the documents must be available and functional.
- The access level of each individual staff member must ensure that they have clearance to access the documents they require.
- Internet connectivity must be provided by the employer if the documents are to be accessed via the internet.
- Where information provided can be periodically updated via the internet, such as clinical guidelines provided on an application, connectivity (via internet or mobile data bundles) must be made available by the employer to allow for the updates to be effected.

Electronic documents and/or information provided must be current and must be dated. Outdated documents should be removed from access and archived in the same way as hard copy documents to prevent access to erroneous information which may cause unnecessary harm to patients or result in the implementation of incorrect and potentially unsafe processes.

## 12.2. Official acknowledgement of documents

All electronic documents must be authorised, as for hard copy documents, to indicate acknowledgement by the accounting officer that the document has been endorsed officially.

As with hard copy documents, any electronic documents that do not have a legal requirement for a signature must be dated and authorised. Electronic signatures can be used for authorisation, or the document can be acknowledged officially by other means, such as organisational or departmental logos. Scanned copies of documents that have been signed manually can also be accepted as evidence of authorisation.

Electronic documents the do not meet the legal requirement for signatures, such as policies and standard operating procedures, will be regarded as non-compliant.

### 12.2.1. What is an electronic signature?

According to the Electronic Communications and Transactions (ECT) Act, No. 25 of 2002, an electronic signature is any data attached to or logically associated with other data, which is intended to be a signature and has a relationship with the data. This relationship can be a number of things, including a data signature residing in the same file, or data in a different file to which the original document points.

David Luyt, Associate at Michalsons Attorneys states: "This may seem overly complicated, however, the important aspects here are the intent, and the relationship between the document and the signature. Basically, an electronic signature is a piece of data attached to an electronically transmitted document as verification of the sender's identity and his or her intent to sign the document."

Under South African law, a written signature is not necessarily required for a valid contract – contracts are generally valid if legally competent parties reach an agreement, whether they agree verbally, electronically or physically on a paper document. Section 13(2) of the ECT Act specifically confirms that contracts cannot be denied enforceability merely because they are concluded electronically or through data messages.

### 12.2.2. The ECT Act and South African Common Law

South African common law allows for a variety of different formats to be recognised as signatures including Xs, thumbprints and other markings that explicitly demonstrate intent and consent. South African common law implies that a document must have the name or mark of the person signing, which has been applied by the person him/herself, and the person signing must have intended to sign the document. According to Luyt, this paves the way for electronic signatures to be recognised as legally binding and enforceable.

The ECT Act specifically makes allowances for the legality of electronic signatures. The Supreme Court recently recognised an email signature as a valid electronic signature, because it meets the two most important criteria:

- There is an association or relationship between the document and the signature.
- The person intended it to be a signature.

The majority of documents signed in South Africa do not legally require a signature – this is more of a custom and process requirement to verify that parties are who they say they are. An electronic signature may be more capable of fulfilling these requirements perhaps than paper-based solutions, as electronic signature processes create a tamper-evident audit trail that clearly identifies any areas of risk or suspicion.

The ECT Act recognises a variety of digital formats as an "electronic signature" as long as they comply with the criteria of intention and relationship to the document.

A standard electronic signature is typically used in:

- HR documents, such as employment contracts, benefits paperwork and other new employee onboarding processes
- Commercial agreements between corporate entities, including national development agencies, procurement documents and sales agreements
- Consumer agreements, including new retail accounts for opening documents
- Real estate documents, including lease agreements for residential and commercial real estate not lasting a period of more than 20 years.

When a signature is required by law, but the law does not specify the type of signature required, it can only be signed with an "advanced electronic signature" as defined by the ECT Act, which is, in practice, equivalent to Europe's QES (qualified electronic signature). South Africa's advanced electronic signature would be required for:

- A suretyship (General Law Amendment Act, No. 50 of 1956)
- Signing as a Commissioner of Oaths (Justices of the Peace and Commissioners of Oaths Act, No. 16 of 1963).

The advanced electronic signature meets the following requirements:

- It is uniquely linked to the signature
- It is capable of identifying the signatory
- It is created using methods that are under the signatory's sole control
- It is linked to other electronic data in such a way that any alteration to said data can be detected.

A QES is a digital signature that has met the particular specifications of a government, including using a secure signature creation device, and has been certified as "qualified" by either that government or a party contracted by that government.

### 12.3. Implications for OHSC — an interpretation of SA legislation currently in force

1. Documents received from the department – circulars, policies, notices and guides – are official papers received from the Office of the Director-General (nationally) or the Superintendent (provincially) and will be sent to all clinics, hospitals, etc. The signature on these documents will be a photocopy, but their authenticity may be ascertained by consulting the Registar of Circulars, in terms of the Deeds Registries Act, No. 47 of 193. On receipt these documents should be entered into their own circular register.

2. Emails may have an electronic signature. The ECT Act states that the requirements are met if the document or information is in the form of a data message and is accessible in a manner usable for subsequent reference to a person who either wants to rely on the existence of a particular agreement or for record purposes.

3. Hard copy: All official communication between government entities should be in the form of Accounting Officer to Accounting Officer. As such any hard copies should be signed in ink.

### 12.4. Compendium of documents

The Compendium of Documents for PHC is attached as Annexure A.

The Compendium of Documents for CHC and Hospitals will be made available on the OHSC website once finalised.

# 13 ASSESSING COMPLIANCE EVIDENCE & COMPLIANCE STATUS FRAMEWORK

## 13.1. Inspection Principles

The principle behind inspection is to find evidence that safety and the quality of care provided to users is considered to be paramount. The approach to inspection is to assess health establishments for systems, processes and procedures that promote and ensure quality health services as per the prescribed norms and standards. The Office does not regulate individual health practitioners or personnel directly. Therefore, it is imperative that the head of the health establishment or departmental managers put in place systems to ensure basic quality of care is provided. Systems must be developed in a structured and logical manner that can benefit the health establishment and protect health care users from risk.

Delegation to other individuals to do the work is permitted but evidence of such delegation is required and monitoring of outputs is essential. The Office requires the evidence to be in writing and available in the functional areas. The assessment tools provide directed guidance as to what sort of evidence the health establishment must provide, and the methodology used.

## 13.2. Compliance Status Framework

The Compliance Status Framework is a tool used by the OHSC to determine the degree of compliance by a health establishment to regulated norms and standards, utilising the data collected during an inspection.

Details of how the evidence collected is evaluated and the categorisation of health establishment as certifiable or not certifiable can be found in Annexure D.

# 14 GLOSSARY OF TERMS

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| **Access** | Ability of service users or potential service users to obtain required or available services when needed within an appropriate time. |
| **Accountability** | Responsibility and requirement to answer for tasks or activities. This responsibility may not be delegated and should be transparent to all stakeholders. |
| **Adverse event** | An undesired outcome or occurrence, not expected within the normal course of care or treatment, disease process, condition of the patient, or delivery of services. |
| **Airborne infection** | An undesired outcome or occurrence, not expected within the normal course of care or treatment, disease process, condition of the patient, or delivery of services. |
| **Airborne infection** | Infections contracted by inhalation of microorganisms or spores suspended in the air, water droplets or dust particles. |
| **Antimicrobial** | A chemical substance that inhibits or destroys bacteria, viruses and fungi, including yeasts or mould. |
| **Antiseptic** | A chemical substance for reducing bacteria from the skin's surface. This is not interchangeable with surface disinfectants which should never be used on the skin. |
| **Appropriate** | A chemical substance for reducing bacteria from the skin's surface. This is not interchangeable with surface disinfectants which should never be used on the skin. |
| **Appropriate** | The degree to which something is suitable for a specific purpose, e.g. a service that is consistent with a user's expressed requirements. |
| **Assessment tools** | Questionnaires used by inspectors to assess the health establishment, usually within a specific functional area. |
| **Building engineering services** | Includes ventilation and air-conditioning, medical gas installations, electrical installations (including generators), electronic installations and wet services (water supply and drainage). |

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| **Building regulations** | The building regulations issued in terms of any of the following regulations:<br><br>• National Building Regulations and Buildings Standards Act, No. 103 of 1977<br>• Regulations Governing Private Hospitals and Unattached Operating Theatre Units, published in Government Gazette, Notice No. R. 158 of 1 February 1980<br>• Regulation Governing Private Health Establishments, Western Cape, published in Provincial Gazette Extraordinary 5728, Notice No. 187 of 22 June 2001. |
| **Category of health establishment** | The category contemplated in section 35 of the National Health Act, No. 62 of 2003. |
| **Certificate of compliance** | A certificate referred to in regulation 18(2), issued to the health establishment by the Office. A health establishment found to be compliant with the prescribed norms and standards will be issued with a certificate of compliance. The certificate shall be valid for a period of four years and is subject to renewal. |
| **Certification** | Formal recognition of compliance with set standards validated by an external validator. |
| **Clinic** | Any health establishment that provides mainly preventative care and/or outpatient services to the community. |
| **Clinical audits** | A quality assurance tool that seeks to monitor and improve the quality of clinical practice, user care and outcomes through the systemic review of care against explicit standards. |
| **Clinical governance** | A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved by creating an environment in which there is transparent responsibility and accountability for maintaining standards and by allowing excellence in clinical care to flourish. |
| **Clinical outcomes** | The condition of the user at the end of treatment or a disease process, including the degree of wellness and the need for continuing care, medication, support, counselling, or education. |
| **Clinical practice guidelines** | A systematically developed statement to assist health care professionals and patient decisions about appropriate health care for specific circumstances. |
| **Clinical risk** | The likelihood that an adverse incident will cause injury or harm to users. |
| **Community Health Centre (CHC)** | Any health establishment that provides mainly outpatient services and short stays to the community. |

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| **Competence/ Competent/ Competency** | An individual's knowledge and skills are appropriate to the services provided and assurance that the knowledge and skill levels are regularly evaluated. |
| **Compliance notice** | A notice referred to in regulation 21(1), issued to the health establishment by an inspector. |
| **Confidentiality** | A notice referred to in regulation 21(1), issued to the health establishment by an inspector. |
| **Confidentiality** | Guaranteed limits on the use and distribution of information collected from individuals or organisations. |
| **Consent** | Voluntary agreement or approval given by an individual. |
| **Coordination** | The process of working together effectively with collaboration among providers, organisations, teams and services inside and outside the organisation to avoid duplication, gaps or breaks. |
| **Criteria** | Specific steps to be taken, or activities to be performed to reach a decision or a standard. |
| **Disinfection** | A process of reducing microbial load without complete sterilisation. The use of a physical process or chemical agent to destroy vegetative pathogens, but not bacterial spores. |
| **Early warning systems** | The surveillance system that collects information on serious user-related incidents, which prompts interventions by the health establishment, Office or relevant authority. |
| **Effectiveness** | The degree to which services, interventions or actions are provided in accordance with current best practices in order to meet goals and achieve optimal results. |
| **Emergency** | An unanticipated or sudden occasion, as in emergency surgery needed to prevent death or serious disability. |
| **Environment** | The overall surroundings where health care is being delivered, including the building, fixtures, fittings and services such as air and water supply. Environment can also include other patients, visitors and the workforce. |
| **Essential medicine list** | A list of medicines that satisfy the priority health care needs of the population and should be available within the context of functioning health systems at all times, in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. |
| **Forum** | A platform for meetings and discussion of issues of common interest. A forum could include a dedicated team, a sub-committee/working group within a larger structure, or a special task team.<br><br>Terms of reference of the forum and standing items of the agenda are evidence that it is an active working group, and attendance, participation, and progress can be monitored. |

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| **Harm** | Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. |
| **Harmful incident (adverse event)** | An incident that results in harm to users that is related to medical management, in contrast to disease complications or underlying disease. |
| **Hazard** | Any source of potential damage, harm, adverse health effects on users or health care personnel, or any threat to their safety; or a circumstance, agent or action with the potential to cause harm (PSI Framework, p10). |
| **Head of health establishment** | The owner and occupier of a health establishment as contemplated in section 88(a) of the Act. |
| **Health** | A state of complete physical, mental and social well-being and not merely the absence of diseases and infirmity. |
| **Health care associated infection** | Also referred to as a nosocomial or hospital-associated infection. It is an infection acquired in a health care facility by a health care user, health care worker or a visitor to a health care facility who was in the facility for a reason other than infection. Such infection should have neither been present or incubating at the time of admission or when initial contact with the facility was made. |
| **Health care service** | Includes all services dealing with the diagnosis and treatment of disease, or the promotion, maintenance and restoration of health, including personal and non-personal health services provided by public and private health establishments. |
| **Health establishment** | 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. |
| **Health record** | Any record made by a health care provider, at the time of or shortly after seeing the user, upon examination or treatment, that contains information about the health of the user and includes any results of diagnostic investigations performed on the user. It is recorded by a health care provider, either personally or under his/her direction. |
| **Infection prevention and control programme** | A comprehensive programme that encompasses all aspects of infection prevention and control, covering education and training, surveillance, environmental management, waste management, outbreak investigations, development and updating of infection prevention and control policies, guidelines and protocols, cleaning, disinfection and sterilisation, employee health, and quality management in infection control. |

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| **Inspection** | On-site visits to health establishments for the purpose of gathering information and evidence, to assess compliance or investigate breaches in norms and standards. |
| **Level of care** | The type of medical/clinical intervention required for a patient, according to their medical condition. It also refers to the level of service delivery – primary (PHC), secondary (CHC) or tertiary (hospital). |
| **Management** | The executive management and all heads of departments, including clinical and non-clinical service areas of a health establishment. |
| **Medical equipment** | Any instrument, apparatus or machine intended for use in the clinical diagnosis, treatment, monitoring and direct care of users that needs to be calibrated, maintained, repaired or decommissioned. |
| **Medical supplies** | Products and devices other than medicines that are used for therapeutic purposes. |
| **National department** | The national department responsible for health. |
| **Norm** | An expected pattern of behaviour. |
| **Occupational health and safety** | WHO definition: Occupational health deals with all aspects of health and safety in the workplace and has a strong focus on primary prevention of hazards. It encompasses the social, mental and physical well-being of workers. |
| **Patient information** | Formal information provided by health services to a user. Patient information ensures users are informed before making decisions about their health care. |
| **Patient's records** | A collection of documents that provides an account of each episode in which a user visited or sought treatment and received care or referral from a health care facility. Generally, records are confidential, and held by the facility. The information is shared with other health personnel on a need-to-know basis. It is a legal document as it can be used as evidence in the event of legal action. It is also an important tool for clinical audits and quality assurance to assess the quality of client care. |
| **Patient safety** | The reduction of risk of unnecessary harm associated with health care to an acceptable minimum. |
| **Patient safety incident** | An event or circumstance that could have resulted in or did result in harm to a user of health care services provided, and not due to an underlying health condition. |
| **Personal protective equipment** | Items specifically used to protect the health care worker from exposure to bodily substances, or from droplets, or airborne organisms. Personal protective equipment includes, but is not limited to, gloves, gowns, caps, masks and protective eyewear. |
| **Prevention** | Every effort made to identify possibilities for infection and to put in place interventions for its prevention. |

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| **Prophylaxis** | A measure taken for the prevention of a disease or condition. |
| **Quality improvement** | A combined team effort to make the changes that will lead to better user health outcomes, better systems performance and better professional development. |
| **Quality improvement plan** | A plan designed to improve health service delivery, health systems and health outcomes. It is an integral part of the quality improvement process as it identifies priorities and necessary action. |
| **Referral letter** | A letter used to refer clients:<br><br>• From one level of care to another within the health care system.<br>• To different departments/health practitioners within a health establishment.<br>• To other services outside the health establishment or sector. |
| **Referral policy** | Identifies key aspects of the process for effective referrals to ensure optimum care. |
| **Relevant authority** | A provincial department of health, district health authority, municipal authority or executive management of a private hospital or private hospital group. It addresses non-compliance and gaps identified during inspections. |
| **Report** | An analysis of a situation, with key findings/results/issues and an action plan/recommendation. Reports can be sourced from: a dedicated report, minutes of meetings, quarterly/annual reports, etc. |
| **Responsible authority** | A sub-district, district or management of a private health care establishment that provides supervisory support to the health establishment. |
| **Risk assessment** | The assessment of an environment to identify any hazards or circumstances that compromise safety and have the potential to cause harm or loss. |
| Risk management | All processes involved in identifying, assessing and judging risks, from assigning ownership, to taking action, to mitigating or anticipating them, and monitoring and reviewing progress. |
| **Root cause analysis** | A quality improvement problem solving method used to analyse the possible causes of a problem/gap/non-compliance. The process seeks to understand the causes and reasons for the gap, to provide the basis for targeted action to improve the situation. Examples of quality improvement methodologies to identify the root cause include the “Fish bone” and “The five whys”. |
| **Safety** | The degree to which the health establishment’s buildings, grounds and equipment do not pose a hazard or risk to patients, staff or visitors. |

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| **Security system** | Systems to ensure safety of staff, clients, patients and the public. In this context, it includes lighting (particularly at night in commonly used public areas), codes for doors with limited access, security guards present and screening movement, and security cameras in working condition and monitored via radio control. |
| **Security threats and risks** | Any criminal activity or threat of potential criminal activity on the property, or threat to health care personnel or users in the health establishment, including theft, assault, abuse and injury. |
| **Service operating times** | The times during which the health establishment will be providing services. |
| **Stakeholder** | A person, group or organisation that has a direct interest in an issue. |
| **Standard** | A statement that defines the performance expectations, structures, or processes that must be in place for an organisation to provide safe and treatment and service. |
| **Sterilisation** | A process that destroys or removes all viable micro-organisms including spores. Sterilisation can be achieved through the use of heat, steam, gas or chemicals. |
| **Structure** | A designated team, committee or forum. |
| **System** | A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim. |
| **Toxic waste** | Chemical by-products which, when touched, ingested or inhaled by humans, can cause physiological damage or illness. |
| **Tracer medicine/medical supplies** | Essential medicines/supplies as per the essential drug list or formulary. |
| **Triage** | The process of determining the priority of users' treatments based on the severity of their condition. This process allocates patient treatment efficiently when resources are insufficient for all patients to be treated immediately. |
| **User** | The person receiving treatment from a health establishment or using health services. It includes caregivers or guardians in the case of vulnerable users. |
| **User experience of care** | A mechanism to obtain feedback from users as per district, provincial or national protocol. It could include a formal survey, individual interviews and/or focus group discussions. It can also include an analysis of other mechanisms to acquire user feedback, e.g. a suggestion box or comment book. It can be done internally or by an external organisation. |
| **User information** | Formal information that is provided by health services to a user to ensure the user is informed before making decisions about their health care. |

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| **Waiting list** | A list of people waiting for care or treatment pending the availability of hospital resources. |
| **Waiting times** | The time the user spends waiting for service/s in a facility per visit. It is calculated from the time the patient enters the facility (taking into consideration the official opening time of the facility) to the time that the user leaves the facility.<br><br>Waiting times in health care can include the following:<br><br>• Waiting for an ambulance<br>• Waiting in queues at the health establishment for services, at different service delivery points<br>• Waiting for admission into a ward for outpatients, for accident and emergency.<br>• Waiting for an appointment for referral to another level of care/facility, specialist care, medical procedures and surgery (emergency and elective). |
| **Waste management system** | All the administrative and operational activities involved in the production, handling, treatment, conditioning, storage, transportation and disposal of waste generated by health care establishments. |

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40. http://www.health.gov.za/index.php/2014-03-17-09-09-38/policies-and-guidelines/category/91-2011p?download=160:essential-steps-in-the-management-of-common-conditions-associated-with-maternal-mortality
41. https://www.wcbs.org.za/village/wpbnew/sites/default/files/clinical_guidelines_5th%20Edition_2014.pdf
42. https://apps.who.int/iris/handle/10665/206946
43. https://www.achs.org.au/programs-services/equip6/

### 15.3. South Africa – Provincial Governments: Other Organisations' Guidelines

1. https://emssa.org.za/practice-guidelines/
2. http://www.samj.org.za/index.php/samj/article/view/4418
3. http://www.scielo.org.za/pdf/samj/v101n3/v101n3a21.pdf
4. https://emssa.org.za/wp-content/uploads/2011/04/SATS-Manual-A5-LR-spreads.pdf
5. https://emssa.org.za/documents/em002.pdf
6. https://emssa.org.za/documents/em004.pdf

7. http://cohsasa.co.za/wp-content/uploads/2019/08/COHSASA_Backgrounder_July_2019.pdf
8. https://www.researchgate.net/publication/50303415_Guideline_for_the_assessment_of_trauma_centres_in_South_Africa
9. https://www.mm3admin.co.za/documents/docmanager/3C53E82B-24F2-49E1-B997-5A35803BE10A/00133607.pdf
10. https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%2012%20Guidelines%20for%20the%20management%20of%20health%20care%20waste%20September%202016.pdf
11. https://isystems.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%2012.pdf
12. https://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/transforming-mental-health-london-kingsfund-sep2014.pdf
13. https://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/transforming-mental-health-london-kingsfund-sep2014.pdf
14. https://www.who.int/docs/default-source/mca-documents/advisory-groups/quality-of-care/standards-for-improving-quality-of-maternal-and-newborn-care-in-health-facilities.pdf?sfvrsn=3b364d8_2
15. https://www.cqc.org.uk/sites/default/files/20140725_nhs_fppr_and_doc_consultation_final.pdf
16. https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%209%20Keeping%20of%20Patient%20Records%20September%20%202016.pdf
17. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
18. https://www.tb-ipcp.co.za/tools-resources/documents-paper-and-articles/19-risk-assessment-and-management-tool-for-hospitals-draft2/file
19. https://section27.org.za/wp-content/uploads/2010/04/Chapter8.pdf
20. http://www.sajaa.co.za/index.php/sajaa/issue/view/11
21. https://www.isqua.org/media/attachments/2018/03/20/guidelines_and_principles_for_the_development_of_health_and_social_care_standards__4th_edition_v1.2.pdf
22. http://isqua.newsweaver.co.uk/Newsletter/i8rrfufy-cos?a=4&p=47933962&t=28079613
23. https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf
24. https://www.ifc.org/wps/wcm/connect/a61283a6-f527-442e-9db0-3215fd94af6a/1TCntntsIntrdctn.pdf?MOD=AJPERES&CVID=jkCXkm7
25. http://www.api.org/environment-health-and-safety/environmental-principles
26. http://www.health.gov.za/tender/docs/tenders/2018-19/NDOH_07_2018-2019_Maternal-Care-Guidelines-2015_FINAL-21.7.15.pdf
27. http://scholar.google.co.za/scholar?q=27.%09Essential+Postnatal+Care+(EPOC)+Handbook%3F&hl=en&as_sdt=0&as_vis=1&oi=scholart
28. https://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/epoc_qes_protocol_and_review_template.pdf
29. https://www.up.ac.za/media/shared/Legacy/sitefiles/file/44/1066/2074/up_research_publications2012.pdf
30. http://www.health.gov.za/index.php/shortcodes/2015-03-29-10-42-47/2015-04-30-08-18-10/2015-04-30-08-24-27?download=889:national-perinatal-morbidity-and-mortality-committee-napemmco
31. http://www.dnaeconomics.com/assets/Usealexconstantinoudnaeconomicscom/

OHSC-Regulating-the-Quality-of-Health-Services.pdf
32. https://www.cqc.org.uk/
33. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
34. https://isystems.hpcsa.co.za/Uploads/editor/UserFiles/downloads/medical_dental/BOARD_EXAMINATION_GUIDELINES_FOR_MEDICINE_2019.pdf
35. https://www.tei.org.za/phocadownloadpap/Research_Reports/booklet1and2.pdf
36. https://www.who.int/patientsafety/safesurgery/checklist/en/
37. https://sasom.org/wp-content/uploads/2018/12/Medico-Legal-Aspects-of-the-Practice-of-Occupational-Health-Nursing-Practitioners-in-South-Africa-2018.pdf
38. http://whqlibdoc.who.int/hq/2003/WHO_EIP_OSD_2003.1.pdf
39. http://library.nhsggc.org.uk/mediaAssets/library/nhsggc_risk_management_strategy_2007-05.pdf
40. https://www.idealhealthfacility.org.za/docs/guidelines/Quality%20Improvement%20Guide%202012.pdf
41. https://gsdrc.org/document-library/batho-pele-people-first/
42. http://new.paho.org/hq/documents/maximizingqualityofcarethroughhealthsectorreformtheroleofqualityassurancestrateg-EN.pdf
43. https://www.westerncape.gov.za/other/2009/7/ggf.pdf
44. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4068985/
45. http://www.sajcn.co.za/index.php/SAJCN/article/view/286/281
46. https://www.praxiom.com/
47. https://people.well.com/user/vamead/demingdist.html
48. https://curationis.org.za/index.php/curationis/article/download/1340/1296
49. https://www.researchgate.net/publication/272886377_Improving_the_quality_of_nursing_documentation_An_action_research_project
50. http://www.kzntransport.gov.za/reading_room/acts/national/National%20Land%20Transport%20Regulations%205%20of%202009.pdf
51. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
52. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
53. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
54. http://hpp.ukzn.ac.za/Libraries/HPP_Information_Sheet/CPD_Guidelines_April_2009.sflb.ashx
55. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
56. https://pdf4pro.com/cdn/health-professions-council-of-south-africa-468a9e.pdf
57. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
58. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
59. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
60. https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%205%20Confidentiality%20Protecting%20and%20Providing%20Information%20September%202016.pdf
61. https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%206%20Gen%20Ethical%20Guidelines%20for%20Management%20of%20Patients%20with%20HIV.pdf
62. https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%207%20Guidelines%20withholding%20and%20withdrawing%20treatment%20September%202016.pdf
63. https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf
64. http://www.adsa.org.za/Portals/14/Documents/pPolicy20on20Undesirable20Business20Practices.pdf

65. https://www.hpcsa.co.za/?contentId=0&menuSubId=47&actionName=Professional%20Boards
66. https://www.dmr.gov.za/Portals/0/Resource%20Center/Guidelines%20for%20the%20Mandatory%20Codes%20of%20Practice/Guidance%20Note_Tuberculosis%20Control%20Programme.pdf?ver=2018-03-13-013131-310
67. https://www.dmr.gov.za/Portals/0/Resource%20Center/Guidelines%20for%20the%20Mandatory%20Codes%20of%20Practice/DMR%2016323%20Occupational%20Medicine/Minimum%20Standards%20of%20Fitness%20to%20Perform%20Work%20at%20a%20Mine_Distribute.pdf?ver=2018-03-13-014456-610

# Annexure A:

## PHC Compendium of Documents

## ANNEXURES

Annexure A: PHC Compendium of Documents

| (A) CC04 Dispensary/Medicine Room: Documents Required |
|---|
| Standard operating procedure (SOP) for management of medicines includes:<br><br>1. Cleaning and appearance of the medicine room/dispensary<br>2. Storage and organisation of the medicine room/dispensary<br>3. Security and control of access to the medicine room/dispensary (within and outside normal working hours)<br>4. Cold chain management<br>5. Emergency cupboard/trolley management<br>6. Management of medicines in the consulting room<br>7. Pest control<br>8. Calculation and use of minimum, maximum and re-order stock levels<br>9. Completion and management of stock (bin) cards<br>10. Stock taking (counting) procedure<br>11. Management of short-dated stock<br>12. Procurement (ordering) of medicines<br>13. Ordering and delivering schedule for stock<br>14. Receipt of medicines into the medicine room/dispensary (ordered or borrowed stock)<br>15. Managing return of stock to the depot<br>16. Managing stock transfers between health establishments<br>17. Medicine availability monitoring procedure/guide<br>18. Separation and handling of expired, obsolete, unusable or patient-returned medicines (Schedule 0–4 medicines)<br>19. Disposal of expired, obsolete, unusable and patient-returned medicines (Schedule 0–4 medicines)<br>20. Managing recall of medicines<br>21. Storage and control of schedule 5 and schedule 6 medicines<br>22. Separation and disposal of expired, obsolete and unusable medicines (schedule 5 and schedule 6 medicines) |
| **Re-ordering stock levels (min/max) are determined for each item on the district/ health establishment formulary.** |
| **Evidence that a stock take of medicine was done in the last 12 months.** |
| **The administration register for schedule 5 and 6 medicines is completed correctly.** |
| **The dispensing register for schedule 5 and 6 medicines is completed correctly.** |

| (B) MC14A Clinic Manager: Documents Required |
|---|
| **Complaints records reflecting compliance with the national guidelines to manage complaints/compliments/suggestions include:**<br><br>• The health establishment/district SOPs to manage complaints/compliments/ suggestions<br>• Statistical report for indicators and classifications for complaints<br>• Complaints register<br>• Complaints letters (check the last 5 complaints resolved)<br>• Complaints redress letters/minutes (check the last 5 complaints resolved) |
| **SOP to prioritise very sick, frail and elderly patients** |
| **Pre-determine the emergency medical services (EMS) response time to the health establishment** |
| **The health establishment monitors EMS response times.** |
| **The health establishment reports delays in EMS response times to the relevant authority.** |
| **Evidence that professional nurses have been trained in basic life support** |
| **The SOP on referral system should cover the following aspects:**<br><br>• District referral network<br>• Referral register<br>• Standardised patient referral form<br>• Standardised patient referral feedback form |
| **Evidence that compliance with waiting time target(s) is monitored by the health establishment.** |
| **A waiting time survey report is available.** |
| **A quality improvement plan indicates corrective measures taken if targets are not met.** |
| **The SOP for key functions of health records management should include:**<br><br>• Accessing of user records<br>• Tracking of user records<br>• Filing of user records<br>• Storage of user records<br>• Archiving of records<br>• Disposal of records |
| **SOP for informed consent:**<br><br>• The signatory providing consent must be legally entitled to give informed consent.<br>• *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 section 129(2)(a)(b);129(3)(a)(b)(c)*<br>• The exact nature of the operation/procedure or treatment, including the site and side |
| |

where relevant, must be communicated to the user.
- The user's full names must appear on the consent form.
- The age of user must be reflected on the consent form.
- 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).
- The consent form must be signed by the health care provider who will perform the procedure.
- The consent form must be dated.
- All entries on the form must be legible.

**Evidence that health care personnel have been informed about the clinical policies and guidelines with respect to the following national guidelines on priority health conditions:**

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
2. National Tuberculosis Management Guidelines, 2014
3. National Guidelines for the Management of Tuberculosis in Children, 2013 OR 2014
4. National Management of Drug-Resistant Tuberculosis. Policy Guidelines, 2013
5. Infection Prevention and Control Guidelines for TB, MDR-TB and XDR-TB, 2015
6. Guidelines for Maternity Care in South Africa, 2016
7. Sexually Transmitted Infections Management Guidelines, 2015
8. National Management of Type 2 Diabetes at Primary Care Level, 2014
9. National Clinical Guidelines for the management of hypertension, 2006

**Evidence that the clinical risk aspects listed below are addressed in the quality improvement plan:**

- Complaints statistical data – relating to clinical care
- Patient safety incident reported
- Clinical record audit
- Annual risk assessment for infection prevention and control
- Loss to follow-up of HIV and TB users
- Tracer list medicine stock-out
- Laboratory specimen collection material stock-out

**Evidence that training is provided to professional nurses on the following clinical guidelines topics:**

- 80% of professional nurses have been trained in adult primary care OR given a Practical Approach to Care Kit.
- 80% of professional nurses have been trained in integrated management of childhood illnesses.
- 50% of professional nurses have been trained in BANC Plus.

**The health establishment conducts clinical audits of the following priority programmes at least annually:**

- HIV
- TB

| (B) MC14A Clinic Manager: Documents Required |
|---|
| • NCD (diabetes and hypertension)<br>• Maternal health (ANC and PNC)<br>• Well baby<br>• IMCI (sick child) |
| **Evidence that 80% of user records audited for clinical audits are compliant:**<br><br>• HIV<br>• TB<br>• NCD (diabetes and hypertension)<br>• Maternal health (ANC and PNC)<br>• Well baby<br>• IMCI (sick child) |
| **Evidence that national guidelines are followed for all notifiable medical conditions:**<br><br>• Notifiable medical conditions are recorded in the notification booklet or entered electronically in a web-based system.<br>• All notifiable diseases are reported using the prescribed form or electronically in a web-based system.<br>• Proof of submission of completed forms is available. |
| **Evidence that the targets for proxy indicators for clinical risk are met:**<br><br>• TB treatment success rate is at least 87%.<br>• TB (new pulmonary) defaulter rate < 5%.<br>• Antenatal visit rate before 20 weeks gestation is at least 70%.<br>• Antenatal patient initiated on ART rate is at least 97%.<br>• Immunisation coverage under one year (annualised) is at least 86%. |
| **Evidence of improvement in proxy indicators for clinical risk:**<br><br>• TB treatment success rate has increased by at least 5% from the previous year.<br>• TB (new pulmonary) defaulter rate has improved by at least 5%.<br>• Antenatal visit rate before 20 weeks gestation has increased by at least 5% from the previous year.<br>• Antenatal patient initiated on ART rate has increased by at least 5% from the previous year.<br>• Immunisation coverage under one year (annualised) has increased by at least 5% from the previous year. |
| **The SOP for the management of patients with highly infectious diseases:**<br><br>• Users with highly infectious diseases are accommodated in a designated room or area in the clinic.<br>• Terminal cleaning of the emergency room is conducted immediately after the user leaves the room.<br>• Personal protective equipment is available. |
| **The guideline or SOP for standard precautions:**<br><br>1. Hand hygiene<br>2. Personal protective equipment |

| (B) MC14A Clinic Manager: Documents Required |
|---|
| 3. Prevention of respiratory infections (respiratory hygiene or cough etiquette)<br>4. Safe injection practices<br>5. Disposal of sharps<br>6. Environmental cleanliness<br>7. Patient care equipment<br>8. Handling of linen<br>9. Wound care<br>10. Waste management and disposal |
| **Evidence that all health care personnel have been trained on all the above-mentioned standard precautions topics in the past two years** |
| **Evidence that all health care personnel are made aware of the provincial letter or memo or circular that informed staff of the procedure to follow for prophylactic immunisations:**<br><br>• Letter or memo or circular from the provincial head of health or the delegated staff member at the provincial office that informs staff of the procedure to follow for prophylactic immunisations is available.<br>• Letter or memo or circular from the provincial head of health or the delegated staff member at the provincial office indicates the recommended vaccinations as determined by the disease profile of the health establishment or region.<br>• Letter or memo or circular from the provincial head of health or the delegated staff member at the provincial office indicated sets out the procedure to follow to obtain prophylactic immunisations, including who will bear the cost of immunisations.<br>• Staff has signed acknowledgment indicating that they are aware of and know the content of the letter or memo or circular and its application. |
| **Evidence that staff who experience needle stick injuries receive post exposure prophylaxis.** |
| **The SOP for handling, storage and safe disposal of waste:**<br><br>• Segregation containers<br>• Handling of segregated waste<br>• Storage of segregated waste<br>• Collection<br>• Disposal |
| **A signed copy of waste removal SLA between the health department and the service provider** |
| **Evidence that waste is removed in line with the contract** |
| **Evidence that the waste manager or designated person monitors and manages the SLAs for waste removal and disposal** |
| **Evidence that identified breaches in the contract are escalated to the relevant authority** |
| **Adverse events reporting register is available in the health establishment** |
| **The SOP for patient safety incident reporting and learning** |
| **Evidence that the SOP for patient safety incident reporting and learning is adhered to:** |

## (B) MC14A Clinic Manager: Documents Required

- 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.
- Statistical report for classifications of agents involved.
- Statistical report for classifications of incident type.
- Statistical report for classifications of incident outcome.
- Statistical report for indicators for patient safety incidents.

**Evidence that all Severity Assessment Code (SAC) 1 adverse events are reported to the next level of management within 24 hours**

**Evidence of a functional clinic committee**

*The following documents should be available:*

**Formal appointment:**

- Signed appointment letters from Office of the MEC or delegated person
- Adopted and signed constitution as per provincial guidelines
- Code of conduct for Clinic Committee

**Training:**

- Attendance register for orientation and training conducted within the first 12 months of appointment

**Services planning, monitoring, evaluation and meetings:**

- List of community needs as discussed by the clinic committee in the past 12 months
- Agendas indicating that community needs and progress against the operational plan were discussed at least twice in the past 12 months
- Signed minutes indicating that progress against the operational plan was discussed at least twice in the past 12 months
- The current year plan indicating scheduled meetings (at least two within the next 12 months)
- Attendance registers indicating that meetings held formed a quorum
- Minutes of clinic committee meetings indicating that statistical data on population health indicators are discussed
- Minutes of clinic committee meetings indicating that the clinic's HR situation is discussed
- Minutes of clinic committee meetings indicating that the situation relating to equipment and supplies is discussed

**Complaints, compliments and suggestion management (check record of the past six months):**

- Proof that the clinic committee took part in opening complaints boxes according to the stipulated schedule (signed register)

| (B) MC14A Clinic Manager: Documents Required |
|---|
| • Minutes indicate that the management of complaints are discussed at clinic committee meetings<br>• Accountability and communication:<br>• Contact details of clinic committee members clearly displayed in reception area |
| **Evidence that staffing needs have been determined in line with workload requirements** |
| **Evidence that staff appointment is in line with the determined requirements** |
| **Evidence that the performance management system is adhered to Instructions:**<br><br>Request five performance management files that have been finalised for the following categories of health care personnel: two professional nurses, one enrolled nurse, one nursing assistant and one cleaner.<br><br>*Records should indicate the following:*<br><br>• Performance management agreement is signed by the supervisor and employee<br>• Annual work plan activities are aligned to the operational plan of the health establishment<br>• Completed personal development plan is available<br>• Objectives and targets are reviewed for each quarter<br>• Annual (final) assessment report (PMDS) |
| **Evidence that all health care professionals have current registration with relevant health professional bodies.**<br><br>*Categories of staff:*<br><br>• Clinical nursing practitioner<br>• Professional nurse<br>• Enrolled nurse<br>• Nursing assistant<br>• Medical officer – full time<br>• Medical officer – sessional<br>• Private GP<br>• Pharmacist (where applicable)<br>• Pharmacist assistant (where applicable) |
| **The SOP for management of occupational health and safety incidents** |
| **Evidence that an occupational health and safety risk assessment has been conducted in the past two years** |
| **Evidence that risk mitigation interventions are implemented for identified risks** |
| **Occupational health and safety incidents are recorded in a register** |
| **Occupational health and safety incident investigations are recorded** |
| **Evidence that remedial action to address identified occupational health and safety incidents are implemented** |
| **The SOP for safety and security** |
| **A signed copy of the SLA between the security company and the provincial department of health** |

| (B) MC14A Clinic Manager: Documents Required |
|---|
| **Evidence that the designated person monitors the SLA for security services** |
| **Security breaches are recorded in a register** |
| **Remedial actions to address security breaches identified are implemented.** |
| **Evidence that security services are rendered according to SLA OR provincial security policy.**<br><br>**If armed response is available:**<br><br>• Response time indicated in register for security breaches<br>• If there were breaches, did they respond in time?<br><br>**If security guards are available:**<br><br>• Duty patrol register updated (occurrence book) |
| **Evidence that security guards have received training** |

| PC01 Clinical Services: Required Documents |
|---|
| **Referral register that records referred users which includes details listed below:**<br><br>• Name of referred user<br>• Date of referral, time of referral<br>• Service to which the user is referred<br>• Reason for referral |
| **Clinical guidelines are available in all consulting rooms:**<br><br>1. Adult Primary Care guide (APC) – 2016/17 or Practical Approach to Care Kit (PACK), 2017<br>2. Integrated Management of Childhood Illness Chart Booklet, 2014<br>3. Standard Treatment Guidelines and Essential Medicines List for Primary Health Care, 2014 or 2018 once available<br><br>**Clinical guidelines are available in consulting room used by the doctor:**<br><br>1. Standard Treatment Guidelines and Essential Medicines List for Primary Health Care, 2014 or 2018 once available<br>2. Standard Treatment Guidelines and Essential Medicines List for Hospital Level, Adults, 2015<br>3. Standard Treatment Guidelines and Essential Medicines List for Hospital Level, Paediatrics, 2017<br>4. New-born Care Charts Management of Sick and Small New-borns in Hospital SSN Version 1 |

| SC01 Clinic Maintenance Service: Required Documents |
|---|
| **Building(s) complies with safety regulations:**<br><br>• Fire compliance certificates<br>• Electrical compliance certificates |
| **Maintenance schedules for building(s) and grounds** |
| **Evidence that health establishment has access to a functional back-up electrical supply in case of power supply disruptions:**<br><br>• The generator is tested for functionality in accordance with the manufacturer's instructions. (applicable if health establishment uses a generator as a backup). Explanatory note: The manufacturer's instructions must be available as well as the logbook indicating the testing done on the emergency generator. The log book must reflect that the generator has been tested in accordance with the manufacturer's instructions.<br>• Where an emergency generator provides an emergency power supply, it is maintained in accordance with the manufacturer's instructions. Explanatory note: The manufacturer's instructions must be available, as well as the log book documenting the maintenance done on the emergency generator. Maintenance records must demonstrate that maintenance has been carried out in accordance with the manufacturer's instructions.<br>• The solar system is functional.<br>• Where the solar system provides an emergency power supply, it is maintained in accordance with the manufacturer's instructions. Explanatory note: The manufacturer's instructions must be available, as well as the log book documenting the maintenance done on the solar system. Maintenance records must demonstrate that maintenance has been carried out in accordance with the manufacturer's instructions.<br>• The power inverter system is functional.<br>• Where the power inverter system provides emergency power supply, it is maintained in accordance with the manufacturer's instructions. Explanatory Note: The manufacturer's instructions must be available, as well as the log book documenting the maintenance done on the power inverter system. Maintenance records must demonstrate that maintenance has been carried out in accordance with the manufacturer's instructions. |
| **Evidence that all official vehicles used to render services or transport users are licensed annually** |
| **Evidence that all official vehicles used to render services or transport users are serviced according to manufacturer's schedule** |
| **Evidence that staff driving official vehicles to render services or transport users have a valid driver's license** |
| **Copy of a valid professional driver's permit for each driver** |

# Annexure B:

## National Health Act Norms and Standards

GOVERNMENT GAZETTE, 2 FEBRUARY 2018 No. 41419

**DEPARTMENT OF HEALTH**

**NO. 67** **02 FEBRUARY 2018**

**NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)**

# NORMS AND STANDARDS REGULATIONS APPLICABLE TO DIFFERENT CATEGORIES OF HEALTH ESTABLISHMENTS

The Minister of Health has. under section 90(IA) of the National Health Act, 2003 (Act No, 61 of 2003), and after consultation with the Office, to make the Regulations in the Schedule.

## SCHEDULE

## ARRANGEMENT OF REGULATIONS

## GOVERNANCE AND HUMAN RESOURCES

18. Governance
19. Human resources management
20. Occupational health and safety

## GENERAL PROVISIONS

21. Adverse events
22. Waiting time
23. Short title and commencement

## DEFINITIONS, PURPOSE AND APPLICATION

### 1. Definitions

"building regulations" means the building regulations issued in terms of any of the following legislation or regulations—

a. National Building Regulations and Buildings Standards Act, 1977 (Act No. 103 of 1977); or
b. Regulation Governing Private Hospitals and Unattached Operating Theatre Units, published in Government Gazette, Notice No. R. 158 of 1 February 1980; or
c. Regulation Governing Private Health Establishments, Western Cape, published in Provincial Gazette Extraordinary 5728, Provincial Notice No. 187 of 22 June 2001;

**"clinic"** means any health establishment that provides mainly outpatient services to the community.

**"clinical risk"** means the likelihood that an adverse incident will cause injury or harm to users.

**"Community Health Centre (CHC)"** means any health establishment that provides mainly outpatient services and short stay to the community.

**"hazard"** means any source of potential damage, harm, adverse health effects on users or health care personnel, or any threat to their safety.

**"health record"** may be defined as any relevant record made by a health care practitioner at the time of or subsequent to a consultation and / or examination or the application of health management; that contains information about the health of the user and includes any results of diagnostic investigations performed on the user and is recorded by a health care provider, either personally or under his or her direction;

**"management"** means the executive management and all heads of departments, Including clinical and non-clinical service areas of a health establishment.

**"medical equipment"** means any instrument, apparatus or machine, intended for use in the clinical diagnosis, treatment, monitoring and direct care of users that needs to be calibrated, maintained, repaired and decommissioned.

**"medical supplies"** means products and devices other than medicines that are used for therapeutic purposes.

**"national department"** means the national department responsible for health.

**"Pharmacy Act"** means the Pharmacy Act, 1974 (Act No. 53 of 1974).

**"responsible authority"** means a sub-district, district or management of a private health care establishment that provides supervisory support to the health establishment.

**"security threats and risks"** means any criminal activity or threat of a potential criminal activity on the property, health care personnel or users in the health establishment including theft, assault, abuse and injury; and

**"structure"** means a designated team, committee or forum.

**2. Scope and application**

These Regulations apply to the health establishment to the extent specified in the measurement tools obtainable from the National Department of Health.

**3. Purpose of Regulations**

The purpose of these Regulations is to promote and protect the health and safety of users and health care personnel.

## USER RIGHTS

**4. User information**

1. Health establishments 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.

2. For the purposes of sub-regulation (1), a health establishment must—
   a. provide users with information relating to—

      i. the health care services provided by the health establishment.
      ii. service opening and closing times,
      iii. visiting hours where relevant; and
      iv. complaints, compliments and suggestions management system.

   b. provide users with information on any fees that are payable for health care services, insofar it being practical to do so before the commencement of the provision of health care services; and

c. display the results of user experience of care surveys conducted within the past twelve months.

**5. Access to care**

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,

1. For the purposes of sub-regulation (I), a health establishment must—

   a. implement a system of triage.
   b. 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; and
   c. adhere to clinical guidelines on stabilizing users presenting in an emergency before referring them to another health establishment.

2. The health establishment must maintain a system of referral as established by the responsible authority,

3. For the purposes of sub-regulation (3), a health establishment must—

   a. ensure that users are provided with information relating to their referral to another health establishment; and
   b. ensure that a copy of the referral document is kept in the user's health record.

**CLINICAL GOVERNANCE AND CLINICAL CARE**

**6. User health records and management**

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.

2. For the purposes of sub-regulation (1), the health establishment, must

   a. have a health record filing, archiving, disposing, storage and retrieval system which complies with the law.
   b. ensure confidentiality of health records; and
   c. secure health records with appropriate security control measures in the records Storage area and in the clinical service area in accordance with the Protection of Personal Information Act. 2013 (Act No. 4 of 2013).

3. The health establishment must create and maintain a system of health records of users in accordance with the requirements of section 13 of the Act.

4. For the purposes of sub-regulation (3), a health establishment must—

   a. record the biographical data of the user and the identification and contact information of the user and his or her next of kin; and

b. record information relating to the examination and health care interventions of users.

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

6. The health establishment must issue a discharge report to users in accordance with section 10 of the Act.

**7. Clinical management**

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

2. For the purpose of sub-regulation (1) a health establishment must—

a. ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel; and
b. establish and maintain systems, structures and programmes to manage clinical risk.

**8. Infection prevention and control programmes**

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

2. For the purposes of sub-regulation (I), a health establishment must—

a. ensure that there are hand washing facilities in every same area.
b. provide isolation units or cubicles where users with contagious infections can be accommodated.
c. ensure there is clean linen to meet the needs of users; and
d. ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations

**9. Waste Management**

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

2. For the purposes of sub-regulation (1), the health establishment must—

a. have appropriate waste containers at the point of waste generation.
b. implement procedures for the collection, handling, storage and disposal of waste.

# Annexure C:

## National Health Act Procedural Regulations

## Annexure C: National Health Act Procedural Regulations

The Minister of Health has, after consultation with the Office, made the regulations contained in the Schedule hereto, in terms of section 90(1) of the National Health Act, 2003 (Act No. 61 of 2003).

**DEPARTMENT OF HEALTH**

**40350** **13 October 2016**

**NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)**

**PROCEDURAL REGULATIONS PERTAINING TO THE FUNCTIONING OF THE OFFICE OF HEALTH STANDARDS COMPLIANCE AND HANDLING OF COMPLAINTS BY THE OMBUD**

**SCHEDULE**

**ARRANGEMENT OF REGULATIONS**

**CHAPTER 1**

**DEFINITIONS, PURPOSE AND APPLICATION**



**CHAPTER 2**

**COLLECTION OF INFORMATION AND DESIGNATIONOF PERSON IN CHARGE**



**CHAPTER 3**

**INSPECTORS AND INSPECTIONS**

## CHAPTER 4

## ENTRY, INSPECTION AND SEARCH OF HEALTH ESTABLISHMENT



## CHAPTER 5

## CERTIFICATION



## CHAPTER 6

## COMPLIANCE NOTICE, ENFORCEMENT AND APPEAL



## CHAPTER 7

## COMPLAINTS HANDLING, INVESTIGATION AND OMBUD

## CHAPTER 8

## GENERAL PROVISIONS

## CHAPTER 1

## DEFINITIONS, PURPOSE AND APPLICATION

### 1. Definitions and interpretation

1.1. In these Regulations, unless the context indicates otherwise, a word or expression to which a meaning has been assigned in the Act, has the same meaning, and—

**"category of health establishment"** means the category contemplated in section 35 of the Act;

**"certificate of compliance"** means a certificate referred to in Regulation 18(2), issued to the health establishment by the Office;

**"compliance notice"** means a notice referred to in regulation 21(1), issued to the health establishment by an inspector;

**"early warning system"** means the surveillance systems that collect information on serious user-related incidents that prompt interventions by the health establishment, Office or relevant authority;

**"head of the health establishment"** means the owner and occupier of a health establishment as contemplated in section 88(a) of the Act;

**"health care service"** includes all services dealing with the diagnosis and treatment of disease, or the promotion, maintenance and restoration of health including personal and non-personal health services provided by public and private health establishments;

**"inspection"** means on site visits to health establishments for the purpose of gathering information and evidence to assess compliance or investigate breaches of norms and standards;
"person" means a legal person, except where the context indicates otherwise;

**"person in charge"** means a person designated as a person in charge of a health establishment, in terms of regulation 6(1);

**"relevant authority"** means a provincial department of health, district health authority, municipal authority or executive management of a private hospital or private hospital group;

**"self-assessment"** means the information or data resulting from an assessment conducted by the health establishment against a tool or framework published by the Office from time to time;

**"serious breach"** means a breach in safety procedures which results in the user suffering permanent loss of function or death unrelated to natural causes;

**"serious risk"** means any risk that could have severe negative effects on public health or result in the death of a user or permanent loss of function;

**"the Act"** means the National Health Act, 2003 (Act No. 61 of 2003); and
"working day" means any day other than a Saturday, Sunday or public holiday.

## 2. Purpose of Regulations

The purpose of these Regulations is to set out procedures and processes for the collection of information from health establishments by the Office, the certification of health establishments, the conducting of inspections, the dealing with non-compliance by health establishments with norms and standards, as well as the procedures and processes for the consideration, investigation and disposal of complaints relating to non-compliance with norms and standards, by the Ombud.

## 3. Scope and application

3.1. (Subject to sub-regulation (2), these Regulations apply to all categories of health establishments referred to in section 35 of the Act,

3.2. Despite sub-regulation (1), and with the exception of Chapter 7, these Regulations will come into force in relation to each category of health establishment only once the norms and standards for such category of health establishment have been established.

# CHAPTER 2

# COLLECTION OF INFORMATION AND DESIGNATION OF PERSON IN CHARGE

## 4. Collection of or request for information

4.1. All health establishments and users that are required by the Office to provide information relating to norms and standards, in terms of section 79(2)(b) of the Act, must do so by 31 March of each year.

4.2. A request for information from health establishments, referred to in sub-regulation (1), must be in writing, and the required information must be in the form of Form 1 and include, at least, the following:

a. Name of health establishment;
b. legal status;
c. physical address;
d. contact details, including telephone, fax, email and website details, if any;
e. names and contact details of the person in charge;
f. category of health establishment;
g. health district in which the health establishment falls;
h. services offered;
i. operating days and times; and
j. results of the most recent annual self-assessment against norms and standards.

4.3. The Office may publish the request for information, referred to in sub-regulation (2), in

the Government Gazette or on its public website.

4.4. The request for information from users, referred to in sub-regulation (1), must be accompanied by details of the required information and the manner in which such information must be submitted.

4.5. Any information that may be required by the Office from health establishments or users, in terms of section 79(2)(b) of the Act, may be submitted electronically.

4.6. If the person in charge, referred to in regulation 6(1), fails to provide the Office with the required information within the specified period, the Office must refer the matter to the head of the national or provincial department of health, the health department of a municipality or health establishment, as the case may be.

4.7. For the purposes of sub-regulation (2) "legal status" means the status of the health establishment in law, whether it is a private or public company, partnership, trust, sole proprietorship, cooperative or any other legally recognised form.

**5. Indicators of risk**

5.1. In terms of section 79(1)(d) of the Act, the Office must monitor indicators of risk in respect of the early warning system and provide guidance to health establishments on the—

a. indicators of risk by category of health establishment;
b. approach to measuring and calculating the indicators of risk;
c. frequency of collection of the indicators of risk; and
d. reporting to the Office on such indicators.

5.2. The Office must use the information referred to in sub-regulation (1) to—

a. identify indicators of significant clinical risks to quality and safety, adverse events and health care associated infections as part of an early warning system and report serious breaches of norms and standards to the Minister without delay; or

b. decide on the need for and conduct an inspection as contemplated in regulation 14 or 15, as the case may be.

**6. Designation of person in charge**

6.1. he Office must request the head of the national or provincial department of health or the health department of a municipality or, in the case of a private health establishment, the head of a health establishment or the executive management of a private hospital group to designate as a person in charge of the health establishment the most senior employee in rank, who will deal with all matters relating to norms and standards.

6.2. The designation of a person in charge, referred to in sub-regulation (1), must be in writing and signed by the head of the national or provincial department of health or the health department of a municipality or the head of the health establishment, or their

delegatees.

6.3. The Office must maintain a database of persons in charge, and any changes to the particulars of the person in charge must be submitted by such person to the Office within 20 working days of such a change occurring.

**7. Duties of person in charge**

7.1. The person in charge contemplated in regulation 6(2) must—

a. supply the Office or Ombud with information necessary to discharge its or his or her responsibilities, as the case may be, in terms of the Act;

b. provide assistance to an inspector in the preparation for and during an inspection contemplated in section 82(1) of the Act;

c. receive and acknowledge receipt of a compliance notice contemplated in section 82A of the Act and regulation 13;

d. provide assistance to the Ombud during an investigation contemplated in section 81A(1) of the Act;

e. consider and respond to any report from the Office regarding compliance by the health establishment with norms and standards and implement remedial measures within specified timeframes;

f. foster a culture of compliance with norms and standards within the health establishment;

g. design and implement programmes to improve compliance by health care personnel in the employ of the health establishment;

h. disseminate information supplied by the Office to the health care personnel in the employ of the health establishment;

i. maintain an updated record of inspections by the Office or investigations by the Ombud; and

j. render any assistance to the Office or Ombud on all matters relating to norms and standards.

7.2. The person in charge may assign any of his or her responsibilities, referred to in subregulation (1), to any senior employee in rank within the health establishment in writing.

## CHAPTER 3

## INSPECTORS AND INSPECTIONS

### 8. Appointment of inspectors

8.1. The Chief Executive Officer must issue a person who has been appointed as an inspector in terms of section 80(2) of the Act with a certificate of appointment as an inspector, in accordance with section 80(3) of the Act, once the person has successfully completed a minimum training programme approved by the Office.

8.2. The certificate of appointment as an inspector, referred to in sub-regulation (1), must be issued in the form of Form 2, and include, at a minimum, the following information:

a. The name and surname of the inspector;
b. a unique identification number supplied by the Office;
c. the date of issuance;
d. the address and contact details of the Office;
e. the signature of the Chief Executive Officer, and
f. a form of photographic identification.

### 9. Skills and experience for inspectors

9.1. An inspector appointed in terms of section 80(2) of the Act must—

a. be a qualified health professional, who is registered with the Allied Health Professions Council of South Africa, the Health Professions Council of South Africa, the South African Nursing Council, or the South African Pharmacy Council, referred to in the definition of “statutory health professional council” in section 1 of the Act;

b. maintain his or her registration and good standing with the relevant statutory health professional council referred to in paragraph (a), at the time of and for the duration of his or her appointment as an inspector; and

c. have experience in the delivery of health care services in a public or private health establishment.

### 10. Code of conduct for inspectors

10.1. The Chief Executive Officer must develop and enforce a code of conduct for inspectors appointed in terms of section 80(2) of the Act.

10.2. The Office must publish the code of conduct for inspectors in the Government Gazette within three months of the promulgation of these Regulations.

10.3. A copy of the code of conduct for inspectors referred to in sub-regulation (1), must be signed by all the inspectors prior to the commencement of their duties.

## 11. Formal credentials for person rendering assistance

11.1. If an inspector is accompanied by any person reasonably required to assist him or her in the conduct of the inspection, as contemplated in section 82(2) of the Act, the Chief Executive Officer must issue such a person with formal credentials.

11.2. The formal credentials referred to in sub-regulation (1) must include, at least, the following information:

a. Name and surname of the person rendering assistance;
b. a unique identification number;
c. date of issuance;
d. contact details of the Office;
e. signature of the Chief Executive Officer; and
f. a form of photographic identification.

## 12. Inspection strategy, procedures and plan

12.1. The Board must approve an annual inspection strategy to guide the inspection activities of the Office.

12.2. The annual inspection strategy referred to in sub-regulation (1), must be published on the Office's public website, and include, at least, the following:

a. An approach to prioritising, scheduling and conducting inspections; and
b. resources for the implementation of the inspection strategy.

12.3. The Office must develop an inspection procedure manual and tools for inspectors to ensure that inspections are carried out in a consistent, fair, equitable and transparent manner.

12.4. An inspector must prepare an inspection plan, which sets out a clear approach to carrying out the inspection for each health establishment to be inspected.

12.5. The inspection plan referred to in sub-regulation (4) must be appended to the Notice of Inspection referred to in sub-regulation 13.

## 13. Notice of inspection to health establishments

13.1. An inspector must, at any time, before commencing with an inspection contemplated in section 82 of the Act, issue a notice of inspection to the health establishment.

13.2. The notice of inspection referred to in sub-regulation (1), must be in the form of Form 3, and include, at least, the following information:

a. the purpose of the inspection;
b. the date of the inspection;
c. the estimated duration;
d. the inspection plan referred to in sub-regulation 12(4);

e. the number of authorised personnel expected to take part in the inspection;
f. the contact details of the inspector primarily responsible for the inspection; and
g. the responsibilities of the health establishment.

13.3. The notice of inspection referred to in sub-regulation (1), must be signed by the Chief Executive Officer or his or her delegatee.

13.4. Despite sub-regulation (1), the Office may, if it has reasonable grounds to believe that compliance with the notification requirements referred to in regulation (1) may jeopardise user safety or quality of care, conduct an unannounced inspection of a health establishment.

**14. Inspection process**

14.1. Upon arrival at the premises of the health establishment, the inspector must clearly identify himself or herself to the person in charge by presenting—

a. a notice of inspection, referred to in regulation 13(1), if applicable;(b) a certificate of appointment as an inspector, issued in terms of section 80(3) of the Act; and

b. an entry and search warrant issued in terms of section 84(5) of the Act, if applicable.

14.2. During an inspection, the health establishment must make available the necessary staff, resources and space to allow inspectors to complete the inspection in a timely and expeditious manner.

14.3. An inspector may question any user, occupant, health care personnel or any person on the premises of a health establishment about any information that is relevant to the inspection, or require the person in charge to produce any document, record or material for inspection.

14.4. The person in charge may provide the inspector with any relevant information, documents, records, objects or materials for the inspector's consideration during the inspection visit.

14.5. Within 20 working days of the completion of the inspection, the inspector must provide his or her preliminary findings to the person in charge in writing.

14.6. The preliminary findings must—

a. identify the main areas of non-compliance with norms and standards;
b. set out the consequences of non-compliance, contemplated in section 82A(2) and (4) of the Act; and
c. set out the steps that must be undertaken to achieve compliance and timeframes for corrective action.

14.7. The inspector must provide the person in charge not more than 20 working days to respond to the preliminary findings in writing.

14.8. Within 20 working days of receipt of the response contemplated in sub-regulation 7, the inspector must consider such response and issue a final report to the person in charge.

14.9. After issuing a final report contemplated in sub-regulation 8, the inspector—

a. may recommend to the Office the issuing of a compliance certificate to the health establishment, in terms of regulation 18(2); or

b. must issue a compliance notice to the health establishment, in terms of section 82A(1) of the Act, if any norms and standards have not been complied with.

**15. Additional inspection**

15.1. An inspector may, at any time, subject to section 82(1) of the Act, conduct an additional inspection, provided that he or she has reasonable grounds to believe that—

a. such an inspection is needed to establish whether non-compliance has been remedied within the health establishment;
b. the health establishment is contravening the Act or any relevant regulations;
c. there are serious breaches of norms and standards by the health establishment, based on the indicators of risk; or
d. 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.

15.2. The provisions of sub-regulation (1) or (4) of regulation 13 apply, with the necessary changes, to an inspection contemplated in this regulation.

## CHAPTER 4

## INSPECTION OF HEALTH ESTABLISHMENT

**16. Information on approach to carrying out inspections**

16.1. The Office may, within 2 weeks of the beginning of each financial year, inform the head of the national or provincial department of health, the municipal manager or, in the case of the private health establishment, the head of a health establishment or the executive management of a private hospital group, of its approach to carry out inspections.

16.2. For the purposes of sub- regulation (1), the Office may submit to the head of the national or provincial department of health, the municipal manager or in the case of the private health establishment, the head of a health establishment or the executive management of a private hospital group, an annual inspection strategy containing information on such approach to inspections.

## 17. Entry, inspection and search warrant

17.1. An inspector may, in terms of section 82(1) of the Act, enter any health establishment, at any reasonable time, for purposes of carrying out an inspection contemplated in section 82(1) of the Act.

17.2. Where entry into the health establishment as contemplated in sub-regulation (1) is refused, the Office must apply for a warrant in terms of section 84(1) of the Act.

17.3. The application for a warrant must include, at least, the following information:

a. the name and address of the health establishment to be inspected, and where possible, the area or areas of the health establishment to which the warrant relates;
b. the legislative provisions governing the inspection;
c. the reasons and motivation for the inspection; and
d. the most recent inspection results, if the establishment had been inspected previously.

17.4. Subject to section 84(3) of the Act, an inspector may question any user, occupant, health care personnel or any person on the premises of a health establishment, provided he or she has—

a. explained to the said user, occupant or any person on the premises his or her legal rights, including their right to remain silent or not to incriminate themselves; and
b. obtained—

I. written approval from the user, occupant or any person on the premises for the questioning or recording of the interview; or
II. verbal approval from the user, occupant or any or person on the premises for the questioning or recording of the interview, in the presence of a witness.

17.5. Despite sub-regulation (2), an inspector may enter, inspect and search the health establishment's premises without the authority of a warrant in terms of section 86(b) of the Act, if there are reasonable grounds to believe that, if applied for, a warrant for entry and search would be issued and that the delay in obtaining the warrant would defeat the object of the warrant.

## CHAPTER 5

## CERTIFICATION

### 18. Certification of health establishments

18.1. Within 15 working days of receipt of the recommendation for certification of a health establishment referred to in regulation 14(9)(a) or renewal of certification referred to in regulation 19(1), the Office must issue the health establishment that meets all the compliance requirements with a certificate of compliance.

18.2. A certificate of compliance referred to in sub-regulation (1), must—

a. be signed by the Chief Executive Officer and be placed in the public, visible place within the health establishment and posted on its public website; and
b. be issued in the form of Form 4, and include, at least, the following information:

I. the name and physical address of health establishment;
II. the category of health establishment;
III. the address for the service of legal processes and notices, if that address is not the same as the physical address;
IV. the date of the last inspection; and
V. the date of expiry of the certificate.

### 19. Renewal and extension of certification

19.1. The health establishment must, within a period of not more than six months before the expiry of the compliance certificate referred to in regulation 18(1), submit an application to the Office for the renewal of its certificate.

19.2. The application for renewal of the certificate of compliance must be made in the form of Form 6, and include annual self-assessments of the health establishments compliance with norms and standards and its most recent quality improvement plans.

19.3. A renewal of a certificate of compliance will be based on a recommendation for certification referred to in regulation 14(9)(a), as well as compliance by the health establishment with the requirements contained in sub-regulation (2).

19.4. The Office may extend the certification status of the health establishment that has applied for renewal in terms of regulation 19(1) for a period of not more than one year from the date of expiry, to afford the Office an opportunity to schedule and conduct an inspection for the purposes of renewal of certification.

### 20. Suspension of certificate

20.1. A certificate of compliance issued in terms of regulation 18(2), remains valid for a period of not more than four years, subject to an extension contemplated in regulation 19(4).

20.2. Despite sub-regulation (1), a compliance notice referred to in regulation 21 (1), suspends the validity of that certificate of compliance, until the conditions set out in the said compliance notice are fulfilled.

20.3. The Office must, within 15 working days of the confirmation of fulfilment of the conditions of compliance referred to in sub-regulation (2), reconfirm the compliance status of the health establishment.

## CHAPTER 6

## COMPLIANCE NOTICE, ENFORCEMENT AND APPEAL

### 21. Compliance notice to health establishment

21.1. An inspector must—

a. after issuing a final report, issue a compliance notice in terms of section 82A(1) of the Act, to the person in charge, if any norms and standards have not been complied with; or

b. at any time during an inspection, issue a compliance notice in terms of section 82A(1) of the Act, to the person in charge, if there are reasonable grounds to believe that the health establishment or a part thereof poses a serious risk to public health or the health and safety of users.

21.2. The compliance notice referred to in sub-regulation (1), must be issued in the form of Form 7, and must contain all the information set out in section 82A (2) of the Act.

21.3. The person in charge must, within the period specified in the compliance notice, provide the inspector with the health establishments quality improvement plan that details—

a. the actions that will be undertaken to achieve compliance with the norms and standards; and
b. the timeframe for achieving compliance.

21.4. If the health establishment fails to comply with the compliance notice issued in terms of section 82A(1) of the Act, the Office may invoke any of the sanctions listed in section 82A(4) of the Act.

### 22. Compliance enforcement

22.1. The Office must develop an enforcement policy which sets out the Office's approach to enforcing compliance.

22.2. The Chief Executive Officer must publish the enforcement policy referred to in sub-regulation (1) and any subsequent amendments thereof, in the Government Gazette, within 25 working days of their approval by the Board.

22.3. Compliance enforcement must, as far as possible, be applied in a progressive

manner, after taking into account the following, with regards to each health establishment:

a. The nature and severity of non-compliance with the norms and standards and the consequences thereof;
b. the compliance history of the health establishment;
c. frequency of transgressions in relation to the norms and standards;
d. any offences by the health establishment in terms of section 89(1) of the Act; and any mitigating or aggravating factors.

**23. Written warning**

23.1. The Office may issue a written warning to the person in charge, in terms of section 82A(4)(a) of the Act, for failure to comply with a compliance notice referred to in regulation 21 (1) (a).

23.2. A written warning to the person in charge referred to in sub-regulation (1) must be issued in the form of Form 8, and must include, at least, the following information:

a. The name of the person to whom it is addressed and the date;
b. the health establishment to which the warning applies;
c. the norms and standards that have not been complied with;
d. the nature and extent of non-compliance;
e. the actions to be undertaken by the health establishment to remedy non-compliance; and
f. the steps already taken by the Office to ensure compliance, if applicable.

**24. Request for response**

24.1. If the Office issues a written warning to the person in charge, it must request a written response from the person in charge in terms of section 82A(4)(b) of the Act, and set a timeframe within which the health establishment must respond and the consequences of any failure to respond.

24.2. The person in charge must acknowledge receipt of a written warning referred to in subregulation (1), in writing.

24.3. If the person in charge fails to respond to a request for a response referred to in subregulation (1), or provides an unsatisfactory response, the Office may—

a. recommend to the relevant authority any appropriate and suitable action, in terms of section 82A(4)(c) of the Act;

b. initiate a formal hearing to consider a possible revocation of a certificate of compliance or imposition of a fine, in terms of sections 82A(4)(d) and 82A(4)(e) of the Act, respectively; or

c. refer the matter to the National Prosecuting Authority for criminal prosecution, in terms of section 82A(4)(f) of the Act.

## 25. Monitoring of recommendations to relevant authority

If a recommendation is made to the relevant authority in terms of regulation 24(3)(a), the Office must monitor and report to the Minister on the implementation of the said recommendation by the relevant authority.

## 26. Formal hearing

26.1. Before revoking a certificate of compliance or imposing a fine, the Office must notify the person in charge of the health establishment and the relevant authority of its intention to revoke the certificate of compliance or to impose a fine, as the case may be, and initiate a hearing to allow the health establishment an opportunity to make representations, before a final decision is taken.

26.2. The Chief Executive Officer must appoint a suitable person to preside over the hearing contemplated in sub-regulation (1).

26.3. The person contemplated in subregulation (2) may appoint not more than 2 persons with technical expertise on the relevant subject as his or her assistants, as may be required.

26.4. The presiding officer must provide both the Office and the health establishment with, at least,

10 working days' written notice to prepare for the hearing and may—

a. require written representations from both parties to be submitted to him or her, at least, 5 working days prior to the hearing;

b. allow oral testimony to be presented by the parties or any other interested person, upon application, in relation to the matter.

26.5. The notice of hearing referred to in sub-regulation (1) must be issued in the form of Form 8, and include, at least, the following information: (a) The date, time and place of the hearing;

a. 20
b. the subject matter of the hearing;
c. the legal rights of the parties and how to exercise them;
d. the required documents, records, objects or materials, if any; and the consequences of failure to attend the hearing.

26.6. The procedure for the conduct of the hearing contemplated in sub-regulation (1) must be determined by the person presiding at the hearing.

a. The hearing of the matter— must be conducted expeditiously and in compliance with the principles of administrative justice, set out in the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000);

b. may be conducted in an informal manner, consistent with paragraph (a); and

c. must be open to the public: Provided that the person presiding at the hearing may exclude members of the public, or specific persons or categories of persons, from attending the proceedings—

I. if evidence to be presented is confidential information, but only to the extent that the information cannot otherwise be protected;
II. if the proper conduct of the hearing requires it; or
III. for any other reason that would be justifiable in civil proceedings in a Court.

26.7. At the end of the hearing, the person presiding at the hearing may recommend to the Office to revoke or not to revoke the certificate of compliance of the health establishment, or to impose a fine, as the case may be.

26.8. The Office must, within 10 working days after the hearing, make a decision and provide the person in charge of the health establishment and the relevant authority with written reasons for any adverse decision.

26.9. For the purposes of this regulation “suitable person” means a person who has extensive knowledge and experience in the administration of law and the norms and standards for the health establishments as well as the general laws and regulations applicable to the health care sector.

**27. Revocation of certification and recommendation to Minister**

27.1. If a health establishment fails to comply with the compliance notice referred to in regulation 21(1)(b), the Office may, after complying with regulation 26(1), revoke the certificate of compliance of a health establishment and recommend to the Minister a temporary or permanent closure of the health establishment or a part thereof that constitutes a serious risk to public health or the health of users, in terms of section 82A(4)(d) of the Act

27.2. A recommendation to the Minister in terms of sub-regulation (1) must be in writing and include, at least, the following information:

a. the details of non-compliance; (b) the nature and extent of the risk posed to public health or to users;
b. the period of non-compliance;
c. the consequences of continued non-compliance;
d. an indication of the part or parts of the heath establishment to be closed, and
e. any other relevant information.

27.3. Before exercising his or her powers in terms of sub-regulation (1), the Minister must comply with the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000).

## 28. Fine

28.1. Before imposing a fine in terms of section 82A(4)(e) of the Act, and after complying with regulation 26(1), the Office must afford the person in charge of the health establishment an opportunity to submit a request for leniency.

28.2. A fine contemplated in section 82A(4)(e) of the Act may not exceed the thresholds determined by the Minister.

28.3. In determining the quantum of the fine, the Office must take into account—

a. the nature and extent of non-compliance;
b. the actions taken by the health establishment to remedy non-compliance;
c. any requests for leniency presented by the health establishment; and
d. the potential impact of the fine on the finances of the health establishment.

28.4. If the fine is imposed in terms of section 82A(4)(e) of the Act the health establishment must, within 20 working days of the decision, pay such a fine into a designated banking account contemplated in sub-regulation (5).

28.5. The Office must establish and maintain a separate banking account for the payment of fines in accordance with the provisions of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

## 29. Referral to National Prosecuting Authority

29.1. Despite regulation 23, the Office may, at any time, refer the matter to the National Prosecuting Authority for criminal prosecution, in terms of section of the Act, if any failure to comply with a compliance notice issued in terms of the Act is considered to amount to a criminal offence in terms of section 89(1) of the Act.

29.2. For the purposes of sub-regulation (1), the Office must prepare and hand over any and all evidence that may be relevant to the prosecution of the health establishment to the National Prosecuting Authority.

## 30. Appeal against decisions of Office or Ombud

30.1. An appeal to the Minister in terms of section 88A(1)of the Act must be lodged by written notice.

30.2. The notice referred to in sub-regulation (1) must be in the form of Form 9, and must set out the grounds for the appeal and sufficient information or documentation to support the application for appeal.

30.3. The ad hoc tribunal contemplated in section 88A(2) of the Act must determine the rules and procedure for the conduct of its proceedings.

30.4. The proceedings of the tribunal must be open to the public, but the chairperson of the tribunal may exclude members of the public, or specific persons or categories of

persons, from attending the proceedings—

a. if evidence to be presented is confidential information, but only to the extent that the information cannot otherwise be protected;
b. if the proper conduct of the hearing requires it; or
c. for any other reason that would be justifiable in civil proceedings in a Court.

**31. Publication of reports and tribunal decisions**

31.1. The Office must—

a. within 25 working days of the issue of the decision, publish the decision of the ad hoc tribunal in the Government Gazette and on its public website;

b. every six months, publish on its public website and in any other appropriate publication platform, a report which covers all the—

i. inspections conducted, with the names and location of the health establishments;

ii. compliance certificates issued, with the names and location of health establishments;

iii. hearings conducted, with the names and location of health establishments and the outcome of the hearings;

iv. the recommendations made to the relevant authorities in terms of section and

v. complaints received and resolved by the Ombud, by category.

c. on an annual basis, publish on its public website and in any other any appropriate publication platform, a report which—

i. sets out the compliance status of all health establishments; and

ii. summarises the number and nature of the compliance notices issued.

## CHAPTER 7

## COMPLAINTS HANDLING AND INVESTIGATION

**32. Who may lay complaint**

32.1. Any person may lay a complaint with the Ombud, in terms of section 81A(1) of the Act, for breach by a health establishment of any norms or standards.

32.2. Any person, guardian or representative of a person to whom a health care service was provided, may lay a complaint to the Ombud.

32.3. A complaint may be dealt with by the Ombud despite the death of the person contemplated in sub-regulation (2), if—

a. a person dies and, if the person were alive, he or she could lay a complaint about a particular matter; or

b. a person makes a complaint but dies before the complaint is finally dealt with.

32.4. If sub-regulation (3)(a) applies, a complaint may be laid on behalf of the person.

32.5. If sub-regulation (3)(b) applies, the Ombud may, at another person's request, permit the other person to be substituted as the complainant.

32.6. If a complaint is laid in terms of sub-regulation (2) by a representative on behalf of a person to whom a health care service was provided, other than under the circumstances contemplated in sub-regulation (3), the Ombud may request the person to whom a health care service was provided to confirm the complaint.

**33. How to lay complaint**

33.1. A complaint to the Ombud may be laid—

a. orally, including by telephone; or
b. in writing, including by email or other electronic means.

33.2. If a complaint is laid orally, the Ombud must—

a. make a record of the complaint; and
b. request the complainant to confirm the accuracy of the recording.

33.3. The Ombud must give a complainant reasonable assistance to lay a complaint, and to take necessary measures to ensure reasonable access to the Ombud by the users of health care services and other concerned persons.

33.4. The complaint must contain adequate information regarding the complaint including, at least, the contact details of the complainant or his or her representative, and the evidence or basis for the complaint, and such other particulars as the Ombud may require to deal with the complaint.

**34. Acknowledgement of complaint and request for additional information**

34.1. The Ombud must acknowledge receipt of a complaint within 48 hours of the laying of a complaint, in an appropriate manner.

34.2. The Ombud may request any additional information from the complainant, to be provided within a reasonable period stated in the request.

34.3. The Ombud may not deal with the complaint, or deal further with the complaint, until the complainant complies with a request contemplated in sub-regulation (2), to the

extent the complainant is reasonably able to comply therewith.

34.4. A complainant's non-compliance with a request may be a ground for a decision to take no further action on the complaint.

**35. Screening of complaints**

35.1. The purpose of the screening is to obtain and analyse information relevant to the complaint and decide the most appropriate way to deal with it further.

35.2. The screening may be undertaken in any manner the Ombud considers appropriate, including—

a. analysing information provided by the complaint;
b. analysing information obtained in terms of regulation 34(2) from the complainant;
c. considering submissions received in terms of regulation 36(1) from the complainant or the relevant health establishment or any other person;
d. communication with the complainant or the relevant health establishment; or
e. consultation with any person or entity with relevant technical knowledge or expertise regarding the subject of the complaint.

**36. Submissions regarding complaints**

36.1. The Ombud may give notice to the complainant or the relevant health establishment, inviting submissions regarding a complaint, to be provided to the Ombud within a stated period.

36.2. The period for providing submissions must be reasonable, but may not be more than 20 working days from the date of notice.

36.3. The Ombud must consider each submission received within the period referred to in regulation 36(1).

**37. Period for completing screening**

37.1. The Ombud must complete the screening within 15 working days of the laying of the complaint or of receiving the additional information in terms of regulation 34(2).

37.2. The Ombud may extend the period for screening the complaint by a further period of up to 15 working days if necessary owing to—

a. the size or complexity of the complaint; or
b. the time taken to obtain additional information in terms of regulation 34(2) or submissions in terms of regulation 36(1).

**38. Decision following screening**

38.1. Upon completion of the screening, the Ombud must—

a. make a decision on whether—

I. to investigate the complaint;
ii. to refer the complaint to any other statutory authority or other appropriate or suitable body or entity; or
iii. to take no further action in relation to the complaint;

b. give notice of the decision to the complainant and the relevant health establishment, and reasons for the decisions.

**39. Cooperation with other entities**

The Ombud must consult and cooperate with other public entities with functions that are relevant to, or may impact on, the Ombud's functions.

**40. Referral from other entities and the public**

If the Ombud becomes aware of a particular matter, other than through a formal complaint, by way of a referral from—

a. a health establishment;
b. other statutory authority or any other appropriate or suitable body or entity, including the Office; or
c. in any other manner and decides to deal with the matter, the Ombud may, with the relevant person's consent, deal with the matter as if it were a complaint and the person were the complainant.

**41. Decision to take no further action on complaint**

41.1. At any time, the Ombud may decide to take no further action on a complaint if the Ombud reasonably considers that—

a. the complaint

i. is frivolous, vexatious, trivial or not made in good faith;
ii. is misconceived or lacking in substance;
iii. is being adequately dealt with by another appropriate entity;
iv. has been resolved or otherwise appropriately finalised by the Ombud or another appropriate entity; and
v. despite reasonable efforts by the Ombud or another appropriate entity, cannot be resolved; or

b. the complainant-

i. has failed, without reasonable excuse, to—

- satisfactorily cooperate with the Ombud to resolve the complaint; and
- comply with a request from the Ombud for additional information, evidence or submissions the Ombud needs to deal properly with the complaint.

41.2. The Ombud may decide to take no further action on a matter if—

a. the complaint is withdrawn;
b. the matter from which the complaint arose, and the complainant was aware of the matter, at least 2 years before the complaint was laid; or
c. a complainant, or other relevant person dies and the Ombud reasonably considers that no further action is necessary.

**42. Complaint investigations**

The procedure for conducting an investigation must be such as the Ombud considers appropriate in the circumstances of the case, and in particular, he or she may make such inquiries, as he or she deems fit and must be in line with the applicable legislation.

**43. Notice to health establishment being investigated**

The Ombud must notify the relevant health establishment regarding the investigation and the process of investigation, before or when the investigation has been started.

**44. Progress reports**

The Ombud must, every two months, give notice of the progress of an investigation to—

a. any health establishment being investigated; and
b. the complainant.

**45. Period for completing investigation**

45.1. The Ombud must complete an investigation referred to in Regulation 42 within a period of 6 months, unless extended in terms of sub-regulation (2), after the decision to carry out the investigation.

45.2. The Ombud may extend the period for completing an investigation if the Ombud reasonably considers that, in view of all the circumstances, including the size and complexity of the matters being investigated, it is not possible to complete the investigation by the due date.

45.3. The period for completing an investigation may be extended more than once, but each extension may not be more than 3 months, provided the total period of the investigation does not exceed 2 years.

**46. Investigations register**

**46.1.** The Ombud must keep a register, on its public website, of all investigations.

46.2. The register must list the following matters for each investigation

a. type of norm or standard breached;
b. general nature of the matter being investigated;
c. date on which it was decided to carry out the investigation;
d. current due date for completing the investigation;
e. current status of the investigation; and
f. reason for each extension of the period of investigation.

46.3. The register must not include information that identifies or puts at risk a complainant, health establishment or person to whom a health care service was provided.

**47. Report to Minister**

47.1. If an investigation is not completed within 2 years after the decision to conduct it, the Ombud must give notice to the Minister stating—

a. the details of the matter being investigated; and
b. the reasons why the investigation has not been completed.

47.2. The Minister may make any decision regarding the matter, including a decision to—

a. close the matter;
b. extend the investigation for a specified period; or
c. refer the matter to another statutory authority, body or entity.

**48. Notice of decision after investigating complaint and investigation report**

48.1. Within 10 working days after completing an investigation contemplated in regulation 42, the Ombud must—

a. inform the complainant and the health establishment of his or her findings and recommendations, in accordance with section 81A (11) of the Act; and

b. submit a report containing his or her findings and recommendations to the Chief Executive Officer, in accordance with Section 81A(9) of the Act, for appropriate action.

**49. Referral to and reports from other statutory authority or other appropriate and suitable body or entity**

49.1. When referring the matter, the Ombud must give the relevant statutory authority, or other appropriate and suitable body or entity, all relevant information that the Ombud has regarding the matter, including, details of the complaint, the complainant and the relevant health establishment.

49.2. The statutory authority or other appropriate and suitable body or entity to which the matter was referred must provide the Ombud—

a. written reports regarding progress on the matter, at regular intervals; and
b. within 25 working days after completing the investigation, a written report of the results of the action taken regarding the matter.

49.3. For the purposes of this regulation "statutory authority" means any authority established by or under a provincial or national legislation.

**50. Confidentiality of information**

50.1. Information obtained by the Ombud or persons designated in terms of section 81 (3)(c) of the Act in the course of or for the purposes of an investigation may not be disclosed to any third party, except for the purposes of the investigation and any report to be made in respect thereof.

50.2. A health establishment may, by written notice explaining why the information is confidential, claim any information to be confidential.

50.3. The Ombud must, within 10 working days of receipt of the notice referred to in subregulation (2), determine whether or not the information is confidential, and if the Ombud finds that the information is confidential, make any appropriate order concerning access to that information.

50.4. The health establishment may, within 10 working days of the determination of the Ombud in terms of sub-regulation (3), lodge an appeal against such determination or an order contemplated in sub-regulation (3), to the Minister in terms of section 88A of the Act.

## CHAPTER 8

## GENERAL PROVISIONS

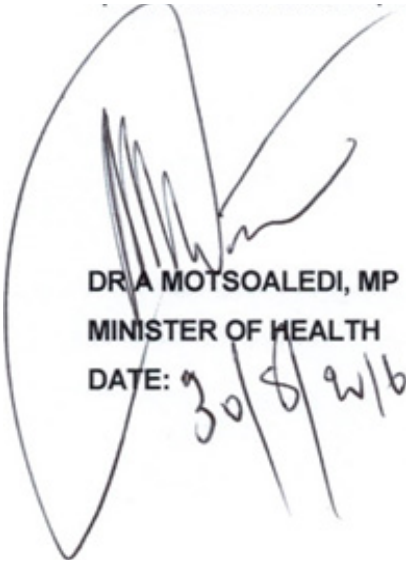
**51. Prescribed forms**

51.1. The forms prescribed for purposes of these Regulations are set out in the Annexure to these Regulations.

51.2. Any form that must or may be submitted by any health establishment or user to the Office in terms of these Regulations may be submitted electronically.

**52. Short title and commencement**

These Regulations are called the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, and come into operation on the date of publication in the Gazette.




ANNEXURE PRESCRIBED FORMS

| Form No. | Section No. | Regulation No. | Description |
|---|---|---|---|
| OHSC 1 | | 4(2) | Health establishment information |
| OHSC 2 | 80(3) | 8(2) | Certificate of appointment as an inspector |
| OHSC 3 | | 13(2) | Notice of inspection to health establishments |
| OHSC 4 | | 18(1) | Certificate of compliance |
| OHSC 5 | 79(1) | 19(2) | Application for renewal of certification |
| OHSC 6 | 82A(1) | 21(2) | Compliance notice to health establishments |
| OHSC 7 | | 23(2) | Written warning |
| OHSC 8 | | 26(5) | Notice of hearing |
| OHSC 9 | 88A | 30(2) | I. Notice of appeal |

# Annexure D:

## Information about the Health Establishment (OHSC 1)

## Annexure D: Information about the health establishment (OHSC 1)

All health establishments and users that are required by the Office to provide information relating to norms and standards, in terms of section 79(2)(b) of the National Health Act,2003 (Act No. 61 of 2003), must do so by 31 March of each year. If the person in charge, referred to in regulation 6(1), fails to provide the Office with the required information within the specified period, the Office must refer the matter to the head of the national or relevant provincial department of health or the health department of a municipality or the head of the health establishment, as the case may be, for intervention in accordance with the intervention policy and procedure of the relevant authority.

| | |
|---|---|
| Name of health establishment | |
| Legal status | |
| Details of relevant authority (head of national, provincial or municipal health department, head of the health establishment or private hospital group) | |
| Physical address of health establishment | |
| GPS coordinates - latitude and longitude | |
| Contact details of the health establishment including — telephone no., e-mail address website details | |
| Name of person in charge | |
| Contact details of person in charge | |
| Category of health establishment (according to Policy on Management of Public Hospitals published in Government Gazette, No 34522 of 12 August 2011); | |
| Health district in which the health establishment falls | |
| Services offered by speciality, including number of beds by service or number of consulting rooms | |
| Operating days and times:<br>In patient unit<br>Outpatient unit<br>Emergency unit<br>Pharmacy | |
| Human resources – Number of staff by category:<br>Health care professionals<br>Management<br>Administrative<br>Clinical support services | |
| Results of the most recent self-assessment against norms and standards | |
| Chief Executive Officer<br><br>Signature: _____ | Date: _____ |

# Annexure E:

## Certification of Appointment as an inspector (OHSC 2)

## Annexure E: Certificate of appointment as an inspector (OHSC 2)

This certificate of appointment as an inspector of the Office of Health Standards Compliance is hereby issued in terms of section 80(2) of the National Health Act, 2003 (Act No. 61 of 2003), read together with regulation 8 of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud.

| | | |
|---|---|---|
| Name and surname:<br>_____<br>_____<br>OHSC Number: _____ | (photograph) | Date of issue:<br>_____<br>Date of expiry:<br>_____ |
| Chief Executive Officer<br>Signature: _____ | OHSC contact telephone:<br>_____ | OHSC address:<br>_____<br>_____<br>_____ |

| | |
|---|---|
| Name of health establishment | |
| Address of health establishment | |
| Consent for inspection OR warrant to enter (specify) | |
| Date of inspection | |
| Estimated duration of inspection | |
| Date for reporting and comments | |
| Number of authorised personnel taking part in the inspection | |

# Annexure F:

## Notice of Inspection (OHSC 3)

## Annexure F: Notice of inspection (OHSC 3)

**Purpose of inspection**

In terms of regulation 13 of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance (OHSC) and handling of complaints by the Ombud, an inspector must issue a notice of inspection to the health establishment before commencing with an inspection contemplated in section 82 of the Act.The purpose of inspection is for duly certified inspectors of the OHSC to monitor the degree of compliance with the norms and standards for quality of healthcare as mandated by the National Health Act, No. 61 of 2003, and the regulations pertaining to the functioning of the OHSC and handling of complaints by the Ombud.

**Responsibilities of the health establishment**

The responsibilities of the health establishment during this visit are to make available the necessary staff, resources and space to allow inspectors to complete the inspection in a timely and expeditious manner.

**Powers of inspectors**

In terms of section 82(1) of the Act, an inspector may enter any health establishment at any reasonable time, and-

a. inspect such a health establishment, as the case may be, in order to ensure compliance with the Act;

b. question any person who her or she believes may have information relevant to the inspection;

c. require the person in charge of the health establishment to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document, including a health record contemplated in Section 15 of the Act, which such a person is required to maintain in terms of the law. (d) take any samples of any substance or photographs relevant to the inspection.

| | |
|---|---|
| Chief Executive Officer<br><br>Signature: _____ | <br><br>Date: _____ |

# Annexure G:

## Certificate of Compliance (OHSC 4)

## Annexure G: Certificate of compliance (OHSC 4)

This certificate of compliance is issued by the Office of Health Standards Compliance in terms of section82(7) of the National Health Act, 2003 (Act No. 61 of 2003) as read with regulation18(1) of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations)

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

| | |
|---|---|
| Name of health establishment certified as compliant | |
| Category of health establishment | |
| Physical address | |
| Address for the service of legal processes and notices (if not the same as physical address) | |
| Date of inspection | |
| Chief Executive Officer<br><br>Signature: _____ | Date of certification<br><br>_____<br><br>Date of expiry of certification<br><br>_____ |

# Annexure H:

## Application for Renewal and Extension of Certification (OHSC 5)

## Annexure H: Application for renewal and extension of certification (OHSC 5)

| |
|---|
| In terms of section 82(7) of the National Health Act, No. 61 of 2003 as read together with regulation 19 of the procedural regulations pertaining to the functioning of the Office of Health Standards Compliance (OHSC) and handling of complaints by the Ombud (the Regulations), an application for renewal of a certificate must be submitted to the Office, within a period of not more than six months before the expiration of the certificate of compliance. This certificate will be renewed following an inspection as set out in regulation 14, provided that the Office may extend the certification for up to one year pending an inspection. |

| | |
|---|---|
| Name of health establishment applying for extension of certification | |
| Address | |
| Name of person in charge | |
| Date of last inspection | |
| Date of certification | |
| Date of expiry of certification | |
| Certificate number | |
| Person in charge of health establishment<br><br>Signature: _____ | Date: _____ |
| Attachments:<br><br>1. Most recent report submitted<br><br>2. Last 6 months of reporting on indicators of risk<br><br>3. Annual self-assessment reports since last inspection<br><br>4. Most recent quality improvement plan | |

# Annexure I:

## Compliance Notice (OHSC 6)

## Annexure I: Compliance notice (OHSC 6)

A compliance notice is issued to the person in charge of a health establishment in terms of section 82A(1) of the National Health Act, 2003 (Act No. 61 of 2003), ("the Act") as read together with regulation

21(1) of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations, when the health establishment is found on inspection by the Office of Health Standards Compliance not to be compliant with the norms and standards contemplated in the Act.

The penalties that may be imposed by the Office of Health Standards Compliance in the event of continued non-compliance in terms of section 82A(4) of the Act are as follows:

a. issue a written warning to achieve compliance within a set period of time in a manner prescribed;

b. require a written response from the health establishment regarding the continued noncompliance;

c. recommend to the relevant authority any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the noncompliance or continued non-compliance;

d. revoke the compliance certificate and recommend to the Minister the temporary or permanent closure of the health establishment or pan thereof that constitutes a serious risk to public health or to health service users;

e. impose upon that person or health establishment a fine as determined by the Minister in the Gazette from time to time; or

f. refer the matter to the National Prosecuting Authority for prosecution.

| | |
|---|---|
| Name of contact person in OHSC for submission of documentation | |
| Annexures:<br><br>1. Norms and standards that have not been complied with;<br><br>2. details of the nature and extent of noncompliance;<br><br>3. steps that are required to be taken and the period over which such steps must be taken | |

# Annexure J:

## Written Warning (OHSC 7)

## Annexure J: Written warning (OHSC 7)

| |
|---|
| The Office of Health Standards Compliance may issue a written warning to the person in charge, in terms of section 82A(4)(a) of the National Health Act, No. 61 of 2003 ("the Act") as read together with regulation 23(1) and (2) of the procedural regulations pertaining to the functioning of the Office of Health Standards Compliance (OHSC) and handling of complaints by the Ombud, for failure to comply with a compliance notice issued in terms of section 82A of the Act, as read with regulation 21(1) of the regulations. |

| | |
|---|---|
| Name of health establishment | |
| Address of health establishment | |
| Name of person in charge | |
| Contact details of person in charge | |
| Annexures:<br><br>1. Norms and standards that have not been complied with<br><br>2. The nature and extent of non-compliance<br><br>3. Actions undertaken by the health establishment to remedy non-compliance | |
| Steps already taken by the Office to ensure compliance | |
| Date by which the person in charge must respond to the written warning | |
| Name and address for response | |

# Annexure K:

## Notice of Formal Hearing (OHSC 8)

## Annexure K: Notice of formal hearing (OHSC 8)

| |
|---|
| Before revoking a certificate of compliance or imposing a fine in terms of section 82A(4) of the National Health Act, No. 61 of 2003 ("the Act"), the Office must, in terms of regulation 25 of the procedural regulations pertaining to the functioning of the Office of Health Standards Compliance (OHSC) and handling of complaints by the Ombud ("the Regulations"), notify a 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 to allow the health establishment an opportunity to make representations, before a final decision is taken. |

| | |
|---|---|
| Name of health establishment | |
| Address of health establishment | |
| Name of person in charge | |
| Contact information of person in charge | |
| Name of relevant authority | |
| Contact information for relevant authority | |
| Date, time and place of hearing | |
| Name and position of presiding officer | |
| Subject matter of hearing | |
| Required documents, records, objects or materials | |
| Date for submission of above | |
| Annexures:<br><br>1. Norms and standards that have not been complied with<br><br>2. The nature and extent of non-compliance<br><br>3. Actions undertaken by the health establishment to remedy non-compliance<br><br>4. Actions taken by the Office to ensure compliance | |

# Annexure L:

## Notice of Appeal (OHSC 9)

## Annexure L: Notice of appeal (OHSC 9)

| |
|---|
| In terms of Section 88A of the National Health Act, 2003 (Act No. 61 of 2003), any person aggrieved by any decision of the Office or any finding and recommendation of the Ombud in relation to a matter regulated by this Act, or a person acting on his or her behalf, may within 30 days of gaining knowledge of that decision, lodge a written appeal with the Minister, who must appoint an independent ad hoc tribunal to whom the appeal received must be submitted. |

| | |
|---|---|
| Name of establishment | |
| Address of establishment | |
| Name of person lodging appeal | |
| Contact information of person lodging the appeal | |
| Decision, finding or recommendation against which appeal is being lodged | |
| Date of such finding, appeal or recommendation | |
| Grounds for appeal | |
| In annexure:<br><br>Any documentation or representations relevant to the appeal | |

# Annexure M:

## Compliance Status Framework

# TABLE OF CONTENTS

# 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 a health establishment's compliance with 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 an organisation to become compliant, it must take steps to comply with relevant laws, policies and regulated norms and standards.

## 4. Risk rating

Risk rating is a methodology used to determine 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 that non-compliance may have on users. Risk is measured in the area where it occurs. In the context of the OHSC, risk is measured at a functional area level. The OHSC has applied the Australian risk rating methodology to assign the risk level for each measure.

## 5. Risk ratings for primary health care clinics (PHCs)

1. Vital
2. Essential

## 6. Definition of risk ratings

1. Vital

Vital risk rated measures are considered to be critical to ensuring the safety of personnel and users so as not to result in harm or irreversible ill health. Within the vital measures, are designated measures that have been identified as non-negotiables, which health establishments are required to meet. Non-negotiable vital (NNV) measures are those that can cause loss of life or require a prolonged period of recovery.

***NNV** -Emergency trolley is stocked with the medicines and equipment.

- An oxygen cylinder with pressure gauge is available.
- The oxygen available in the cylinder is above the minimum level.

2. Essential

Essential risk rated measures are those which are considered to be 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

Inspections are conducted in the functional area, which is a department, ward or area within a health establishment where services are provided. The clinic assessment tool comprises four functional areas:

1. Clinic management
2. Dispensary/medicines room
3. Clinical services
4. Maintenance support

Table 1 below indicates the number of measures contained in the assessment tool that fall under the two types of risk rating.

**Table 1: Number of measures by risk rating**

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

Table 2 below shows the breakdown of measures in terms of the functional areas in the clinic.

**Table 2: Number of measures by functional area and risk rating**

| 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 uses the four-point Likert scale to determine compliance grading for health establishments as follows:

1. Excellent
2. Good

3. Satisfactory
4. Unsatisfactory

### 8.1. Excellent

Services exceed the minimum set norms and standards. 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 of safety. The risk rating for this category is below satisfactory limits as outlined in the matrix (V < 60% and E <50%).

Table 3: Grading model

| 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 |

## 9. Compliance status framework

According to this model, risk is 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.

Table 4 provides an example of an unsatisfactorily performing clinic (based on a pilot inspection conducted in May 2019).

Table 4: Unsatisfactorily performing clinic

**Compliance Status Framework**

| Grading | Model 3 | Measures | Grading level Outcome |
|---|---|---|---|
| Excellent | NNV – 100% | 4/4 | 76-100% |
| | V ≥ 80% | 51/63 | |
| | E ≥ 70% | 44/63 | |
| Good | NNV – 100% | 4/4 | 66-75% |
| | 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 | |
| | V > 60% | >38/63 | 0-55% |
| | E > 50% | >32/63 | |

**Application of CSF**

| Risk Ratings | | Clinic Manager | Medicine Room | Clinical Services | Maintenance Support Services | Overall Risk Grading Outcome |
|---|---|---|---|---|---|---|
| Vitals | *NNV | | | 2/3= 66.66% | | 33/64=51.56% Unsatisfactory |
| | V | 4/24=17% | 4/7=57% | 21/29=72% | 3/4= 75% | |
| Essentials | | 6/27=22% | 2/7=24% | 5/8=64% | 2/5=35% | 15/47=31.9% Unsatisfactory |
| | | | | | Grading | Unsatisfactory |

**Interpretation of the rating**

**Overall health establishment grading:**

Vital measures = 50% which falls in the **Unsatisfactory** range

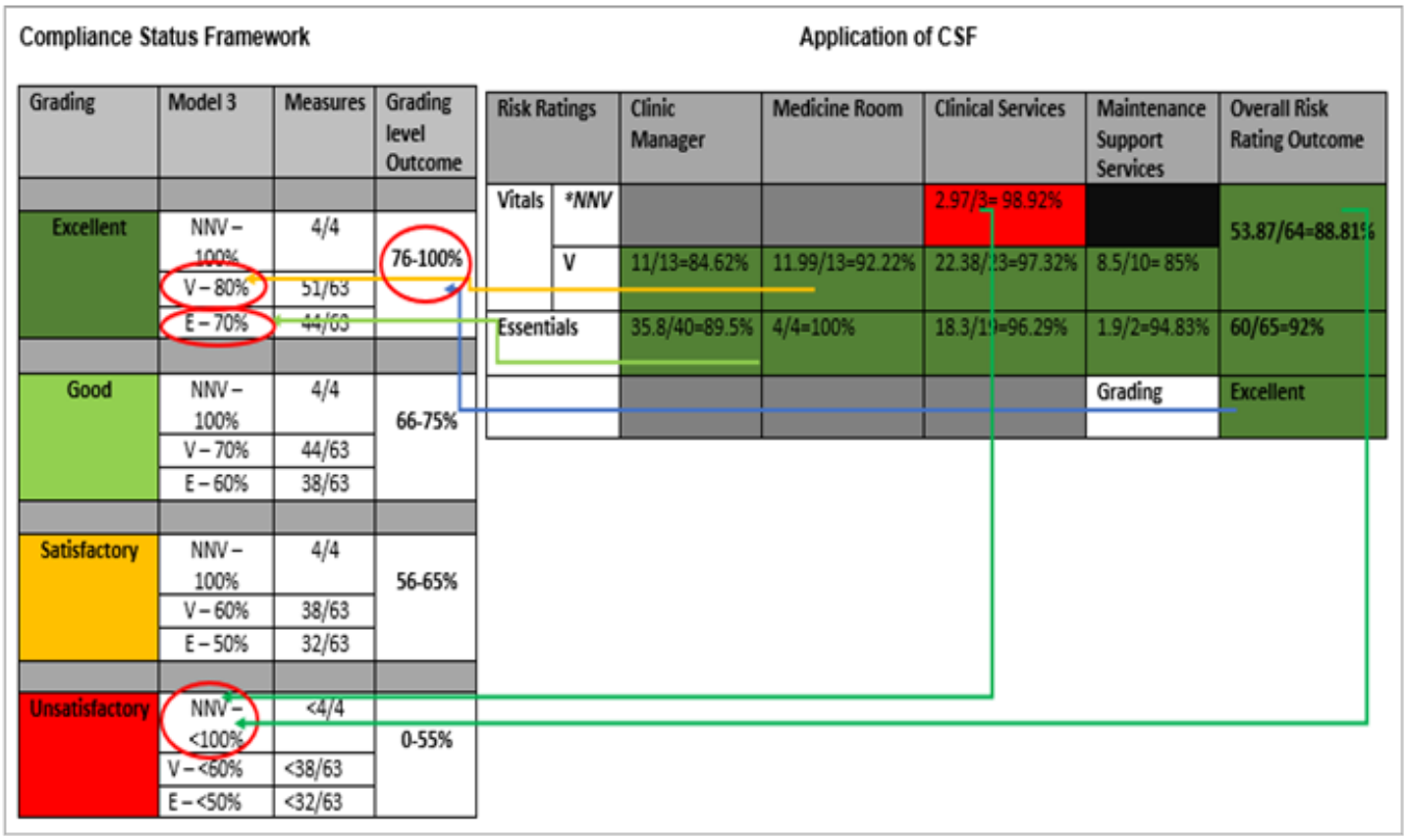
Essential measures = 32.9% which falls in the **Unsatisfactory** range

Therefore, the overall grading of the facility = **Unsatisfactory**

**Compliance Decision** = health establishment is **Non-compliant**

A second example, as shown in Table 5 depicts a clinic that received a good performance rating.

**Table 5: Clinic with good performance rating (based on pilot conducted in May 2019)**



Compliance Status Framework

| Grading | Model 3 | Measures | Grading level Outcome |
|---|---|---|---|
| Excellent | NNV – 100% | 4/4 | 76-100% |
| | V – 80% | 51/63 | |
| | E – 70% | 44/63 | |
| Good | NNV – 100% | 4/4 | 66-75% |
| | 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 | |

Application of CSF

| Risk Ratings | | Clinic Manager | Medicine Room | Clinical Services | Maintenance Support Services | Overall Risk Rating Outcome |
|---|---|---|---|---|---|---|
| Vitals | *NNV | | | 2.97/3= 98.92% | | 53.87/64=88.81% |
| | V | 11/13=84.62% | 11.99/13=92.22% | 22.38/23=97.32% | 8.5/10= 85% | |
| Essentials | | 35.8/40=89.5% | 4/4=100% | 18.3/19=96.29% | 1.9/2=94.83% | 60/65=92% |
| | | | | | Grading | Excellent |

**Interpretation of the rating**

**Overall health establishment grading:**

Vital measures = 91% which falls in the **Excellent** range
Essential measures = 92% which falls in the **Excellent** range
Therefore, the overall grading of the facility = **Excellent** range

**Compliance decision: Non-Compliant**

Health establishment is Non-compliant as the non-negotiable vital measures are < 100%. In this case the health establishment has an opportunity to address the non-compliant non-negotiable vital measures and be awarded with a **Certificate of Compliance Graded as Excellent.**

## 10. Decision making regarding compliance

Each functional area is assessed separately according to the measures appropriate to that particular functional area. The functional areas are graded according to how they performed on the Vital and Essential measures. The overall (all functional areas) performance for the Vital and Essential measures is used to determine the health establishment's grading level.

Compliance status is determined by the performance outcomes of the Vital and Essential risk-rated measures meeting the minimum requirements of the set ranges of the grades, provided the outcomes of NNVs is 100%. An Unsatisfactory grading will automatically be

deemed Non-Compliant.

## 11. Rules governing application of the compliance status framework

1. A health establishment must achieve 100% of measures designated as non-negotiable within the Vital measures (NNV). Failure to achieve 100% of non-negotiable vital measures on any grading level will result in the health establishment being non-compliant irrespective of their performance in Vital and Essential measures.

2. Health establishments will be graded at the lowest achieved grading when the outcome of the risk ratings have different grades, e.g. When Vital achieves 70% (Good) and Essential achieves 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 an Excellent, Good or Satisfactory grading, provided they have met all the non-negotiable vital measures. The three grading levels for certification will have conditions that health establishments must adhere to for the duration of the certificate, as shown in Table 6 below.

Table 6: Conditions for certification

| GRADING | CONDITIONS | DURATION |
|---|---|---|
| **Excellent** | 1. Grading level of 75–100%<br>2. Compliance certificate issued<br>3. Submission of progress report (approved by person in charge/District Manager/CEO) with related evidence<br>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%<br>2. Compliance certificate issued<br>3. Submission of progress report (approved by person in charge/District Manager/CEO) with related evidence<br>4. Specific steps including time frames to remedy areas of non-compliance | 4 years and as per regulations |

| | | |
|---|---|---|
| **Satisfactory** | 1. Grading level of 55–64%<br>2. Compliance certificate issued<br>3. Submission of progress report (approved by person in charge/District Manager/CEO) with related evidence<br>4. Specific steps including time frames to remedy areas of non-compliance | 4 years and as per regulations |
| **Unsatisfactory** | 1. Grading level of <55%<br>2. Compliance notice (Non-compliant)<br>3. Submission of progress report (approved by person in charge/District Manager/CEO) with related evidence<br>4. Specific steps including time frames to remedy areas of non-compliance | Additional inspection within12 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:

1. Submission of annual self-assessment reports
2. Submission of annual returns
3. Reporting on indicators of risk

## 14. References

1. Australian Capital Territory Government (2009).
2. Care Quality Commission. (2015) Acute hospitals: provider handbook. [Online] Available from https://www.cqc.org.uk/file/159001 [Accessed on 11 June 2019]

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ISBN:
978-0-620-90157-4