OCTOBER 17, 2022

GENERAL PRACTICE INSPECTION TOOL DISCUSSION DOCUMENT DRAFT 3

Introduction to the General Practice Inspection Tool Discussion Document Draft 3

Dear Colleague

Thank for participating in the development of Inspection tools for General Practices.

The purpose of review of the proposed Inspection tool for General Practices, as included in this document, is to determine whether the requirements included are relevant to general practice and represent adequate scope of functions related to service delivery, beneficial to users and those responsible for delivering the services, clear and easy to understand and achievable.

The inspection tools have been aligned to the Norms and Standards Regulations applicable to Different Categories of Health Establishments. The Domain, Sub-domain and Standard statements have all been extracted from the regulations. The majority of criterion have also been extracted from the regulations. Statements extracted from the regulations are indicated **bold, red text which has been underlined**. Criterion statements not extracted from the regulations are indicated by **bold black text, which is not underlined**.

Regulations which are not applicable to General Practice and will therefore not be inspected in Practices are indicated by ~~**bold, red text with strikethrough**~~.

The sub-regulation number for each standard and criterion statement is included just before the text of the statement, e.g. **4.(1) A Health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.**

The content of the draft Standards for General Practices follows the structure of the National Core Standards and the current OHSC Inspection tools: domain – sub-domain – standard – criterion - measure.

The format of the document to denote the various levels of the architecture, which is related to the regulatory statements as follows:

Domain 1: = Chapter

Sub-domain 2: = Regulation heading

Standard 3: = Sub-regulation

Criterion 1: = Sub-regulation

Measures

1.
2.
3.

Domain 1:USER RIGHTS

Sub-domain 1: User information

Standard 1: 4. (1) A Health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.

Rationale:

Informing users about services provided by the practice and the times when these services are available is important in order for users to be able to access these services. Just as important is that these services are provided in accordance with the information communicated to users. Where users have placed their trust in the healthcare providers at the practice to be responsible for their medical care, the healthcare providers have a moral obligation in return to show themselves worthy of that trust. This includes the provision of services in accordance with the information communicated.

Criterion 1: 4.(2)(a)(i) Health establishment must provide users with information relating to the health care services provided by the health establishment.

Measures:

1. The services provided are visibly displayed. ***OBSERVATION***

   Explanatory note: The information notice must include the services provided over and above standard general practitioner services. This will include but is not limited to sexual and reproductive health, child health, travel health or minor surgery. This information must be displayed to inform users whether the practice can meet their health needs prior to approaching the reception desk. This may be at the entrance to a practice which is the sole occupant of a building or in the foyer or waiting room for a practice that shares a building with other businesses. The information can be a board, poster or electronic notice board. Alternatively, this information can be available in booklets or pamphlets which are made available to users or a notice indicating the information is available on the practice's website.

   Not applicable: Never

Criterion 2: 4.(2)(a)(ii) Health establishment must provide users with information relating to service opening and closing times.

1. The operating hours of the practice are clearly visible. ***OBSERVATION***

   Explanatory note: There must be an information notice displaying the operating hours of the practice. The information can be displayed in the same manner as the services provided.

   Not applicable: Never

~~**Criterion: 4.(2)(a)(iii) The health establishment must provide users with information relating to the health care visiting hours where relevant.**~~

Criterion 3: 4.(2)(b) The health establishment must 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.

Measures:

1. Users are informed of indicative costs related to services provided by the practice prior to these costs being incurred. ***HEALTH RECORD AUDIT/DOCUMENT***

   Explanatory note: Please note that this requirement refers to an indicative and not definitive cost. This is applicable to interventions to be provided by the practice only, including but not limited to assessment, investigation, management of their condition and any invasive procedures. HPCSA Booklet 2 7.6) A practitioner shall explain to the patients the benefits, costs and consequences associated with each service option offered. This requirement reflects S6(1)(c) of the National Health Act. Routine costs, e.g. consultation costs, can be communicated by means of a poster or notice at reception. Additional costs should be communicated at the time that the service is recommended.

   Not applicable: Never

2. For elective procedures performed by healthcare providers at the practice, the practice confirms that the user has obtained authorisation for the procedure prior to commencement of the procedure. ***RECORD AUDIT/DOCUMENT***

   Explanatory note: This measure will apply to elective procedures provided by health professionals at the practice, including but not limited to elective MMCs, TOPs and exercise tolerance tests, which incur costs additional to the standard consultation fee. Where authorisation from a medical aid is required, ***the user*** *is responsible for obtaining the authorisation and must provide evidence of the authorisation to the practice. The practice must then document the authorisation code prior to conducting any cost-bearing intervention to avoid financial risk to the user or the practice.*

   Not applicable: Where the practice does not provide elective procedures of any kind that will require pre-authorisation.

3. Where authorisation cannot be confirmed, the practice informs the user of the risk that they may be liable for the cost of the intervention and provides an indicative cost. ***HEALTH RECORD AUDIT/DOCUMENT***

   Explanatory note: This is applicable to interventions to be provided by the healthcare professionals at the practice only. A document informing users of their financial responsibility/liability for the service/s provided is made available to users before commencement of treatment. This could be communicated through signage/notice at the reception area or documented in the user's health record.

   Not applicable: Where authorisation is confirmed and/or where the practice does not provide procedures requiring advance authorisation by the health insurer.

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

Rationale:

The user experience survey should preferably be done by an independent provider. This will provide a measure of anonymity for the users surveyed, which is likely to result in more honest feedback about user experience. It will also allow for more objective analysis of the feedback provided, thereby providing more reliable information about the user's experience of the practice.

This process should be seen as an opportunity to meet user expectations more comprehensively, thereby improving user experience and making the practice more attractive to new users requiring medical services.

Where the survey is done in-house, an adequate number of users (sample size) must be included in the survey in order to provide reliable results. The table below can be helpful in determining how many users to include in the survey.

Estimate sample sizes using sample size calculator

Population of Interest	Sample size estimate (using confidence level of 95% and confidence interval of 5%)
800	260
1,000	278
1,500	306
2,000	322
2,500	333
3,000	341

Measures:

1. The practice displays information on how users can provide feedback on their experience of care. ***OBSERVATION***

   Explanatory note: This will include compliments, complaints and suggestions. Collecting, analysing and responding to this information can benefit the practice in several ways, including improving user experience and therefore increasing the number of users attending the practice, avoiding formal complaints by responding quickly to user concerns or dissatisfaction, improving user outcomes by tailoring service delivery to meet user needs, etc. Although it may feel uncomfortable to institute such a system, it can provide significant added value for both users and the practice.

   Not applicable: Never

2. User experience surveys are conducted at least every two years. ***DOCUMENT***

   Explanatory note: A validated user experience survey must be used for this purpose. The practice should also ensure that a representative sample of users is surveyed.

   Not applicable: Never

3. The results of user experience surveys are analysed to identify areas for improvement. ***DOCUMENT***

   Explanatory note: Raw data is insufficient to guide quality improvement activities. Basic aggregation of the data can provide an indication of strengths and weaknesses, which can then inform improvement activities. Summarising the findings into a simple report can be helpful and facilitate monitoring of service delivery over time.

   Not applicable: Never

4. Corrective measures are developed and implemented to address areas requiring improvement. ***DOCUMENT***

   Explanatory note: The measures to be adopted should be documented in a quality improvement plan or in a report as relevant to the planned intervention.

   Not applicable: Never

5. Corrective measures implemented are evaluated for their effectiveness in delivering improvements in user experience. ***DOCUMENT***

   Explanatory note: Implementation of the planned activities to achieve the improvements required must be documented, either in a quality improvement plan or in a report, as appropriate. This is an integral part of the quality improvement process, to provide the ability to review progress and to provide a record for future reference. Documented evidence that the corrective measures have been evaluated must be available, this could but not limited to capturing the evaluation in the quality improvement or a report

   Not applicable: Never

6. The practice displays the results of the most recent user experience survey. ***OBSERVATION***

   Explanatory note: The results from the most recent user experience of care survey for the practice must be visibly displayed. Alternatively, there is a notice informing users on how to access the user experience of care survey results for the practice. The survey must have been conducted within the previous 24 months.

   Not applicable: Never

Criterion 5: 4.(2)(a)(iv) The health establishment must provide users with information relating to the health care complaints, compliments and suggestions management system.

1. Users are informed of how to make a complaint. ***OBSERVATION***

   Explanatory note: This can be by means of a poster in the waiting area, pamphlets, practice information leaflet or website, or any other means that makes the information available to all users of the practice.

   Not applicable: Never

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

Criterion 1: The practice must ensure that users are able to lodge a complaint.

1. A designated team member is responsible for managing complaints. ***DOCUMENT***

   Explanatory note: In a single-handed practice, this will be the practitioner themselves. HPCSA Booklet 22.12 COMPLAINTS ABOUT HEALTH SERVICES Everyone has the right to complain about health care services, to have such complaints investigated and to receive a full response on such investigation.

   Not applicable: Never, although in a single-handed practice that employs no staff, the GP will be the designated team member by default.

2. Users are provided with the means to make a complaint. ***OBSERVATION***

   Explanatory note: This can be the provision of a form to complete, paper to document the complaint, a person to assist the user to document the complaint, or any other means of registering the user's complaint.

   Not applicable: Never

3. CHECKLIST: A standard operating procedure for the management of complaints is available. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained

   The mechanism(s) by which users can report a complaint.

   a. The information to be collected to document the complaint.
   b. The recording of the complaint in the complaints register.
   c. The classification of the complaint according to type and severity
   d. All complaints must be acknowledged within 5 working days of receipt.

      Explanatory note: This acknowledgement can be performed by any member of staff at the practice.

   e. The procedure for investigating complaints.
   f. The procedure for redress of complainants, including timelines for responses.
   g. Time intervals at which progress reports will be provided to complainants and the manner in which such reports will be provided.

4. Complaints are logged in a register. ***DOCUMENT***

   Explanatory note: The practice must log all complaints in a register, which is a documented record containing information on complaints lodged. The register may be in the form of a paper-based or an electronic record. Request the complaints register and check if complaints are documented.

   Not applicable: Where no complaints have been received in the 12 months prior to the inspection.

5. CHECKLIST: Information regarding the resolution of the complaint is made available to the complainant. ***DOCUMENT***

   Instructions: Select three records of resolved complaints from the complaints folder or file. Verify whether a record of the communication of the resolution of the complaint to the complainant is available in the folder or file, including the outcome of the investigation and redress agreed. Where minutes of a meeting are sent as a record of the resolution, the complainant must have been present at the meeting. Redress may include one or more of the following:

   • An apology, explanation or an acknowledgement of responsibility; and/or

   • Remedial action that may include:

      (i) the review or changing of a decision on the service or care provided to an individual user.

      (ii) revising published material.

      (iii) revising a procedure to prevent the recurrence of an adverse event or incident; and

      (iv) the training of health care personnel or strengthening of their supervision; or any combination of the above. Score 1 if the documentation is available in the file and 0 if not available.

         a. Complaint 1
         b. Complaint 2
         c. Complaint 3

6. Complaints are reviewed as part of quality management to ensure that any identified deficiencies are addressed. ***DOCUMENT***

Sub-domain 2: Access to care

Standard 1: 5.(1)The health establishment must ensure that users are attended to in a manner which is consistent with the nature and severity of their health condition.

Criterion 1: 5.(2)(a) The health establishment must implement a system of triage.

Rationale

The practice must implement a system of triage (Sorting) to identify users who are likely to decompensate if they are kept waiting for a significant period of time. Triage processes for different categories of primary care personnel are available, including for non-clinical members of personnel.

Users should be informed of the triage system and its intended purpose to avoid any dissatisfaction and potential conflict.

Measures:

1. There is a system in place to identify users requiring urgent care. ***DOCUMENT/OBSERVATION***

   Explanatory note: This system should include the availability of an appropriately trained health care provider and/or health care worker (such as a receptionist) to implement a formal triage service to identify users likely to decompensate while waiting to be seen.

   Not applicable: Never

2. A standard operating procedure to prioritise frail users, infants and acutely unwell users is available. ***DOCUMENT***

   Explanatory Note: Frailty is defined as a clinically recognizable state of increased vulnerability resulting from aging-associated decline in reserve and function across multiple physiologic systems such that the ability to cope with every day or acute stressors is comprised[1]. It has been operationally defined by Fried et al. as meeting three out of five phenotypic criteria indicating compromised energetics: low grip strength, low energy, slowed waking speed, low physical activity, and/or unintentional weight loss[2].

   Not applicable: Never

3. Users are informed of this system of triage and the reason for its implementation. ***OBSERVATION***

   Explanatory Note: This will ensure that users are not frustrated by apparent "queue jumping" by users needing urgent attention. This could be in the form of a poster in the waiting room informing the users of what triage is, and how and why it is implemented. The process to implement the fast-tracking of vulnerable users must be evident on observation of the waiting room/reception area. This can include a poster or information provided to users about the process or observing users who have been fast-tracked in the waiting area.

   Not applicable: Never

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

1. CHECKLIST: A standard operating procedure for contacting emergency user transport is available.

   Instructions: Verify whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained. ***DOCUMENT***

   a. Contact number of emergency medical transport service(s)

   b. Backup number/s

   c. Documents to accompany the user, e.g. referral letter, printout of current medication and past medical history, etc.

[1] Xue QL. The frailty syndrome: definition and natural history. Clin Geriatr Med. 2011 Feb;27(1):1-15. doi: 10.1016/j.cger.2010.08.009. PMID: 21093718; PMCID: PMC3028599.

[2] Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. JGerontolA BiolSciMedSci. 2001;56(3):M146–M156.

2. CHECKLIST: Practice personnel are aware of how to request emergency transport. ***STAFF INTERVIEW***

   Instructions: Interview practice personnel responsible for requesting emergency transport to determine whether they are able to explain how they request emergency transport. Score 1 if they explain the procedure as described in the standard operating procedure and 0 if not.

   a. Service provider to be contacted.

   b. Documentation to be completed, e.g. register.

   c. Documents to accompany user.

3. Contact details for emergency user transport services are available in the area where the telephone call will be made. ***OBSERVATION***

   Explanatory note: Check whether emergency contact numbers are displayed next to each telephone in the relevant area. It could be 112 and other numbers. (The requirement will be met if only 112 is displayed as calls can be re-routed from this service.) If the practice utilises official mobile phones/cellphones, score positive if the emergency numbers are displayed within the practice t.

   Not applicable: Never

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

Standard 2: 5.(3)The health establishment must maintain a system of referral as established by the responsible authority.

Criterion 1: 5.(4)(a) The health establishment must ensure that users are provided with information relating to their referral to another health establishment.

Measures:

1. CHECKLIST: A standard operating procedure specifies the referral information to be given to the user. ***DOCUMENT***

   Instructions: Verify whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

   a. Documentation to be provided to user (if any).

   b. Reason for referral

   c. Service to which user will be referred, i.e. health establishment, health care provider or outpatient department.

2. CHECKLIST: Health care providers responsible for referring users are able to explain what information they provide to users being referred. ***STAFF INTERVIEW***

   Instructions: Interview the health care provider to determine whether the information they provide to users requiring referral includes the aspects listed below. Score 1 if the aspect is explained and 0 if not explained.

   a. Documentation to be completed (if any).

   b. Reason for referral

   c. Service to which user will be referred, i.e. the health establishment, health care provider or outpatient department.

Criterion 2: 5.(4)(b) The health establishment must ensure that a copy of the referral document is kept in the user's health record.

1. CHECKLIST: A copy of the referral letter for users referred out of the health establishment is available ***HEALTH RECORD AUDIT***

   Instructions: Request a documented record of referrals from the practice (this may include but is not limited to a referral register or book or electronic equivalent) and request the health records of the last three users who were referred. Verify whether a copy of the referral letter is filed in the health record or available in a file or

electronic system and whether the aspects listed below are recorded. Score 1 if the aspect is recorded in the referral letter and 0 if not recorded. Score 0 if the referral letter is not kept in the user's health record. NB: Health records kept/filed in electronic health system are acceptable.***(Referral Policy for South African Health Services And Referral Implementation Guidelines, August 2020.pg 16)*** ***Standardised template to use for GPs***

1. Name of user
2. User's age
3. User's gender
4. Presenting complaints
5. Previous medical and surgical history
6. Current medication
7. Allergies
8. Examination findings
9. Results of investigations to date (where available)
10. Treatment to date
11. Response to treatment (where relevant)
12. Special equipment required by the patient (where relevant)
13. Reason for referral
14. Name and signature of the referring healthcare provider
15. Stamp of the referring healthcare provider (where the practice uses stamps)
16. Name of referring health establishment
17. Name of receiving health establishment

Standard 3:7(2)(b) The health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 1: The practice must implement a system for the referral of users to other service providers.

Rationale

Where the practice is not able to provide the services required by a user, systems must be in place to ensure the efficient transfer of care to a health establishment that is able to meet the user's needs. This will require the identification of local establishments providing services not provided at the practice, the establishment of referral pathways, documentation of the contact details of establishments to which users will be referred, and documentation of the information to be provided to users regarding the referral). The establishment of these systems will require collaboration between the practice and the establishments to which they will refer users. All aspects of the system should be documented to ensure continuity of service provision. The documentation should be available to all practice personnel involved in the referral process, particularly locums and new members of personnel.

Where users have more complex health needs, it may be necessary to refer the user to more than one discipline for them to access the care that they require.

Wherever possible, the practice must try to ensure healthy communication and collaboration with district health services in the public sector, in order to promote integrated health care delivery to users receiving services from both the public and private sectors.

Measures:

1. CHECKLIST: A standard operating procedure for referral of users to other service providers is available. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

   a. How to arrange emergency transport when necessary

      Explanatory note: The standard operating procedure should advise the person responsible of who to contact, how and what back up services to contact if the initial service contacted is unable to assist.

   b. The management of emergency users requiring referral

      Explanatory note: All emergency users must be stabilised prior to transfer, according to the level of care provided at the referring practice.

   c. The responsibilities of the referring and receiving health establishment are detailed.

      Explanatory note: This will include the responsibility of the referring practice to ensure that the user to be referred is discussed with a colleague in the receiving health establishment to ensure they are aware of the impending arrival of the user. In addition, the protocol must detail the clinical responsibilities of the referring practice and receiving health establishment.

   d. The procedure to be followed for the transfer of users with infectious diseases.

      Explanatory note: Infection control procedures for all personnel involved in the transport of the user should be included in this standard operating procedure, including drivers and other passengers accompanying the user.

   e. How to notify the transferring personnel if the user has an infectious disease.

      Explanatory note: This refers to infectious diseases requiring control practices by ambulance staff and the receiving health establishment, such as TB, MRSA, etc.

   f. The referring practice confirms that the receiving health establishment is able to provide the user with the care required.

      Explanatory note: See HPCSA Booklet 3. Sending a user to a health establishment that is not able to provide the required care for whatever reason will result in further delay in accessing treatment. In some circumstances, this delay could result in further deterioration of the user's condition which may result in avoidable harm. To reduce this risk to user safety, the referring clinician must ensure that the user is sent to a health establishment that is equipped and staffed appropriately to be able to meet the user's health care needs.

   g. The contact details of the referral health establishments listed above are documented

      Explanatory note: Documentation of the contact details will expedite the referral process by ensuring that the required information is readily available and accessible.

2. The contact details of all service providers in the referral chain are available in areas of the practice where referrals are made. ***OBSERVATION***

   Explanatory note: This list should include all service providers in the referral chain, such as local hospitals or specialist rooms, therapeutic support services, NGO/NPO. "Service provider" includes health establishments and healthcare providers. The ready availability of these details, such as details displayed on a notice board, will reduce the time required to complete a referral.

   Not applicable: Never

Sub-domain 3: Waiting times.

Standard 1: 22.The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

Criterion 1: The practice must provide an appointment system which caters for specific user needs.

Rationale:

The purpose of the appointment system is to improve the efficiency with which services are provided to users, thereby reducing waiting times. The appointment system should therefore be designed to meet the needs of the users and personnel at the practice, ***acknowledging that some users will prefer not to have scheduled appointments***. The purpose of this requirement is not to dictate the system that must be in place, but to require the practice to implement a system that achieves this

purpose (i.e. minimise waiting times), within the context of their practice population. As an example, it does *not* need to be 10 min appointments assigned to each user who requests a consultation, but can be less rigid, such as staggered appointment times where users are requested to attend either in the morning or afternoon, or between 8 and 9, or any other system that meets the intent of this requirement.

An urgent appointment refers to a user's request for an appointment for a clinical condition that must be accommodated on the same day, such as severe or protracted vomiting, a high temperature in a young child, a urinary tract infection in an elderly user, etc. ***NB: "Urgent" does not refer to the user's convenience or social situations. Waiting time for EMS on the GP side (similar to Clincs)***

Measures:

1. There is a system for booking user appointments in advance. ***DOCUMENT/OBSERVATION***

   Explanatory note: For practices where booked appointments are not the norm or not the preference of the community served, it is not necessary for all appointments to be scheduled in advance. However, the practice must have systems in place to accommodate such requests.

   Not applicable: Never.(However, please read the Rationale paragraph above – strictly scheduled appointment slots are not required if that is not the preferred time management style preferred by users, or convenient for the practice).

2. Urgent appointments are available on request for high-risk clinical symptoms. ***STAFF INTERVIEW***

   Explanatory note: "High-risk symptoms" includes but is not limited to chest pain, breathlessness, bleeding, severe abdominal pain or an unrousable infant. This measure does not require that requests for urgent appointments due to social circumstances must be accommodated, but that a system must be in place to accommodate clinically urgent consultations.

   Not applicable: Never

3. The practice accommodates users who are unable to make a scheduled appointment. ***STAFF INTERVIEW / USER INTERVIEW***

   Explanatory note: This will apply to practices who provide appointments for users as routine. It is not necessary for these users to be seen immediately on arrival unless their condition requires urgent medical care. However, as some users may be unable to contact the practice prior to their attendance, a system should be in place to accommodate them.

   Not applicable: Where unscheduled appointments are the default appointment style at the practice.

4. When requested, users can make an appointment with a specific health care provider. ***STAFF INTERVIEW/ USER INTERVIEW***

   Explanatory note: This will apply only to practices with more than one health care provider.

   Not applicable: In single-handed practices without a nurse.

5. Users are informed of any delays affecting their scheduled appointment time. ***OBSERVATION***

   Explanatory note: Reception staff or equivalent should inform users on arrival when the health care provider with whom they have an appointment is running behind schedule, with an indication of the anticipated delay.

   Not applicable: Where there are no delays observed at the time of inspection.

DOMAIN 2: CLINICAL GOVERNANCE AND CLINICAL CARE

Sub-domain 1: User health records and management

Standard 1: 6.(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

Criterion 1: 6.(2)(a) The health establishment must have a health record filing, archiving, disposing, storage and retrieval system which complies with the law.

Rationale

Efficient management of health records is to ensure continuity of care for the user. [*Medical Protection Society Factsheet: Medical Records; 1 Feb 2015]* If a medical record cannot be located, the user may suffer because information, which could be vital for their continuing care, is not available. If the medical/health record cannot be produced when needed for user care, the medical record system is not working properly and confidence in the overall work of the medical/health record service is affected. *[Medical Records Manual, WHO 2006]*

Measures:

1. A nominated individual is responsible for health record management. ***DOCUMENT***

   Explanatory note: In a single-handed practice which does not employ any other staff, this will be the general practitioner. In other types of practices, this responsibility must be documented in some way, including but not limited to a letter allocating the responsibility or in the individual's job description.

   Not applicable: Never

2. CHECKLIST: A standard operating procedure for health records management is available. ***DOCUMENT***

   Instructions: Verify whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained. For practices that store no paper records, score aspects NA as indicated. The aspects will remain applicable for practices that do not scan and destroy paper documents.

   a. The creation of a new user record with a unique identifier

   b. The content and sequencing of the health record

   c. The system used to prevent misfiling of user information.

      Explanatory note: This means filing one user's information in another user's file.

      Not applicable: Where no paper records are in use.

   d. The manner in which health records are filed (such as alphabetically, by unique identifier, by address, by family, by medical aid, etc.).(*Not applicable: Where no paper records are in use).*

   e. The storage period for health records(*Not applicable: Where no paper records are in use).*

   f. The archiving of health records(*Not applicable: Where no paper records are in use).*

   g. The destruction of health records

      Explanatory note: The standard operating procedure for the destruction of health records must ensure that the confidentiality of the record is maintained, whether the destruction is done internally or by a contracted service provider. **Medical Records in South Africa: An MPS Guide Appendix 1: Retention and Destruction of Records S Anthony June 2016 MPS**

      Not applicable: Where no paper records are in use.

   h. Maintaining confidentiality of health records, including confidentiality of records during destruction

   i. Maintaining confidentiality and security of electronic health records (where these are used)

      Explanatory note: This aspect of the standard operating procedure must comply with legislative prescripts, where these are available and minimum standards specified in government policies and guidelines. Please note this will apply to all IT systems where user information is stored and not only the electronic health record.

   j. User access to their health records

   k. The preparation and release of health record documentation to third parties

      Explanatory note: This section must include signed consent by the user for the information to be released to the requesting third party, prior to release of the information.

3. CHECKLIST: Personnel responsible for health record management have received training in the areas listed below as a minimum. ***DOCUMENT***

   Instructions: Documented evidence of training is required, including but not limited to training certificates for external training attended, or attendance registers for in-house training. Documentation must confirm the aspects of records management covered by the training. Score 1 if the documented evidence of training is

available and 0 if not available.

a. Health record content

Explanatory note: This will include but is not limited to what should be filed in the record and sequencing of the information.

b. Storage of records

Explanatory note: This will include storage of electronic records in accordance with legislation, policy and guidelines.

c. Retrieval of records

d. Archiving of records

e. Destruction of records

f. Confidentiality of records

Explanatory note: The requirements set out in the HPCSA's Booklet 10 must be addressed in the practice's standard operating procedures. This will include confidentiality requirements for electronic health records and user data stored in other IT systems.

4. CHECKLIST: The practice complies with health records management guidelines. **OBSERVATION**

Instruction: Use the checklist below to determine whether the health establishment adheres to the requirements listed below. Score 1 if compliant and score 0 if not compliant

a. A standardised, unique record registration number is assigned to files. (One of the following methods is consistently used: user's surname, identity document number or date of birth, or a set of practice assigned and recorded numbers).

b. The record registration number is clearly displayed on the cover of the user record

c. A register of archived records is available

d. A register of disposed records is available(Not applicable for electronic records)

e. A copy of disposal certificates is available - copies must correspond with entries in the disposal register(Not applicable for electronic records)

5. Personnel responsible for health record management are able to explain the process for retrieval and filing of a health record. ***STAFF INTERVIEW***

Explanatory note: The individual(s) responsible for these processes must be able to explain them comprehensively to the inspector. This will confirm that the process is executed in accordance with the standard operating procedure.

Not applicable: Never

6. Adequate space is identified to archive inactive user records for the stipulated period as per the Act. ***OBSERVATION***

Explanatory note: "Adequate space" means that there is sufficient space to allow for orderly storage of all records held by the practice. This means that all records are readily accessible for retrieval, i.e. not stored in boxes on top of filing cabinets, on the floor or on counters, or similar disorganised arrangements. If the practice does not have sufficient space, archived records may be stored offsite or by a service provider. The practice must ensure that the service provider can maintain the confidentiality and integrity of the records for the duration of the storage period. Not applicable: Where the practice does not store any paper records.

7. When a user transfers their care to a general practitioner at another practice, there is a system for forwarding a summary of the user's medical record to the new general practitioner. ***DOCUMENT***

Explanatory note: This measure applies when a user chooses to cease care with their current general practitioner and seek care from another general practitioner. To ensure continuity of care for the user, the current GP must make arrangements for a summary of the user's current medical record to be forwarded to the new GP. The summary should include all relevant information to permit the new GP to provide comprehensive care to the user. This requirement is in accordance with the guidance provided by the HPCSA Booklet 2: General Ethical Rules Section 10 Supersession.

Not applicable: Never

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

Measures:

1. Records are not left unattended in public areas and are only accessible to practice personnel. Observation

   Explanatory note: Observe how user health records are managed in various areas within the practice and determine whether unauthorised individuals would be able to access the information in the health records. This will include the health records of users waiting to be seen, users who have already been seen but their records have not yet been returned to the records storage area/room, health records being used for clinical audit or other administrative purposes, or health records outside the records storage area/room for any other reason. Such records should be kept in a manner which safeguards against unauthorised access to the content of the record.

   Not applicable: Never

2. CHECKLIST: There is a standard operating procedure defining how confidentiality of user information is protected when shared electronically with other health care providers. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained. Score Not Applicable in practices where information is not shared electronically.

   a. Information must be shared over encrypted networks
   b. Electronic devices used to share user information must be password protected
   c. Electronic devices used to share information must not be left unattended while user information is visible on the screen
   d. Information shared using electronic devices must be transferred to the user's health record as soon as possible and deleted from the device

3. Electronic health records are protected against unauthorised access. ***OBSERVATION***

   Explanatory note: This will include unauthorised viewing of the record while opened on a screen as well as unauthorised access to the system.

   Not applicable: Where electronic health records are not used.

Criterion 3: 6.(2)(c) The health establishment must 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).

1. CHECKLIST: Records storage area or cabinet meets the requirements listed below. ***OBSERVATION***

   Instructions: Inspect the record storage and archives area or cabinet to verify whether it complies with the requirements listed below. Score 1 if compliant and 0 if not compliant.

   a. Adequate space is available for user health records.

      Explanatory note: "Adequate space" means that there is sufficient space to allow for orderly storage of all records held by the practice. This means that all records are readily accessible for retrieval, i.e. not stored in boxes on top of filing cabinets, on the floor or on counters, or similar disorganised arrangements.

      Not applicable: Where the practice does not store any paper records.

   b. Access to health records is controlled.

      Explanatory note: This includes paper records (access-controlled entry to storage area or cabinets) and electronic records (access control via passwords and access rights).

   c. Health records are secured against theft.

d. Paper health records are protected from destruction.

Explanatory note: This includes but is not limited to damage from fire, flooding and insects. This can include but is not limited to fire doors, fire extinguishers, fireproof cabinets, wooden shelves, shelving starting 100mm above the floor, using metal rather than wooden shelving and ensuring regular pest control.

Not applicable: Where the practice holds no paper records.

e. Electronic records are protected against degradation.

Explanatory note: This refers to decay of the stored data such that the information can no longer be accessed. This can result from circumstances such as damage to a server, or the data being destroyed by malware.

f. Where electronic health records are in use, software upgrades are regularly downloaded and installed.

Standard 2: 6.(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.

Criterion 1: 6.(4)(a) The health establishment must record the biographical data of the user and the identification and contact information of the user and his or her next of kin.

Measures:

1. CHECKLIST: The practice has a system in place to ensure that the details listed below are documented for all users. ***HEALTH RECORD AUDIT***

   Instructions: Select records of three users. Using the checklist below, verify whether user records comply with the requirements. Score 1 if compliant and 0 if not compliant.

   a. User's name
   b. User's address
   c. User's email address(*where available)*
   d. User's date of birth
   e. User's gender
   f. ID number or unique identifier/number
   g. Physical address
   h. Postal address(*where available)*
   i. Contact numbers
   j. Occupation
   k. Method of payment
   l. Name of next of kin (this can include cohabitees)
   m. Contact details of next of kin.

2. All user's contact details are updated on a regular basis. ***DOCUMENT / HEALTH RECORD AUDIT/OBSERVATION.***

   Explanatory note: The regular updating of these details is fundamental to ensuring that users can be contacted when necessary, particularly in an emergency. This will include but is not limited to confirming contact details routinely as part of every user contact episode ;using electronic means to request users to update their detail(e.g. email, or a document that is completed by users at the practice(NB: Check various practices during piloting of tool)

   Not applicable: Never

Criterion 2: 6.(4)(b) The health establishment must record information relating to the examination and health care interventions of users.

Measures:

1. CHECKLIST: At the user's initial visit to the practice, the health information listed below is documented in the patient record. ***HEALTH RECORD AUDIT*** Date, time and sign the entry in the patient record

   Instructions: Select three user health records and review the record to confirm that the information listed below was recorded at the user's first visit to the practice. Score 1 if the aspect is recorded and 0 if it is not.

   a. Past medical and surgical history
   b. Family history
   c. Current medication (including over-the-counter medicines, traditional medicines and alternative medicines)
   d. Allergies

2. The above information is updated at least every five years and as necessary. ***HEALTH RECORD AUDIT***

   Explanatory note: This information should be updated as information comes to light, e.g. the user develops chronic illnesses or develops allergies to medication. The information should be formally reviewed every five years.

3. CHECKLIST: Clinical assessment and management plan for the user is recorded in the user record. ***HEALTH RECORD AUDIT***

   Instructions: Select records of users who were seen at the time of inspection and assess whether clinical assessment, diagnosis, treatment and follow up have been recorded in the user's health record for each practice visit. Score 1 if the aspect is documented or 0 if it is not documented. Score not applicable if the aspect is not relevant for the consultation audited.

	ASPECT	RECORD 1	RECORD 2	RECORD 3
a.	The presenting complaint or review of symptoms for follow up consultations for the same complaint			
b.	Sexual history and partners (where relevant)			
c.	Vital signs including blood pressure, heart rate, temperature and respiratory rate as applicable			
d.	Physical examination details (where relevant)			
e.	Side room investigations (where relevant) *Explanatory note: This will include side room investigations such as Hb, urinalysis, blood glucose, etc.)*			
f.	Working diagnosis or final diagnosis			
g.	Diagnostic coding *Explanatory note: The coding used must comply with NHI requirements.*			
h.	Treatment plan (which includes medication, education, counselling, referral to specialists, further investigations, sick leave)			
i.	Follow up requirements(where relevant). *Explanatory note: This will include routine follow up requirements as well as situations requiring urgent review, including but not limited to post-procedural infections; complications of treatment such as sciatica post injection; development of adverse drug reactions; deteriorating clinical condition; red flag symptoms such as development of neurological deficits in users with back pain.*			

j. Response to treatment *Explanatory note: Please note that this will only be relevant where the user attends for follow up, e.g. for non-communicable disease review or where they attend for review of an acute problem or attends with the same problem at a later date.*			

3. CHECKLIST: The request and receipt of diagnostic investigations is documented in the user's health record. ***HEALTH RECORD AUDIT***

Instructions: Select records of users who have had investigations done and assess whether the information listed below is available in the user's health record. Score 1 if the aspect is available and 0 if it is not available. Score not applicable if the investigations were not requested for the user.

a. Diagnostic radiological investigations requested.

b. Diagnostic radiological report filed.

Explanatory note: The report can be filed electronically or in the user's paper record.

c. Diagnostic laboratory investigations requested

d. Diagnostic laboratory test result filed.

Explanatory note: The report can be filed electronically or in the user's paper record.

e. Results in the record belong to the correct user.

f. Diagnosis is recorded, as appropriate.

Explanatory note: In the event that a final diagnosis has not been reached, a working diagnosis should be documented.

4. CHECKLIST: The user's clinical notes in the health record comply with medico-legal and HPCSA requirements for record keeping, as listed below. ***HEALTH RECORD AUDIT***

Instructions: Select records of users who were seen at the time of inspection and assess whether the information recorded about the consultation(s) meets the requirements listed below. Score 1 if the aspect is available and 0 if it is not available.

a. All records are legible.

b. All entries are in indelible ink.

Explanatory note: Ideally, handwritten records should be made in black ink, as this provides the best quality photocopied documents.

c. All entries are dated.

d. The time of each entry is recorded.

e. Each entry made is accompanied by the signature, name and surname of the health care provider who examined or attended to the user.

Explanatory note: A stamp can be used to enter the name, surname and designation of the healthcare provider. For electronic records, this information is automatically recorded as part of the audit trail, linked to the system user's login details.

f. The health care provider's name is legible.

g. Health care practitioners record their designation.

4. All interventions agreed with users should be in accordance with approved evidence-based guidelines. ***HEALTH RECORD AUDIT***

Explanatory note: This requirement seeks to protect users from over servicing, which can result in unnecessary depletion of their insurance. Adherence to approved evidence-based practice guidelines can be demonstrated by means of clinical audit.

Not applicable: Never

Standard 3: 6.(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

Criterion 1: A documented procedure which describes the information to be collected and discussed during the process to obtain informed consent is implemented, in accordance with HPCSA requirements.

Measures:

1. CHECKLIST: A standard operating procedure for obtaining informed consent is available, which includes the details listed below as a minimum. ***DOCUMENT***

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

   a. The user's full names must be documented on the consent form.

   b. The user's legal standing to give informed consent must be documented on the consent form.

      Explanatory note: "Legal standing" refers to the user's mental capacity to provide consent, or the legal authority of the person providing consent on behalf of the user where the user does not have the mental capacity to provide consent, as defined in HPCSA Booklet 9.

   c. The consent form must be dated to reflect the day on which consent was granted.

   d. The exact nature of the operation, procedure or treatment must be documented on the consent form.

   e. The consent form must contain a statement that the treatment options, their risks, benefits, costs and consequences have been explained to the user.

      Explanatory note: Treatment options must be discussed with the user including benefits and risks and an option must be agreed with the user. This process and the final decision agreed with the user should be recorded on the consent form, as described in the measure. Indicative costs must be explained to the user prior to commencement of the procedure, including liability of the user for any costs not covered by the medical aid.

   f. Major complications, where relevant, must be discussed with the user.

   g. The information recorded on the form must be legible.

   h. The consent form must be signed by the health care provider performing the procedure/treatment.

   i. For users unable to write, a thumb print must be used and labelled according to the hand and finger used.

      Explanatory note: For electronic consent forms, a biometric device can be used to record consent for users unable to write.

   j. The consent form must be filed in the user's health record.

2. CHECKLIST: A standard operating procedure for obtaining informed consent from users requested to participate in research to be conducted at the practice is available ***DOCUMENT***

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

   a. Users participating in research projects must be provided with comprehensive and understandable information about the aim of the research to be undertaken.

   b. Users participating in research projects must be provided with comprehensive and understandable information about the risks and benefits of participating in the research.

   c. Users participating in research projects must be provided with comprehensive and understandable information about their entitlements as a result of participating in the research.

d. Users participating in research projects must be provided with comprehensive and understandable information to ensure fully informed consent.

e. Users must be informed that they can withdraw from the research project at any time and for any reason should they wish to do so with no negative influence on the care provided to them by the practice.

f. The consent form must be filed in the user's health record.

3. CHECKLIST: Forms used for informed consent are completed correctly by health care providers, including the details listed below. ***HEALTH RECORD AUDIT***

Instructions: Use the checklist below to check whether user health records comply with the requirements. Select three records of users who had to sign informed consent for a procedure or treatment. Score 1 if the aspect is recorded and score 0 if the aspect is not recorded.

a. The user's full names are written on the consent form.

b. The user was legally entitled to give informed consent.

c. The consent form is dated.

d. The exact nature of the procedure/treatment is written on the consent form.

e. Confirmation that the treatment options, their risks and benefits, costs and consequences have been explained.

Explanatory note: Treatment options must be discussed with the user including benefits and risks and an option must be agreed with the user. This process and the final decision agreed with the user should be recorded on the consent form, as described in the measure. Indicative costs must be explained to the user prior to commencement of the procedure, including liability of the user for any costs not covered by the medical aid.

f. Major complications have been discussed, as relevant to the procedure, including but not limited to infections, bleeding, DVT, nerve injury and pain.

g. The consent form is signed by the health care provider performing procedure or treatment.

Explanatory note: Ideally, the consent process should be performed by the healthcare provider who will perform the procedure. The healthcare provider conducting the consent process must sign the consent form as well, as confirmation of their actions.

h. The consent form is signed by the user.

Explanatory note: This will include a labelled thumbprint for illiterate users and electronic signatures for electronic consent forms.

Not applicable: Where the consent form has been signed by a legal representative, guardian or parent of the user

i. Where the user is not legally competent to provide consent, the consent form is signed by the legal representative of the user or parent/guardian as appropriate for children.

j. The information documented in the consent form is legible.

~~**Standard :6.(6) The health establishment must issue a discharge report to users in accordance with section 10 of the Act.**~~

Sub-domain 2: Clinical management

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

Criterion 1: 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.

Rationale

Clinical guidelines are aids to providing good quality user care. They summarise the best evidence available about how clinical conditions should be managed. ***They are not intended as rigid instructions to healthcare***

providers on what they must do, but rather as a reference document to ensure that the healthcare provider has all the available information they require to make the best possible decisions for individual users when providing care. In addition, they act as an aide memoire to ensure that no essential steps in investigation and treatment are omitted during the customisation of a treatment regime for an individual user.

When used correctly, clinical guidelines assist in reducing variations in care which in turn leads to improved user outcomes.

The national guidelines for priority health conditions must be available at the practice, the content of the guidelines should be communicated to those health care providers who will be using them and wherever possible, training on the content of the guidelines should be provided. Ideally, clinical audits should be conducted to ensure that users are managed in accordance with the guidelines.

Measures:

1. CHECKLIST: Clinical guidelines are available in consultation rooms. **DOCUMENT**

   Instructions: Use the checklist below to check the availability of clinical guidelines. Select two consultation rooms if the practice has more than one consultation room. Score 1 if the guideline is present and score 0 if the guideline is not present. Guidelines can also be available electronically or via Apps. Check that the most current guidelines are being used. Guidelines for services not provided in the practice must e marked not applicable.

Child, Youth and School Health

a. Integrated Management of Childhood Illness Chart Booklet, 2019

Communicable diseases

a. Antiretroviral Treatment Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates (2019)
b. National HIV Testing Services Policy (2016)
c. National guidelines for the management of Viral Hepatitis (2019)

Non-Communicable diseases

d. National User Guide on the Prevention and Treatment of Hypertension in Adults at PHC Level (2021)

Tuberculosis

e. National Tuberculosis Management Guidelines (2014)
f. National Guidelines for the Management of Tuberculosis in Children (2013)
g. Management of Rifampicin Resistance - A Clinical Reference Guide (2019)

Women, Maternal and Reproductive Health

h. Guidelines for Maternity Care in South Africa (2016)
i. Cervical Cancer Prevention and Control Policy (2017)
j. Clinical Guidelines for Breast Cancer Control and Management (2019)
k. National Contraceptives clinical guidelines (2019)
l. National Consolidated guidelines for the management of HIV in adults, adolescents, children and infants and prevention of mother-to-child transmission (2020)
m. Clinical Guideline for Genetics Services (2021)
n. National Clinical Guidelines for Safe Conception and Infertility (2021)

Other

o. Standard Treatment Guidelines and Essential Medicines List for Primary Health Care, 2020
p. Standard Treatment Guidelines and Essential Medicines List for Hospital Level, Adults, 2019 (only in consultation room used by the doctor)
q. Antimicrobial stewardship guidelines

r. Practical Manual for Implementation of the National Strategic Framework for Infection Prevention and Control

s. National Medical Male Circumcision Guidelines (2016)

2. There is evidence that healthcare providers have been informed about guidelines on priority health conditions. ***DOCUMENT***

Explanatory note: Documented evidence that personnel have been informed about the clinical policies and guidelines must be available, this could include but is not limited to distribution lists which include personnel signatures to indicate they have read and understood the document (which must be dated and signed), proof of attendance of meeting where policies and guidelines are discussed or similar evidence for electronic distribution.

Not applicable: Never

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

Criterion 1: Users are involved in decision-making in relation to their care.

Measures:

1. Users are informed of their diagnosis. ***USER INTERVIEW***

Explanatory note: This can be a working diagnosis where a definitive diagnosis is not yet established. Please note that comprehensive details of the conversation required for this measure do not need to be recorded in the user's health record. Even when a working diagnosis is not available, the patient should be given information regarding a differential diagnosis and an indication of the path to be followed to determine a more definite diagnosis.

Not applicable: Never.

2. The diagnosis and its implications are discussed with users. ***HEALTH RECORD AUDIT***

Explanatory note: Please note that comprehensive details of the conversation required for this measure do not need to be recorded in the user's health record. This will include lifestyle and self-care advice relevant to the condition.

Not applicable: Where the discussion has been had during a previous consultation and the user is consulting for the same condition.

3. Treatment plans are negotiated with users. ***HEALTH RECORD AUDIT***

Explanatory note: Details of the treatment options selected and agreed with the user must be documented in full.

Not applicable: Where the patient is attending for review and the treatment plan is not changed.

4. Follow up requirements are agreed with users and documented in the user record. ***HEALTH RECORD AUDIT***

Explanatory note: Where a user is advised to return for follow up, details of the follow up required must be documented in full.

Not applicable: Where follow up is not required.

Criterion 3: The practice must ensure that results of diagnostic investigations requested are received and acted upon.

Measures:

1. CHECKLIST: A standard operating procedure for the management of diagnostic investigations is available. ***DOCUMENT***

Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

a. Procedure to request investigations.

Explanatory note: This should describe not only the correct forms to be completed but also confirming the user's preferred laboratory, explaining how to access the service, how to obtain the result, whether to expect contact from the lab or the practice, etc.

b. Action to be taken by the practice when urgent results are not received.

Explanatory note: This will only apply in clinically urgent situations, where the results are required urgently to make a decision about clinical management of the user. A safety netting process must be in place to ensure that users attend for these tests and that the laboratory provides the results the same day.

c. Review of incoming results by the requesting clinician or their deputy.

Explanatory note: All results received must be reviewed by the requesting clinician prior to filing the results. If the requesting clinician will be unavailable when the result is received, a "deputy" should be appointed to review the result in their absence. The deputy must have the appropriate training to be able to interpret the results and the authority to request further action as indicated by the result.

d. The timeframe for review of results, according to the level of urgency identified.

e. Communication of test results to relevant personnel, when appropriate

Explanatory note: This could include but is not limited to sharing test results with midwives, physiotherapists, specialists, or other members of the multidisciplinary team providing care to the user.

f. Procedure to inform users about their results and of further action required, including documentation of the communication.

Explanatory note: This will include general information provided to the user at the time of the request, e.g. how to obtain their test result if they do not hear from the lab or the practice. Relevant contact details should be provided.

g. Follow up actions to be taken where users do not respond to the request for additional interventions in response to test results.

Explanatory note: Where the test results indicate an abnormality requiring additional interventions, the practice must make a reasonable effort to contact the user. This can include but is not limited to phone calls or messages sent to the user

h. Procedure to file the results.

Explanatory note: This must specify that results must not be filed prior to being reviewed by the requesting health care provider or their deputy.

2. Any action required in response to test results is documented. ***HEALTH RECORD AUDIT***

Explanatory note: Where the test results indicate an abnormality requiring additional interventions, the action taken is documented. This can include but is not limited to discussing treatment options, treatment prescribed or referral for further management.

Not applicable: Where no action is required.

3. Users are contacted if they fail to respond to requests for further action. ***HEALTH RECORD AUDIT / DOCUMENT***

Explanatory note: The practice must demonstrate that it has attempted to contact the user. This can be documented in the user's health record, or in a register or similar. This can include but is not limited to phone call or messaging sent to the user.

Not applicable: Never

4. All results are signed by the requesting doctor to confirm review of the result prior to being filed in the user's health record. ***HEALTH RECORD AUDIT***

Explanatory note: Following the receipt and review of the results ;the health care provider who has reviewed the result must sign it to confirm that he/she has reviewed the results. If using electronic systems, notes can be made indicating results have been reviewed. This can include the reviewer's electronic signature indicating that they have access the result and provided instruction on further management, including no action required.

Not applicable: Never

Criterion 4: The practice must arrange emergency care for users when the practice is closed.

Rationale:

"Emergency care" refers to urgent health care needs arising outside practice opening hours, which cannot wait until the practice has reopened, such as severe abdominal pain, suspected myocardial infarction, very high temperature in infants, etc. The practice is obliged to make provision for such situations for users who routinely access the practice's services for their primary healthcare needs. This can be provided by the practice, a locum service, a local emergency room or another mechanism. Whatever mechanism is in place must be communicated to such users, to ensure they are aware of how they can access healthcare services urgently when the practice is closed.

Measures:

1. A system is in place to provide emergency care for users when the practice is closed. ***DOCUMENT***

   Explanatory note: This cover can be provided by doctors at the practice itself, by a local service provider such as another practice, locum tenens, standing agreement with a local emergency unit at a state or private health facility (if required), or any other arrangement which provides adequate care for users.

   Not applicable: Never

2. The health care provider providing the emergency care must be appropriately credentialed and experienced. ***DOCUMENT***

   Explanatory note: This is only applicable where a health care provider is providing the service, e.g. a locum tenens. The practice must confirm that the health care provider is appropriately credentialed and experienced prior to engaging their services for the provision of emergency care. Documented evidence of the provider's credentials must be available at the practice.

   Not applicable: Where the service is not provided by an individual health care provider.

3. Users are informed of how to contact the emergency service provider. ***OBSERVATION***

   Explanatory note: A visible notice must be displayed on the door or wall of the practice, providing users with instructions of how to access emergency care or a telephone number to contact available health care professionals, outside of the business hours of the practice.

   Not applicable: Never

Criterion 5: The practice must have systems in place to ensure users requiring resuscitation receive an immediate response by health care providers trained in resuscitation.

Rationale:

Resuscitation in this criterion refers exclusively to situations where CPR is required. For the majority of practices, the ability to provide basic life support only will be acceptable. However, practices providing services that put users at risk of cardio-respiratory arrest, including but not limited to exercise ECGs or minor surgical procedures, will be required to have an AED. However, all practices must be equipped to provide basic life support.

Measures:

1. All health care providers have undergone Basic Life Support(BLS) training in the previous two years. ***DOCUMENT***

   Explanatory note: Training must be provided by an accredited service provider. A certificate of competence must be available. The certificates are valid for two years. Not applicable: Never

2. Practices offering procedures with a recognised complication of cardiac arrest must be able to access a defibrillator or Automated External Defibrillator(AED) within 2 minutes of an arrest. ***OBSERVATION***

   Explanatory note: This is not required for practices that do not provide with a recognised complication of cardiorespiratory arrest.

   Not applicable: Where the practice does not provide services with a recognised complication of cardiorespiratory arrest.

3. The defibrillator or Automated External Defibrillator(AED) must be tested weekly and prior to each procedure to confirm that it is functional and fully charged. ***DOCUMENT***

   Explanatory note: This is not required for practices that do not provide services with a recognised complication of cardiorespiratory arrest.

   Not applicable: Where the practice does not provide services with a recognised complication of cardiorespiratory arrest.

4. There is at least one emergency bag in the practice. ***OBSERVATION***

5. The emergency bag is stored in a location which is only accessible to authorised personnel.

   Explanatory note: The bag must be stored in an area that can be accessed immediately in the case of an emergency. However, the storage area should provide adequate security for the bag.

   Not applicable: Never

6. CHECKLIST: The emergency bag includes the medication and equipment listed below, or an equivalent. ***OBSERVATION***

Instructions: Use the checklist below to check whether the emergency bag is stocked with unexpired medicines and the equipment listed below. Check whether the equipment and medicines are available in the emergency bag and also check the expiry dates of medicines. Score expired medication as "0". Score 1 if the aspect listed is available, functional and not expired (if applicable) and score 0 if the aspect is not available or functional or expired (if applicable).

Medication

a. Adrenaline 1mg/ml

b. Atropine 0,5 mg/ml or 1mg/ml

c. Furosemide 20mg/2ml

d. Glyceryl trinitrate 0.5mg tablets (Sublingual TNT)

e. Amlodipine 10mg tab

f. Aspirin 300mg Tablets

g. Magnesium Sulphate 50% 1 g in 2 ml amp

h. Hydrocortisone 100mg/2ml

i. Nebulising machine or face mask with nebuliser chamber.

j. Ipratropium nebulisation or Salbutamol nebulising solution Lignocaine 2%

k. Dextrose 50%

l. Glucagon 1mg

m. Diazepam 5mg/ml (IN SCHEDULE 5 CUPBOARD OR BOX IN DOCTOR'S BAG)

n. Promethazine 25mg/ml OR 50mg/2ml IV (IN SCHEDULE 5 CUPBOARD OR BOX IN DOCTOR'S BAG)

o. Oxygen cylinder or oxygen concentrator*(if practice uses oxygen concentrator it must have a backup power supply)*

IV SOLUTIONS

a. Water for Injection 10-20ml

b. 0.9% NaCl 1000mls

c. 10% Dextrose 1000mls

EQUIPMENT

a. Oropharyngeal airways (sizes 0- 5) (Guedel airways)

b. Nasal prongs/cannulae

c. Oxygen mask or nasal cannulae adult 24%

d. Oxygen mask or nasal cannulae adult 40%

e. Oxygen mask or nasal cannulae, paediatric 24%

f. Ambu bag

g. Stethoscope

h. Pulse oximeter with adult & paediatric probes – (must be available in vicinity not necessarily on the trolley)

i. IV administration sets (20mls drop/60 mls drop)

j. Current algorithm from Resuscitation Council of South Africa or equivalent organisation. https://resus.co.za/subpages/RCSA_Information/Resources/Algorithms.html

7. The contents of the emergency bag is checked on a regular basis, according to practice protocol. Document

Explanatory note: Request documented records of checking the emergency bag from the previous 30 days.

Not applicable: Never

Criterion 6: The practice must implement measures and processes to protect users undergoing high risk procedures.

Measures:

1. CHECKLIST: A standard operating procedure for safe injection practices is available. ***DOCUMENT***

Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

a. Prepare injections using aseptic technique in a clean area.

b. Disinfect the rubber septum on a medication vial with alcohol before piercing

c. Do not use needles or syringes for more than one user (this includes manufactured prefilled syringes and other devices such as insulin pens).

d. Do not use single-dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution for more than one user.

e. Do not combine the leftover contents of single-use vials for later use.

The following apply if multidose vials are used:

f. Date multidose vials when first opened and discard within 28 days unless the manufacturer specifies a different date.

https://www.cdc.gov/oralhealth/infectioncontrol/faqs/safe-injection-practices.html

2. CHECKLIST: A standard operating procedure detailing the response required if a user has an adverse drug reaction to an injection is available. ***DOCUMENT***

Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

a. Immediate action taken to manage the user

b. Identification of the drug that caused the reaction

c. Documentation of reaction into user health record

d. Reporting of adverse drug reaction to relevant authority

e. Providing feedback to user

3. CHECKLIST: There is a standard operating procedure on invasive procedures which includes the details listed below. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

   a. Where in the practice they can be performed.
   b. Infection control procedures to be implemented.
   c. Surgical care and anaesthetic care required.
   d. Appropriate monitoring to be provided before, during and after the procedure.

4. CHECKLIST: A standard operating procedure for local anaesthesia is available. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained.

   a. Local anaesthetic agents approved for use at the practice.
   b. Emergency response required for adverse reactions to the approved agents.
   c. The dosage for administration, relevant to the procedure and user characteristics
   d. The route of administration
   e. The appropriate injection site.
   f. The frequency with which the agent may be re-administered.

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

1. CHECKLIST: Standard operating procedures define how user rights in relation to the conducting of research are protected. ***DOCUMENT***

   Instructions: **Only applicable where research is conducted at the practice.**

   a. Research conducted at the practice must be approved by a health research ethics committee registered with the National Health Research Ethics Council.

      Explanatory note: All research conducted on human subjects in the Republic of South Africa must be approved by a Health Research Ethics Council registered with the National Health Ethics Research Council, as per Regulation 6(a) of the Regulations relating to research with human participants, R719, 19 Sept 2014.

      Not applicable: Where users are not recruited for research by the practice.

   b. Users enrolled in research programmes are provided with the necessary support.

      Explanatory note: This will include printed matter as a reminder of information discussed during the consent process as well as services required by users as a result of their participation in the research, including but not limited to helplines, access to urgent care and access to the research team.

      Not applicable: Where users are not recruited for research by the practice.

   c. The practice has the required documents, or a copy thereof, that indicate permission was granted for the researcher to conduct the research at that practice.

   d. The practice must confirm that the researchers have declared any potential conflict of interest in relation to the research to be conducted.

   e. The practice must confirm that the research organisation has sufficient insurance cover in place to compensate research participants in the event that users are harmed as a result of their participation.*Explanatory note: Regulation 5(m) of the Regulations relating to research with human participants, R719, 19 Sept 2014 stipulates that users must be informed of insurance in the event of research-related injury.*

Criterion 9: The practice must ensure that insurance cover is obtained for the services provided.

Measures:

1. Each health care provider is covered by adequate indemnity insurance according to the health care services they provide. ***DOCUMENT***

   Explanatory note: The HPCSA published regulations under Health Professions Act on the 30th of August 2010 that requires all health practitioners practising for their own account to obtain professional indemnity insurance.
   https://www.gov.za/sites/default/files/gcis_document/201409/33498755.pdf

Sub-domain 3: Infection prevention and control programmes

Standard 1: 8.(1) The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

Criterion 1: 8.(2) (a) The health establishment must ensure that there are hand washing facilities in every service area.

1. CHECKLIST: Hand washing facilities are available in every service area. ***OBSERVATION***

Instructions: Verify whether the hand washing items listed below are available in every service area. Score 1 if the item is available and 0 if not available. Hand washing facilities adjacent to consulting rooms can be scored 1.In relation to the checklist below, only service areas available in the practice will be assessed.

Service area	Consulting room 1	Consulting room 2	Treatment room	Bathroom / toilet	Kitchen
a. Hand washing basin. *Explanatory note: The basin must not be blocked, broken, have deep cracks causing leaking of water, or have hairline cracks.*					
b. Poster on correct hand washing technique					
c. Poster on correct use of alcohol-based hand rub *Explanatory note: Posters must be placed at strategic places and above alcohol dispensers in the health establishment as stipulated in page 33 of Practical Manual for Implementation of IPC Strategic framework March 2020.*					
d. Taps					
e. Running water					
f. Wall mounted soap dispenser. *Practical Manual for Implementation of IPC Strategic framework March 2020;pg.142*					
g. Plain liquid soap					
h. Paper towels					

i. Paper towel dispenser					
j. Bin					
k. Alcohol based hand rub. *Explanatory note: Item does not necessarily have to be in the hand washing basin/facility area*					

Criterion 2: 8.(2) (b) The health establishment must provide isolation units or cubicles where users with contagious infections can be accommodated.

1. An area or room within the practice is identified to accommodate users with infectious diseases. ***OBSERVATION***

   Explanatory Note: This is for users with confirmed or suspected infections with high fatality rates or high transmissibility including but not limited to meningitis, diarrhoea and TB, or users attending during outbreaks with symptoms of that infection, including but not limited to measles, cholera and influenza variants. Please note that it is not necessary for the area to be used exclusively for this purpose, but the area should provide protection to non-infected users attending the practice and be amenable to terminal cleaning, e.g. all surfaces should be smooth and impermeable to allow for adequate disinfection. This can include outside areas with adequate shelter which permit observation of the user where necessary.

Criterion 3: 8.(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

Rationale

The provision of sufficient clean linen for users is an important aspect of meeting the users' rights. Systems must be in place to monitor the practice's linen stock. Linen must be stored securely in accordance with infection control principles. Used and soiled linen must be stored, transported and washed in accordance with infection control principles. This requirement is applicable to practices using cloth and disposable linen.

Measures:

1. There is linen to meet the needs of the practice. ***OBSERVATION***

   Explanatory note: Observe if there is clean linen available in the practice at the time of inspection. This can be disposable or cloth linen)

   Not applicable: Never

2. CHECKLIST: The linen rooms or storage cupboards meet the requirements listed below. ***OBSERVATION***

   Instructions: Use the checklist below to check whether the linen is stored correctly. Score 1 if the aspect is compliant and score 0 if it is not compliant. Score Not Applicable where only disposable linen is used.

   a. Well ventilated
   b. Properly labelled with the type of linen stored
   c. Well ventilated

3. The practice has a designated area for the storage of dirty linen. ***OBSERVATION***

   Explanatory note: This is only required where the practice uses cloth linen.

   Not applicable: Where only disposable linen is used.

4. CHECKLIST: A standard operating procedure for washing of linen must include the steps listed below. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included

and explained and 0 if not included or not explained. Please note that this measure must be scored Not Applicable in practices that do not launder their own cloth linen. PLEASE NOTE: Washing of linen by hand is strongly discouraged. However, where it is done, it must be done safely, as described below.
Interim Infection Prevention and Control Guidance for Care of Patients with Suspected or Confirmed Filovirus Haemorrhagic Fever in Health-Care Settings, with Focus on Ebola December 2014 WHO

a. Linen must be washed promptly.
b. Personnel must be provided with appropriate personal protective equipment for the method of washing employed by the practice.
c. Correct utilisation of personal protective equipment must be monitored.
d. If linen will be washed at a low temperature, it must be washed with detergent and water and then soaked in 0.05% chlorine solution for approximately 15 min.
e. If linen is to be washed by hand, empty into a large container filled with water and detergent and stir with a stick.
f. Empty the water and refill the container with a 0.05% chlorine solution and soap for 15 min.
g. Remove the linen and rinse in clean water.
h. Linen can be dried inside or outside.

Criterion 4: 8.(2) (d) The health establishment must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.

1. CHECKLIST: Personal protective equipment is available in the practice ***OBSERVATION***

   Instructions: Use the checklist below to check up to three consultation rooms and the treatment room (where relevant) to determine whether protective clothing and equipment are available and worn. Score 1 if the items are available and worn and score 0 if they are not available or worn. Score NA (not applicable) where personnel are not in a situation where they need to wear protective clothing at the time of the inspection.

	Consulting room 1		**Consulting room 2**		**Consulting room 3**		**Treatment room**	
	Available	**Worn**	**Available**	**Worn**	**Available**	**Worn**	**Available**	**Worn**
a. Latex or nitrile gloves – non-sterile								
b. Gloves – sterile								
c. Domestic gloves(cleaners only) *(Practical Manual for Implementation of IPC Strategic framework March 2020;pgs.40-41)*								
d. Disposable gowns or aprons								
e. Protective face shields or goggles								
f. Face masks								
g. N95 or KN95 or FFP2 respirators *Explanatory note: The particle filtration efficiency of the respirator must be 95% for particles with a size of 0.3 microns or less, i.e. it must prevent at least 95% of such particles passing through the respirator.*								

2. CHECKLIST: Health care personnel are informed about prophylactic immunisations for high-risk infections as listed below. ***DOCUMENT***

   Instructions: Use the checklist below to check whether health care personnel are made aware of prophylactic vaccinations available for high-risk infections. There should be documented evidence of the communication. Health care personnel must be advised of the risks of the infections and the protection provided by vaccines. Score 1 if compliant and score 0 if not compliant.

   a. Hepatitis B
   b. BCG
   c. Varicella (only for personnel who do not have natural immunity)
   d. Influenza
   e. Routine vaccinations (DPT, MMR)

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

Criterion 1: The practice implements infection prevention and control processes to reduce the risk of transmission of infection.

Measures:

1. There is a nominated individual responsible for oversight of infection prevention and control activities. ***DOCUMENT***

   Explanatory note: In a singlehanded practice, this will be the general practitioner.

   Not applicable: Never

2. The nominated individual has been orientated in relation to infection prevention and control principles relevant to the services provided by the practice. ***DOCUMENT***

   Explanatory note: Evidence may include but is not limited to orientation documents, or information recorded in personnel record/file.

   Not applicable: Never

3. The practice has identified infection hazards associated with service delivery, including home visits. ***DOCUMENT***

   Explanatory note: This will include, but is not limited to, invasive procedures (such as venepuncture, cervical smears, removal of sutures, minor surgery), use of examination couches, dressing changes, waste management, hand hygiene and sterilisation of reusable equipment. The hazards will differ depending on the services provided.

   Not applicable: Never

4. Standard operating procedures are developed to minimise the risk of transmission of infection for each of these identified hazards. ***DOCUMENT***

   Explanatory note: The standard operating procedures should be aligned to the principles described in the Practical Manual for Implementation of the National Strategic Framework for Infection Prevention and Control.

   Not applicable: Never

Criterion 2: The health establishment must report information on health care associated infections and notifiable diseases to the appropriate public health agencies.

5. Notifiable infections are reported to the relevant authority in accordance with national guidelines. ***DOCUMENT***

   Explanatory note: Documented evidence of reports sent to the relevant authority will be required. In this case, "relevant authority" refers to the district/municipal, provincial and/or national authority responsible for the initial collection of data relating to notifiable conditions, in accordance with local policy. Notifiable medical conditions can be reported manually or entered electronically in a web-based system. http://www.nicd.ac.za/notifiable-medical-conditions/ or via your cell phone app store.Not applicable: Never

Criterion 3: The practice must train health care personnel and users on infection prevention and control practices.

Rationale

For health care personnel to comply with infection control principles, they must be informed regarding these principles. Therefore, all personnel, including contracted personnel, should receive infection control training as part of their orientation to the practice. The title of the training provided must be documented along with a brief summary of the information provided. Attendance registers should be kept in order to keep track of the training provided to all personnel and identify topics to be addressed in future in order to ensure all personnel are aware of their responsibilities in relation to infection control practices.

Because of the potential for knowledge to decay over time, it is important that personnel and users are reminded about these principles regularly. This can be achieved by regular in-service training, user education sessions, posters and leaflets. Important principles in infection prevention and control, such as hand washing, should be revisited in training sessions on a regular basis, annually as a minimum.

Measures:

1. Health care personnel have received in-service training on infection prevention and control in the previous 12 months. ***DOCUMENT***

   Explanatory note: *Attendance registers which include the title and date of the training must be made available for inspection.*

   Not applicable: *Never*

2. CHECKLIST: The in-service training plan for infection prevention and control covers the topics listed below as a minimum. ***DOCUMENT***

   Instructions: Check the training plan to confirm that all the topics listed below are included. Score 1 if the aspect is included and 0 if it is not included. Please note that training provided should be tailored to the functions of each category of personnel. Therefore not all topics listed below will be relevant for all personnel.

   a. Contact precautions (PPE, segregation/isolation, safe injection practices, and respiratory precautions)
   b. Prevention of respiratory infections, especially TB
   c. Hand washing and hand hygiene
   d. Waste management and disposal
   e. Safe injection practices
   f. Sharps safety
   g. Blood and Body Fluid Spill Management
   h. Environmental cleanliness

3. CHECKLIST: Educational material is available and displayed for personnel and users on infection control including the topics listed below. ***OBSERVATION***

   Instructions: Review the posters and literature available in the practice to confirm that all the material listed below is available. Score 1 if the material listed is available and 0 if it is not.

   a. Hand hygiene
   b. Donning and removal of personal protective equipment.
   c. Cough etiquette
   e. The safe use and disposal of sharps
   f. Cholera precautions (where relevant, i.e. during outbreaks and conditions likely to lead to outbreaks)
   h. Malaria precautions ‘(where relevant, i.e. malaria areas and areas where the catchment population includes individuals who travel to and/or from malaria areas)
   i. Rabies precautions

Criterion 4: Decontamination processes provide safe, effective decontamination of medical devices.

Rationale:

NB: Practices are not required to have decontamination processes in place. If the practice does not perform decontamination themselves, most of this section will be scored not applicable, except for the cleaning of instruments.

Decontamination is a general term used to describe processes that include cleaning, disinfection and sterilisation. (Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework, pg. 62).Although many practices may not disinfect or sterilise their own equipment, all practices with reusable devices must implement safe practices for cleaning these devices prior to handing them over to the service provider to sterilise them.

Where a practice does conduct sterilisation in-house, it must be done in a manner that sterilises the devices effectively and ensures the safety of personnel responsible for the decontamination process.

Decontamination processes must be documented, personnel must be trained on the implementation of the processes and refresher training should be attended on a regular basis by staff responsible for decontamination. Oversight of the processes should be allocated to a single individual who will be responsible for ensuring that standard operating procedures are updated, new personnel are orientated and all personnel receive ongoing in-service training for decontamination processes. Staff should be trained in accordance with the process in place at the practice, i.e. the full decontamination process for practices that sterilise their own instruments, or only cleaning processes for practices who contract with a service provider. Where only single use devices are used, training requirements for decontamination processes will be not applicable.

Practices that do not sterilise their own instruments must either have a service level agreement in place with a sterilisation service provider or use disposable instruments. Where practices do not need to sterilise their own instruments, such as when only disposable instruments are used, this standard becomes not applicable.

Instruments can be sterilised at low cost using either bleach or hydrogen peroxide. Instructions are as follows:

0.1% Chlorine solution: If boiled water is used to make the solution, 0.1% chlorine (1-part bleach to 45 parts water) may be used for HLD. If not, one should use 0.5% solution (one-part bleach to nine parts water). The contact time required is 20 minutes. The solution is very corrosive to stainless steel. After disinfection, instruments should be thoroughly rinsed with boiled water and then air-dried or dried with a sterile cloth before use. The shelf life of prepared solution is one week.

6% Hydrogen peroxide solution: It can be prepared by adding one part of a 30% solution to four parts of boiled water; the contact time is 30 minutes. After disinfection, instruments should be thoroughly rinsed with boiled water and then air-dried or dried with a sterile cloth before use. However, this solution will damage the external surfaces of rubbers and plastics, and corrode copper, zinc, and brass instruments after prolonged use.

IARC Screening Group Chapter 14: Decontamination, cleaning, high-level disinfection and sterilization of /instruments used during the diagnosis and treatment of cervical neoplasia http://screening.iarc.fr/colpochap.php?lang=1&chap=14 accessed 19 Jan 2017

Measures

1. There is a designated individual responsible for overseeing the decontamination service. ***DOCUMENT***

   Explanatory note: In a single-handed practice which does not employ any other staff, this will be the general practitioner.

   Not applicable: Where single use devices are used.

2. The designated individual has undergone training in decontamination processes. ***DOCUMENT***

   Explanatory note: All staff must know how to clean used medical devices. Where sterilisation is not done, training on cleaning only will be required

   Not applicable: Where single use devices are used.

3. CHECKLIST: A standard operating procedure for decontamination processes is available. ***DOCUMENT***

Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained. ***DOCUMENT***

a. Segregation of clean and dirty sections in the decontamination area

b. Safe handling of used instruments

c. Manual cleaning and drying of instruments.

d. Monitoring effectiveness of the decontamination equipment

Not applicable where no decontamination equipment is used

e. System for investigating sterilisation failures

Not applicable where sterilisation is not done at the practice

f. Maintenance of decontamination equipment

Not applicable where no decontamination equipment is used

4. Personnel responsible for decontamination of reusable instruments have received training on decontamination processes. ***DOCUMENT***

Explanatory note: All staff undertaking this task must have received formal training, either as part of their undergraduate qualification or by attending a course in decontamination. See page 181 of the Practical Manual for implementation of the National Infection Prevention and Control Strategic framework.

Not applicable: Where single use devices are used.

5. CHECKLIST: Personnel responsible for decontamination are able to explain the procedure by which used instruments are sterilised. ***STAFF INTERVIEW***

Instructions: Interview up to up to three members of staff responsible for this process and ask them to describe how this task is performed. Score 1 for each item mentioned in the list below, or 0 if it is not mentioned. In practices where only one or two members of staff are responsible for this process, it is not necessary to document three responses. Not applicable where sterilisation is not done at the practice.

a. Personnel must wear personal protective equipment including goggles, mask, household gloves and plastic aprons.

b. Instruments are unpacked with care, checked against the list for the tray or pack and inspected for damage.

Explanatory note: To meet this requirement, packs must be dry when they are stored, shelves must be off the floor, the packaging must be: This will only be relevant for practices offering minor surgical procedures.

c. Instruments are opened and cleaned by soaking them in an enzymatic cleaner solution.

d. Instruments are rinsed thoroughly in hot water.

e. The washer and/or disinfector is used as per manufacturer's instructions and instruments are then dried.(*Not applicable where the practice does not use this machine)*

The following aspects are only measured in practices who undertake sterilisation of their own instruments:

f. The preparation area for packing is kept clean with a clean instrument tray liner.

g. The tips of delicate/sharp instruments are covered with silicone tubing to prevent damage.

h. Instruments are packed according to the control slip specifically for the autoclave in use.

i. The control slip is signed and dated.

j. An autoclave indicator slip (policeman) is placed in all sets and towels.

k. Packing is done in wraps or containers according to manufacturer's instructions and SANS standards (ISO 11607)

l. Each pack and set is marked with a tracking system indicator which identifies and records all items sterilised to facilitate recall of the pack or set when necessary.

m. Packs are stored in a manner which ensures the integrity of the materials.

Explanatory note: *To meet this requirement, packs must be dry when they are stored, shelves must be off the floor, the packaging must be intact and there must be adequate ventilation in the storage area.*

6. All sterilisation failures are investigated to determine the cause of the failure. ***DOCUMENT***

   Explanatory note: *Documented evidence of investigation of sterilisation failures must be available.*
   Not applicable: *Where there have been no failures, or where sterilisation is not done at the practice.*
7. Where necessary, corrective measures are implemented to prevent recurrence of these incidents. ***DOCUMENT***

   Explanatory note: *Documented evidence of steps taken to prevent further incidents of sterilisation failure from the same cause must be available.*
   Not applicable: *Where there have been no failures, or where sterilisation is not done at the practice.*
8. Where sterilisation services are outsourced, there is a service level agreement with the service provider. ***DOCUMENT***

   Explanatory note: *A copy of the service level agreement must be available at the practice.*
   Not applicable: *Where service is not outsourced.*
9. Adherence to the indicators of the service level agreement is monitored. ***DOCUMENT***

   Explanatory note: *The practice must have a checklist completed following each incident of service delivery to check that all specified criteria in the agreement have been met.*
   Not applicable: *Where service is not outsourced.*
10. Action is taken when the indicators of the service level agreement are not met. ***DOCUMENT***

    Explanatory note: *Where the service is not delivered in accordance with the agreement, there must be evidence that this is discussed with the service provider to ensure delivery of adequate, safe services.*
    Not applicable: *Where service is not outsourced, or where there have been no breaches of contract.*

Criterion 5: The practice must manage and maintain the equipment used for decontamination to ensure sustainability of decontamination services.

Measures:

1. Calibration records are maintained for all decontamination equipment. ***DOCUMENT***

   Explanatory note: *There must be a register where all decontamination equipment is recorded. The register should indicate the required calibration intervals, the last calibration date and the next date at which calibration should be done.*
   Not applicable: *Where decontamination is not done at the practice.*
2. There is a planned maintenance schedule for each machine. ***DOCUMENT***

   Explanatory note: *There must be a register where all decontamination equipment is recorded. The register should indicate the required service intervals, the last service date and the next date at which the service is due. This can be the same register used for recording calibration events.*
   Not applicable: *Where decontamination is not done at the practice.*
3. Machines are serviced in accordance with the maintenance schedule. ***DOCUMENT***

   Explanatory note: *The register will be reviewed to confirm that servicing has been done in accordance with the manufacturer's instructions.*
   Not applicable: *Where decontamination is not done at the practice.*
4. Personnel responsible for decontamination have received training to ensure that machines are used in accordance with the manufacturer's instructions. ***DOCUMENT***

   Explanatory note: *The training can be done by the company from which the equipment was purchased or can be done inhouse. The purpose of the training is to ensure the machine is used properly to reduce the risk of decontamination failures, harm to staff or damage to the equipment. Documented records can include but are not limited to attendance registers, certificates of training or signed confirmation of training received.*
   Not applicable: *Where decontamination is not done at the practice.*

Criterion 6: The practice must have systems in place to keep the environment clean by -

(i) ensuring that cleaning personnel are trained to clean all areas.

(ii) implementing pest control measures in all areas; and

(iii) monitoring the performance of the cleaning services and take corrective measures where applicable.

Measures:

1. There is a nominated individual responsible for overseeing the cleaning service. ***DOCUMENT***

   Explanatory note: *In a single-handed practice which does not employ any other staff, this will be the general practitioner.*

   Not applicable: *Never*

2. CHECKLIST: Cleaning materials of verifiable quality are available as listed below. ***OBSERVATION***

   Instructions: Check the available cleaning materials and storage facilities. Score 1 if the item is present and 0 if it is not present. Score N/A if the item is not part of the routine supplies of the health establishment.

   a. Chlorine compounds – sodium hypochlorite (bleach)
   b. Alcohol cleaning agent (for disinfection of surfaces)
   c. Wet polymer for polishing floors (where applicable)
   d. Plain liquid soap or detergent

      Explanatory note: *This can include but is not limited to dishwashing liquid or ammonia-based cream cleaner*

3. CHECKLIST: Cleaning personnel are trained on the topics listed below as a minimum. ***DOCUMENT***

   Instructions: Review in-service training records to verify whether cleaning personnel have received training on the aspects listed below. As a minimum, training on these aspects must be provided as part of the orientation of cleaning staff. Score 1 if training has been provided and 0 if not provided. Where the service is outsourced the service provider/contractor must provide this information to the practice.

   a. Hand hygiene
   b. The use of personal protective equipment
   c. Standard precautions
   d. Sharps safety
   e. The management of blood and body fluid spills
   f. The management of chemical spills
   g. Correct dilution of cleaning solutions

4. Cleaning materials are stored safely. ***OBSERVATION***

   Explanatory note: *Cleaning materials should be stored where they are not accessible to patients, ideally behind a locked door when not in use.*
   Not applicable: Never

5. Cleaning materials are clearly labelled. ***OBSERVATION***

   Explanatory note: *Cleaning materials must be clearly labelled to prevent accidents, e.g. accidental ingestion or incorrect use of cleaning materials.*

   Not applicable: *Never*

6. Material Safety Data Sheets (MSDS) leaflets are available for all cleaning materials. ***OBSERVATION***

   Explanatory note: *MSDS leaflets must be easily accessible to facilitate rapid response to accidents.*
   Not applicable: *Never*

7. Daily inspections of clinical areas are conducted to ensure that cleaning has been performed. ***DOCUMENT***

   Explanatory note: *The nominated individual responsible for overseeing the cleaning service must check all patient care areas to ensure that they have been thoroughly cleaned. This is to prevent user or staff harm due to health care associated infections. These checks must be document in a checklist or similar.* *Not applicable:* *Never*

8. CHECKLIST: All service areas in the practice are clean. ***OBSERVATION***

Instructions: Use the checklist below to check whether the service areas are clean. Score 1 if the area is clean and score 0 if it is not clean. Score NA (not applicable) if the facility has fewer than the areas indicated, or for any aspects not found in the area.

a. Toilets
b. Waiting areas
c. Consulting rooms
d. Treatment rooms
e. Kitchen rooms
f. Storage rooms

The following will be checked in each area, as appropriate to fixtures and fittings present in each area. Score NA if the aspects are not found in the area assessed.

a. Windows are clean.
b. Window sills are clean.
c. The floor is clean.
d. Skirting boards are free of dust.
e. The countertops are clean.
f. The door handles are clean.
g. Mirrors are clean.
h. Walls are clean.
i. Bins are not overflowing.
j. Bins are clean.
k. The area is odour-free.
l. The area is free of cobwebs.
m. Toilets/urinals are clean.
n. Sanitary bins are not overflowing.
o. Sanitary bins are clean.

9. The practice is inspected for pest infestation on a regular basis. ***DOCUMENT***

Explanatory note: Regular pest control will ensure that infestations of the building are prevented. The health establishment must have a documented schedule for pest control. Services must be delivered according to schedule. where there is no evidence of pests documented confirmation of the visit and inspection must be available. For health establishments that are not provided with an invoice, evidence of pest control can include signatures in the visitor's book or similar proof.
Not applicable: Never

10. Pest control interventions are implemented when required. ***DOCUMENT***

Explanatory note: In cases where the service provider has found evidence of pests, fumigation or other relevant treatment is done as required.
Not applicable: Never

Sub-domain 4: Waste Management

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

Criterion 1: 9.(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

1. CHECKLIST: Waste containers are available in the consulting rooms. ***OBSERVATION***

   Instructions: Use the checklist below to check whether health care risk waste is managed as required. Score 1 if the aspect is compliant and score 0 if it is not compliant. In practices where the examination is adjacent to the consulting room, medical waste and sharps containers will be evaluated in the examination room.

   a. Sharps container
   b. General waste container
   c. Medical Waste container

2. CHECKLIST: Waste containers are available in the non-clinical areas ***OBSERVATION***

   Instructions: Use the checklist below to check whether health care risk waste is managed as required. Score 1 if the aspect is compliant and score 0 if it is not compliant. If disposable boxes for sanitary waste with gel granules in the bottom of the box for treating the waste are used, no bag is required and the practice can score 1.

   Waiting area

   a. General waste container
   b. Bins for general waste are lined with appropriate coloured bags (Black, beige, white or transparent packaging can be used.)

   Toilets

   a. General waste container
   b. Bins for general waste are lined with appropriate coloured bags (Black, beige, white or transparent packaging can be used.)
   c. Sanitary disposal bins with a fitting lid or healthcare risk waste box with a lid.
   d. Sanitary disposal bins or boxes lined with red plastic bags.
   e. Sanitary disposal bins or boxes are clean and not overflowing.

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

Measures:

1. CHECKLIST: Standard operating procedures for waste management are available. ***DOCUMENT***

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

   a. Segregation of waste
   b. Handling and transport of waste
   c. Storage of waste
   d. Disposal of waste

2. Waste is segregated according to practice standard operating procedures. ***OBSERVATION***

   Explanatory note: *Inspectors will look in waste containers for different kinds of waste to confirm that staff discard waste into the correct containers.*
   Not applicable: *Never*
3. There is a service level agreement in place with an accredited waste management service provider. ***DOCUMENT***

   Explanatory note: *A copy of the service level agreement must be available at the practice.*
   Not applicable: Never
4. Adherence to the indicators of the service level agreement is monitored. ***DOCUMENT***

   Explanatory note: *The practice must have a checklist completed following each incident of service delivery to check that all specified criteria in the agreement have been met.*
   Not applicable: *Never.*
5. Action is taken when the indicators of the service level agreement are not met. ***DOCUMENT***

   Explanatory note: *Where the service is not delivered in accordance with the agreement, there must be evidence that this is discussed with the service provider to ensure delivery of adequate, safe services.*
   Not applicable: *Where there have been no breaches of service level agreement.*

Sub-domain 5: Adverse events

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

Criterion 1: 21.(2)(a) The health establishment must have a register for all adverse events.

1. CHECKLIST: An adverse event reporting register is available in the practice. ***DOCUMENT***

   Instructions: Adverse events are a subset of patient incidents. The National Guideline for Patient Safety Incident Reporting and Learning defines an adverse event (harmful incident) as follows: An incident that results in harm to a health care user that is related to medical management, in contrast to disease complications or underlying disease. The adverse event register can be manual or electronic and must include columns for the aspects listed below. Score 1 if the aspect is included in the register and 0 if it is not.

   a. Name and surname of affected person
   b. Date of incident
   c. Summary of incident
   d. Findings of the investigation of the incident
   e. Recommendations (if available)
   f. User outcome (if available)

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

Rationale

Systems and processes in the practice should be designed (and redesigned in response to experience) in order to minimise the likelihood of adverse events occurring, and minimise the impact of the adverse event, should it occur.

This can be achieved by learning from the experience of others (i.e. benchmarking, following evidence-based practice guidelines for clinical and non-clinical processes, literature reviews etc.) and by learning from the practice's own experience.

In order to achieve the latter effectively, it is beneficial to record adverse events, aggregate and analyse the data and interpret the findings. This requires a system of reporting and recording adverse events and a designated

individual or team to investigate each event, aggregate the findings of multiple events over time, identify common underlying causes, develop and implement action plans to prevent recurrence of the event and evaluate the effectiveness of these action plans.

Effective action plans should be incorporated into the standard operating procedures of the practice and personnel should be trained on the revised method of performing the procedure(s).

Measures:

1. CHECKLIST: The management of adverse events is guided by standard operating procedures, which include the details listed below as a minimum. ***DOCUMENT***

   Instructions: Read through the standard operating procedure and confirm whether the aspects listed below are included and explained in the standard operating procedure. Score 1 if the aspect is included and explained and 0 if not included or not explained

   a. Identification of adverse events
   b. Classification of adverse events
   c. Forms to be completed when reporting an adverse event.
   d. The process to be followed for escalation and communication of adverse events.
   e. How to investigate an adverse event
   f. How to respond to the user and family to whom a patient safety incident has occurred.
   g. The process to be followed to inform the user and family to whom an adverse event has occurred.
   h. The monitoring and analysis of reported adverse events to identify patterns and trends.

2. Personnel receive training on the management of adverse events. ***DOCUMENT***

   Explanatory note: Documented records of training must be available. Documented records can include but are not limited to attendance registers, certificates of training or signed confirmation of training received.

   Not applicable: Never

3. There is evidence of implementation of action plans to minimise the risk of recurrence of reported adverse events. ***DOCUMENT***

   Explanatory note: Documented evidence can include but is not limited to documented evidence of training of staff regarding the actions to be implemented, evidence of monitoring that required changes in activities are adhered to or repeat data collection to determine any change in the indicators selected as evidence of successful implementation of the changes.
   Not applicable: Where no adverse events have occurred in the 12 months prior to the inspection.

4. The effectiveness of implemented action plans is evaluated. ***DOCUMENT***

   Explanatory note: This will be a data collection process to determine whether implementation of the action plan has delivered the desired change in outcome.
   Not applicable: Where no adverse events have occurred in the 12 months prior to the inspection.

5. Administrative personnel can describe how urgent matters can be communicated to clinical personnel. ***STAFF INTERVIEW***

   Explanatory note: This process is essential to prevent avoidable adverse events. There should be a standard process to communicate such information known to all staff members.
   Not applicable: Never

DOMAIN 3: CLINICAL SUPPORT SERVICES

Sub-domain 1: Medicines and Medical supplies

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

Criterion 1: 10.(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

Rationale

The implementation of an effective stock control system can prevent wastage of medicines with the consequent wastage of funds. The ordering and storage of medicine is a vital aspect of good medicine management and essential to the provision of good quality user care.

Medicine should be ordered from licensed suppliers only.

Measures:

1. CHECKLIST: A documented stock control system for medicines and/or medical supplies is implemented. ***DOCUMENT***

   Instructions: Read through the document and confirm whether the aspects listed below are included and explained. Score 1 if the aspect is included and explained and score 0 if it is not included or included but not explained.

   a. Minimum and maximum or re-order or preferred stock levels
   b. Tracking of stock balance
   c. Ordering of stock
   d. Correlating goods received with goods ordered.
   e. Quality check of goods received.
   f. Issuing of stock
   g. Checking of expiry dates
   h. Stock rotation

2. There is evidence that a stock-take was done in the last 12 months. ***DOCUMENT***

   Explanatory note: Documented evidence of a formal stock take will be required, indicating that the stock take has been completed in the last 12 months. The stock taking report should detail amongst others-expired medicine and its monetary value.
   Not applicable: Never

Criterion 2:10.(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

Rationale

Medicine will lose its potency if not stored under the correct conditions, particularly thermolabile medicines. The result of using inactive medicine can be catastrophic, such as inactive insulin or vaccines, which can be life-saving. All medicines must therefore be stored in accordance with the manufacturer's instructions from the point of manufacture to the point of administration to a user. Where medicines have been exposed to temperatures outside the recommended range for a duration long enough to cause inactivation according to the manufacturer's instructions, they should be disposed of in accordance with local policy.

Practices which store thermolabile medicines but do not have a generator must have contingency plans in place to maintain the cold chain during power failures.

Measures:

1. The dispensary, medicine store or medicine room is fitted with security measures. ***OBSERVATION***

   Explanatory note: Each dispensary, store or medicine room will require unique security measures based on the setting and infrastructure of the practice. The measures implemented should guard against unauthorised entry and theft. These measures can include but are not limited to burglar bars, security doors, functional alarm system and/or CCTV. A combination of these and / or other security measures may be required to meet the intent of the measure.
   Not applicable: Where the practice does not store medicine for dispensing.

2. Access to the dispensary, medicine store or medicine room is controlled at all times. ***OBSERVATION***

   Explanatory note: The door and burglar door/security door to the dispensary must be lockable. Observe during the inspection if this is kept locked at all time. The purpose of access control is to prevent unauthorised access to medication.
   Not applicable: Where the practice does not store medicine for dispensing

3. There are no cracks, holes or signs of water damage in the medication storage area. ***OBSERVATION***

   Explanatory note: The inspector will evaluate the area / room where medicine is stored for these deficiencies.
   Not applicable: Where the practice does not store medicine for dispensing
4. There is sufficient space in the dispensary, medicine store or medicine room. ***OBSERVATION***

   Explanatory note: The inspector will check that medicine is not stored up to the ceiling or against windows. There should be sufficient space to move around the storage area without the risk of injury while attempting to locate and retrieve medicine.
   Not applicable: Where the practice does not store medicine for dispensing
5. The storage area is clean and tidy. ***OBSERVATION***

   Explanatory note: The area must be free from dirt, dust and stains. Check if the shelves, floors and items in the store room are free from dirt, dust and stains. A clean storage area is required to adhere to infection control principles. A tidy storage area will assist in the identification of required medicines and stock control measures, such as cycle counts and checking of expiry dates.
   Not applicable: Where the practice does not store medicine for dispensing
6. Medicines are stored neatly on shelves according to a classification system. ***OBSERVATION***

   Explanatory note: The inspector must ascertain the classification system used by the practice, including but not limited to storage by formulation, physiological system, alphabetical order, or another method, and confirm that the selected system is followed. Where medication is not stored in accordance with a classification system, but stacked on shelves at random, this measure will be scored non-compliant.
   Not applicable: Where the practice does not store medicine for dispensing
7. There are no medicines stored in direct contact with the floor. ***OBSERVATION***

   Explanatory note: There are no medicines/ medicine boxes stored in direct contact with the floor. Acceptable storage methods will include, but are not limited to, shelves, cupboards, or storage on wooden palisades.
   Not applicable: Where the practice does not store medicine for dispensing
8. There is no evidence of pests in the dispensary, dispensary store or medicine room. ***OBSERVATION***

   Explanatory note: The Inspector will observe the presence of any pests or evidence of pests, such as droppings or damage caused by pests.
   Not applicable: Where the practice does not store medicine for dispensing
9. Medicines are packed according to FEFO (First Expired, First Out) principles. ***OBSERVATION***

   Explanatory note: Items with the shortest expiry date should be stored at the front of the shelf so that they are picked and dispensed first.
   Not applicable: Where the practice does not store medicine for dispensing
10. Medicines are issued according to FEFO (First Expired, First Out) principles. ***OBSERVATION***

    Explanatory note: Medicines with the shortest expiry date, i.e. which will expire first (but not expired yet), are issued first. The routine issue of stock with the shortest expiry date first will prevent stock expiring on the shelves. However, care must be taken by the dispenser to ensure that the course of medicines dispensed will be completed by the user prior to the expiry date.
    Not applicable: Where the practice does not store medicine for dispensing
11. There is a procedure to check expiry dates on medicine in the medicine room. ***OBSERVATION / DOCUMENT***

    Explanatory note: A standard operating procedure should be available which describes the process to be followed to check expiry dates on medicines. The procedure should specify the method/s to be used to check expiry dates (such as a colour coded system for items that expire in a certain month, documentation of expiry dates in a book that is monitored daily, or any other system) as well as the frequency with which the checks should be performed.
    Not applicable: Where the practice does not store medicine for dispensing
12. There are no expired medicines observed in the dispensary, dispensary store, medicine room or medicine cupboard. ***OBSERVATION***

    Explanatory note: "Expiry date" means the date up to which a medicine will retain the strength and other properties which are mentioned on the label which strength and other properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used (Medicines and Related Substances Act 101 of 1965 - Regulations and Notices - Government Notice R510).
    Not applicable: Where the practice does not store medicine for dispensing
13. CHECKLIST: The cold chain for thermolabile medicines is maintained. ***DOCUMENT***

    Instructions: Use the checklist below to check whether the cold chain for vaccines is maintained. Score 1 if the aspect below is met and score 0 if it is not met.

    a. Each refrigerator has a functional temperature monitoring device.

       Explanatory note: Each refrigerator must have a working thermometer. This should be placed inside the refrigerator, next to the medication stored in the refrigerator so that the temperature recorded accurately reflects the temperature of the medication.

b. The temperature inside the refrigerator is measured twice a day and recorded on a chart.

Explanatory note: A temperature monitoring sheet must be available which indicates that the temperature is monitored twice a day - in the morning and in the afternoon. The monitoring sheet should be marked to indicate the acceptable temperature range. For refrigerators with electronic monitoring devices, historic electronic readings must be made available for review.

c. The temperature in the refrigerator is maintained between 2 and 8°C.

d. No medicines or vaccines are stored in the door of the refrigerator.

e. There is a cooler box for storage of thermolabile medicines and vaccines if needed.

f. Ice packs are available for use in the cooler box

g. There is a functional thermometer for use in the cooler box

Criterion 3: The practice must implement controls for the management, recording and distribution of medicines listed in Schedules 5 and 6 of the Medicines and Related Substances Act.

Rationale

Legislative requirements regarding Schedule 5 and 6 medicine must be met. This provides protection for the health care provider, the user, the practice and the potential recipients of illegally obtained medicine. This legislation must be strictly enforced and adherence to legislative requirements must be monitored within the practice.

Measures:

1. Schedule 5 and 6 medication stored in the doctor's bag is kept in a locked container. ***OBSERVATION***
2. Schedule 5 and 6 medication is stored at the practice is in a locked cabinet which cannot be physically removed from the premises. ***OBSERVATION***

Explanatory note: This measure will only apply to practices with a dispensing license, who stock Schedule 5 and 6 medication. In such practices, the medication must be stored in accordance with Good Pharmacy Practice.

3. CHECKLIST: Entries in the schedule 5 and/or 6 register are complete and correct, in accordance with the relevant legislation. ***DOCUMENT***

a. Date of receipt

b. Quantity received.

c. Date of issue

d. Name of user

e. The quantity issued.

f. The name of the prescriber

g. The name, signature and designation of person who issued the medicine.

h. Balance totals are recorded at the frequency defined in practice protocols

Explanatory note: This must not be less frequently than specified in Good Pharmacy Practice, i.e. last day of March, June, September and December of each year.

i. Balance totals are signed and countersigned by the health care providers responsible for checking.

j. Recorded balance totals are correct.

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

Criterion 1: The practice must ensure that medication is prescribed in accordance with legislation and best practice guidelines.

Measures:

1. CHECKLIST: Users are provided with all relevant information when medication is prescribed. ***USER INTERVIEW***
    a. How to take the medicine
    b. When to take the medicine
    c. The duration of treatment
    d. Potential side effects of the medicine prescribed
    e. Potential interactions with other prescribed medicines, where relevant
    f. The potential for interactions with other medicines, including over the counter medicines, traditional medicines and remedies used by alternative medicine practitioners
    g. Relevant adverse drug reactions associated with the medicine prescribed.
    h. The action to be taken should they experience an adverse drug reaction.
    i. When to return for review

Criterion 2: The practice ensures that medication is dispensed in accordance with legislation, and to minimise the risk of user harm.

Measures

1. Where a practice dispenses medication, the necessary license has been obtained in accordance with Regulation 11(a) of the General Regulations made in terms of the Medicines and Related Substances Act, 1965(Act no. 101 of 1965): Amendment. ***DOCUMENT***
2. The user is given the opportunity to ask questions about the medicine dispensed. ***USER INTERVIEW***
3. CHECKLIST: Medicines are labelled in accordance with applicable procedures. ***OBSERVATION***

    Instruction: Request permission from three users to assess the medicine that has been dispensed to them on the day of the inspection. Verify whether the medicine dispensed complies with the requirements below. Score 1 if the aspect is compliant and 0 if not compliant.

    a. Labels of dispensed medicines are clear and legible.
    b. The label is attached to the medicine and does not obstruct or cover the expiry date.
    c. The label includes the name of the medicine.
    d. The label includes the name of the user.
    e. The label includes the directions for use of the medicine.
    f. The label includes the address of the health establishment supplying the medicines.
    g. The label includes the date the medicine was dispensed.
    h. The label includes the date of expiry of the medicine.

Criterion 3: The practice ensures that medicines are administered safely in accordance with standard operating procedures to minimise adverse events.

Measures:

1. CHECKLIST: A standard operating procedure for the administration of medicine to users is available. ***DOCUMENT***
    a. The five “rights” are checked prior to administration (right user, right drug, right dose, right route, right time)
    b. The date and time of administration are recorded.

c. The route and dose of administration are recorded in the user record.

d. The person administering the medicine signs to confirm that the medicine was given.

e. The person administering the medicine records their name, designation and qualifications next to their signature.

2. There is a standard operating procedure detailing the response required should the user experience a serious adverse drug reaction to the medication administered. ***DOCUMENT***

Explanatory note: A serious adverse drug reaction is defined by SAHPRA as any untoward medical occurrence that at any dose:

- *results in death.*
- *is life-threatening.*
- *requires hospitalisation of the user or prolongation of existing hospitalisation.*
- *results in an abortion, premature delivery, congenital anomaly/birth defects.*
- *results in persistent or significant disability/incapability; or*
- *is a medically significant/ important event or reaction*

Sub-domain 2: Diagnostic services

Standard 1:7(2)(b) The health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 1: The practice has access to reliable diagnostic services to ensure accurate diagnosis and management of users.

Measures

1. The practice can refer users for diagnostic investigations. ***DOCUMENT***

Explanatory note: This can include a list of service providers used by the practice

Sub-domain 2: Medical equipment

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

Criterion 1: 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

Measures:

1. CHECKLIST: Functional essential medical equipment is available. ***OBSERVATION***

Instructions: Use the checklist below to check whether essential equipment is available and functional in the practice. Score 1 if the item listed is available and functional and score 0 if it is not available or functional. Please note that practices will only be expected to have the equipment for services that they provide. For example, where health care providers do not provide sigmoidoscopy services, a flexible sigmoidoscope will be scored not applicable.

a. Stethoscope
b. Blood pressure machine (manual or electronic) with adult and paediatric cuffs
c. Stadiometer (to measure height)
d. Adult weighing scale
e. Baby weighing scale
f. Diagnostic sets (wall mounted or portable)
g. Tape measure

h. Thermometer (clinical)

i. Gestation calculator

j. Foetal stethoscope or handheld Doppler

Explanatory note: A sonar machine can be used to determine foetal heart activity and rate, as long as there are no excess costs charged to the user relative to the use of a foetal stethoscope or doppler

k. Eye chart (Snellen or equivalent), alphabet/illiterate

l. Patella hammer

m. Tuning fork

n. Cusco speculum or disposable vaginal speculum

Not applicable: Where the practice does not provide cervical screening services

o. Cervi brush or Ayre spatula

Not applicable: Where the practice does not provide cervical screening services

p. ECG machine(where applicable)

q. Examination couch/table

r. Steps

s. Ceiling or wall mounted or portable examination light.

t. Peak flow meter-adult and paediatric

u. Nebulizer – electronic with additional accessories

v. Ear syringe (normal 50ml syringe with IV catheter can be used)

w. Crocodile forceps

x. Dressing cart/trolley

y. Glucometer

z. Portable oxygen cylinder or oxygen concentrator

aa. Fridge for storing medication and vaccines

bb. Nasal speculum

Not applicable: Where the practice does not provide ENT services

cc. Vulsellum forceps

Not applicable: Where the practice does not provide ENT services

2. CHECKLIST: The room used for minor surgical procedures is equipped with the items listed below. ***OBSERVATION***

Instructions: Use the checklist below to check whether essential equipment is available and functional in consultation or examination rooms. Select the number of areas to review as indicated in the scoring columns. Score 1 if the item listed is available and functional and score 0 if it is not available or functional. Where the practice does not offer minor surgical procedures, this measure will be scored not applicable. Only equipment necessary for the procedures offered at the practice will be required. For example, where minor ocular procedures are not provided, Meibomian speculum will not be required.

A. GENERAL

a. Adequate lighting

b. A mechanism for summoning assistance

c. Clean linen

d. Hand wash basins

e. Disinfectant for skin preparation, e.g. chlorhexidine or similar

f. Access to sterilisation and disinfecting facilities

g. A safe storage area for medicine and surgical supplies

h. Local and regional anaesthetic (such as lignocaine, bupivacaine, or similar)
i. Oxygen supply
j. Iris scissors
k. Suture material
l. Electrocautery machine
m. Crocodile forceps
n. Scalpel with disposable blades
o. Toothed and non-toothed forceps
p. Suture holder
q. Appropriate dressings
r. Appropriate couch for procedures
s. Steps
t. Mosquito clamps
u. Dissecting scissors

B. SUTURING TRAY

v. Small stitch tray
w. Stitch scissors
x. Fine toothed forceps
y. Non–toothed forceps
z. Blades - BP Handle size 4 or 5
aa. Mosquito straight
bb. Mosquito curved
cc. Artery forceps straight
dd. Artery forceps curved
ee. Needle holder
ff. Swab holder
gg. Mayo safety pin
hh. Gillies Forceps
ii. Stainless steel Kidney dishes
jj. Round stainless-steel dishes

C. REQUIRED ONLY WHERE RELEVANT SERVICES OFFERED

<u>For ophthalmic procedures:</u>

kk. Topical anaesthetic for use in eyes
ll. Meibomian speculum

<u>For ENT procedures:</u>

mm. Oral anaesthetic spray for anaesthetising throat when inspecting for e.g. foreign body swallowed.
nn. Manual ear syringe/vacuum
oo. Thudicum' s speculum for inspecting nose.
pp. Ribbon gauze for packing nose
qq. Nasal catheter or Foley's catheter for nose bleeds unresponsive to packing alone

<u>For orthopaedic procedures:</u>

rr. POP scissors or rotary cutter

ss. X-Ray viewing box

For wart removal:

tt. Sharp curette for curettage of plantar warts

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

Criterion 1: The practice must ensure that medical equipment is safe for users and used in accordance with the manufacturer's specifications.

Rationale

Safety of medical equipment relates to the functioning of the equipment as well as infection control measures required.

In order to ensure medical equipment is available and functional, preventive and reactive maintenance services must be in place. Documented evidence of implementation of the system must be available at the practice.

In order to ensure that equipment remains functional, users of the equipment must receive instruction in the correct use of the equipment. New personnel should receive training in the use of equipment relevant to their role as part of their orientation training. When new equipment is procured or investigation of adverse events indicates that incorrect use of machines is contributing to adverse events, in-service training should be provided to ensure that personnel are correctly informed regarding the use of the equipment. Records for servicing and/or calibration will be required.

Measures:

1. Medical equipment is maintained in accordance with a planned preventive maintenance schedule. ***DOCUMENT***

   Explanatory note: Preventive maintenance refers to regularly scheduled maintenance activities to help prevent unexpected failures. A schedule for servicing of each item of medical equipment should be compiled in accordance with the manufacturers' guidelines. The practice manager or equivalent should ensure that equipment is serviced according to schedule. The schedule can be paper-based or electronic. This will include calibration of equipment used for measurement, e.g. blood pressure machines, weighing scales, etc.
   Not applicable: Never

2. There is access to a corrective maintenance service when equipment malfunctions. ***DOCUMENT***

   Explanatory note: Corrective maintenance refers to repairing equipment in response to a malfunction or failure. Preventive maintenance should reduce the need to access such services, which prevents patient safety incidents, loss of availability of services and income, and inconvenience. Preventive maintenance can reduce overall running costs by avoiding costly repair bills and prolonging the useful life of equipment.
   Not applicable: Never

3. Personnel are trained to use the equipment relevant to their role. ***DOCUMENT***

   Explanatory note: Medical equipment is expensive and can be damaged if not used correctly. It is therefore important that those who use equipment have been trained to ensure that they are aware of how to use the equipment correctly. This can be part of orientation for new personnel and in-service training for all personnel when new equipment is purchased.
   Not applicable: Never

4. There is a system for ensuring that only competent health care providers are permitted to use medical equipment. ***DOCUMENT***

   Explanatory note: Before health care providers are allowed to use equipment, they should be assessed to ensure they use the equipment correctly. This can be done informally for simpler equipment such as dynamaps, but where more complex equipment is used, such as defibrillators, a formal assessment should be undertaken and documented.

   Not applicable: Never

DOMAIN 4: GOVERNANCE AND HUMAN RESOURCES

~~Sub-domain 1: Governance~~

~~Standard 1: 18.The health establishment must have a functional governance structure with written Terms of Reference.~~

Sub-domain 2: Human resources management

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

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

Measures:

1. Health care personnel have job descriptions which formally detail their roles, responsibilities, activities and duties. ***DOCUMENT***

   Explanatory note: Job descriptions should be included in personnel files, signed by the employer and employee and updated as part of the performance review process, or in response to changing needs within the practice.

2. CHECKLIST: New personnel undergo orientation to the practice which includes the topics listed below. ***DOCUMENT***

   Instructions: Review orientation records at the practice and confirm that the topics listed below have been addressed. New employees should indicate that the information has been shared, either by signing relevant documentation to indicate that they have read material provided as part of an orientation pack, or by means of signing to confirm attendance at training sessions. This measure will be scored not applicable if the practice has not employed any new personnel in the 12 months prior to the inspection.

   a. Familiarising new personnel with policies and/or related standard operating procedures

      Explanatory note: This will include both the general standard operating procedures applicable to all personnel and the standard operating procedures relevant to the individual's role within the practice.

   b. Health and safety of users and personnel

   c. Quality of clinical care

   d. Quality improvement methodology

      Guideline Quality improvement is a systematic approach to addressing the deficiencies identified during quality assurance processes within health establishments. Quality assurance focuses on the quality control measures and identifies any deficiencies within these controls.

   e. Infection Prevention and Control

   f. Users' rights

3. New personnel are oriented within 7 days of joining the practice. ***DOCUMENT***

   Explanatory note: Orientation ensures new personnel are fully aware of their role within the practice, understand the way the practice operates and the correct ways to perform key tasks, and can keep themselves, users and expensive assets at the practice safe.

   Not applicable: Where the practice has not employed new employees in the 12 months prior to the inspection.

4. The practice has in the previous 12 months provided in-house work integrated learning sessions, informed by the quality improvement and peer review process. ***DOCUMENT***

   Explanatory note: Evidence to support this process can include the means by which learning topics have been identified, a schedule for training and attendance registers.

   Not applicable: Never

5. The practice identifies educational needs based on practice and personnel development needs. ***DOCUMENT***

Explanatory note: CPD attendance and other training opportunities should be selected to ensure that users receive optimum care. Training sessions should therefore be selected to meet identified training needs within the practice, or areas of interest for personnel. These training needs can be to offer an additional service based on the needs of the practice population, to address knowledge gaps identified in health care providers, to remain up to date with current best practice, etc. In order to maximise the benefit of training activities for users and personnel, it is advisable to identify training needs first and then identify relevant courses which address these needs.

Not applicable: Never

Criterion 3: 19.(2)(c) The health establishment must, as appropriate to the type and size of the establishment have a system to monitor that health care personnel maintain their professional registration with the relevant councils on an annual basis.

Measures:

1. A system is in place to ensure that all health care providers hold current registration with the relevant authority. ***DOCUMENT***

Explanatory note: The practice must have a list of health care providers for whom registration is required and copies of their current registration certificates. NB: Please note other Statutory bodies/councils will issue a virtual card which must be accepted.
Not applicable: Never

Sub-domain 3: Occupational health and safety

Standard 1: 20 The health establishment must comply with the requirement of the Occupational Health and Safety Act, 1993.

Criterion 1: The practice protects the health and safety of employees by implementing the requirements of the Occupational Health and Safety Act, 1993 (Act No.85 of 1993).

Measures:

1. There is a designated individual responsible for health and safety. ***DOCUMENT***

Explanatory note: The designated individual will be responsible for the activities outlined in S18 of the Occupational Health and Safety Act, 101 of 1993.
Not applicable: Where there are less than 20 employees in a practice.

2. The practice conducts health and safety risk assessment every 24 months. ***DOCUMENT***

Explanatory note: The risk assessment will identify hazards at the practice, such as wet floors during cleaning, and each hazard will be allocated a risk rating according to the likelihood of the hazard causing harm and the severity of the harm expected in the event that the hazard causes harm. The resultant risk rating will assist in identifying those hazards with a high-risk rating. The practice should decide the cut off point for risk ratings requiring mitigating actions. This responsibility is required in terms of Sections 8 and 9 of the Occupational Health and Safety Act, 101 of 1992.
Not applicable: Never

3. The practice implements actions to mitigate the serious risks identified in the health and safety risk assessment conducted in the previous 24 months. ***DOCUMENT***

Explanatory note: These mitigating actions are not required for all risks identified, only those which are likely to happen and those with serious consequences.
Not applicable: Never, as it is impossible for any workplace to represent no risk to employees and those affected by the practice's activities, which will include users and other visitors to the practice.

4. Health care personnel who have had a needle stick injury have received post exposure prophylaxis. ***DOCUMENT***

Explanatory note: Proactive management of needlestick injuries is necessary to prevent the development of blood borne diseases. Documented evidence must be available to demonstrate that personnel who have had a needle stick injury receive prophylaxis in accordance with the National Clinical Guidelines of Post Exposure Prophylaxis for Occupational and Non-occupational Exposures (2020).
Not applicable: Where no needle stick injuries have been reported or where the personnel member is known to be HIV positive.

5. Health care personnel who have had a needle stick injury have been re-tested for HIV infection at six weeks and four months. ***DOCUMENT***

Explanatory note: Re-testing must be done for HIV negative personnel, as HIV tests measure proteins generated by the host's immune system, which take time to become measurable. This is known as the "window period". It is therefore imperative that the tests are repeated in personnel with negative tests immediately following the injury. The HIV test should be repeated at six weeks and four months, in accordance with the National Clinical Guidelines of Post Exposure Prophylaxis for Occupational and Non-occupational Exposures (2020).
Not applicable: Where no needle stick injuries have been reported or where the personnel member is known to be HIV positive.

6. There is a protocol for the use of personal protective equipment. ***DOCUMENT***

Explanatory note: Each situation requiring the use of personal protective equipment should be identified and documented along with the personal protective equipment to be worn in that situation.
Not applicable: Never

Criterion 2: The practice must have documented systems in place to respond to fire.

Measures:

1. Fire safety requirements for public buildings are met, in accordance with relevant legislation and regulations. ***OBSERVATION***

   Explanatory note: This will include the availability of fire extinguishers, clear signage for fire exits and clear signage to direct occupants of the practice towards the nearest fire exit.
   Not applicable: Never
2. The practice has a protocol for the response to fire. ***DOCUMENT***

   Explanatory note: All practice personnel should be aware of how to respond to such situations to minimise the risk of harm to themselves and other occupants of the premises.
   Not applicable: Never

DOMAIN 5: FACILITIES AND INFRASTRUCTURE

Sub-domain 1: Management of buildings and grounds

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

Criterion 1: 14.(2)(a) The health establishment must as appropriate for the type of buildings and grounds of the establishment have all the required compliance certificates in terms of the building regulations.

1. CHECKLIST: The building(s) complies with safety regulations. ***DOCUMENT***

a. Fire safety compliance certificates.

Explanatory note: The certificate is issued when the building is commissioned or when there has been major renovations done in the building. This refers to the certificate issued by the municipality.

b. Electrical compliance certificates

Explanatory note: Electrical Certificates of Compliance (C.O.C) are documents issued by a qualified and registered electrician. They function as a guarantee that all work carried out within an office or building conforms to the regulations set out by the Electrical Contracting Board of South Africa (ECB)

2. Fire extinguishing devices are serviced annually. ***DOCUMENT / OBSERVATION***

Explanatory note: Each fire extinguishing device must have a label indicating the date that it was serviced and the date that the next service is due.
Not applicable: Never

Criterion 2: 14.(2)(b) The health establishment must as appropriate for the type of buildings and grounds of the establishment have a maintenance plan for buildings and the ground.

Measures

1. There is an annual inspection for the practice premises and grounds to ensure early identification of any faults. ***DOCUMENT***

   Explanatory note: The purpose of this inspection is to identify any developing faults early to prevent major expenditure, accidents or security incidents. This should ideally be conducted using a template checklist designed to ensure that all areas of the building are proactively evaluated. Where the premises are leased, this should form a requirement in the lease agreement.
   Not applicable: Never
2. Grounds are maintained and clean with no overgrown areas. ***OBSERVATION***

   Explanatory note: Poorly maintained grounds can present various to users and personnel, including but not limited to providing concealment for attackers, intruders and wildlife, or present a falls risk for users. Where the premises are leased, maintenance of the grounds should form a requirement in the lease agreement. Not applicable: Never

~~**Criterion: 14.(2)(c) The health establishment must as appropriate for the type of buildings and grounds of the establishment ensure emergency exit and entrance points are provided in all service areas and kept clear at all times.**~~

Criterion 3: 14.(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

1. CHECKLIST: The practice has natural ventilation or functional mechanical ventilation to prevent the transmission of respiratory infections. ***OBSERVATION***

   Instructions: The National Building Regulations stipulate that satisfactory ventilation is only provided by forcing outdoor air into a space mechanically or passively through either ducting or apertures open to the outside such as windows or ventilation grilles. Check if the areas listed below have passive ventilation (windows and doors that can be opened and ventilation grilles) or functional mechanical ventilation (i.e. ducting system). Score 1 if the aspect is compliant and 0 if it is not compliant. NB: Inspect areas available in the practice if practice has one area - inspect that area only if practice has more than two areas-select two areas for inspection.

   a. Reception
   b. Waiting area
   c. Consultation room
   d. Examination room
   e. Treatment room

Sub-domain 2: Engineering services

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

Criterion 1: 15(2) The health establishment must have: 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

Rationale:

Health care services cannot be delivered safely in the absence of adequate handwashing facilities, which includes running water. Practices operating in areas where municipal water cannot be accessed must make alternative provision to ensure that adequate hand hygiene is maintained. This can include alcohol-based hand rub for hands that are not visibly soiled. Any dirt on hands will prevent adequate disinfection of hands by the topical alcohol.

Practices are not required to have generators. However, in practices that store medicines and vaccines which must be kept in the refrigerator, the practice must have contingency plans in place to ensure the cold chain is maintained in spite of power failures.

Measures:

1. The health establishment has a functional piped water supply. Observation

   Explanatory note: The practice must provide water in a manner that protects the water from contamination. A water reticulation system refers to a piped water network. When a tap is opened, it provides instant access to pure, clean water supply. The water supply for the practice must be connected to the reticulation system.
   Not applicable: Never
2. An emergency water supply is available at the practice. ***OBSERVATION***

   Explanatory note: An emergency water supply should be available to ensure that infection prevention and control practices can be implemented despite interruption of supply from the usual water source. It is not necessary for this water to supply the entire practice,

only those areas where water is required for cleaning purposes, such as hand washing, environmental cleaning, and cleaning and disinfecting of instruments. However, water must always be available to flush toilets and clean up unanticipated biohazardous spills.
Not applicable: Never

3. Toilets are available for users and personnel. ***OBSERVATION***

Explanatory note: It is acceptable for a practice to have only one toilet to be used by all occupants of the practice premises, but the single toilet must then meet the requirements for disabled users.
Not applicable: Never

4. The sewerage system is functional. ***OBSERVATION***

Explanatory note: The Inspector will carry out rudimentary visual inspections of the sewerage system to ensure that no blocked pipes, leaking pipes or other potential hazards are identified at the time of inspections. Pit toilets will be scored non-compliant.

5. An oxygen cylinder with pressure gauge is available. ***OBSERVATION***

Explanatory note: In practices where an emergency trolley is available, the oxygen on the trolley will suffice.
Not applicable: Where an oxygen concentrator is in use.

6. The oxygen available in the cylinder is above the minimum level. ***OBSERVATION***

Not applicable: Where an oxygen concentrator is in use.

7. The oxygen concentrator is available and functional. ***OBSERVATION***

Explanatory note: Please note that where an oxygen concentrator is used, a back-up electricity supply must be available to ensure that the unit will be functional during interruptions in power supply. If no back-up electricity supply is available, the measure will be scored 0.
Not applicable: Where an oxygen concentrator is in use.

~~Sub-domain 3: Transport management~~

~~Standard: 16.(1) The health establishment must ensure that vehicles used to transport users and health care personnel are safe and well maintained.~~

~~Criterion: 16(2)(a) The health establishment must ensure that vehicles, owned or used, are licensed and maintained.~~

~~Criterion: 16(2)(b) The health establishment must ensure that drivers have valid driver's license and or public transport driving permit.~~

Sub-domain 4: Security services

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

Criterion 1: 17.(2) The health establishment must ensure that security staff are capacitated to deal with security incidents, threats and risks.

1. Security systems are in place. ***OBSERVATION***

Explanatory note: Verify whether access control measures are available, including but not limited to closed-circuit television or gated entry.
Not applicable: Never