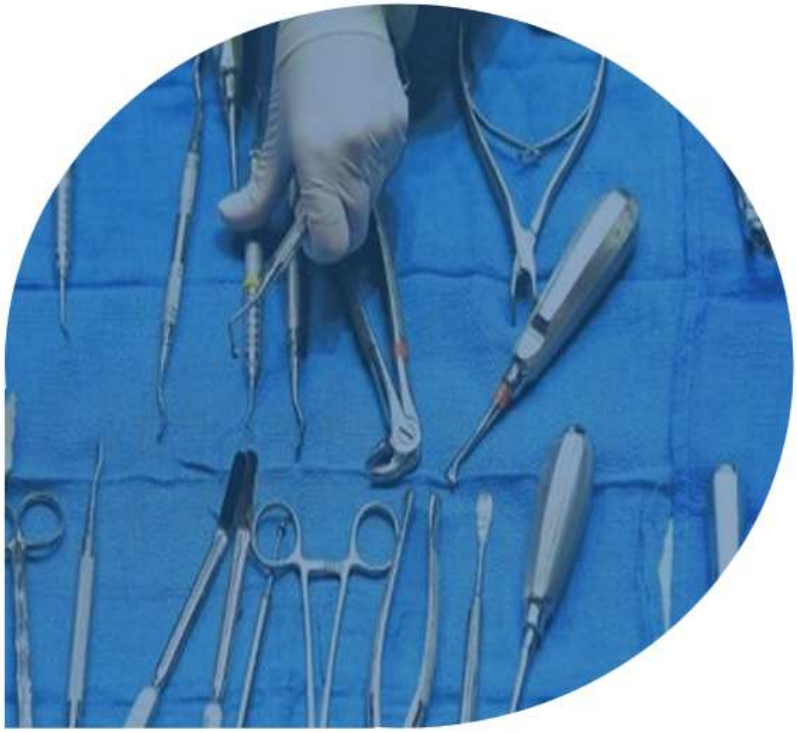
OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care



CSSD

v1.2.1

Regulatory Private Acute Hospital Inspection tool

Facility: Date:

- **Tool Name:** Regulatory Private Acute Hospital Inspection Tool v1.2.1
- **HEs Type:** Hospitals
- **Sector:** Private
- **Specialization:** Private Acute Hospital
- **Created By:** Health Standards Development and Training

31 CSSD

Domain 31.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 31.2.1 7 Clinical management.

Standard 31.2.1.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 31.2.1.1.1 7 Health care personnel must be informed about standard operating procedure and guidelines.

31.2.1.1.1.1 Health care personnel have been informed about the policy or standard operating procedure or procedure or guideline of the unit and health establishment.

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

Documented evidence that personnel have been informed about the policy or standard operating procedure or procedure or guideline 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 at meetings where policies, guidelines and standard operating procedures are discussed, or similar evidence for electronic distribution which could include but not limited to email distribution or documents deposited in intranet or other electronic platforms. Score 1 if such evidence is available and score 0 if it is not available.

Score	Comment

Aspects	Score	Comment
1. Decontamination and sterilisation processes.		
2. Management of adverse events		
3. Managing of chemical and biohazardous spills		
4. Use of Personal protective equipment (PPE)		

Standard 31.2.1.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 31.2.1.2.1 7 Standard operating procedures for decontamination processes must be available.

31.2.1.2.1.1 A policy or standard operating procedure or procedure or guideline for decontamination processes is available.

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

The aspects listed below are included and explained in the policy or standard operating procedure or procedure or guideline. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the relevant authority responsible for approving the document, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to the maximum of every 5 years. Document could be from the corporate head office. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Safety awareness in decontamination area		
2. Departmental dress code – personal protective equipment		
3. Management and decontamination of health establishment loan sets – SANS 1541		
4. Receiving and handling of potentially infectious instruments and materials for reprocessing		
5. Safe management and use of hazardous chemicals		
6. Management of missing/lost instruments		
7. Safe collection and handling of soiled, contaminated and/or used instruments		
8. Testing and use of equipment for disinfecting		
9. Tracking system for product sterilisation, identification, recording and recalls		
10. Manual decontamination of instruments, including hand hygiene requirements		
11. Preparation and operation of automated decontamination		
12. Checking and assembling instrument sets		
13. Sterile packaging		
14. Steam sterilisation procedure – loading/unloading		
15. Sterile pack storage		
16. Delivery and distribution of processed/sterile items		
17. Environmental cleaning and disinfection of central sterile services department. Explanatory note: This includes, but is not limited to, scrubbing down of walls and floors.		

31.2.1.2.1.2 A policy or standard operating procedure or procedure or guideline for the use of decontamination and sterilisation supplies, instruments and equipment is available.

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

The aspects listed below are included and explained in the policy or standard operating procedure or procedure or guideline. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the relevant authority responsible for approving the document, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to the maximum of every 5 years. Document could be from the corporate head office. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Cleaning of steam autoclaves		
2. Monitoring of steam autoclaves		
3. Steam sterilisation procedure		
4. Quality control of all equipment		
5. Action to be taken in the event of equipment failure		
6. Validation of equipment		

31.2.1.2.1.3 A policy or standard operating procedure or procedure or guideline that details the procedure for sterilisation of used instruments from start to finish is available.

Assessment type: Document - **Risk rating:** Essential measure
The aspects listed below are included and explained in the policy or standard operating procedure or procedure or guideline. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the relevant authority responsible for approving the document, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to the maximum of every 5 years. Document could be from the corporate head office. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Personal protective equipment to be worn, including but not limited to caps, goggles, masks, gauntlet gloves and plastic aprons		
2. Detergent solution to be constituted according to manufacturer’s instructions		
3. Cleaning, rinsing and drying of instruments		
4. Packing done in wraps according to manufacturer’s instructions and South African National Standard (SANS) (ISO 11607)		
5. Autoclave indicators slip (policeman) to be included in all sets and towels		
6. Tracking system indicators to be marked on packs and sets		
7. Storage of instruments to maintain integrity of the sterilised materials		

31.2.1.2.1.4 Health care personnel are able to explain the procedure for sterilising used instruments.

Assessment type: Staff interview - **Risk rating:** Essential measure
Interview three health care personnel and ask them to describe how they perform sterilisation of instruments according to the standard operating procedure. Score 1 if the aspect is described and 0 if not described.

Score	Comment

Unit 1 Health care personnel 1

Aspects	Score	Comment
1. Personal protective equipment to be worn, including caps, goggles, masks, gauntlet gloves and plastic aprons		
2. Clean sink to be filled with water and detergent		
3. Detergent solution to be constituted in accordance with manufacturer’s instructions		
4. Instruments to be fully immersed in solution		
5. Instruments to be brushed, wiped, agitated, and irrigated to dislodge and remove all visible material. Explanatory note: These actions must be performed while holding the instruments under water.		
6. Instruments to be rinsed thoroughly		
7. Instruments to be drained before drying		
8. Sterile packaging to be done according to procedure		
9. In-pack chemical indicator to be placed in all sets and towels		
10. Tracking system indicators to be marked on packs and sets		
11. Storage to ensure integrity of materials		

Unit 2 Health care personnel 2

Aspects	Score	Comment
1. Personal protective equipment to be worn, including caps, goggles, masks, gauntlet gloves and plastic aprons		
2. Clean sink to be filled with water and detergent		
3. Detergent solution to be constituted in accordance with manufacturer’s instructions		
4. Instruments to be fully immersed in solution		
5. Instruments to be brushed, wiped, agitated and irrigated to dislodge and remove all visible material. Explanatory note: These actions must be performed while holding the instruments under water.		
6. Instruments to be rinsed thoroughly		
7. Instruments to be drained before drying		
8. Sterile packaging to be done according to procedure		

9. In-pack chemical indicator to be placed in all sets and towels		
10. Tracking system indicators to be marked on packs and sets		
11. Storage to ensure integrity of materials		

Unit 3 Health care personnel 3

Aspects	Score	Comment
1. Personal protective equipment to be worn, including caps, goggles, masks, gauntlet gloves and plastic aprons		
2. Clean sink to be filled with water and detergent		
3. Detergent solution to be constituted in accordance with manufacturer’s instructions		
4. Instruments to be fully immersed in solution		
5. Instruments to be brushed, wiped, agitated and irrigated to dislodge and remove all visible material. Explanatory note: These actions must be performed while holding the instruments under water.		
6. Instruments to be rinsed thoroughly		
7. Instruments to be drained before drying		
8. Sterile packaging to be done according to procedure		
9. In-pack chemical indicator to be placed in all sets and towels		
10. Tracking system indicators to be marked on packs and sets		
11. Storage to ensure integrity of materials		

31.2.1.2.1.5 Healthcare personnel working with the reprocessing or sterilisation of medical devices are trained.

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

Using the checklist below, verify whether health care personnel have received in-service training on reprocessing or sterilisation of medical devices in the past two years. Select two health care providers and two cleaners from the health establishment's personnel. Request the training records (attendance registers). Score 1 if the health care workers have been trained and 0 if not.

Score	Comment

Unit 1 Health care provider 1

Aspects	Score	Comment
1. Sterilisation procedures		
2. Use of sterilisation equipment		

3. Hand hygiene		
4. Use of personal protective equipment		

Unit 2 Health care provider 2

Aspects	Score	Comment
1. Sterilisation procedures		
2. Use of sterilisation equipment		
3. Hand hygiene		
4. Use of personal protective equipment		

Unit 3 Cleaner 1

Aspects	Score	Comment
1. Hand hygiene		
2. Use of personal protective equipment		

Unit 4 Cleaner 2

Aspects	Score	Comment
1. Hand hygiene		
2. Use of personal protective equipment		

31.2.1.2.1.6 A policy or standard operating procedure or procedure or guideline detailing clear responsibilities for the various aspects of the decontamination cycle for sterilisation services is available.

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

The aspects listed below are included and explained in the policy or standard operating procedure or procedure or guideline. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the relevant authority responsible for approving the document, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to the maximum of every 5 years. Document could be from the corporate head office. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

Score	Comment

Aspects	Score	Comment
1. Receiving of contaminated items		
2. Cleaning of contaminated items		

3. Pre-treatment of new items		
4. Flow of items within central sterile services department to avoid mixing of contaminated and decontaminated items		
5. Availability of facilities at each location		
6. Availability of equipment at each location		
7. Training of personnel in operation of central sterile services department equipment		
8. Availability of personal protective equipment		
9. Monitoring of compliance with wearing of personal protective equipment		
10. Handling of detergents and disinfectants as per manufacturer's instructions		
11. Adherence to manufacturer's instructions on use of detergents and disinfectants		
12. Validation of equipment in accordance with manufacturer's instructions		
13. Maintenance of equipment in accordance with manufacturer's instructions		
14. Testing of equipment in accordance with manufacturer's instructions		
15. Temporary storage of decontaminated items		
16. Dispatch of decontaminated items		
17. System for tracking and tracing items. Explanatory note: This is done so that in the unlikely event of a sterilisation cycle failure, items can then be recalled.		
18. Handling of defective items Reference: https://www.fidssa.co.za/Content/Images/CFSA_SOP_2018.pdf https://www.tb-ipcp.co.za/tools-resources/documents-paperand-articles/14-ipc-policy/file		

31.2.1.2.1.7 The unit is segregated into service areas.
Assessment type: Observation - **Risk rating:** Vital measure
To comply with infection prevention and control procedures, the central sterile services department must be segregated into the service areas listed below. Score 1 if the unit has the segregated area and 0 if areas are not segregated.

Score	Comment

Aspects	Score	Comment
1. Dirty area/section (for cleaning and inspection of equipment)		
2. Clean area/section (assembly, packaging and sterilisation)		
3. Sterile packs storage area		
4. The set-up of the unit allows flow of instruments from dirty to clean areas. Explanatory note: The set-up of the unit must allow the sterilisation processes to progress from the dirty area, where used instruments are received, to the clean area, where sterilised instruments are stored and issued		

Criterion 31.2.1.2.2 7 Medical equipment management systems must be in place to minimise the risk of patient safety incidents related to medical equipment.

31.2.1.2.2.1 Sterilisation equipment in the unit has been maintained according to a schedule.

Assessment type: Document - **Risk rating:** Vital measure
The unit manager must keep a record of all sterilisation equipment in the unit (part of the unit's inventory/asset register) along with a schedule of when each item of equipment was last serviced and when the next service is due.
Not applicable: Never

Score	Comment

Criterion 31.2.1.2.3 7 Procedures to minimise the risk of health care-associated infections must be implemented.

31.2.1.2.3.1 An emergency eyewash station or eyewash kit is available.

Assessment type: Observation - **Risk rating:** Vital measure
The emergency eyewash station or eye wash kit must be easily accessible.
Not applicable: Never

Score	Comment

31.2.1.2.3.2 Sterile sealed eyewash kit is checked.

Assessment type: Document - **Risk rating:** Essential measure
Request documented evidence from the previous month indicating when the eyewash kit was checked for leaks and expiry dates.
Not applicable: Never

Score	Comment

Criterion 31.2.1.2.4 7 The management of used and soiled linen must meet infection prevention and control requirements.

31.2.1.2.4.1 The central sterile services department has a designated, access-controlled area for the storage of dirty linen.

Assessment type: Observation - **Risk rating:** Essential measure
The area used to store dirty linen must have a door.
Not applicable: Never

Score	Comment

Criterion 31.2.1.2.5 7 The success of sterilisation procedures must be monitored.

31.2.1.2.5.1 All sterilisation failures are documented.

Assessment type: Document - **Risk rating:** Vital measure
Any identified failures must be documented to provide a record for further analysis.
Not applicable: Where no failures are identified.

Score	Comment

31.2.1.2.5.2 All sterilisation failures are investigated.

Assessment type: Document - **Risk rating:** Vital measure
All sterilisation failures must be investigated to determine the cause of the failure. A report of the investigation must be available.
Not applicable: Where no failures are identified.

Score	Comment

31.2.1.2.5.3 Action plans are implemented to address gaps identified in the sterilisation process.

Assessment type: Document - **Risk rating:** Vital measure
Addressing gaps identified during the investigation will prevent further failures from the same cause.
Not applicable: Where no gaps have been identified.

Score	Comment

Criterion 31.2.1.2.6 7 Where sterilisation services are outsourced, the service level agreement must be managed effectively.

31.2.1.2.6.1 A service level agreement with an approved sterilisation service provider is available.
Assessment type: Document - **Risk rating:** Essential measure
The service level agreement must be valid (not expired) and must be signed by the service provider and the delegated authority.
Not applicable: Where the service is not outsourced.

Score	Comment

31.2.1.2.6.2 Service level agreement for decontamination services is monitored.

Assessment type: Document - **Risk rating:** Vital measure
This is to ensure that service providers adhere to their contractual obligations. This includes, but is not limited to, monitoring checklists, minutes of meetings, reports.
Not applicable: Where the service is not outsourced.

Score	Comment

Sub Domain 31.2.2 8 Infection prevention and control programmes.
Standard 31.2.2.1 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 31.2.2.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area. 31.2.2.1.1.1 Hand washing facilities are available.

Assessment type: Observation - **Risk rating:** Vital measure
Inspect the hand washing facilities for the items listed below. Score 1 if the item is available and 0 if not available.

Score	Comment

Aspects	Score	Comment
1. Hand washing basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Poster on correct hand washing technique		
3. Poster on the 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.		
4. Taps		
5. Running water		
6. Plain liquid soap or Chlorhexidine based soap		
7. Wall mounted soap dispenser		
8. Paper towels		
9. Paper towel dispenser		
10. Bin		
11. Alcohol based hand rub.		

Criterion 31.2.2.1.2 8(2)(c) The health establishment must ensure there is clean linen to meet the needs of users.

31.2.2.1.2.1 There is a designated area for storage of linen.

Assessment type: Observation - **Risk rating:** Essential measure
This could be but not limited to a room or a storage cupboard.
Not applicable: Never

Score	Comment

Criterion 31.2.2.1.3 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.

31.2.2.1.3.1 Central sterile services department personnel have access to and use appropriate protective clothing and equipment.

Assessment type: Observation - **Risk rating:** Vital measure
Verify whether the protective clothing and equipment listed below are available and worn. Score 1 if the items are available and worn and 0 if they are not available or not worn. Score NA where, at the time of the inspection, personnel are not in a situation in which they are required to wear protective clothing.

Score	Comment

Unit 1 Dirty area: Available

Aspects	Score	Comment
1. Gloves – non-sterile		
2. Disposable gowns or aprons		
3. Face masks		
4. Protective eyewear (goggles or face shields)		

Unit 2 Dirty area: Worn

Aspects	Score	Comment
1. Gloves – non-sterile		
2. Disposable gowns or aprons		
3. Face masks		
4. Protective eyewear (goggles or face shields)		

Unit 3 Clean area: Available

Aspects	Score	Comment

1. Gloves – non-sterile		
2. Disposable gowns or aprons		
3. Face masks		
4. Protective eyewear (goggles or face shields)		

Unit 4 Clean area: Worn

Aspects	Score	Comment
1. Gloves – non-sterile		
2. Disposable gowns or aprons		
3. Face masks		
4. Protective eyewear (goggles or face shields)		

Sub Domain 31.2.3 9 Waste management.

Standard 31.2.3.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 31.2.3.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

31.2.3.1.1.1 The central sterile services department has appropriate containers for disposal of all types of waste.

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

Verify whether the waste containers listed below are available. Health care risk waste containers must have the appropriate international hazard symbol and be marked as prescribed in SANS 10248-1: Management of Health Care Waste, Part 1: Management of healthcare risk waste from a health facility. Score 1 if the waste container is available and 0 if not available. Where a particular type of waste is not generated in the unit, score NA.

Score	Comment

Aspects	Score	Comment
1. Infectious non-anatomical waste (red)		
2. Sharps (yellow)		
3. General waste (black, beige, white or transparent packaging may be used)		

Criterion 31.2.3.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

31.2.3.1.2.1 Sharps are safely managed and discarded in the unit.

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

Select three areas and verify whether sharps, needles and the collection of sharps are correctly managed. Score 1 if the aspect is compliant and 0 if not compliant.

Score	Comment

Unit 1 Area 1

Aspects	Score	Comment
1. Sharps containers available at site of use		
2. Sharps containers have correctly fitting lids		

Unit 2 Area 2

Aspects	Score	Comment
1. Sharps containers available at site of use		
2. Sharps containers have correctly fitting lids		

Unit 3 Area 3

Aspects	Score	Comment
1. Sharps containers available at site of use		
2. Sharps containers have correctly fitting lids		

31.2.3.1.2.2 There is a temporary healthcare risk waste storage area.

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

In all areas where waste is held for collection and removal to the central storage area, a designated area for temporary storage of waste must be available. Some health establishments will have a purpose-built temporary waste storage area, others will utilise a specific area within the available space. Score 1 if the aspect is compliant and 0 if not compliant, or where there is no designated area. Score not applicable for any aspects not found in the temporary waste storage area.

Score	Comment

Aspects	Score	Comment
1. Space available to store waste containers		
2. Area is well ventilated		
3. Area is well lit		
4. Area has impervious floor surfaces (waterproof or resistant, not cracked)		

Domain 31.3 CLINICAL SUPPORT SERVICES

Sub Domain 31.3.1 13 Medical equipment.

Standard 31.3.1.1 13(1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

Criterion 31.3.1.1.1 13(2)(b) The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.

31.3.1.1.1.1 Functional essential equipment is available.

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

Request the list of medical equipment for the unit and randomly sample ten items on the equipment list. Check whether the sampled equipment is available and functional. Document the name of the noncompliant equipment that was sampled. Score 0 if a selected item on the equipment list is not available or not functional or if the list is not available.

Score	Comment

Aspects	Score	Comment
1. Equipment 1		
2. Equipment 2		
3. Equipment 3		
4. Equipment 4		
5. Equipment 5		
6. Equipment 6		
7. Equipment 7		
8. Equipment 8		
9. Equipment 9		
10. Equipment 10		

31.3.1.1.1.2 The sterilisation unit manager has determined the number of surgical packs required for the unit.

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

To ensure sufficient sterile packs are available for the sterilisation unit to cover all theatres and procedures that are performed at the health establishment, it is necessary to determine the requirements for the unit, i.e. how many sterile packs are required to ensure that all theatres and procedures are covered this could be influenced by the number of booked cases.

Not applicable: Never

Score	Comment

31.3.1.1.1.3 The unit has a method for tracking surgical packs issued from and returned to the central sterile services department.

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

This may be a manual or electronic register to track sterile packs sent to and received from the theatres and other functional areas. The purpose of the system is to ensure that the sterilisation unit keeps track of all sterile packs.

Not applicable:

Score	Comment

31.3.1.1.1.4 The storage of sterile packs ensures the integrity of materials.

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

The manner in which sterile packs are stored must prevent physical damage to packages, avoid exposure of packages to moisture. Packages should not be stored in a manner that will crush, bend, puncture, or compress them. Therefore, packs should not be wet or have water damage, they should be intact (not opened or torn).

Not applicable: Never

Score	Comment

Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.
To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Private Acute Hospitals.

Acknowledgments

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- The internal OHSC teams (Compliance Inspectorate, for their contribution during the update of the Private Acute Hospital inspection tools).

It is hereby certified that the Regulatory Private Acute Hospital Inspection tools version 1.2.1 was updated by the Office of Health Standards Compliance.

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