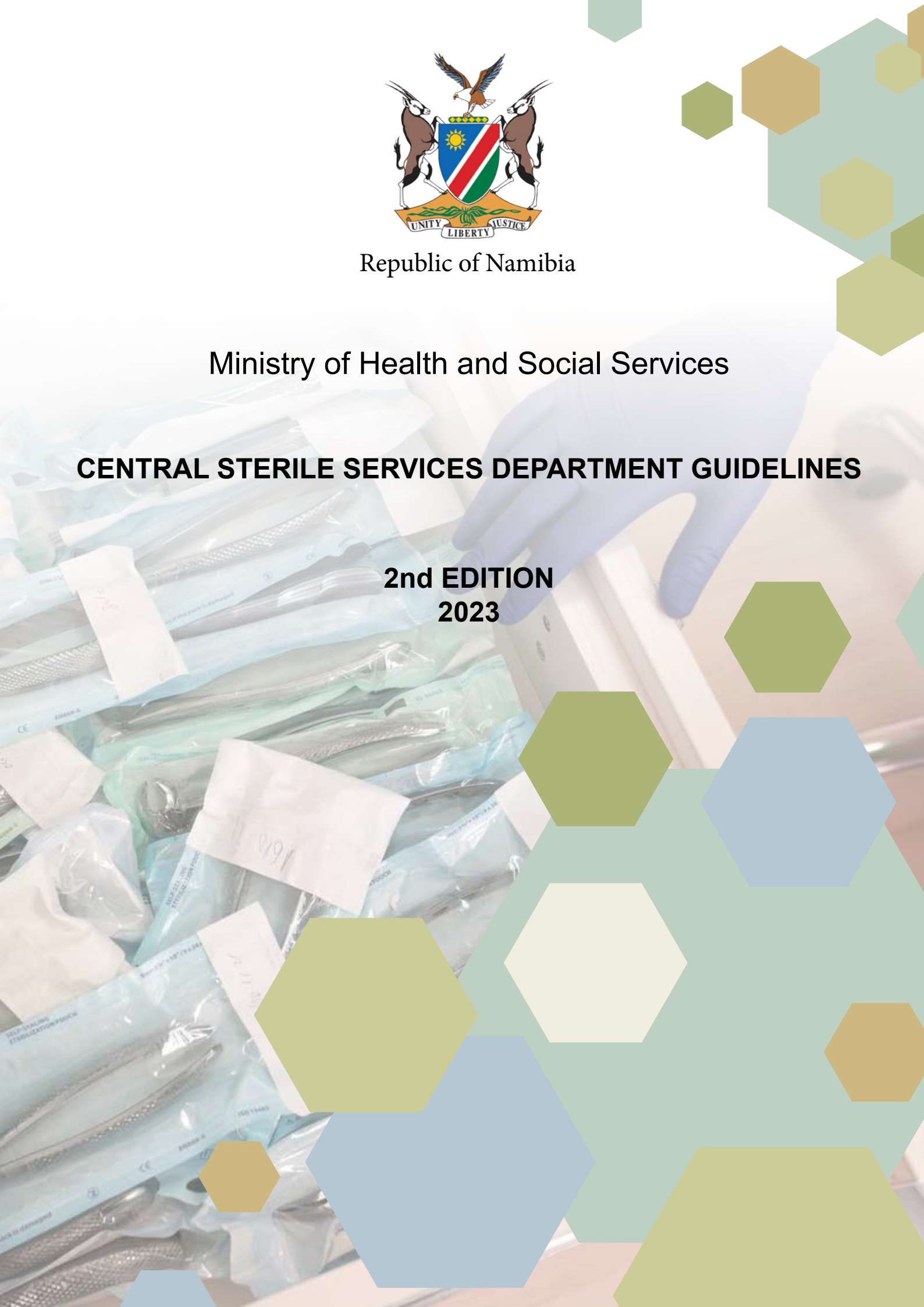
Republic of Namibia

Ministry of Health and Social Services

CENTRAL STERILE SERVICES DEPARTMENT GUIDELINES

2nd EDITION
2023



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Division: Quality Assurance

Private Bag: 13198, Windhoek, Namibia

Telephone: +264 61 2032523/2097

Facsimile: +264 61 224051

ACKNOWLEDGEMENTS

The Ministry of Health and Social Services (MoHSS) acknowledges all the collaborative efforts made in shaping the 2nd Edition of the Central Sterile Services Department (CSSD) Guidelines. This milestone was achieved through an extensive and reiterative consultative process, guided by the indispensable contributions of healthcare professionals at multi-hospital levels, incorporating district, intermediate, as well as national referral hospitals. Operating theatre and CSSD cadres and infection prevention and control (IPC) practitioners from both public and private facilities, along with representatives from district, regional, and national health directorates, played a pivotal role in this developmental journey.

This includes the Namibia Institute of Pathology (NIP) as well as esteemed academic institutions like the University of Namibia (UNAM), Welwitchia University, International University of Management (IUM), Lady Pohamba Private Hospital, Roman Catholic Hospital, World Health Organization (WHO), and Centers for Disease Control (CDC), who all provided invaluable insights and expertise during stakeholder meetings held on 5-9 June 2023 and 17-21 July 2023. Their contributions to the development of these guidelines were invaluable, and they have made a significant contribution to the finalising the guidelines.

The MoHSS further conveys its heartfelt appreciation to the Quality Assurance Division (QAD) for diligently overseeing the meticulous revision process of the CSSD Guidelines. Our special gratitude is extended to Briette du Toit Ludick, the lead consultant, for her indispensable technical assistance in the finalisation of these guidelines. The development of the guidelines was furthermore made possible by dedicated technical and financial support provided by the World Health Organization (WHO). The MoHSS is profoundly appreciative of the WHO's invaluable contributions.

FOREWORD

The Central Sterile Services Department (CSSD) at any hospital plays a pivotal role in patient safety through incorporating infection prevention and control principles with validated decontamination processes. This is to ensure safe medical equipment and devices for delivering surgery and patient care services.

The field of surgery stands as a foundational pillar in global healthcare. According to data from the Lancet Commission on Global Surgery published in 2015, an estimated 312.9 million surgical procedures are performed annually worldwide. Alarmingly however, are the common, often preventable surgical complications that continuously persist. Among the considerable risks associated with surgical procedures is the potential introduction of pathogens, culminating in infection. Failure to meticulously disinfect or sterilise equipment not only risks breaching host barriers, but also facilitates person-to-person transmission (e.g., hepatitis B virus) and the spread of environmental pathogens (e.g., *Pseudomonas aeruginosa*).

In this context, the CSSD plays a pivotal role in ensuring the meticulous decontamination of surgical instruments and medical equipment, rendering medical devices free from bacteria, to guarantee their safety during surgical procedures. Cleaning, disinfection, and sterilisation are imperative practices to avert the transmission of infectious pathogens to patients through medical devices. Healthcare policies must discern, judiciously, whether cleaning, disinfection, or sterilisation is necessary, based on the intended use of items, as sterilisation for all patient-care items is not always obligatory. The choice of disinfectant, the concentration, and exposure time is contingent upon the risk associated with using the equipment and other pertinent factors delineated in these guidelines. Unfortunately, studies conducted across various countries have demonstrated lack of adherence to established guidelines for disinfection and sterilisation, resulting in numerous infectious outbreaks. This guideline underscores a pragmatic approach, accentuating the meticulous selection of optimal methods for cleaning, disinfection, and sterilisation of medical devices, as well as the cleaning and disinfection of the healthcare environment.

The first edition of the CSSD guideline, initiated by the MoHSS in 2015, planted the seeds of progress to improve the activities of this department. As we progress to this 2nd Edition, we have enriched the guideline with comprehensive information about the layout, design and infrastructure requirements. In addition, the guidelines include chapters on Infection Prevention and Control (IPC) procedures, healthcare worker safety, inspection, assembly, and packaging, as well as quality assurance, monitoring, and quality improvement. Furthermore, this edition has been thoughtfully aligned with the Namibian Quality Standards for Healthcare Facilities and other essential guidelines like the Operating Theatre and IPC guidelines.

We extend our heartfelt congratulations to all individuals who played a vital role in the development of these guidelines. Every healthcare worker involved in the preparation, processing, and distribution of medical devices, critical to diagnostics, treatment and ongoing patient care, is unequivocally required to adhere to these guidelines.

With our collective dedication and unwavering adherence to these guidelines, we affirm our commitment to ensuring a safer surgical environment and to improving healthcare outcomes for the patients we are committed to diligently serve.

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BEN NANGOMBE
EXECUTIVE DIRECTOR

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LIST OF ACRONYMS AND ABBREVIATIONS

ABHR	Alcohol based hand rub
ACH	Air changes per hour
BP	Blood Pressure
CSSD	Central Sterile Services Department
COHSASSA	Council for Health Services Accreditation of Southern Africa
ETO	Ethylene Oxide
FIFO	First in-first out
HAI	Healthcare-associated Infection
HBV	Hepatitis B Virus
HCF	Healthcare Facility
HCW	Health Care Worker
HEPA	High Efficiency Particulate Air
HLD	High Level Disinfection
IAP	Inspection, Assembly and Packaging
ICU	Intensive Care Unit
ID	Identification
IPC	Infection Prevention and Control
MDRO	Multidrug resistant organisms
MEPD	Medical Equipment Processing Department
MMIS	Multimodal Improvement Strategy
MoHSS	Ministry of Health and Social Services
MSDS	Material Safety Data Sheets
NICU	Neonatal Intensive Care Unit
OPA	Ortho-Phthalaldehyde
OPD	Outpatient Department
OT	Operating Theatre
PEP	Post-Exposure Prophylaxis
PPE	Personal Protective Equipment
PVC	Polyvinyl chloride
RO	Reverse Osmosis
SMS	Senior Medical Superintendent
SMO	Senior Medical Officer
SOP	Standard Operating Procedure
SP	Standard Precautions
WHO	World Health Organization

GLOSSARY OF SELECTED TERMS

Alcohol-based hand rub	A liquid, gel or foam formulation of alcohol (e.g., ethanol, isopropanol), used to reduce the number of micro-organisms on hands in clinical situations when hands are not visibly soiled - they contain emollients to reduce skin irritation and are less time-consuming to use compared to hand washing
Autoclave	An autoclave or steriliser is a device used to sterilise equipment and supplies by subjecting them to high pressure and steam at 121˚C or above - for the purposes of this document, the term autoclave refers to a large industrial steriliser used at a central sterile services department
Bioburden	The number of viable organisms that contaminate a device
Biological indicator	Test systems containing viable bacterial spores providing a defined resistance to a sterilisation process
Chemical indicator	Test systems that reveal a change in one or more predefined variables based on a chemical or physical change resulting from exposure to the process e.g., colour change
Cleaning	The first step required to physically remove contamination by foreign material, e.g., dust, soil - it will also remove organic material, such as blood, secretions, excretions and micro-organisms, to prepare a medical device for disinfection or sterilisation
Contamination	The soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter
Critical equipment	Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity
Decontamination	Removes soil and pathogenic micro-organisms from objects so they are safe to handle, subject to further processing, use or disposal
Detergent	A cleaning agent that increases the ability of water to penetrate organic material and break down grease and dirt - detergents are necessary to allow effective and efficient cleaning
Disinfection	A process to reduce the number of viable micro-organisms to a less harmful level - this process may not inactivate bacterial spores, prions and some viruses
Disinfectant	A chemical agent that can kill most pathogenic micro-organisms under defined conditions, but not necessarily bacterial spores - this is a substance that is recommended for application to inanimate surfaces to kill a range of micro-organisms - the equivalent agent, which kills micro-organisms present on skin and mucous membranes, is called an antiseptic
Doffing	To remove or take off clothing or equipment such as personal protective equipment
Donning	The act of putting on clothing or equipment such as personal protective equipment
High Level Disinfection	Disinfectants that kill all vegetative forms of bacteria, including mycobacteria and viruses, but require a prolonged exposure time to kill spores - mainly used for heat sensitive critical devices such as endoscope[1]
Medical device	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used for humans for the purposes of the diagnosis, prevention, monitoring, treatment or alleviation of an injury or handicap
Non-critical equipment	Items in contact with intact skin

[1] Mehtar. S. 2010. Understanding Infection Prevention and Control. Juta & Co. Claremont. South Africa

Prion	A small proteinaceous infectious unit that appears to cause transmissible spongiform encephalopathies - these are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans, and are highly resistant to disinfection and sterilisation
Quality assurance	A programme for the systematic monitoring and evaluation of the various aspects of a service e.g., decontamination, to ensure that the standards of quality are met
Quality improvement	Continuous and ongoing efforts to achieve measurable improvements in the efficiency, effectiveness, performance, accountability, outcomes, and other indicators of quality in services or processes which achieve equity and improve the health of the community[2]
Reprocessing	All steps that are necessary to make a contaminated reusable medical device ready for its intended use - these steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation
Semi-critical equipment	Items in contact with mucous membranes or body fluids
Single-use device	A device intended for one use only or on a single patient during a single procedure
Soil test	Commercially manufactured product that mimics dried blood used to validate cleaning processes
Spores	A primitive usually unicellular, environmentally resistant dormant or reproductive body produced by plants, fungi, and some micro-organisms capable of development into a new cell, either directly or after fusion with another spore
Steam sterilisation	Steam sterilisation is a process that uses saturated steam under pressure as the sterilant - it is the preferred method for sterilising critical medical devices - the removal of air is essential to ensure an efficient sterilisation process as sterilisation cannot occur in the presence of air
Sterilisation	Validated process used to render a product free from viable micro-organisms - the complete destruction or removal of micro-organisms, including bacterial spores[3]
Sterility	State of being free from viable micro-organisms
Validation	Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilise instruments and other medical devices[4]

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[2] https://www.hopkinsmedicine.org/nursing/center-nursing-inquiry/nursing-inquiry/quality-improvement.html

[3] https://www.merriam-webster.com/dictionary/spore

[4] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

CHAPTER 1: INTRODUCTION

The Central Sterile Services Department (CSSD) is responsible for the processing of re-usable medical devices and ensuring that they are safe to use on patients. The decontamination of medical devices plays an important role in the prevention of healthcare-associated infections (HAIs). Despite advances made in healthcare, inadequate sterilisation and disinfection of reusable medical devices, including endoscopic devices, respiratory care devices, and haemodialysis devices, still occur in many settings, leading to HAIs.

In addition, the inappropriate reuse of single-use medical devices is a common practice and the procedures to decontaminate these devices are inadequate, not standardised and often unvalidated. The processes of decontamination are complex, require specific infrastructure and equipment and involve several steps that need to be precise, from device collection, receipt by the unit, processing and storage, up to distribution throughout the facility. Quality control procedures are of utmost importance throughout the process to ensure the correct functioning of the equipment.[5]

Certain medical devices are designed for reuse, but can potentially transmit infections such as hepatitis B, C, and HIV if any of the steps involved in reprocessing are inadequate or faulty. It is therefore imperative to ensure that all CSSD staff receive comprehensive training on all aspects related to CSSD, to equip them with in-depth knowledge regarding decontamination processes as well as an understanding of the risks related to their work.

Effective decontamination procedures play a crucial role in preventing healthcare-associated infections (HAIs). Consequently, the provision of appropriate CSSD services is vital for the success of an IPC programme. By implementing this guideline, healthcare workers will be guided in determining the appropriate decontamination process to be used for specific items or equipment (e.g., cleaning, disinfection, or sterilisation).

1.1 Purpose of the guidelines

This guideline covers a number of key aspects related to the decontamination of re-usable medical devices in a variety of healthcare settings. It also covers the design and layout of the CSSD and its relationship to other departments, staff requirements as well as the application of Standard Precautions (SP) and adherence to IPC principles. This is to prevent HAIs as well as to ensure the safety of healthcare workers (HCWs).

1.2 Objectives of the guidelines

The objectives of this guideline are to ensure:

- Processing of medical devices according to the Spaulding classification for the intended level of use
- Standardisation of decontamination processes in line with validated required standards
- Standardisation of processes in line with minimum requirements (for cleaning, disinfection and sterilisation) and standards[6] ensuring that healthcare facilities are providing medical devices that are safe to use on patients
- Ensure adequately trained healthcare workers at the CSSD who understand how to protect themselves while performing their duties
- Continuous education and training
- Well written instructions on reusable medical device processing are provided to CSSD staff

[5] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

[6] Namibia Hospital Quality Standards. 1st Edition 2021

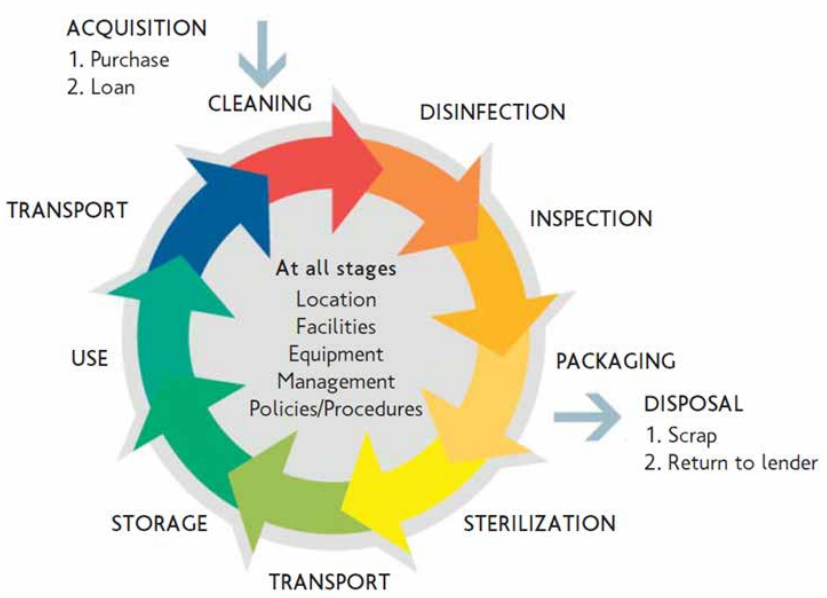
CHAPTER 2: OVERVIEW OF THE CENTRAL STERILE SERVICES DEPARTMENT

The Central Sterile Services Department (CSSD) is the area in the hospital where medical devices, both sterile and non-sterile, are cleaned, packed, disinfected/sterilised, stored and then issued for patient care. The CSSD is accountable and responsible for the provision of medical devices that are safe to use on patients in all clinical areas and should have close working relationships with the users of such medical devices.[7] Furthermore, the CSSD is a vital part of an effective IPC programme. The expertise and knowledge of CSSD personnel is key to ensure high standards of reprocessing of medical devices to prevent HAIs.

2.1 Overview of the decontamination life cycle

The decontamination life cycle illustrates the main steps of the decontamination process, with each step as vital as the next step (Figure 1). The cycle starts when dirty medical devices are brought to the CSSD, then cleaned, disinfected, inspected, packed, sterilised, transported, stored, used and again transported back to the CSSD.

FIGURE 1: DECONTAMINATION LIFE CYCLE [8]



Each step of the decontamination cycle is crucial to ensure the safe use of sterile reusable medical devices during surgical interventions. An error during any of the stages of the decontamination cycle may lead to huge costs, serious suffering, and endangerment of the lives of patients and healthcare workers.[9]

2.2 Scope of work of the CSSD

CSSD services extend beyond the hospital walls, with OT services being one of its key stakeholders. To ensure continuity of service delivery, there must be a direct link between sterilisation and OT services. In instances whereby both units are on-site, it is preferable that they are situated in close proximity to each other, but in separate complexes. This is useful to assist in communication as well as the transfer of dirty, clean and sterile medical devices. It is however ideal to have different managers responsible for the CSSD and OT respectively.

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[7] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[8] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[9] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

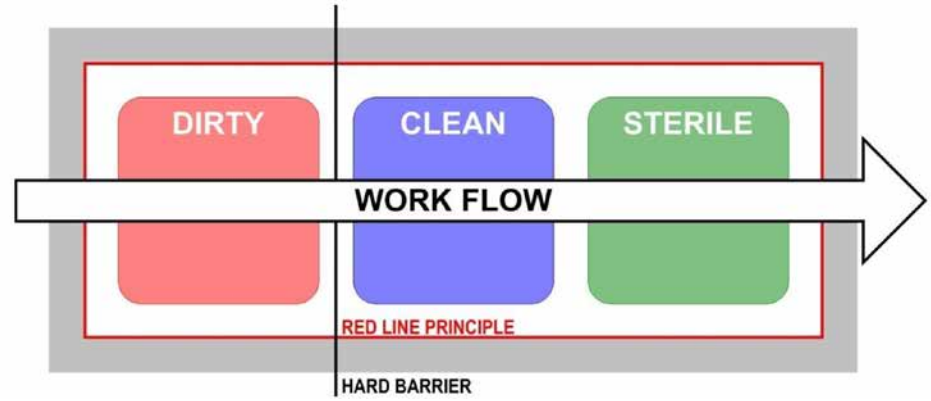
It is essential that CSSD are included/but not limited to consultation in the following instances:

- OT scheduling
- Procurement of reusable medical devices
- OT management meetings
- Peri-operative education and training
- Changes in models of care and processes across peri-operative services
- Plans for the re-development, refurbishment and/or re-design and commissioning of new OT and/or sterilising services
- Must be represented at the IPC Committee

2.3 Establishing a CSSD

Systems should be put in place where all soiled, used, and recyclable equipment is collected from the wards and OT and transferred in a safe manner to the CSSD. The devices are washed, inspected, disinfected or packed, sterilised, and dispatched back to the wards. **The workflow in CSSD should be unidirectional and always from dirty to clean**.

FIGURE 2: WORKFLOW DIAGRAM FOR REPROCESSING OF MEDICAL DEVICES[10]



Note: When dirty items are received, they should be counted and recorded in a logbook - the same applies to dispatch.

2.3.1 Essential requirements of a CSSD worker

Staff working at the CSSD play a very important role in the provision of safe surgery and the prevention of HAIs. CSSD staff need to understand their roles and responsibilities, be adequately trained to perform their tasks and understand how to protect themselves.

2.3.2 Staff uniforms

- Staff should have good personal hygiene and wear a clean uniform every day
- They should be provided with uniforms which have high necklines and sleeves to prevent contamination of the skin with chemicals and body fluids, with no pockets
- Staff should wear dedicated footwear such as boots or closed shoes that can be cleaned regularly
- They should be provided with adequate well-fitting personal protective equipment (PPE)
- Eating and drinking is not allowed in the working area
- Jewellery should be kept to a minimum
- They should be provided with a comfortable work environment and an area to rest during breaks[11]

[10] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[11] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

2.3.2 Staff qualifications

All staff working at the CSSD should be adequately trained in decontamination processes, IPC and hand hygiene. There should be a process in place to ensure continued competency, including ongoing training sessions at regular intervals and periodic competency assessments. All staff should receive orientation when they are appointed, and all training sessions must be documented.[12]

The level of education for HCWs in CSSD may differ according to the level of the healthcare facility and each facility has to stipulate its specific requirements. Staff working at the CSSD should have at least a high school completion certificate, and individuals should be able to read, write and follow instructions. The supervisor should have a minimum of two years' experience in sterile services, and should have attended at least one training course of a minimum of six months where the basic principles of decontamination and sterilisation are explained and practically applied to workplace. They should furthermore be equipped to perform their duties independently and mentor and guide others.

The CSSD Manager should have a higher qualification in health and should have had at least five years or more, experience in sterile services. They should have attended an advanced course in sterile services, and acquired the requisite skills to manage the CSSD. Competencies should include financial, administrative and procurement knowledge. They should furthermore know how to control the flow of medical devices through the CSSD, know basics of the processing equipment and how it works, and most importantly, understand and apply validation. There should be clear roles and responsibilities for all categories of staff working at the CSSD.

Table 1: Education requirements and qualifications

Staff level	Education required
Entry level operator	High school completion certificate
Enrolled Nurses and Registered Nurses	Basic CSSD course (6 months)
Supervisor (Intermediate Hospital)	Basic CSSD course (6 months) and 2 years' experience
Manager (Tertiary hospital)	Advance CSSD course and 5 years' experience

2.2.3 CSSD workers should:

- Protect the patient from harm - understand Duty of Care
- Understand the setup and requirements of each section of the CSSD
- Operate the equipment effectively and safely after training
- Protect themselves and colleagues
- Undergo continuous training and attain new knowledge
- Have basic knowledge of English
- Have basic reading and writing skills
- Have basic calculating skills
- Have knowledge of the principles of IPC
- Understand the principles of disinfection and sterilisation

NOTE: It is not recommended that cleaning staff are involved in the cleaning of medical devices unless they have been trained adequately to perform the tasks and to protect themselves while performing their duties.

[12] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

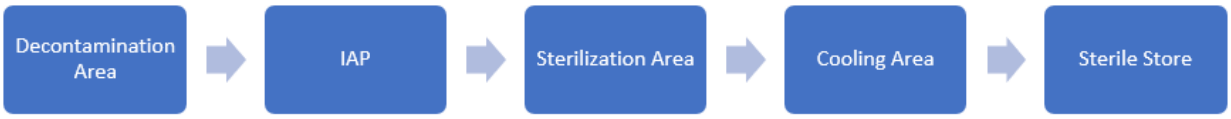
CHAPTER 3: LAYOUT AND DESIGN OF THE CSSD

When designing or reconstructing a CSSD, planning and design should include input from relevant experts, including those involved in the processing of reusable medical devices, engineering and IPC. The location of the CSSD and sterile supply area should be away from the main traffic pattern. The ideal location should be close to the OT, with a dedicated passage or lift from the OT into the decontamination area.

NOTE: CSSDs should be divided into areas that are physically separated with a clear unidirectional workflow from dirty to clean.

The CSSD should be clearly divided into different areas **(Figure 3)** to ensure good workflow from dirty to clean.

FIGURE 3: DIFFERENT AREAS IN CSSD[13]



Ideally, the CSSD must have physical barriers that separate dirty and clean areas in the reprocessing room. **Figure 5** provides an example of the layout of the CSSD, demonstrating the different areas and support structures. Visitors and staff should access the CSSD via a controlled entrance and have access to an area where they can dress into scrubs. Technical staff should have access to the sterilisers and washer disinfectors from a dedicated entrance for servicing.

3.1 CSSD environment

3.1.1 Surfaces

All surfaces in the reprocessing space must be smooth, without cracks and non-porous, easy-to-clean and should be able to withstand chemical disinfection. Surfaces must be made from waterproof materials compatible with cleaning agents. Wood and laminates are not recommended, because they absorb water and chemical solutions. Stainless steel is recommended for work surfaces, sinks and equipment coatings, as these are easiest to clean.

3.1.2 Ceilings

All ceilings must be smooth, straight, without cracks and should be moisture-proof. Panel ceilings are not recommended directly over the clean and sterile working areas as they release dust and debris when disturbed.

3.1.3 Walls

Walls should be continuous, smooth without any peeling paint and coated with washable paint or material. The corners should be protected with metal ridging or similar protection to prevent damage from carts and trolleys.

3.1.4 Floors

All floors should be straight, smooth, without cracks and able to withstand the load of heavy carts transported across them. The floor should be continuous with a non-slip finish, especially in the decontamination and cart washing areas. The corners should be covered, and the flooring covered up to the wall to a minimum of 25cm

[13] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

and sealed to allow for easy cleaning and to reduce dust traps. There should be no sharp corners that allow the collection of moisture, dirt or dust.[14]

3.1.5 Ventilation

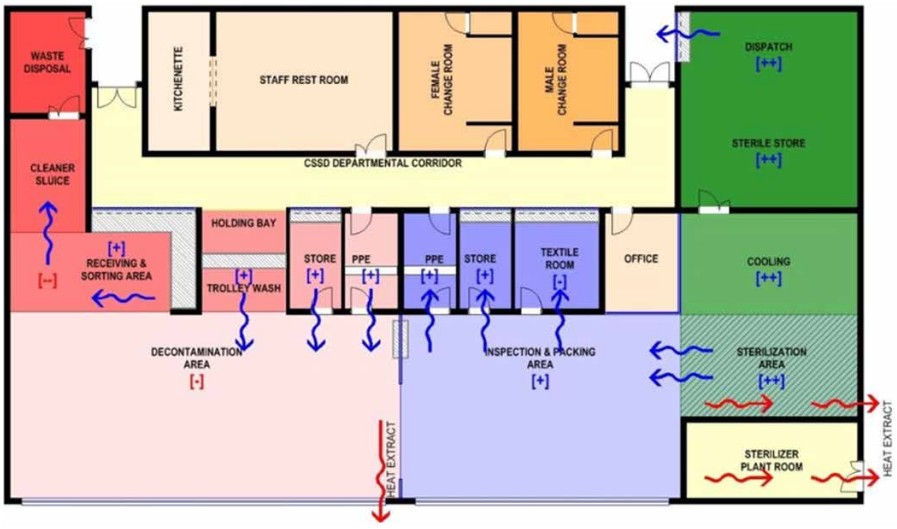
Mechanical or controlled ventilation is recommended for CSSD areas as they are demarcated into dirty and clean areas and have different ventilation requirements for each of the sections. Turbulent air flow and the use of portable fans should be avoided, because rapid, uncontrolled air circulation can spread contamination. Ventilation systems must be cleaned, tested and maintained according to the manufacturer's instructions. There must be a clear maintenance plan at each CSSD to ensure that the ventilation system functions optimally. The different ventilation requirements for different areas of the CSSD are presented in **Table 2**.[15]

Table 2: Different ventilation and pressure requirements in different areas of the CSSD

	Air changes per hour (ACH)	*Pressure*	*Relative humidity*	*Ambient temperature*
Dirty area	10 - 20 ACH	Negative	40 - 50%	18 – 20 ˚C
IAP area	10 - 20 ACH	Positive	40 - 50%	18 – 23 ˚C
Sterile store	10 - 20 ACH	Positive	40 - 50%	15 – 25 ˚C

Figure 4 depicts the different ventilation and pressures required in different areas of the CSSD, with the air flowing from ''clean" (sterile store) to ''dirty" (decontamination area), creating positive pressure in the sterile store and negative pressure in the decontamination area in relation to the Inspection Assembly and Packing (IAP) area.

FIGURE 4: DIFFERENT VENTILATION AND PRESSURE REQUIREMENTS IN DIFFERENT AREAS OF THE CSSD[16]



3.2 Layout and design of the CSSD

Each area of the CSSD, including the entrance and exit, must be carefully considered according to its purpose, space and function. This section will deal with the function and layout of individual areas within the CSSD. **Figure 5** provides an example of the floorplan of a CSSD with the different areas demarcated.

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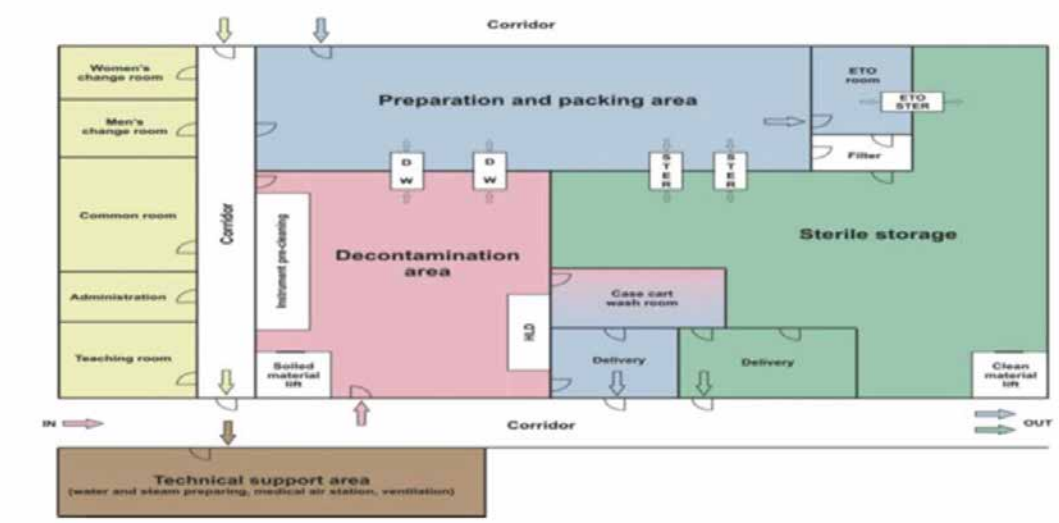
[14] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[15] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

[16] https://thehillside.info/index.php/Central_sterile_services_department#Receiving_and_Sorting. Accessed 20230623

FIGURE 5: LAYOUT AND DESIGN OF A CSSD[17]



*Note the flow of staff and devices

3.2.1 Staff changing rooms

All staff and visitors must dress in scrubs or dedicated clothes for working at the CSSD. This area should contain lockers to lock up personal belongings, toilet facilities and showers as well as clinical hand wash basins with liquid soap and paper towels and/or alcohol-based hand rub (ABHR). Provision should also be made for dirty scrubs to be sent to the laundry with a dedicated area for clean scrubs.[18]

3.2.2 Gowning or PPE area

The gowning or PPE area should be located just outside the decontamination area and should have adequate supplies of recommended PPE such as:

- Gloves
- Masks
- Eye protection (goggles and visors)
- Headgear
- Overshoes are not recommended, and staff are advised to wear dedicated, washable shoes in this area[19]

Staff working in the decontamination area should always were appropriate PPE.
(See Chapter 5 on HCW Safety)

Decontamination area

There should ideally be a separate area with controlled access for receiving dirty medical devices next to the decontamination area. If that is not possible, the dirty devices should be received in a dedicated area within the decontamination area. There should be adequate space in this area to accommodate trolleys with dirty medical devices whilst allowing staff to perform their duties without any risk of contamination or injury. All items received should be recorded.

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[17] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

[18] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[19] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

Requirements for the decontamination area:

- Direct access to contaminated medical devices from the OT, wards, waste removal and dirty laundry removal
- Located adjacent the IAP Area
- No direct movement of staff between decontamination area and IAP and sterilisation areas
- Dedicated sluice and trolley wash area
- Automated washer/disinfectors (preferably double doors) should be installed to separate the decontamination area and the IAP area - ensuring one-way flow of staff and medical devices
- Separate pass-through hatch or window between the IAP and decontamination areas for dirty items identified during inspection
- An area for manual cleaning
- Hand hygiene facilities should be available that include a clinical handwash basin with elbow operated taps, liquid soap and single-use paper towels

NOTE: ABHR is not recommended in this area – hands might be contaminated with blood and body fluids and should always be washed

FIGURE 6: DOUBLE-BASIN SINK FOR MANUAL WASHING[20]

3.2.3.1 Jet guns

There should be an air and water high-pressure jet gun available in the decontamination area to clean out narrow lumen tubing such as suction tubing. The air gun is used to dry the interior of the tubing before hanging it to dry further.

3.2.4 Inspection, Assembly and Packing (IAP) area

The IAP area receives clean medical devices from the decontamination unit and must provide a safe and clean area for the following tasks:

- Inspect all clean medical devices to ensure that it is clean and without any debris or **organic material**
- Perform functioning tests to ensure that all instruments are in good **working order**
- **Assemble and pack** medical **devices**

Requirements for the IAP Area:

- Access from IAP via gowning area only via controlled entry and exit
- Access to sterilisation area
- Storage area for packing materials and other supplies
- Register to document devices that are sent for repair or discarded
- Inspection table for processed items prior to packing
- Adequate workspace
- Good light source for inspection as well as magnifying glasses for inspection
- ABHR for hand hygiene - no handwash basins should be located in the IAP area

Figures 7 and 8 provide examples of packing tables, as well as the magnifying and light sources required in the IAP area.

[20] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

FIGURE 7: TABLES FOR PACKING IN IAP AREA[21]

FIGURE 8: VISUAL INSPECTION OF A CLEAN SET[22]

3.2.5 Sterilisation area

The sterilisation area receives packed items that are ready to be placed into the sterilisers. **Figure 9** demonstrates the packs on a trolley ready to be placed in the autoclave.

[21] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[22] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

FIGURE 9: PACKS READY TO BE STERILISED IN THE AUTOCLAVE [23]

Requirements for the sterilisation area:

- Adjacent to IAP area with access to both areas
- Enough space for trolleys with packed items from the IAP area**.**
- Staff should wear appropriate PPE and **heat resistant gloves**
- There should be easy access to sterilisers for maintenance
- Separate areas for the sterilisation and disinfection of items
- All cycles and cycle failures should be recorded
- Each steriliser should have its own logbook with information on quality records and maintenance
- There should be a dedicated area for records such as registers, used Bowie Dick tests, etc

3.2.6 Sterile Store

Once the packs have been cooled down in a designated area, they are ready to be dispatched to the OT and other clinical areas. Sterile items should be stored and handled in a manner that maintains the integrity of packs and prevents contamination. Sterile storage areas should be clearly indicated and controlled with restricted access.

Requirements for the Sterile Store and shelves (Figure 10):

- The sterile store must be kept clean and free of dust, insects and pests
- There should be adequate space for the appropriate storage of sterile packs and movement of staff and trolleys between shelves
- All items should be stored at least 250mm from the floor level, and at least 440mm from the ceiling.
- The area must be protected from direct sunlight
- Cardboard boxes should not be used as they are porous, cannot be cleaned and might harbour organisms and insects
- The area should be cool and dry - moisture or excess heat may jeopardise the integrity of the protective cover of sterile packs
- Shelves should be made of open metal wire or metal slats to allow good movement of air to keep the packs dry.
- Solid and wooden shelves are not recommended because they trap and retain moisture
- All the shelves should be labelled

[23] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

FIGURE 10: IMAGES OF THE STERILE STORE AND SHELVES [24]

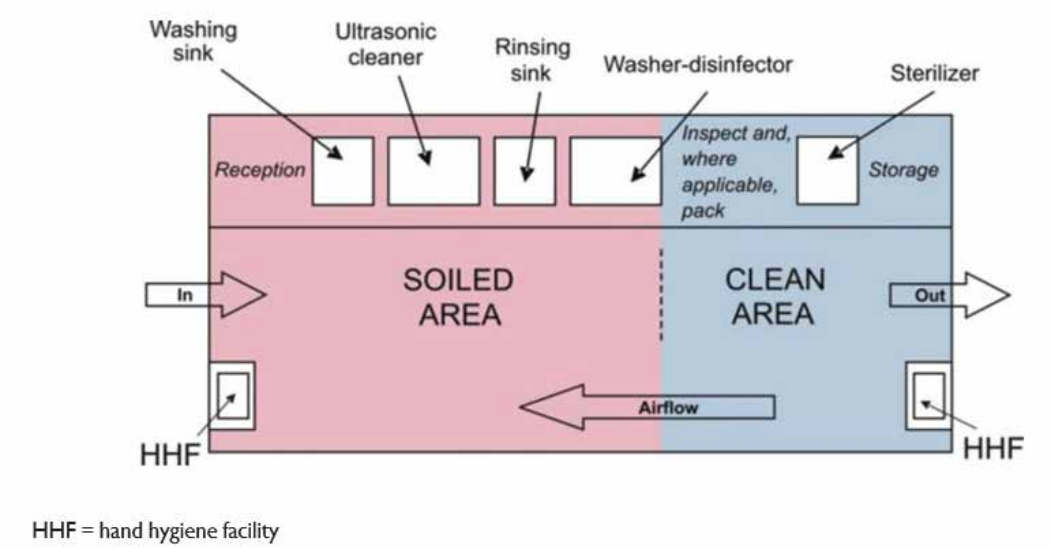
3.2.7 Dispatch area

There should be a dedicated dispatch area to ensure that stock can be controlled. All sterile items that leave the store should be recorded in a logbook and signed by the person receiving the packs.[25] This helps to monitor the use and the loss of instruments.

3.3 Processing of medical devices if a dedicated CSSD is not available

If a dedicated CSSD is not available an existing area can be adapted to ensure safe reprocessing of medical devices. **Figure 11** provides a schematic example of a single-room sterilisation unit.

FIGURE 11: LAYOUT OF A SINGLE ROOM STERILISATION UNIT[26]



HHF = hand hygiene facility

[24] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[25] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[26] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

The flowing is recommended for the processing of medical devices in a single room unit:

- Separate rooms are preferred - one for receiving and cleaning medical devices (the wash or decontamination room) and another for the IAP area for final processing (sterilisation or high-level disinfection) followed by a storage and dispatch area
- There must be clear demarcation between clean and dirty areas - use red lines on the floor (or different coloured lines for different areas), shelves or other ways of separating the different areas
- There must be one-directional flow from dirty to clean to prevent contamination
- Adequate countertop space available for receiving dirty items and for drying and packaging clean items
- There must be at least one sink (two or more are preferable) that is deep enough to allow the manual cleaning of medical devices
- Adequate space for dirty and clean devices so that there is no risk of cross-over
- The high-level disinfection area must be separated from the sterile area and must preferably be in a separate room or area
- The air moves from the clean area to the dirty area
- Clean and dirty areas must have separate storage facilities
- *There are adequate hand hygiene facilities in the different areas which include:*
    - Clinical hand washbasins with elbow operated taps, liquid soap and single use paper towels in the decontamination area
    - ABHR in the IAP area where sterile packs are stored
- Soiled objects should never cross paths with clean, sterilised, or high-level disinfected instruments and other items
- The doors must be kept closed in reprocessing rooms to minimise dust contamination and eliminate flies
- There is separate reprocessing equipment for each area
- The staff in CSSD should work in either clean or dirty areas and never in both or move between the two areas

NOTE: In some health service districts, the potential exists for centralising the provision of sterilising services through one facility with a properly designed and equipped sterilising unit that is able to meet the sterilisation needs of a number of other facilities

3.4 Hand hygiene facilities

A clinical handwash basin with elbow operated taps should be located at the entrance of the decontamination area. Ensure that liquid soap and disposable paper towels are available.

ABHR is indicated for the IAP and sterile storage areas. Water in these areas should be limited due to the risk of splashes and contamination of wrapping material and sterile packs.

*(See the **MoHSS IPC Guideline 3rd Edition 2023** for more detail on the requirements for hand hygiene facilities)*

3.5 Water quality

The quality of water is integral to the cleaning process, as well as the steam produced for sterilisers. Routine water testing is required at healthcare facilities (HCF) to ensure that the water quality is acceptable.[27]

Impact of poor water quality:

- Hard water containing a high load of calcium, magnesium and other salts, may form deposits and scales on the processing equipment and devices and inhibit the performance of detergents
- The presence of chlorides causes pitting and corrosion of instruments
- pH of the water affects solubility of detergents and chemicals

[27] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

- Silicates may interfere with the action of detergents[28]
- Water hardness reduces the killing rate of certain disinfectants
- Hard water reduces the conductivity of heat during sterilisation

The mineral and salt content of the water in CSSD should be low (soft water) to ensure that it does not affect devices or processing equipment.

Several methods can be used to soften water:

- Filtration
- Water softening systems
- Ion exchange
- Reverse osmosis (RO)

An RO system is sometimes recommended by manufacturers of modern and highly sophisticated washer-disinfectors and sterilisers. **It is important to check these requirements before purchasing equipment, particularly if the budget is restricted.**

Some of the mentioned systems are expensive, but it is important to implement some sort of water softening system to protect the processing equipment and medical devices.[29]

NOTE: Proper steam quality prolongs the life of medical devices by reducing the adverse effects of water impurities on device materials. Lime, rust, chlorine and salt can all be left as deposits on devices if demineralised water is not used. These compounds can lead to stress corrosion, pitting and discolouration of the device. Pitting, corrosion, and precipitates must be avoided as their formation provides areas where organisms can accumulate and be protected from the killing effects of the steam process thereby increasing the risk of infection transmission due to inadequate sterilisation[30]

3.6 Commercially prepared items

- Grossly soiled or damaged stock should not be accepted from the supplier as contents may be compromised
- Dust must be wiped from store packs before opening to prevent contamination of the content
- Remove sterile items from the store pack before bringing them into the clean area
- Inspect unit packs or their contents for cleanliness or damage before use as well as expiry dates
- If the package is intact the expiratory date should be considered valid
- Regularly check expiratory dates and ensure that the packs are used according to the most recent expiratory date (FIFO)

3.7 Release of sterile items

Sterile items should be released by educated and authorised staff.

The following requirements should be met before releasing the item:

- All sterilisation parameters should be met, e.g., temperature, pressure and time based on the batch documentation
- Evaluation of the chemical batch control
- Visual inspection of the integrity of packaging - look for the following: holes or tears, wetness or stains, broken seals, dust, evidence of crushing, labelling, and indicators
- **DO NOT** release items where the indicator is missing or has not changed colour

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[28] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[29] World Health Organisation. 2016. Decontamination and reprocessing of medical devices for health-care facilities. Available; https://www.who.int/publications/i/item/9789241549851

[30] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

3.8 Transportation

Transportation of sterile supplies must be in a **clean and dry trolley** which is closed to outside contamination.

3.8.1 General design features for trolleys and transport containers

Equipment must be dedicated for this purpose, e.g., separate equipment for the transportation of **contaminated** and **sterile items.**

The trolleys should have the following characteristics:

- Be covered or closed with a solid bottom shelf
- Can be cleaned, dried and disinfected
- Be in a good working condition
- Be easily maneuverer and fitted with brakes if possible

The transport containers should be:

- Puncture-resistant
- Leak-proof
- Made of either plastic or metal, with a lid or liner that can be closed and cleaned and disinfected

3.8.2 Transport of sterile supplies

Sterility depends primarily on the conditions of storage and the frequency of handling. All items transported should be delivered in a clean container and trolley dedicated for that purpose.

To guarantee sterility of items transported the following procedures should be followed:

- Containers and trolleys used for the transportation of sterile goods should be dedicated and must not be used for non-sterile goods, e.g., transportation of food or garbage
- Transport containers/systems must allow articles to be handled with care and be inspected as necessary
- Boxes or bags used should not be overloaded
- All transportation equipment should be maintained in a clean, dry condition and must be in good working order
- All sterile items for distribution outside the healthcare facility must be securely packed and protected against damage and contamination during transportation
- There must be a regular cleaning programme for all sterile storage areas, including all containers and trolleys - Figure 12 provides examples of transport trolleys

FIGURE 12: EXAMPLES OF TRANSPORT TROLLEYS[31,32]

NOTE: When sterilised devices are transported between wards or facilities, it should be placed in clean containers to prevent contamination and damage to packing and the content

[31] https://metro.com/blog/products-to-improve-sterile-storage-transportation-and-compliance-with-professional-guidelines/

[32] https://www.hupfer.com/en/medical/transport-solutions/container-and-sterile-goods-transport-carts/1021/sterile-goods-transport-cart

IPC is a vital part of CSSD and should be integrated in all CSSD practices to ensure safe processing of medical devices to prevent HAIs while protecting HCWs working in CSSD. Adherence to IPC practices is essential and all CSSD staff should receive IPC training during orientation of new staff, and on a continuous basis.

4.1 The role of infection control teams

The role of the IPC team is primarily to prevent HAIs. This necessitates a close working relationship between CSSD staff and IPC practitioners.

The establishment of committee structures, e.g., Theatre Users Committee, IPC Committee and other means of formal and informal communication (such as WhatsApp Groups) between the IPC team and CSSD staff will ensure timely provision of properly processed equipment at healthcare facilities. A representative from CSSD must be included in the IPC committee meetings and staff working at the CSSD must be included in IPC training initiatives.

Ensure that CSSD is aware of local and national IPC policies that may affect the service they provide. The CSSD should have a responsibility for achieving consistent production and management standards in the reprocessing of reusable medical devices. IPC practitioners and quality improvement staff should do regular audits in CSSD to measure compliance with IPC principles and the Namibian Hospital Quality Standards.[33]

4.2 Standard precautions at the CSSD

Standard precautions (SP) are safe work practices which are required to minimise the risk of infection to both patients and staff. SPs are the minimum standard of IPC practices that should be used consistently by HCW at all times.[34]

*(SP are described in more detail in the **MoHSS Infection Prevention and Control Guidelines 3rd Edition 2023)***
SPs must be selected based on the risk of exposure to blood and body fluids, including secretions/excretions, splashes and/or sprays and contaminated surfaces and the activities performed. SPs must be applied consistently by all HCWs working in the CSSD. The use of SP reduces the risk of transmission of infections while allowing HCWs to deliver high standards of care at all times, while protecting themselves.

*(**Table 3** provides a short overview of the different SPs and their application)*

[33] Namibia Hospital Quality Standards. 1st Edition 2021

[34] WHO. Aide-memoire Standard Precautions for the prevention and control of infections. Available: https://www.who.int/publications/i/item/WHO-UHL-IHS-IPC-2022.1

Table 3: Standard precautions applicable to the CSSD environment

Element	Description

Hand hygiene	• *Hand hygiene in CSSD should be performed:*
	  ○ After removal of gloves
	  ○ After touching dirty/contaminated medical devices
	  ○ Before touching clean medical devices
	  ○ After touching clean medical devices
	  ○ Before touching sterile packs[35]
	• Hands should be washed with soap and water when visibly soiled with blood or body fluids
	• ABHR should be used in the IAP and Sterile store areas
	• Cuts and abrasions on hands must be covered with a waterproof dressing.
	• Staff with exudating wounds and eczema must be evaluated by the Occupational Health Practitioner or Medical Doctor before they wash instruments - it might aggravate the skin condition and increases the risk of infection
	• Wearing of jewellery, artificial nails and nail polish should be discouraged - rings and watches should be removed when on duty
	• Gloves must always be worn:
	  ○ When there is a risk of exposure to blood and body fluids
	  ○ While washing dirty/contaminated devices
	  ○ Domestic gloves must be worn by staff washing instruments
	• Ensure that **liquid soap is NOT topped up,** but new/clean bottles and pumps are used to replace empty bottles
	• If containers are re-used it must be washed properly with soap and water and allowed to dry completely before it is refilled
	• Ensure that bottles are labelled with the name of the content
	• Always write the date on the bottle/container when it is first used or opened and discard after one month or based on the manufacturer's instructions
	• Disposable paper towels must be available to dry hands
	• Monitor the ABHR and liquid soap dispensers daily for adequate content and if they are in working order

Personal protective equipment (PPE)	• CSSD staff should adhere to IPC principles set out in the ***MoHSS IPC Guidelines 3rd Edition 2023*** to protect themselves from being exposed to blood, body fluids and pathogens that can cause infections • Change out of street clothes into CSSD uniform (theatre scrubs) • The selection of PPE should be based on the risk of exposure to blood and body fluids and chemicals used at the CSSD • It is important that adequate PPE is always used in the different areas • Hair and beards should be always covered with a theatre cap and face mask respectively • All staff should be trained on the correct donning and doffing of PPE • See **Chapter 5** for details about PPE for HCWs in CSSD

[35] Almaki, A. et al.2019. Quality Project Manuscript King Fahad Medical Centre. Available: https://www.researchgate.net/publication/337656196_Hand_Hygiene_Revolution_in_CSSD_-_Final_and_published

Management of blood and body fluid spills	• All blood and body fluid spills must be cleaned immediately after they occur to prevent contamination of the environment and HCWs • Always ensure that gross contamination is removed prior to cleaning • Clean the area with a detergent and water after the spillage was removed • Disinfect with hypochlorite 1:10,000 ppm • Ensure that cleaning staff are adequately protected when the spills are cleaned to prevent exposure to blood borne viruses
Linen management	• Soiled and contaminated linen must be segregated in the operating theatre, placed in green plastic bags and sent to the laundry • Adequate PPE must always be worn when contaminated and soiled linen is handled • Single-use drapes are mostly used - these must be discarded according to the Waste Management policy and stored in a dedicated area e.g., sluice until removal to the laundry • See **Chapter 9** for management of linen as part of packing material ***Note**: Refer **MoHSS IPC Guideline3rd Edition 2023** for the Management of Linen*
Healthcare risk waste management	• Waste must be segregated at the point of generation according to the Integrated Health Care Waste Management Plan (2012)[36] • Waste not contaminated with blood and body fluids e.g., clean wrappings are regarded as general waste and should be placed in a black plastic bag • Waste contaminated with blood and body fluids is regarded as medical waste and must be placed in a red plastic bag • Waste bags must be clearly marked with labels • Handling, storage, transport and disposal of waste should be done correctly, according to facility procedures • Waste must be removed daily ***NOTE:** Refer to the **MoHSS IPC Guidelines 3rd Edition 2023** and **Integrated Health Care Waste Management Plan 2012** for detailed guidance*
Management of sharps	• **Needles and used scalpel blades must be removed and discarded in theatre and not sent to CSSD** • Carefully unpack trolleys with used instruments to prevent injury • If a scalpel blade is found on the trolley, it must be removed with an appropriate instrument and not with gloved or bare hands • Never re-cap needles or try to separate the needle from the syringe – discard as a unit • All injuries related to the sharp instruments and used needles must be reported and managed according to the facility policy[37] • Post exposure prophylaxis (PEP) guidelines should be readily available, and staff should know the steps to follow in case of accidental injury[38] *(Refer to the **MoHSS IPC Guidelines 3rd Edition 2023** for the Management of sharps and sharp injuries)*

[36] Integrated Health Care Waste Management Plan (2012)

[37] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[38] Namibia Hospital Quality Standards. 1st Edition 2021.

Healthcare worker safety	• All HCWs working in CSSD must be vaccinated against Hepatitis B[39] • All blood and body fluid exposure and sharp injuries must be reported within 24 hours and managed correctly according to the local standard operating procedure (SOP) • All skin and respiratory conditions must be reported to the supervisor • All cuts and skin lesions must be covered with waterproof dressings • *See **Chapter 6** for HCW safety and the **Ministry of Labour, Industrial Relations and Employment Creation National Occupational Safety and Health Policy, 2021**[40] and **MoHSS National Guideline on PEP for HIV, HBV and Tetanus after workplace exposure and sexual assault**[41] as well as the **MoHSS Namibia Standard Treatment Guidelines**[42]*

4.2.1 Environmental cleaning

Cleaning schedules and practices in CSSD should be based on a risk assessment. The different areas in the CSSD pose different degrees of risk for contamination of the environment and HCWs.

- The decontamination area poses a higher risk and should be cleaned more frequently
- Always clean from **clean (lower risk area) to dirty (higher risk area**) as depicted in **Figure 13**
- Assign separate cleaning staff/teams for different areas if resources permit
- Cleaning staff must be trained and understand the risks related to their work
- Define roles and responsibilities so that cleaning staff and CSSD staff know which areas they are responsible for
- Ensure that there are clear SOPs for each area
- **Cleaning checklists** for different areas are helpful to ensure that all areas and surfaces are cleaned
- Provide separate environmental cleaning supplies and equipment, including PPE for cleaning staff (e.g., reusable rubber gloves, aprons), to prevent cross-contamination between these areas.[43]
- All shelves should be cleaned weekly to remove dust
- All work areas, stands, tables, countertops, sinks and equipment surfaces must be cleaned and disinfected at least once a day
- Provision must be made for storage of cleaning equipment, such as mops and buckets, as well as a dedicated area for cleaning and drying of equipment or linen packed to send to the laundry - clean mops and buckets are stored inverted[44]

[39] Namibia Hospital Quality Standards. 1st Edition 2021.

[40] Ministry of Labour, Industrial Relations and Employment Creation National Occupational Safety and Health Policy, 2021.

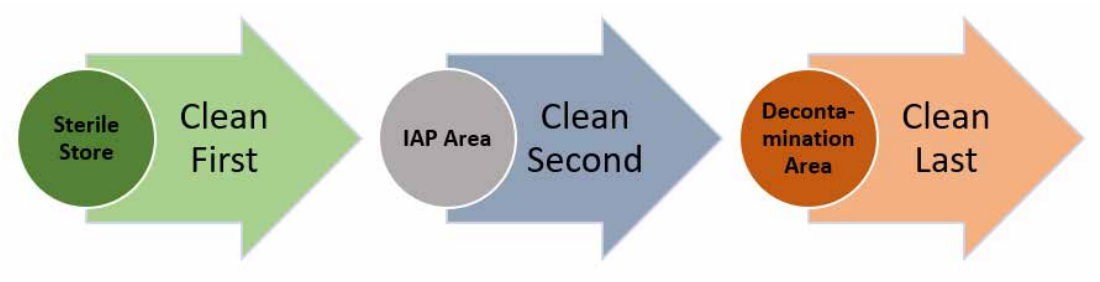
[41] Ministry of Labour, Industrial Relations and Employment Creation National Occupational Safety and Health Policy, 2021.

[42] Ministry of Labour, Industrial Relations and Employment Creation National Occupational Safety and Health Policy, 2021.

[43] CDC. 2019.Best Practices in Environmental Cleaning in HCF in Low Resource Settings V2. https://www.cdc.gov/hai/pdfs/resource-limited/environmental-cleaning-RLS-H.pdf

[44] WHO. 2016. Decontamination and reprocessing of medical devices for health-care facilities. World Health Organization. https://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1&isAllowed=y

FIGURE 13: CLEAN FROM CLEAN TO DIRTY AREAS [45]



4.2.1.1 Frequency of Cleaning in CSSD

The frequency of cleaning will depend on the level of contamination and the risk it poses. **Table 4** provides an example of the frequency of cleaning in different areas of the CSSD.[46]

Table 4: Cleaning frequency in CSSD

Process	Frequency
Sinks used for washing of medical devices - e.g., instruments and endoscopes	Before and after every use
All high-touch surfaces - e.g., countertops, surfaces where equipment is washed, handwash basins, and floors	At least twice a day or more frequently as indicated
Low-touch surfaces, such as the tops of shelves, walls and vents	On a scheduled basis e.g., weekly

*(For more detail about Environmental cleaning consult the **MoHSS IPC Guideline 3rd Edition 2023. For more detail on IPC and infection transmission and prevention refer to the MoHSS IPC Guidelines 3rd Edition 2023)***

[45] CDC. 2019.Best Practices in Environmental Cleaning in HCF in Low Resource Settings V2. https://www.cdc.gov/hai/pdfs/resource-limited/environmental-cleaning-RLS-H.pdf

[46] CDC. 2019.Best Practices in Environmental Cleaning in HCF in Low Resource Settings V2. https://www.cdc.gov/hai/pdfs/resource-limited/environmental-cleaning-RLS-H.pdf

CHAPTER 5: HEALTHCARE WORKER SAFETY AT THE CSSD

It is important that the safety of healthcare workers (HCWs) should be addressed and that they understand the risks of their work. It is the responsibility of the employer to ensure safe working conditions and the necessary PPE and training, but the HCWs also have a responsibility to adhere to the guidelines and safety protocols and wear PPE appropriately.

Note: Staff also have a responsibility to protect themselves by adhering to policies and procedures

5.1 Hazards at the CSSD

There are various hazards at the CSSD. These hazards have to be identified and the risks associated with such hazards must be documented in a Risk Register and managed.[47] The risk of exposure to blood and body fluids, chemicals, heat and sharp objects is high. Table 5 provides an overview of the common hazards, associated risks, possible causes and preventative measure that should be implemented.[48]

Table 5: Table with hazards and risks in CSSD

Hazard	Risk	Cause	Prevention
Biological agents	Infections e.g. • Legionnaires' disease • Bloodborne virus diseases • Viral and bacterial diseases • Fungal infections	• Exposure to contaminated medical devices and organic material e.g., via needlestick or sharp injury or contact with contaminated devices and splashes • Mould growth due to high humidity levels • Environmental exposure via ventilation (*Aspergillus*) or water systems (*Legionella)*	• Body fluid management -spill kits • Personal protective equipment • Vaccination – Hep B • Mechanical ventilation and water systems monitored and maintained
Chemicals	• Respiratory problems, allergies and dermatitis • Fire • Explosion	***Exposure to:*** • Disinfectants and detergents • Ethylene oxide and other gasses • Latex consumables • Use of flammable gasses • ***Lack of:*** ○ Ventilation ○ Appropriate PPE	• Material Safety Data Sheet (MSDS) information available for all chemicals in use and accessible to staff • Spill kit(s) appropriate to the chemical(s) being used are available • Training

[47] Namibia Hospital Quality Standards. 1st Edition 2021.

[48] Health and Safety Authority. https://www.hsa.ie/eng/Your_Industry/Healthcare_Sector/Occupational_Hazards_in_Hospital_Departments/Department_Hazards/CSSD/

Hazard	Risk	Causes	Prevention
Electricity	• Fire • Electrocution • Burns	• Equipment unsuitable for use in damp or wet environment • Contact of equipment with water • Faulty equipment • Overloading of sockets • Unsafe work practices	• Training • Consideration of end users during procurement • Correct installation • Servicing and maintenance
Hot objects	• Burns	• Exposure to hot objects or steam during sterilisation	• Appropriate PPE • Training
Moist & wet surfaces	• Skin conditions and allergies • Falls	• Inappropriate processes • Leaking taps and equipment	• Training • Maintenance • Appropriate PPE
Equipment	• Burns • Cuts • Explosion • Physical injury • Death	• Handling or sorting hot sterilised items or sharp instruments • Exposure to hot objects or steam during sterilisation • Lack of appropriate PPE such as heat proof gloves • Inadequate maintenance or inappropriate use of high-pressure equipment such as autoclaves.	• Training staff on equipment as per manufacturer's recommendations • Appropriate PPE • Timely equipment servicing and maintenance • Related SOPs
Ergonomic hazards	• Pain in back, hands or arms	• Standing for long periods of time • Repetitive motions such as reaching or stretching • Bending over sinks • Poor workstation design or set-up • Chairs too high in packing area	• Fit for purpose equipment, end-user friendly workstations. • Efficient workflows
Sharp objects	• Cuts • Infection • Blood borne virus transmission	• Exposure to sharp items or equipment	• Sharp objects are safely disposed of in puncture resistant containers.
Noise	• Hearing damage or loss • Physiological effects • Work related stress. • Increased risk of accidents	• Prolonged exposure to noisy equipment	• Ear protection[49]

5.2 Reporting of injuries/exposure on duty

All occupational injuries have to be reported according to the National Occupational Safety and Health Policy and the facility SOP.

- The supervisor must be informed of all needle stick injuries and other injuries and exposure
- The HCW should immediately receive counselling and PEP according to the local SOP and MoHSS National Guideline on PEP for HIV, HBV and Tetanus after workplace exposure and sexual assault,[50] as well as the MoHSS Namibia Standard Treatment Guidelines[51]

5.3 Prevention of injuries at the CSSD

Injuries in CSSD can be prevented by reducing the risk of exposure, following safe practices and by adhering to IPC precautions. *More details are provided in the* ***MoHSS IPC Guidelines 3rd Edition 2023.***

[49] https://www.hsa.ie/eng/Your_Industry/Healthcare_Sector/Occupational_Hazards_in_Hospital_Departments/Department_Hazards/CSSD/

[50] MoHSS National Guidelines on Post-Exposure Prophylaxis for HIV, HBV and Tetanus after workplace exposure and sexual assault. 2010

[51] MoHSS Namibia Standard Treatment Guidelines. 2021

5.4 Personal protective equipment

Protective clothing must be worn during equipment processing to protect the healthcare worker from contact with blood and body fluids. It is also worn to avoid contributing to the bio-burden on medical devices during preparation for sterilisation or subsequent storage.

Protective attire worn during cleaning of used equipment includes:

- Waterproof outer wear (gown or apron with impermeable arm protection)
- Heavy-duty gloves
- Safety glasses (goggles) and masks, or face shields if manual cleaning is undertaken
- Closed shoes with non-slip soles, strong enough to protect against injury if items are dropped accidentally
- Consideration may be given to staff wearing ear protection, depending on the noise levels within the area
- PPE selection is based on the risk of exposure and the area in which you work
- Staff must be trained on the correct use of PPE
- A summary of the PPE based on the risk and the area in which duties are performed are summarised in **Table 6**

*For more detail about the type of PPE and how it should be selected, refer to the **MoHSS IPC Guideline 3rd Edition 2023.***

Table 6: Summary of PPE indicated in different areas of the CSSD [52]

PPE indication	Gloves	Face covers/ visors/ goggles	Headgear	Aprons/gowns	Closed shoes
Decontamination area: • Handling used medical devices • Removal and disposal of sharps • Manual cleaning	• Domestic gloves (heavy duty) • Long • Disposable or tear resistant if reused • Nitrile gloves (preferred)	• Cover mucous membranes and eyes • Mask with integrated visor • Full visor • Face mask with goggles	Yes	Yes	Yes
IAP • Inspection after cleaning • Assembly • Packaging	No	No	Yes	No	Yes
Sterilisation • Loading • Emptying steriliser	• Heavy duty heat resistant gloves	No	Yes	No	Yes
Sterile stores • Loading shelves • Taking inventory • Documentation	Not Indicated	No	Yes	No	Yes
Transportation delivering sterile packs	Not indicated	No	No	No	Yes
Returning used medical devices	Heavy duty domestic gloves	Only when handling open wet trays	Yes	Yes	Yes

[52] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

5.5 Adverse events

Strong detergents and disinfectants may have adverse effects on the skin. Any skin contamination should be washed off immediately and managed as per the Material Safety Data Sheet (MSDS) instructions.

Events including sharp injuries and blood and body exposure should be managed according to the recommendations in the local SOP and ***MoHSS National Guideline on PEP for HIV, HBV and Tetanus after workplace exposure and sexual assault*** [53] *as well as the* ***MoHSS Namibia Standard Treatment Guidelines***[54].

Any member of the CSSD who has the following conditions should report it to the Occupational Health and Safety Practitioner or CSSD Supervisor:

- Exposure to blood and body fluids
- Sharp injury
- Splashes
- Skin rashes, boils or open wounds
- Diarrhoea or gastroenteritis
- Jaundice
- Respiratory illness, either allergic or infectious[55]

[53] MoHSS National Guidelines on Post-Exposure Prophylaxis for HIV, HBV and Tetanus after workplace exposure and sexual assault. 2010

[54] MoHSS Namibia Standard Treatment Guidelines. 2021

[55] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

The purpose of risk management is to identify, analyse and evaluate the risks of the CSSD processes. There are many hazards and associated risks in CSSD. Many of the hazards and risks associated with HCW safety had been addressed in the previous chapter. This chapter will focus on risks associated with medical devices and how risk is classified and managed in CSSD.

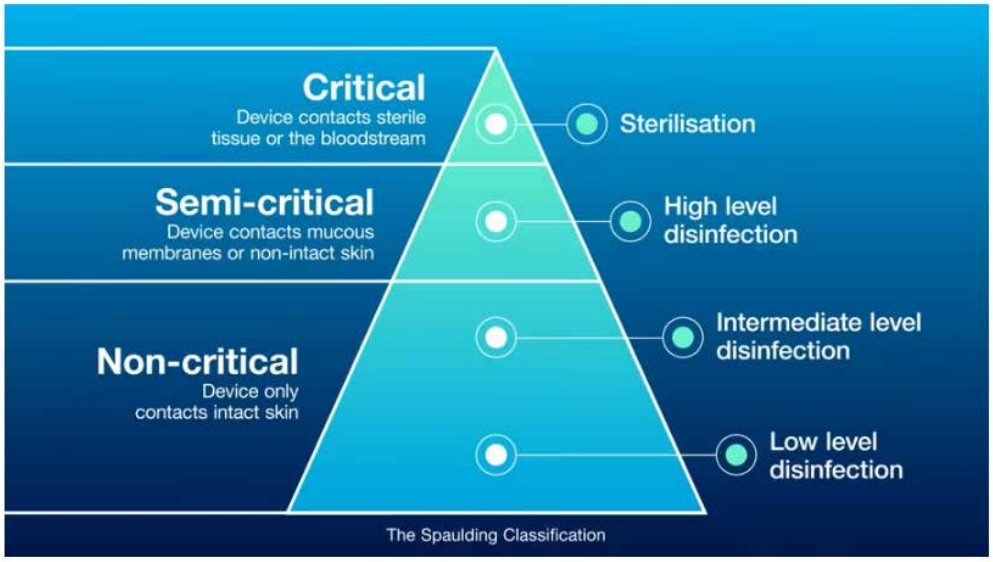
A risk assessment must be done for all devices that are used to establish:

- The level of contamination of the device
- The level of decontamination required for a particular instrument or medical device
- The type of device: non-critical, semi-critical, critical
- The purpose of the device or instrument
- Patient populations (burn unit, ICU, NICU, Haematology, immune compromised)
- Organism profile (MDROs)
- Type of organism: bacteria, virus, spore forming, prions[56]

6.1 Classification of the risk from medical devices

The classification system developed by Spaulding[57] divides medical devices/equipment into three categories based on its intended use and the subsequent level of reprocessing required to ensure that the device is safe to use on patients (**Figure 14**).

FIGURE 14: SPAULDING'S CLASSIFICATION OF MEDICAL DEVICES[58]



56 WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

57 Rowan, N.J., Kremer, T., McDonnell, G. A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability. Science of The Total Environment Vol 878, 20 June 2023. https://www.sciencedirect.com/science/article/pii/S0048969723015942?via%3Dihub

58 https://www.nanosonics.co.uk/infection-prevention/spaulding-classification

Spaulding's classification system divides all medical devices into three categories:

- Critical devices
- Semi-critical devices
- Non-critical devices[59]

Table 7 provides an overview of the category of the device, the associated risk, as well as the level of decontamination required.

Table 7: Spaulding's classification

Classification and risk category	Definition	Recommended level of decontamination	Examples of medical devices
Critical - high risk	Medical devices that enter sterile body cavity, tissues, including the vascular system and involves a break in the skin and mucous membrane	• Cleaning • Followed by sterilisation (steam or chemical)	• Surgical instruments • Biopsy instruments • Rigid endoscopes
Semi-critical -intermediate risk	Medical device that comes in contact with non-intact skin or mucous membranes without penetrate.	• Cleaning • Followed by HLD or sterilisation if indicated	• Respiratory therapy equipment • Anaesthesia equipment • Flexible endoscopes • Laryngoscopes • Bedpans • Urinals
Non-critical - low risk	Medical device that touches only intact skin and not mucous membranes, or does not directly touch the patient	• Cleaning • Followed by low level disinfection • In some cases, cleaning alone is acceptable	• Blood pressure cuffs • Statoscope • ECG Machine

Placing instruments and equipment into one of the above categories can be helpful in choosing the adequate level of decontamination required to protect patients and HCWs.

6.2 Single-use items

A single-use medical device is designed by the manufacturer to be used on a single patient only, and then discarded. Single-use devices are usually labelled by the manufacturer with the international symbol shown in **Figure 15.**

These items may be used in critical, semi-critical, or noncritical areas. These are however single-use items that are pre-packaged with the appropriate level of disinfection or sterilisation and then disposed of after a single use. Examples include gloves, needles, syringes, urinary catheters, and oxygen masks, to mention a few.

FIGURE 15: INTERNATIONAL SYMBOL FOR SINGLE-USE DEVICES[60]

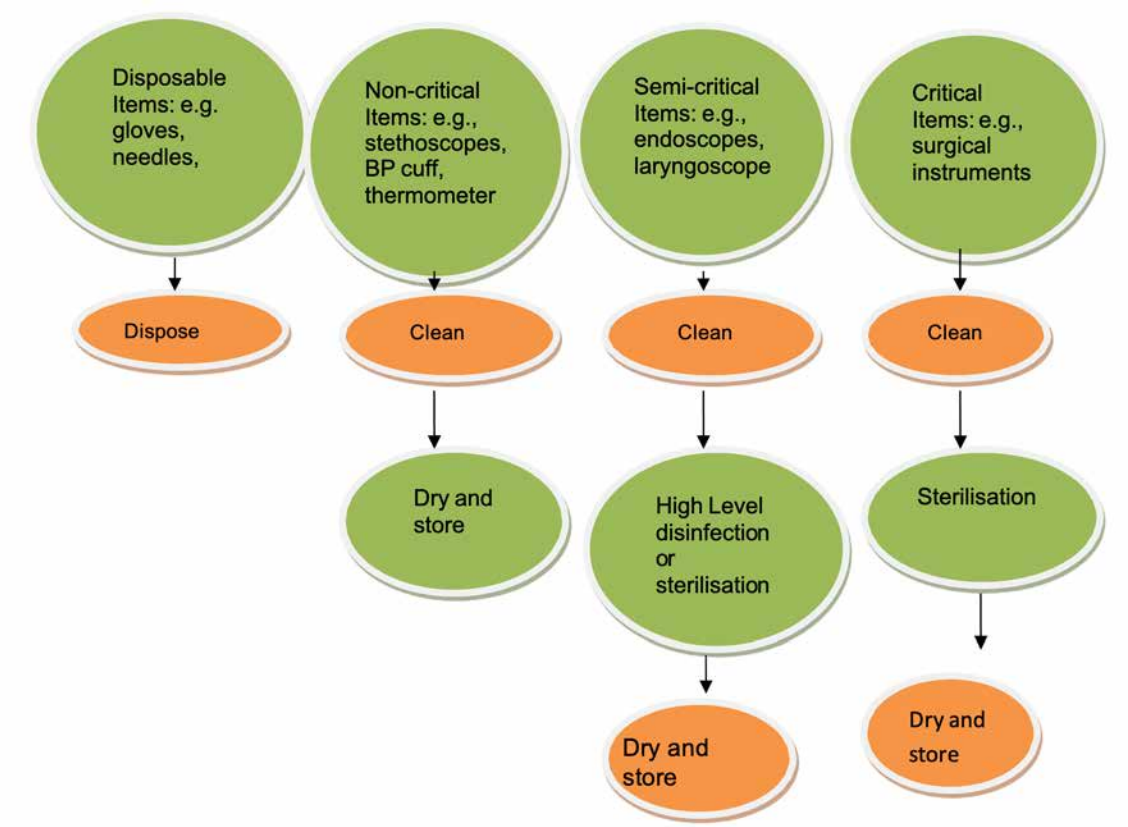
[59] Rowan, N.J., Kremer, T., McDonnell, G. A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability. Science of The Total Environment Vol 878, 20 June 2023. https://www.sciencedirect.com/science/article/pii/S0048969723015942?via%3Dihub

[60] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

6.1.1 Risks of re-use

The risks of reusing a single-use device depends on the type of device and the way it interacts with the patient's body. Most non-critical devices, such as compression sleeves, can be cleaned and reused with minimal risk. Opened, but unused, sterile instruments can sometimes be re-sterilised, provided that the materials can withstand the sterilisation procedure. However, some invasive single-use devices, especially those with long lumens, hinged parts, or crevices between components, are difficult or impossible to clean once body fluids or tissues have entered them. Reusing single-use devices carries the obvious risk of transmission of infections, but also increases the probability that the device could malfunction due to the adverse effects reprocessing has on materials and/or delicate components.[61]

FIGURE 16: SUMMARY OF DECONTAMINATION PROCESS



6.3 Management of other risks at the CSSD

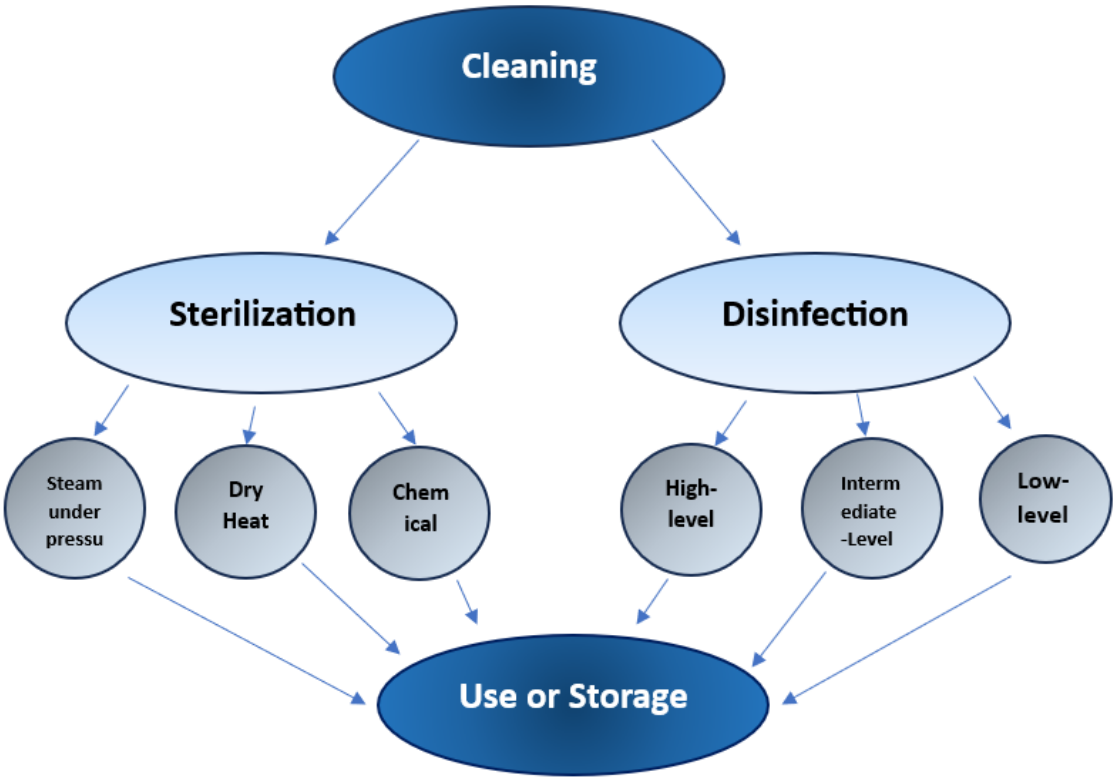
All healthcare facilities, including CSSD need to be able to identify the risks in their own context and implement appropriate interventions to reduce such risks. It is necessary for facilities to conduct regular risk assessments, through audits, the analysis of reported events at the facility, and by ensuring that all staff members understand their responsibilities in managing risks. It is important that factors contributing to risks are investigated to ensure that the appropriate mitigation measures can be implemented.

(Refer to chapter 5 for risks related to HCW safety and Annexure 4 for the management of fires and other disasters in the CSSD)

61 WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

There are several steps that are used when medical devices are reprocessed. (**Figure 17**) of which cleaning is the most important one. Once a medical device is thoroughly cleaned, it can either be disinfected or sterilised, depending on its intended use, its resistance to heat and the manufacturer's guidelines.

FIGURE 17: DECONTAMINATION STEPS



7.1 Cleaning process

Cleaning is the removal of all visible, organic and inorganic material from the object being reprocessed and must always be done prior to disinfection or sterilisation. This is done manually or mechanically using water with detergents or enzymatic products. To ensure quality outcomes for the patient, the cleaning process requires consistency and standardisation.

Cleaning is the first and most important step in the decontamination cycle and is an essential step before disinfection or sterilisation

7.1.1 Pre-cleaning

It is important that all used devices are prepared for reprocessing at the point of use to ensure safe transport and reduce the risk to CSSD staff. Point-of-use preparation helps to prolong the life of surgical instruments as dried blood and saline can cause the decomposition of stainless steel. Additionally, it is difficult to remove dried blood and body fluids from surgical instruments.

NOTE: Point of use cleaning is not a substitute for cleaning

7.1.1.1 Important points about pre-cleaning

- Remove gross soil from instruments by wiping with a damp clean dry cloth - pre-cleaning (e.g., rinse or spray) prevents soil from drying on devices and makes them easier to clean
- Cleaning products should be appropriate for medical devices and approved by the device manufacturer
- If detergent-based products are used, ensure that they are mixed according to the correct in-use dilution
- **Avoid prolonged soaking of devices** [62]
  Do not use saline or hypochlorite as soaking solutions as it damages medical devices
- Contaminated items should be transported in dedicated, fully enclosed, leak-proof and puncture-proof containers
- Soiled instruments should be opened and kept moist:
  - Spray with an enzymatic spray [63] (**Figure 19**)
  - Cover with a moist towel with water (not saline) or foam, spray, or gel specifically intended for this purpose (**Figure 18**)
- Do not transport in containers with water as water is a splash hazard

FIGURE 18: KEEP USED INSTRUMENTS MOIST WITH A DAMP CLOTH

[62] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[63] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

FIGURE 19: KEEP INSTRUMENTS MOIST WITH COMMERCIALLY AVAILABLE SPRAY

Soaking of instruments in hypochlorite solution (Sintol) or any other disinfectant before cleaning, is not recommended -

- It may damage and/or corrode the instruments
- The disinfectant may be inactivated by blood and body fluids, which could become a source of microbial contamination and cause the formation of biofilm
- Transportation of contaminated items soaked in chemical disinfectant may pose a risk to HCWs and result in inappropriate handling and accidental damage
- May contribute to the development of antimicrobial resistance to disinfectants[64]

Failure to properly clean an instrument may allow foreign material (e.g., soil and organic materials, including micro-organisms and inorganic materials and lubricants) located outside and inside of the device to prevent disinfection and/or sterilisation.

Cleaning is done by:

- Manual cleaning with cleaning chemicals (detergent) and water, brushing or flushing
- Ultrasonic washer
- Washer disinfectors to remove foreign material

7.2 Important points about cleaning

- Medical devices should be disassembled to allow effective cleaning
- Physical cleaning reduces the bioburden and the microbial load sufficiently to allow the process of sterilisation or high-level disinfection to be effective
- Dirt protects micro-organisms from contact with the disinfectants, steam and other chemicals, thereby rendering the process ineffective
- *Some chemicals used for reprocessing devices are inactivated:*
  - In the presence of organic matter
  - When mixed with other chemicals (incompatible)
- The life of the instruments is prolonged if soil and debris is removed regularly

[64] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

7.3 Factors affecting cleaning

There are several factors that can affect the efficacy of the cleaning process as detailed in Table 8.

Table 8: Factors affecting the efficacy of the cleaning process

Amount and type of soil present	• Cleaning chemicals can become diluted or ineffective in the presence of soil
Water quality and temperature	• Cleaning chemicals are designed to be used at specific temperatures • If clean water is not available, the water itself might deposit toxins on medical devices • Water hardness can affect the cleaning chemicals and can cause spotting and leave deposits on medical devices
Availability and use of cleaning chemicals.	• If cleaning chemicals are not available, cleaning must be done through water and friction only • It is important to follow the manufacturer's instructions regarding the chemical to water dilution rate as the dilution strength impacts the efficacy of the cleaning process
Staff training	• It is essential that staff who are responsible for the cleaning process are adequately trained in the use of the equipment, chemicals and tools used at the CSSD, and • Understand the cleaning requirements for different devices

7.3.1 Cleaning products (Detergents)

The purpose of cleaning products (detergents) is to remove organic, inorganic and microbial contaminants. A cleaning product should reduce the surface tension and break down the fat and organic matter.

7.3.1.1 Considerations when selecting a detergent

- Follow the manufacturer's recommendation for the most suitable detergent for the **type of device and the type of soil as well as compatibility**
- Degree of **water hardness**

NOTE: Only use appropriate detergents for instrument cleaning in the CSSD - detergents used for home cleaning or laundry use are not suitable for the cleaning of medical devices - hand soap must also not be used as the fatty acids in the soap react with hard water to leave soap scum on the instruments

7.3.1.2 Enzymatic (proteolytic) cleaners (e.g., Endozyme)

- Gross soil should first be removed by rinsing with detergent and water
- If blood or exudates or has dried or hardened, soaking in a warm (not hot) solution with an enzymatic cleaner (Endozyme) is required - cleaning agents containing enzymes break down proteinaceous matter and can be used, based on the manufacturer's instructions

NOTE: Consult the Manufacture's guideline for the dilution of enzymatic solution, temperature and time- enzymatic cleaners are not disinfectants and only remove protein from surfaces - rubber or nitrile gloves are recommended when handling enzymatic solutions because enzymatic cleaners degrade latex gloves

To ensure effective cleaning, it is important that the detergents are prepared in the concentration/s recommended by the manufacturer. To achieve the **correct concentration**, the **correct volume** of **concentrated detergent** must be added to the **correct volume of water** at the **correct temperature (Figure 20)**.[65]

[65] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

Chemicals, like disinfectants and detergents, function best at optimally recommended dilutions - making a stronger solution does necessarily not mean it will be more effective

FIGURE 20: DETERGENT PREPARATION [66]

7.3.2 Lubricants

The purpose of a lubricant is to protect the medical device and prolong its lifespan. Lubricants should be soluble in water.

- Lubrication must be done prior to sterilisation and according to the manufacturer's instructions - devices must be decontaminated and free of visible soil and rust before they are lubricated
- Incompatible lubricants can inhibit sterilisation, create harmful by-products, and damage the device or the steriliser
- Lubricants must be discarded if they are past their expiry date or visibly soiled[67]

7.4 Cleaning methods

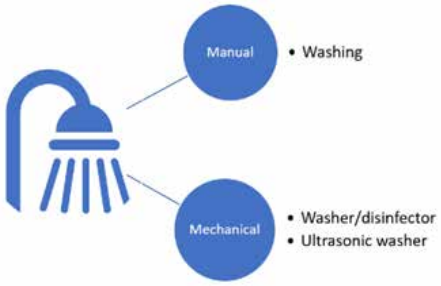
Cleaning is essential for the penetration of disinfectants or steam and must therefore precede reprocessing. **Cleaning is normally accomplished using water, detergents and mechanical actions.** A detergent is essential to dissolve proteins and oil that can reside on instruments and equipment after use.

One can clean without sterilisation, but one cannot sterilise without cleaning!

Cleaning may be carried out by the following means **(Figure 21):**

- Manual
  - Washing
- Mechanical
  - Washer/disinfector
  - Ultrasonic washer

FIGURE 21: MANUAL AND MECHANICAL CLEANING



66 WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

67 WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

7.4.1 Manual cleaning

Manual cleaning is indicated when:

- Mechanical cleaning facilities are not available
- Medical devices cannot be immersed (e.g., electrical of battery-powered devices)
- Devices require special cleaning (e.g., narrow bore lumens or delicate devices[68]

Important points about manual cleaning:

- All items requiring disinfection or sterilisation should be taken apart before cleaning
- Lukewarm temperature (not above 45˚Celsius) water is preferred as it will remove most of the protein materials (blood, sputum, etc) - heat (hot water) coagulates protein, making it difficult to remove
- The most simple, cost-effective method is to thoroughly brush the item while keeping the brush below the surface of the water to prevent the release of aerosols
- ***Important points about brushes:***
  - They should be decontaminated and dried after use
  - Should be used for cleaning of box locks, lumens and hard to clean areas
  - Should be made of soft bristles such as nylon to prevent damage to the surface of instruments
  - Brushes used for the cleaning of lumens must be the same diameter as the lumen to ensure that all internal surfaces can be reached and
  - Long enough to exit the distal end of the instrument.
  - ***Steel brushes should never be used - they damage instruments***
- Items must be rinsed in clean water and allowed to dry
- Items are then ready for use (non-critical items) or for disinfection (semi-critical items) or for sterilisation (critical items)
- Cleaning solution and water should be changed at each cleaning session and when visibly soiled
- Always wear utility gloves, a mask, eye protection and closed shoes when cleaning instruments (**Figure 22)**
- Automatic instrument washers are preferable as manual cleaning cannot be validated

FIGURE 22: WEAR UTILITY GLOVES, A MASK, EYE PROTECTION AND CLOSED SHOES WHEN CLEANING INSTRUMENTS

NOTE: Never use abrasive devices such as scourers or metal brushes that scratch or pit instruments - scratches, pits, or grooves can harbour micro-organisms and promote corrosion

[68] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

7.4.1.1 Rinsing

Rinse all devices thoroughly after cleaning to remove loosened soil and left-over detergent that might interact with the disinfectant or sterilant.

7.4.1.2 Drying

Drying is an important step that prevents microbial growth and dilution of chemical disinfectants that may affect the effectiveness of the disinfectants. Devices should be air-dried or dried by hand with a single-use clean, non-linting cloth. Dry lumens with compressed medical grade or high-efficiency particulate absorption HEPA-filtered air, at a pressure specified by the device manufacturer. Dry stainless-steel devices immediately after rinsing to prevent spotting.

7.4.1.3 Care of cleaning tools

- Cleaning tools must be cleaned, disinfected, and dried after every shift
- Inspect brushes and other cleaning equipment for damage after each use and discard if necessary
- The use of single-use cleaning tools is recommended
- If reusable tools are used, they should be disinfected at least daily [69]

NOTE: Never soak medical devices in disinfectants prior to cleaning as this is ineffective and of little value in the presence of organic matter

7.4.2 Mechanical Cleaning

Mechanical cleaning is the preferred method for cleaning of medical devices. Mechanical cleaning equipment provide controlled and uniformly reliable results, if the equipment is well maintained, and cleaning processes are validated. It also involves minimal handling of dirty devices by staff. **Table 9** provides examples of different types of mechanical cleaning options.[70]

Table 9: Mechanical cleaning options

Device	Working	Indication	Validation
Ultrasonic washer	Ultrasonic vibrations pass through the cleaning solution and create bubbles that implode and remove the soil	Hard-to-reach parts of metal instruments	**Daily validation** • Visual inspection of all devices after cleaning • Foil test
Automated washer / disinfector	Uses pressurised water to physically remove the bioburden - a very effective method	All instruments must be in an open position	**Daily validation** • Visual inspection • Soil test

7.4.2.1 Automated washer-disinfector

This method uses pressurised water to physically remove the bioburden and is a very effective method for cleaning and disinfecting instruments, because it uses detergents and thermal action.[71] Multiple steps are included in the cycle including pre-rinse with cold water (water temperature not more than 35˚C), enzymatic wash, detergent wash, and lubrication.[72] A final rinse at a temperature that thermally disinfects (90˚C for 12 seconds or 80C for one minute or 70˚C for three minutes) using de-ionised water will help to prevent mineral deposits, spotting and improve drying. Drying is the last essential step to prevent re-contamination when the load is removed.[73]

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[69] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[70] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[71] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[72] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[73] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

7.4.2.2 Ultrasonic washer

Ultrasonic washers are effective for the hard-to-reach parts of metal surgical instruments, such as box locks, serrations, hinges and lumens. It is not suitable for plastic devices. Ultrasonic vibrations pass through the cleaning solution and create bubbles that implode and remove the soil on the devices. It is an effective method of cleaning, but expensive.[74]

NOTE: It is strongly recommended that catheters, tubing, and other medical devices with small lumens that are very difficult to clean be designated as single-use devices and not be reprocessed and re-used

7.4.3 Proper are of surgical instruments

After the cleaning process the instruments should be checked for the following:

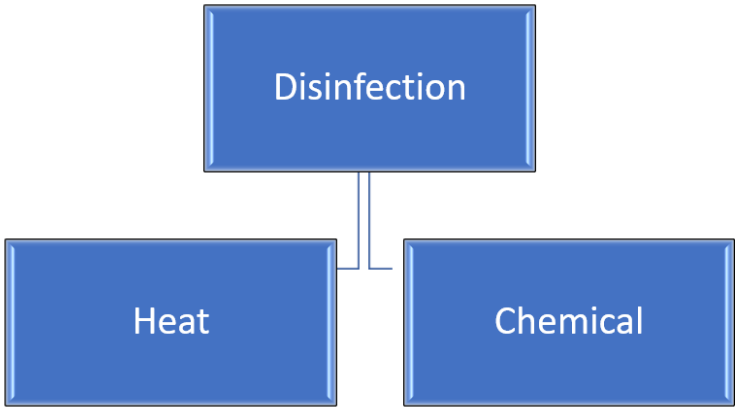
- Cleanliness: All blood and dirt is removed
- Proper functioning and possible breakage
- Scissor blades glide smoothly all the way - blades must not be loose when in a closed position
- Forceps tip properly aligned
- Haemostats and needle holders do not show light between the jaws - they should lock and unlock easily, and the joints must not be too loose
- Check the jaws of needle holders for wear and tear
- Ensure that the blades of cutting instruments and knives are sharp and undamaged

[74] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

CHAPTER 8: DISINFECTION

Disinfection is a process that reduces the numbers of pathogenic micro-organisms (except spores) to a level that is not harmful to human health. Disinfection of medical devices can be achieved by heat or chemicals **(Figure 23)**.

FIGURE 23: DISINFECTION METHODS



Heat (thermal) disinfection is preferred whenever possible because of the following reasons:

- It is generally more reliable than chemical processes
- Leaves no residues
- More easily controlled
- Non-toxic

A temperature of 80˚C for 10 minutes is recommended. Heat sensitive items must be reprocessed with a chemical disinfectant.

Choice of disinfection method will depend on the following:

- Susceptibility of the patient to infection.
- Tolerance of device to heat, chemicals, pressure and moisture
- Nature of contamination or micro-organisms present
- Time available for processing
- Risks to processing staff
- Cost of processing
- Availability of processing equipment[75]

FIGURE 24: FACTORS INFLUENCING THE DISINFECTION PROCESS

There are some factors that affect the effectiveness of the disinfection process which have to be taken into consideration:

- **Number of micro-organisms present** - As the bioburden increases, the amount of time that a disinfectant needs to act also increases and as such, it is therefore essential to first clean all devices prior to disinfection
- **Organic matter -** The presence of biofilms and/or organic matter can inactivate disinfectant by preventing contact between the device and the disinfectant, thereby compromising the effectiveness of the disinfection process

[75] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

- **Resistance of microorganisms** to the chemical agent
- **Concentration of the agents** - Each disinfection requires an optimal concentration to work effectively and higher concentrations may have a negative impact on the material the device is made of - e.g., causing corrosion - ensure that the correct dilution is used
- **Physical and chemical factors** - Some disinfectants have optimal antimicrobial activity at a certain temperature and/or pH, thus water should not be too hot or cold
- **Duration of exposure** - Each disinfection method and agent is associated with a specific amount of time necessary to achieve the desired result
- **Stability** - Some disinfectants are unstable after re-constitution, e.g., chlorine-releasing agents, and should be discarded as per the disinfectant manufacturer's recommendations[76]

NOTE: Organic matter (serum, blood, pus or faecal material) interferes with the antimicrobial efficiency of the disinfectant, therefore, thorough cleaning before disinfection is of greatest importance

Disinfectants are categorised according to a spectrum of activity based on standardised testing methods. There are three levels of disinfection:

8.1 High-level disinfection (HLD) - semi-critical Items

High-level disinfection is used for heat sensitive critical items and semi-critical items. The exposure time will depend on the manufacturer's guidelines. All items should be rinsed with good quality water after exposure to remove any soil residue and prevent the recontamination of processed items with water-associated contaminants.[77]

There are two methods of HLD:

- Use of moist heat at 70˚-100°C
- Chemical disinfection

When sterilisation is not available, HLD is the only acceptable alternative for instruments and other items that come into contact with the bloodstream or sterile tissue. Flaming is not an effective method for HLD, because it does not kill all micro-organisms effectively.

8.1.1 HLD by Boiling

High-level disinfection is best achieved by moist heat such as boiling in water (100°C for 10 minutes holding time), which kills all organisms except for a few bacterial spores. However, **it cannot be adequately controlled and should not be used instead of controlled validated sterilisation.**

- The advantage is that it is cheap, effective and leaves no toxic residue
- The disadvantage is however that it is not suitable for heat-sensitive devices and the process cannot be validated - there are no process controls, such as time and temperature
- There is a risk of burns to staff handling the devices[78]

It is important to note that boiling devices in water will not achieve sterilisation.

8.1.1.1 Guidelines to follow during HLD by boiling:

- Devices are manually cleaned and then placed in the chamber of the boiler
- Instruments and other items must be completely covered with water - disassemble items with multiple parts
- Always boil for 10 minutes - start counting the one minute when the water reaches continuous boiling point - if you forget to start timing the HLD procedure, start timing it at the point when you realise you forgot to time the process

[76] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[77] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[78] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

- Do not add anything to or remove anything from the pot/boiler once boiling begins
- A white, scaly deposit may be left on instruments and other items that have been boiled frequently and on the pot/boiler itself - these are lime deposits caused by lime salts in the water
- To minimise lime deposits, add some vinegar to the water to remove the deposits from instruments, other items, and the inside of the pot/boiler
- Boil the water for 10 minutes at the beginning of each day that the pot/boiler is used; this will precipitate the lime (make it come out of the water and settle on the bottom or sides of the pot/boiler, instead of on the instruments and/or other items) before the instruments or other items are added
- Use the same water throughout the day, adding only enough to keep the instruments and other items below the surface
- Drain and clean out the pot/boiler at the end of each day that it is used, it should be dried and stored in a manner that protects it
- The necessary steps should be taken to prevent burn wounds among staff members handling such devices

8.1.2 HLD by mechanical-thermal disinfection

Disinfection by hot water can also be performed in specially constructed washers/disinfecting machines, where the processes of cleaning, hot water disinfection, and drying are combined in a very effective procedure, rendering some items ready for use (e.g., respiratory circuits), or safe to handle (e.g., surgical instruments). The thorough initial rinsing and washing removes most of the micro-organisms and shortens the disinfection times.

If washer/disinfectors are used, they should be regularly maintained and checked for efficacy. Low- to high-level disinfection is achieved, depending on the type of machine and the complexity of the items.

8.1.3 Chemical HLD

Before deciding to use a chemical disinfectant, consider whether a more appropriate method is available. Chemical disinfection is used mostly for heat-labile equipment (e.g., endoscopes) where single use is not cost effective.

A limited number of disinfectants can be used for this purpose, these include:

- Glutaraldehyde 2% for 10 minutes to half an hour
- Hydrogen peroxide 6% - 7.5% for 20-30 minutes
- Peracetic acid 0.2-0.35% for five minutes
- Ortho-phthalaldehyde (OPA) for 5-12 minutes

The following procedures should be followed:

- The object must be thoroughly rinsed with sterile water after disinfection
- If sterile water is not available, freshly boiled water can be used
- After rinsing, items must be dried thoroughly and stored properly

Steps to be followed during use of chemical HLD:

- Clean and dry all items as water from wet instruments and other items dilutes chemical solutions, thereby reducing effectiveness
- Fresh solutions should be made each day (or sooner if the solution becomes cloudy) or alternatively, based on the manufacturer's guidelines
- If using a previously prepared solution, use an indicator strip to determine if the solution is still effective - record the findings daily in a register/logbook
- When preparing a new solution, put it in a clean container with a lid and mark the container with the preparation and expiry date
- Disassemble items with multiple parts; the **solution must contact all surfaces** for HLD to be achieved.

- Place all items in the solution so that they are **completely submerged** with bowls and containers upright, not upside-down, so that they fill with the solution
- Cover the container and allow items to soak for 20 minutes, depending on the manufacturer's guidelines and do not add or remove any item/s from the container
- Remove the items from the container using, dry, high-level disinfected pick-ups (e.g., forceps)
- Rinse thoroughly with cold boiled water to remove the chemical residue, which is toxic to skin and tissue
- Place items to air-dry on a HLD tray or container before use or storage
- Use instruments and other items immediately or keep them in a covered, dry, high-level disinfected container - use within one week, based on the manufacturer's guidelines

8.1.3.1 Notes on disinfectants:

*The use of disinfectants is covered in the **MoHSS IPC Guidelines 3rd Edition 2023** and is summarized in **Table 10.***
To be acceptable in the hospital environment, the disinfectant must be:

- Easy to use
- Non-volatile **(does not evaporate rapidly)**
- Not harmful to equipment, staff or patients
- Free from unpleasant smells
- Effective within a relatively short time

Always follow the manufacturer's recommendations. Disinfectants should always be stored in a cool, dark place. They should never be stored in direct light or excessive heat.

NOTE: Other chemicals, e.g., chlorhexidine and povidone iodine, are antiseptics and are suitable for decontamination of medical devices, they should only be used on the hands and skin

Table 10: Different types of disinfectants, their actions and limitations

Disinfectant	Actions	Indication	Limitations
Glutaraldehyde 2%	**HLD:** - Broad range of microbial activity - Effectively destroys bacteria, fungi and viruses - Takes long to destroy spores	Endoscopes	- Allergenic - Dangerous, toxic and irritant - Maximum exposure time needed
Ortho-phthalaldehyde (OPA)	**HLD - Sterilant** - Broad range of microbial activity - Poor sporicidal activity - Generally rapid - No odour	Endoscopes	- Expensive - Skin and eye irritant - Unstable when activated - Stains items and skin if not thoroughly removed - Hypersensitivity reactions - Monitor for efficacy levels
Peracetic acid 0.2 to 0.35%	**HLD:** - Broad range of microbial activity - Generally rapid acting including mycobacterium and spores	- Automated endoscopic systems - Sterilisation of heat-sensitive items - Suitable for manual instrument processing	- May be corrosive or damaging - Unstable when activated - May irritate skin, conjunctiva, mucous membranes
Hydrogen peroxide solution	**HLD – sterilant** - Fast virucidal and bactericidal - Slow sporicidal and fungicidal - Non-irritant when mixed and user friendly[79]	Heat-sensitive items	- Corrosive to some metals - Can cause serious eye damage with contact - Dilution must be monitored by regularly testing the minimum effective concentration

[79] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

Alcohol 70% isopropyl alcohol or 60 to 80% ethyl alcohol (ethanol)	**Low to Intermediate** - Rapidly acting against most bacteria and viruses - Main use is for rapidly disinfecting and cleaning surfaces - The alcohol evaporates quickly to leave surfaces dry	- Semi-critical and non-critical devices - Thermometers, stethoscopes - Rubber stoppers on multi-dose vials - Spot cleaning on surfaces	- Flammable - Inactivated by organic matter[80] - Irritates mucous membranes - **Not sporicidal** and has poor penetration
Chlorine releasing agents - Commonly used, is sodium hypochlorite (Bleach)	**Low – high** Rapid and broad range of antimicrobial activity	- Disinfection of surfaces - Hydrotherapy tanks - Water systems in haemodialysis units - Decontaminating blood and body fluid spills	- Damage and discolour fabrics - Causes pitting of metal - High concentrations required for direct application to spills - inactivated by organic material - Release toxic gas when mixed with ammonia Irritate skin and mucous membranes - Unstable when exposed to light or diluted[81,82]

[80] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[81] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

[82] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

CHAPTER 9: INSPECTION, ASSEMBLY AND PACKING

The inspection, assembly and packaging area (IAP) at the CSSD, is where medical devices are visually inspected, tested for correct functioning and packed for further sterilisation after cleaning in the decontamination area **(Figure 25).**

All devices are assembled, checked, and recorded on instrument tray lists before sterilisation. The use of a bright light with a magnifying glass is recommended.

FIGURE 25: INSPECTION ASSEMBLY AND PACKING

Important points:

- Perform hand hygiene before handling clean instruments
- Ensure the workspaces are clean without any clutter
- Do not use oily substances for lubrication
- Staff with skin conditions should not be allowed to perform this activity[83]

9.1 Inspection and function testing (post-cleaning)

- Each device should be checked after cleaning to ensure that it is clean, in working order and that there are no loose or faulty parts
- Each set should be inspected separately and checked for completeness and defects
- All instruments should be inspected for ease of movement, alignment, and sharpness (as applicable)
- Multi-part instruments should be assembled to ensure that all parts are complete and working
- Damaged, incomplete, or malfunctioning devices should be reported to the supervisor
- Cannulated devices should be checked to ensure that the channels are patent
- Telescopes and light cables should be function-checked according to the manufacturer's instructions
- Devices with an outer insulation coating, e.g., diathermy forceps, require close inspection to ensure that the insulation remains intact - damaged surfaces allow dirt and bacteria to collect and can potentially be dangerous for both staff and service users

9.1.2 Placing devices in surgical trays

Devices must be prepared for sterilisation in the following manner:

- Must be cleaned and dried
- Jointed instruments in the open or unlocked position
- Multi-part or sliding pieces disassembled, unless otherwise indicated by the device manufacturer
- Devices with concave surfaces that will retain water must be placed in such a manner that condensate does not collect
- Tips of sharp instruments should be protected
- Heavy items placed underneath to prevent damage to lighter and more delicate items

[83] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

9.2 Assembly

The purpose of assembly and checking is to ensure that all devices are:

- Present in accordance with the surgical tray list
- Assembled correctly according to the manufacturer's instructions
- Placed in the trays that will ensure easy access to the user

The area where assembly and inspection takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the sets.

Important notes:

- All devices should be placed in such a manner that the surfaces are exposed to the steam (or sterilisation media)
- Devices should be placed in one layer on the device trays
- Tray liners should be placed at the base of the surgical tray
- Devices should be spread evenly by weight over the tray surface to prevent condensation
- Plastic items should be evenly placed on the tray - not all of them in one section of the tray
- Ensure that sharp devices are assembled correctly to avoid penetration of the outer packaging
- Any device missing from a tray should be reported to the supervisor for further action and documented
- Checklist to be placed in the set
- Indicator strips should be placed in the set before it is wrapped

9.3 Packaging and wrapping material

Packaging material and techniques are designed to protect devices and to keep them together, facilitate sterilisation and maintain sterility as well as to ensure the aseptic removal of contents at point of use. The material selected depends on the sterilisation method and must comply with international standards.

9.3.1 General principles for wrapping

Packaging should be selected according to the sterilisation method and the devices to be prepared.

- Every package should have an external chemical indicator (internal chemical indicators are optional)
- An identification or label of the content, lot number, expiry date and initials of the operator
- Devices can be packed in any of the recommended sterile barrier systems such as sterilisation wrap, rigid reusable containers or film packages
- The capability of each specific wrapping material must meet the predetermined requirements and criteria when a packaging system is selected
- Wrapping material should completely cover the device that has to be packed[84]
- Hollow ware and medical devices or dressings should not be placed in textile (linen) packs, as combined packs may not dry adequately and may compromise sterilisation due to different rates of temperature increases among these materials
- Hollow-ware items packaged together should be separated by non-porous material to permit efficient steam circulation
- Hollow-ware should be packaged so that all openings face the same direction
- Single-use wraps should be used once only and discarded after use in the appropriate health-care waste stream
- Trays used for packaging devices should be perforated to allow penetration of the sterilant
- Packing material and chemical indicators must be compatible with the sterilisation process
- Sequential wrapping using two barrier-type wrappers is recommended as it prevents microbial migration

[84] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

9.3.2 Requirements for packaging systems

Packing systems should be appropriate for the items being sterilised and comply with the requirements stipulated in **Table 11.**

Table 11: Requirements for packaging systems

Appropriate for the items being sterilised	Appropriate for the sterilisation method	Used according to the manufacturers' instructions
- Permit identification of contents - Permit complete and secured enclosure of items - Protect package contents from physical damage - Permit delivery of contents without contamination - Maintain sterility of package contents until opened - Facilitate aseptic techniques at all times, including opening the package	- Provide adequate seal integrity - Provide an adequate barrier to particulate matter and fluids - Be compatible with and able to withstand physical conditions of the sterilisation process - Allow penetration and removal of sterilant - Maintain integrity of the pack - Permit use of material compatible (e.g., non-degradable) with the sterilisation process	- Resistance to punctures, tears and other damage that may break the sterile barrier and cause contamination - Resistant to penetration by micro-organisms from the surrounding environment - Free of holes - Free of toxic ingredients - Lint-free (or low linting) - Tamper-proof and able to seal only once - Provide an adequate barrier to particulate matter and fluids

9.3.3 Packaging materials

- Should be stored at room temperature of between 18-22˚C and at a relative humidity of 35-70% to maintain the integrity of the product
- Should not be stored adjacent to external walls or other surfaces, which may be at a lower temperature or a higher temperature than the ambient temperature of the storeroom
- **Should be stored on shelves 28 cm above floor level**
- Should be rotated to ensure that it does not exceed its shelf life ("first in, first out")
- Be compatible with the sterilisation method and not contain toxic ingredients or dyes
- Free from loose fibres and particles
- Be compatible with pack contents under the proposed sterilisation conditions
- Withstand high temperatures
- Permit sterilant contact with package contents
- Resistance to penetration by microorganisms following sterilisation
- Allow air removal from packages and contents
- Permit drying of package and contents and prevent the entry of microbes, dust and moisture during storage and handling
- Capable of withstanding normal handling, resistant to tears or punctures
- Allow for aseptic presentation
- Cost effective
- Must comply with the manufacturer's recommendations[85]

9.3.4 Selection of packaging material

Packaging materials are selected according to size, shape, weight and the intended sterilisation process. **Table 12** refers.[86]

[85] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/978924154985

[86] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

Table 12: Various types of packing systems and their use

Type of packaging	Uses	Advantages	Disadvantages	Comments
- Paper (medical grade) - Bleached crepe paper - Cellulose & synthetic fibres	- Steam - Dry heat - ETO	- Penetration of steam, air, chemicals - Effective barrier in dry clean conditions - Free from loose particles; single use only	- Fibres and loose particles if torn or shredded - Not to be used for hydrogen peroxide plasma - absorbs hydrogen peroxide - Do not facilitate aseptic opening	- Follow manufacturers' guidelines, double wrap may reduce steam penetration - Paper bags are not very strong; unable to see content
- Reusable rigid containers - Metals, aluminium, high density polymer or a combination of metal and plastic	- Steam sterilisation for large sets of surgical devices	- Keeps the devices safe after sterilisation and during transportation	- Containers must be loaded properly to avoid moisture built up and increasing drying times	- Lid and base are perforated to allow steam [87] penetration - Disassemble and clean after each use - Routine inspection and maintenance - Must be validated before use
- Woven fabrics. - Two layers of cloth or one each of cloth and paper - Primary packaging	- Steam pre-vacuum or downward displacement (gravity)	- Heavy pack - Stronger resistant to tearing; reusable	- Poor bacterial barrier - Holes in the fabric render them ineffective - Impede air penetration and air removal if thick or tight - Cannot be used alone If too dry, will cause overheating of steam and sterilisation failure - "Sterile" wound infections from lint	- Store clean and dry - Need to be inspected carefully and assess quality during use and reuse - Not recommended for primary packaging alone, must have another layer
Synthetic woven fabrics	Steam sterilisation	- Durable and good to use	- Need to be validated for sterilisation and reliable drying	- Validation required for sterilisation
- Transparent pouches - Polymers - Polyethylene - PVC - Polypropylene & polycarbonates - Nylon	- Steam ETO - Steam Hydrogen peroxide plasma Dry heat only	- Good antimicrobial and dust barrier - Single items - One medical device per pouch - Maintain sterility; contents easily visible	- Can tear or perforate - Need to be properly heat sealed without leaks to maintain sterility - Some impede steam removal and increase air removal time	- Suitable for single devices or light materials. - Some polyethylene pouches do not tolerate vacuum - PVC & nylon pouches are not recommended
- Tyvek- bonded polyethylene - Superior bonded, paper like non-woven	- Steam - ETO - Low temperature steam - Hydrogen peroxide plasma;	- Good barrier properties - Low absorption of chemical sterilant - Can be heat sealed - Chemical indicator incorporated	- None, but expensive	- Good non-woven substitute for linen[88]

[87] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/978924154985

[88] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

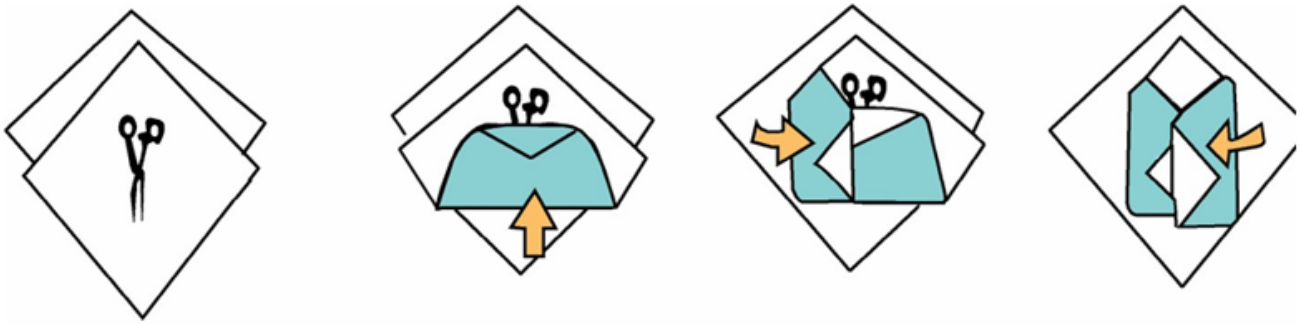
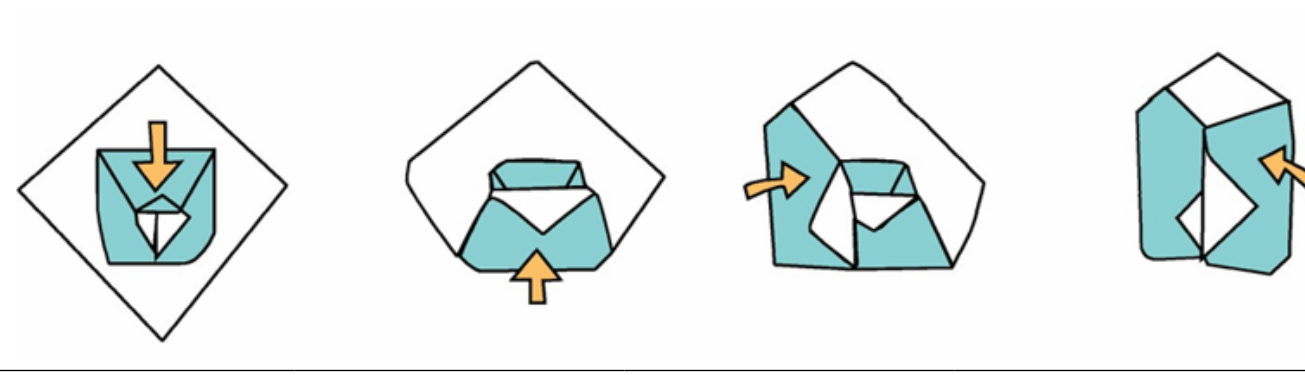
In relation to microbial penetration, non-porous materials are solid barriers, while porous materials are effectively "filters" manufactured to have good control over the probability of penetration by micro-organisms as long as the packaging is kept dry, even at low rates of air flow through the material.

Note: The total weight of instrument sets and their packaging should not exceed 10 kg[89]

9.3.5 Steps for wrapping of medical devices

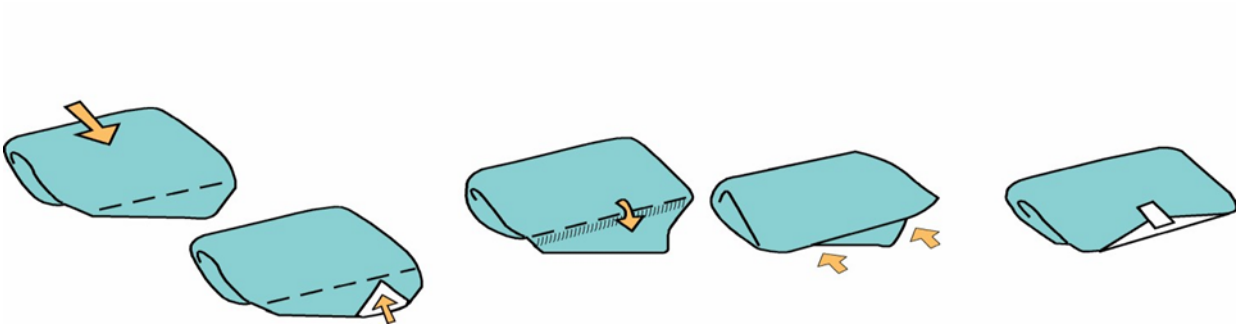
Wrapping instruments and other items before steam sterilisation helps to decrease the likelihood that, after sterilisation, they will be contaminated before use. To wrap instruments and other items for steam sterilisation, use two layers of material such as paper or cotton fabric, however paper is preferred to allow steam penetration. Make points in the wrapping material while wrapping the instruments and other items so that the packs can be easily opened without contaminating their contents (see Table 13 below).

Table 13: Steps for wrapping instruments and other items

Step 1	Step 2	Step 3	Step 4
Place the instrument or other item in the centre of the top wrapper - Items should be positioned so that the points and not the flat edges are at the top, bottom, and sides	Fold the bottom section of the top wrapper to the centre, and fold back the point	Fold the left section to the centre, and fold back the point	Fold the right section to the centre, and fold back the point
			
Step 5	**Step 6**	**Step 7**	**Step 8**
Fold the top section to the centre, and fold back the point	Fold the bottom section of the bottom wrapper to the centre, and fold back the point	Fold the left section to the centre, and fold back the point	Fold the right section to the centre, and fold back the point
			

[89] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

Step 9	Step 10	Step 11	
Fold the top section to the centre, and fold back the point	Tuck the point under the right left sections	Fasten the folds securely, using autoclave tape, if available	



Storage of sterile items should be according to the guidelines as in Chapter 3: Sterile Store.

9.3.6 Preparation of other Items e.g., cotton swabs, gauzes for sterilisation

The preparation is done according to the health facilities standard operating procedures as determined by the CSSD.

9.4 Sealing and indicators

Adhesive tapes, such as sterilisation indicator sealing tape, with a chemical indicator are used to fasten wrappings. The chemical indicator changes colour during the sterilisation process.

Heat sealing for flexible packaging materials should be used. Edges of inner heat seal pouches should not be folded as air may be entrapped in the folds and inhibit sterilisation. When double-wrapping using paper/plastic heat seal pouches, the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the devices to be viewed. It is important to wrap the devices securely to avoid contamination. Use an adhesive device identification label on the outside of the packaging. **Do not write on the paper side of the pouch.**[90]

9.5 Labelling

Packages must be labelled before sterilisation- the information on the label should include the following:

- Name of device/product
- Name of person who packed the devise
- Expiry date and/or sterilisation date
- Load number
- Sterilisation indicator

The sterilisation chemical indicator tape or label must be used to document the label information described above and never on the packaging material. Plastic/paper pouches can be labelled outside the heat seal line and on the clear (laminate) side as the ink may penetrate the paper on the plastic portion. The marking pen used to label the pack should be indelible, non-bleeding and non-toxic. Sharp-tipped, water-based or ballpoint pens should not be used as these may damage the packaging. The labels should remain on the package until the point of use. Operating staff should put the label in the patient's record to assist when items have to be recalled due to decontamination failures.

[90] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

NOTE: Never write on the packing with a sharp-tipped ballpoint pen as it could damage the packaging and compromised sterility

9.6 Specific packaging guidelines for low temperature processes

There are specific requirements and limitations for packing materials of low temperature sterilisation processes that has to be taken into consideration.

9.6.1 ETO

Cotton or polyester/cotton textiles cannot be used in ETO sterilisation because it absorbs moisture, which is necessary to destroy micro-organisms. Sealed containers must not be used. Different packaging materials (as well as the devices being sterilised) will absorb differing amounts of ETO during sterilisation. Removal of this absorbed gas is a slow process requiring a specific aeration stage and equipment. Packaging materials can have a significant effect on the efficacy of the sterilisation process and any change requires revalidation of the process.

9.6.2 Hydrogen peroxide plasma

Only purely synthetic packaging materials can be used in hydrogen peroxide plasma sterilisation, because there is no absorbed moisture in the packaging material, as very small quantities would interfere with the vacuum and the generation of plasma used in this process. Suitable materials may be selected from the range of non-woven wraps and non-cellulose flexible packaging materials available, and should be sealed at 120˚C.

9.6.3 Peracetic acid

Peracetic acid sterilisation uses a liquid sterilant. Porous packaging materials cannot be used as they would be completely saturated with liquid at the end of the process. This process is intended for the sterilisation of unwrapped instruments with only a very short distance for transportation of the goods from the steriliser to the point of use. For this purpose, the load-carrying "cassette" offers some protection following sterilisation, similar to the way packaging materials function, **but these machine-specific, load-carrying systems are not intended to maintain sterility longer than a few minutes after sterilisation.**[91]

[91] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

CHAPTER 10: STERILSATION

Sterilisation is a process which achieves the complete elimination or destruction of all micro-organisms, including bacterial spores.

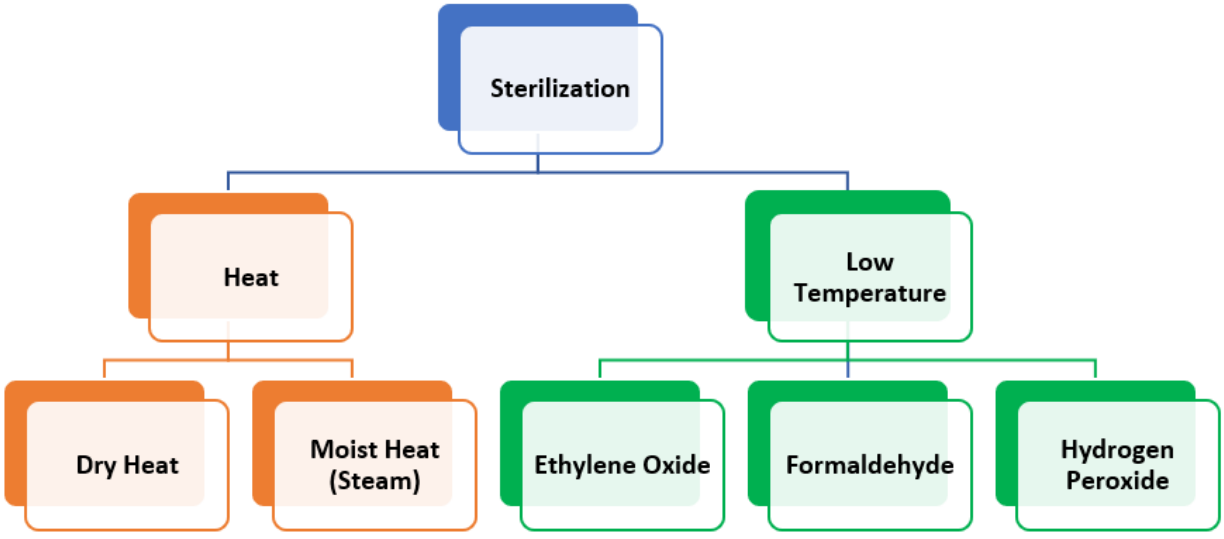
NOTE: The preferred method for sterilisation of heat-resistant critical devices is steam/moist heat sterilisation.

All critical medical devices must first be cleaned and then sterilised. Whenever possible, semi-critical medical devices should also be sterilised.[92] Choosing the correct sterilisation process is important to prevent damage to the device or compromise sterility. Sterilisation and the provision of a sterile device for a patient procedure is dependent on the whole cycle of decontamination, including cleaning, packaging, sterilisation, storage/transport, even up to the point of preparing and using the device on a patient.

If you cannot clean a device, you cannot sterilise it...

Sterilisation is principally accomplished by the processes described in **Figure 26**.

FIGURE 26: STERILISATION METHODS



- Steam under pressure (autoclaving)
- Other sterilisation processes are available for heat sensitive devices:
  - Dry heat (hot air oven)
  - *Low temperature chemical methods:*
- Ethylene Oxide (ETO)
- Hydrogen peroxide
- Peracetic Acid

[92] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

10.1 Steam sterilisation (autoclaving)

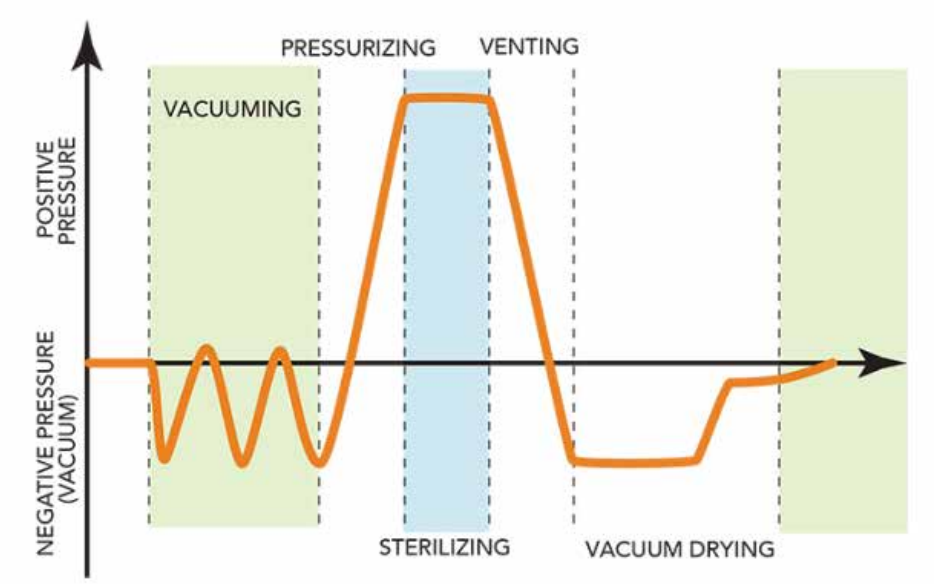
Steam sterilisation is the most common and most preferred method used for sterilisation of all critical medical devices if they are heat stable. It is a process that uses saturated steam under pressure as the sterilant. The removal of air is essential to ensure an efficient sterilisation process - sterilisation cannot occur in the presence of air. The steam is used as a carrier of thermal energy or heat. Steam is a much more efficient carrier of heat than air. The steam softens the outer layer of micro-organisms, which permits the thermal energy or heat to enter the organism and denatures the proteins in the organism/s. The proteins are then unable function normally in the cell, leading to cell death (and death to the organism).

Steam sterilisation is dependable, non-toxic, inexpensive, sporicidal, heats rapidly and is effective in penetrating fabrics.

The autoclave cycle involves the following (Figure 27):

- Removing all air from the autoclave
- Introducing steam at a required pressure
- Achieving required temperature
- Maintaining the temperature for the required time
- Removing condensation/water
- Introducing warm filtered air
- Drying the instruments

FIGURE 27: AUTOCLAVE CYCLE [93]



10.1.1 Types of steam sterilisers

There are several types of steam sterilisers that utilise different methods to remove air from packages and the chamber.

1. Small table-top sterilisers

- Sometimes used in physicians and dentists' offices and clinics
- Are essentially large pressure cookers
- Holding temperature for unwrapped items: 121°C for 20 minutes or 134°C for 3-4 minutes
- Devices are sterile but wet at the end of the cycle

[93] https://www.medicaldesignandoutsourcing.com/what-is-an-autoclave-cycle/

- There is a high risk of contamination of processed devices
- **Not suitable for surgical packs, narrow lumened devices and wrapped instruments**[94]

2. Portable steam steriliser:

- These can be adapted for processing critical devices in low resource settings
- Can provide adequate steam sterilisation in situations where conditions and resources are severely limited
- Dental equipment and open trays only
- **Not recommended for surgical packs, narrow lumened devices and wrapped instruments**

3. Gravity downward-displacement sterilisers:

- Larger than tabletop sterilisers with the addition of more automatic controls
- The chamber fills with steam, displacing the air downward and forcing it out of the drain valve
- Holding temperature for unwrapped items: 121°C for 15 minutes or 134 °C for 3-4 minutes
- **Not recommended for surgical packs, narrow lumened devices and wrapped instruments**
- **Cannot be controlled or properly validated - not recommended**

4. Emergency (flash) sterilisers (these are a form of gravity-displacement steriliser):

- Fast sterilisation of non-porous and/or non-cannulated unwrapped surgical instruments
- Normally located in operating room suite
- Quick sterilisation cycle at 134°C for 3-4minutes
- Should be used only when there is insufficient time to sterilise an item with the preferred pre-packaged method
- Only for unwrapped items
- **It should NEVER be used for sterilisation of surgical trays or packs**

5. High-speed pre-vacuum vacuum sterilisers (porous load autoclaves)

- Similar to downward-displacement sterilisers, with the addition of a vacuum pump system
- Vacuum pump removes the air from the chamber before the steam is admitted, reducing the penetration time and total cycle time
- Holding temperature 134ºC for 3-4 minutes for wrapped items
- Ideally used for wrapped items and porous loads (fabrics, swabs, instruments with lumens, etc)

10.1.2 Sterilisation Times

Table 14: The sterilisation times for the different types of sterilisers

Type of instruments to be sterilised	Sterilisation time (holding time)
Gravity steriliser	
Unwrapped: 121 ºC (1.036 Bar)	15 minutes
Unwrapped: 134 ºC (2.026 Bar) metal and glass	3 minutes
Unwrapped: 134 ºC (2.026 Bar) e.g., rubber	10 minutes
Wrapped: 121 ºC (1.036 Bar)	30 minutes
Wrapped: 134 ºC (2.026 Bar)	15 minutes
High-speed vacuum steriliser	
Wrapped: 134 ºC (2.026 Bar)	4 minutes

[94] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

10.1.3 Monitoring of sterilisation cycles

Monitoring of each steam steriliser and every cycle is essential to ensure the sterility of the reprocessed medical devices.

The following are monitoring methods:

- Physical (notebook, displays and printout)
- Chemical (internal and external indicators)
- Biological indicators

(See Chapter 11 for more detail on indicators and validation)

If the steriliser does not have a built-in printer, the operator should control the physical parameters of the sterilisation process. See **Table 15** for an example of a log to record each cycle.[95]

Table 15: Manual control of physical parameters for steam sterilisation[96]

Date	Autoclave number	Load number	Start cycle	Start sterilization time	End of sterilization time	End cycle time	Signature

10.1.4 *Steps for pressure steam sterilisation (autoclaving)*

1. Correct loading of the autoclave:

- Items should be loaded within the boundaries of the loading tray so that they do not touch the chamber walls or fall off when the load tray is in transit
- Ensure there is sufficient room between items to allow circulation of steam
- Do not overload the chamber
- Racks may be used to allow for adequate separation of packaged instruments
- Packs of hollow-ware and trays of instruments should not be placed above textile packs or soft goods to avoid damp caused by condensation from items above
- Do not load the heavier packs on the top shelf as it is easier to unload the packs from the bottom shelf without dragging it

2. Follow the manufacturer's instruction for operating the autoclave.

- Adjust time, temperature, and pressure according to **Table 14**
- It is best to use a timer, which helps to ensure that the appropriate timing is achieved

3. Do not begin timing until the autoclave reaches the desired temperature and pressure:

- If the timing process is forgotten, start the cycle again
- If the autoclave is automatic, the heat will shut off and the pressure will begin to fall once the sterilisation cycle is complete
- If the autoclave is not automatic, turn off the autoclave after achieving the required time

[95] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[96] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

4. Wait until the pressure gauge reads "0" to open the autoclave.

- Open the lid or door to allow remaining steam to escape
- Leave all items in the autoclave until they dry completely
- It may take up to 30 minutes

5. Unloading of the Autoclave:

- The operator should always wear heat resistant gloves to prevent burns as the packs come out of the autoclave hot
- Remove packs, drums, or unwrapped items from the autoclave using sterile pick-ups to handle unwrapped items
- The packs of equipment should come out of the autoclave dry - wet packs must be considered non-sterile
- On removal of the load, the operator should check the print-out or fill in details about the cycle on the record sheet to indicate that the required parameters have been met
- Sterile items (hot packs) must be placed on cooling racks and not on solid surfaces to prevent condensation
- Do not drag the packs along surfaces as this may result in tears in the packs and compromise the sterility of the pack
- Do not store packs, drums or unwrapped items until they cool down to room temperature - this may take several hours
- Sterile items should be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source

Important points to remember:

- **First clean all items to be sterilised**
- Instruments may be autoclaved individually or in sets
- Place heavy instruments on bottom of set
- Never lock instruments during autoclaving, as this will prevent the steam from reaching and sterilizing the metal-to-metal surfaces - furthermore, heat expansion during autoclaving can cause cracks in hinge areas
- Sterilised packs should always have the date of sterilisation as well as the expiry date clearly written on it

10.1.5 Determination of sterility of a set

- Set must be dry
- Wrapping should be intact e.g., not torn
- Properly wrapped
- Expiry date checked
- Indicator strips changed colour

10.1.6 Types of Chemicals (low temperature) sterilisation methods

Chemical gas (low temperature) sterilisation is used to sterilise heat, and moisture-sensitive medical devices.

Examples include:

- ETO
- Hydrogen peroxide
- Low temperature steam formaldehyde
- Chemical disinfection (not recommended)

Table 16 describes the different methods of sterilisation with the advantages and disadvantages of each.

Table 16: Sterilisation methods

Cycle Time	Indications	Monitoring	Advantage	Disadvantage
		Steam steriliser		
Cycle times vary (3-18 minutes) depending on the sterilisation temperature	Critical devices and semi-critical devices that will not be damaged by moisture or heat	• Biological indicators -at least daily • Chemical indicators -each package • Physical indicators - each cycle • Loads with implantable device shall be monitored with an additional biological indicator	• Inexpensive • Fast • Effective • Penetrates medical packages and device lumens • Non-toxic • Readily available • Easy to control and monitor	• Unsuitable for heat- and moisture-sensitive materials • Knowledge of the operational requirements • Not suitable for heat-sensitive instruments • Might damage microsurgical instruments • Risk of burns
		Flash Autoclave (NOT RECOMMENDED)		
Cycle times vary depending on the sterilisation temperature and the device container	• **For emergency use only** • Not used for implantable devices or complete sets of instruments	• Daily chemical indicators (each package) • Physical indicators (each cycle) • Biological indicator • Cycles must be documented to ensure that the patient are linked to the cycle should there be an adverse event	Fast	• Devices cannot be stored • Process is not validated
		Hydrogen peroxide vapour and gas (may also include plasma)		
Cycle time and temperature will vary, depending on the model of steriliser Times range from 28-70 minutes. Cycle temperatures are less than 60˚C	For critical devices and some semi-critical devices that will be damaged by moisture or heat	• Daily biological indicators • Chemical indicators (each package) • Physical indicators (each cycle)	• Fast cycles (approximately 28-75 minutes) • Safe for the environment • Compatible with heat- and moisture-sensitive devices • Easy installation and operation • No staff monitoring currently required • No aeration required • No chemical residues	• Follow manufacturers guidelines • Cannot sterilise materials that absorb hydrogen peroxide (e.g., linen, gauze, cellulose/paper) • Medical devices must be dry before processing • Limitations to length of lumens that can be effectively sterilised

Cycle Time	Indications	Monitoring	Advantage	Disadvantage
Ethylene Oxide (ETO) gas				
Combined sterilisation and aeration (required) - approximately 15 hours	Critical and some semi-critical devices that will be damaged by moisture and/or heat. e.g., electronic instrumentation	• Biological indicators (each load) • Chemical indicators (each package) • Physical indicators (each cycle)	• Non-corrosive • Penetrates packaging materials and device lumens • Excellent material compatibility • Simple to operate and monitor	• Toxic/carcinogenic • Lengthy cycle due to aeration • Requires control and monitoring • Flammable and explosive • Highly reactive with other chemicals • Expensive compared to steam • Incompatible with some materials, e.g., silicone • Requires packaging materials that are permeable to ETO • High-cost method
Liquid chemicals (e.g., glutaraldehyde)				
High level disinfection - not suitable for critical devices		**Not suitable for sterilisation – high-level disinfection only**	None	• Difficult to control • High probability of recontamination during rinsing or drying • Cannot store • Well-trained staff • Cannot be used for moisture-sensitive • Thorough rinsing is challenging • Takes a long time to achieve sterilisation - 12 hours[97]

10.2 Storage of sterilised medical devices (shelf-life and rotation of stock)

10.1.1 Storage requirements for sterile packs

(More detail about the Sterile Store can be found in Chapter 3)

- Sterile packs should be placed next to each other and not stacked on top of each other
- Stacked packs can trap moisture
- Heavy packs can damage the packaging

Packs should be placed in such a way to ensure that the following is visible:

- Name of the pack
- The content
- Data of processing
- Expiratory date

- Stock should be rotated on a ''first in- firs out'' (FIFO) basis
- **Wrapped items - The length of time (shelf life) that a wrapped, sterile item is considered sterile depends on whether or not a contaminating event occurs and not necessarily on how long an item has been stored**

[97] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

The shelf life depends on the following:

- Handling after sterilisation
- Storage conditions
- Transport conditions
- Amount of handling

- A wrapped pack can be considered sterile as long as it remains intact and dry for no **more than three months from date of processing**
- Sterile packs from supplier should be stored as per supplier's expiry date
- When in doubt about the sterility of a pack, consider it contaminated and re-sterilise the items
- Instruments packed in steri-pouches remain sterile for up to a year as long as they are not punctured
- Do not store instruments or other items such as scalpel blades and suture needles in solutions, always store them in a dry container - micro-organisms can live and multiply in both antiseptic and disinfectant solutions that can contaminate instruments and other items, subsequently leading to infections and outbreaks
- Collection should be regular and there should be a written record of receipt and delivery - this helps monitor use and loss of instruments
- Unwrapped items should be used immediately after removal from the steriliser or keep them in a covered, dry, sterile container for up to one week[98]

NOTE: Rotation of stock should be done on a regular basis by rotating packs from top to bottom, back to front and left to right

[98] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

Each step of the decontamination cycle is crucial to ensure sterile reusable medical devices that can be used safely on patients during surgical interventions. An error during any of the stages of the decontamination cycle may lead to huge costs, serious suffering and endanger the lives of patients and staff. The validation of each step of the decontamination cycle is an important aspect of quality assurance.

11.1 Quality assurance and monitoring

It is important to have an effective management control system in place in the CSSD to cover all aspects of decontamination.

The quality management system should ensure the following:

- Monitoring is carried out to ensure all processes are performing to the required standards
- All processes are validated
- Records are kept of all processes and maintained to demonstrate that activities comply with the stated requirements
- Device and process tracking, and traceability enable tracing an item used on a patient back to the processor in the event of a medical device recall
- Storage and transport is done correctly
- SOPs are in place for the different activities and staff are familiar with the content
- The protocols are adhered to and there is documented evidence of adherence
- Adequate, good quality supplies are always available
- Ensure adequate PPE for HCWs
- There is adherence to IPC principles and SOPs and a representative from CSSD at the IPC Committee
- All decontamination equipment is on a planned maintenance schedule
- Manufacturer's instructions are available for all equipment
- ***Training:***
    - All staff are trained
    - There is an induction programme for all new staff
    - An annual training programme is available
    - Records of attendance are available
- Periodic audits are done, and the results communicated to the management teams

11.1.1 Proper care of surgical instruments

Proper care and maintenance will prolong the lifespan of equipment and medical devices.

- Inspect each instrument for proper functioning and condition
- Make sure that scissor blades glide smoothly all the way (blades must not be loose when in a closed position)
- Check that forceps tips are properly aligned
- Make sure that the haemostats and needle holders do not show light between the jaws, that they lock and unlock easily, and that the joints are not too loose
- Check needle holder jaws for wear and tear
- Examine cutting instruments and knives to be sure that their blades are sharp and undamaged
- Use lubricant and silicone sprays where appropriate

11.1.2 Proper care for CSSD packs

- **Basins and Bowls:** Check for sharp edges and cracks
- **Baskets and Trays:** Check for sharp edges, damaged corners, and open ends
- **Linen, Towels and Gowns:** Check for tears and holes in the material
- **Table surfaces:** Check for rough, sharp edges

All these factors could tear the sterilisation paper and therefore compromise the sterility of the packs. In case of damage, report to the supervisors for the necessary repair and replacement.

11.2 Auditing

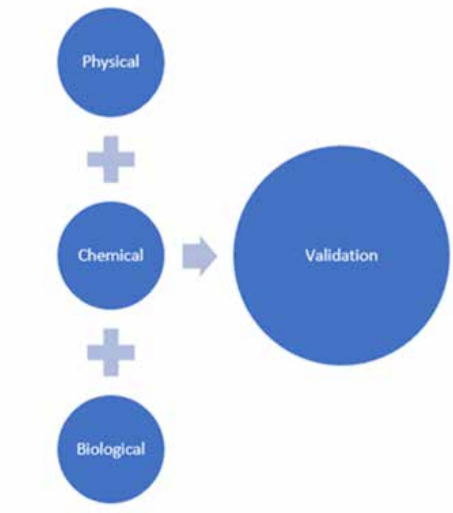
Regular audits should be conducted at the CSSD to ensure compliance with quality standards (Namibian Hospital Quality Standards)[99], SOPs and IPC principles.

- Ensure regular stock taking
- Identify instruments that need replacement
- Availability of Inventory registers

11.3 Validation: monitoring the effectiveness of sterilisation

To ensure that sterilisation has been successful, the **process of sterilisation** (and not the end product) is tested. Indicators have been developed to monitor the effectiveness of the sterilisation process by measuring various aspects of the process through different indicators. These include **mechanical (physical), chemical and biological indicators (Figure 28).**

FIGURE 28: VALIDATION PROCESSES



Physical (mechanical) indicators

Verify that the parameters of sterilisation cycle have been met and that the autoclave/ equipment is working correctly.[100] These indicators, which are part of the autoclave itself, record and allow the observation of **time, temperature, and/or pressure** readings during the sterilisation cycle.

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[99] Namibia Hospital Quality Standards. 1st Edition 2021

[100] Association for the Advancement of Medical Instrumentation (AAMI) ST79 2017. Comprehensive guide to steam sterilization and sterility assurance in HCF. Arlington Association for the Advancement of Medical Instrumentation.

11.1.3 Other important parameters to monitor are:

- Process conditions (how the autoclave functions)
- Visual inspection of the packs

11.1.4 Chemical indicators

Verify that one or more of the conditions necessary for sterilisation have been achieved at a specific location within the load.[101]

- External indicator tape with lines that change colour when the intended temperature has been reached
- Pellets in glass tubes that melt, indicating that the intended temperature and time is reached
- **Indicator strips that show that the intended combination of temperature, time and pressure has been achieved**
- Indicator strips that show that the chemical/s and/or gas is still effective

The **advantage** is that chemical indicators are visible to the user. The **disadvantage** is that **some chemical indicators can change without going through a complete sterilisation process.**

11.1.5 Biological indicators

Verify that the conditions at a location within the load were adequate to kill a specific micro-organism that is resistant to the sterilisation process and demonstrate the effectiveness of the sterilisation process.[102]

- These indicators use heat-resistant bacterial endospores (*Geobacillus stearothermophilus* spores) to demonstrate whether or not sterilisation has been achieved
- If the bacterial endospores have been killed after sterilisation, it is assumed that all other micro-organisms have been killed as well
- After the sterilisation process the strips are placed in a broth that supports aerobic growth and incubated for 20 minutes to 24 hours[103]

The advantage of this method is that it directly measures the effectiveness of sterilisation.

The disadvantage is that the result of this indicator is not available immediately as bacterial culture results are needed before sterilisation effectiveness can be determined.

11.1.6 Recommended ideal monitoring system

Perform the following monitoring activities whenever possible.

11.1.6.1 For steam sterilisation:

- If the autoclave has a recording chart, review it after each load
- If not, record the temperature, time and pressure information in a **logbook** that is reviewed after each load
- Perform the chemical indicator verification (Bowie Dick) test for air removal each day before starting the sterilisation cycle
- Place heat-and steam-sensitive chemical indicators, on the outside of each pack
- Perform testing with biological indicators daily (preferred) or weekly
- Indicators should be in the middle of the item reprocessed (the most difficult part of the load)
- A thermocouple could be put in the most difficult part of the load where air removal is hard and is usually performed by engineers

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[101] Association for the Advancement of Medical Instrumentation (AAMI) ST79 2017. Comprehensive guide to steam sterilization and sterility assurance in HCF. Arlington Association for the Advancement of Medical Instrumentation.

[102] Association for the Advancement of Medical Instrumentation (AAMI) ST79 2017. Comprehensive guide to steam sterilization and sterility assurance in HCF. Arlington Association for the Advancement of Medical Instrumentation.

[103] Steris Healthcare. https://www.steris.com/healthcare/products/sterility-assurance-and-monitoring/biological-indicators

11.1.6.2 For dry-heat sterilisation:

- If the oven has a recording chart, review it after each load an if not, record the temperature and time information in a log that is reviewed after each load
- Place heat-sensitive chemical indicators, if available, on the outside of each pack
- Perform testing with biological indicators weekly (or monthly if testing weekly is not possible)
- Thermocouples are only used if the steriliser has been serviced or is faulty

11.1.6.3 For chemical sterilisation:

- Record the time information in a log that is reviewed after each load
- Use an indicator strip, if available, to determine if the solution is still effective

11.1.7 Correcting sterilisation failure

If monitoring indicates a failure in sterilisation, attempt to determine the cause of the failure and arrange for corrective steps, as follows:

- Immediately check if the autoclave or dry-heat oven is being used correctly
- If correct use of the unit has been documented and monitoring still indicates failure of sterilisation, discontinue using the unit and have it serviced
- **Any instruments or other items that have been processed in the faulty autoclave or dry-heat oven must be considered as non-sterile and processed again with a unit that is functioning properly**.
- **Table 17** provides a summary of the different verification tests.

Table 17: Summary of the different verification tests[104]

Process	What is measured and when	
Cleaning: Manual	N/A	Every item is visually checked/inspected for cleanliness; correct use of cleaning agents - no formal validation - SOP very important!
Cleaning: Automated washer-disinfectors	Daily - Per load	Every item is visually checked/inspected for cleanliness, correct use of cleaning agents, cleaning test per load
Cleaning: Ultrasonic cleaner	Daily - Per load	Every item is visually checked/inspected for cleanliness, correct use of cleaning agents, cleaning test per load, foil test
Disinfection: High-level	N/A	Efficacy checked - correct use of agents, concentration, storage, time of exposure (may be validated by swabs taken on instruments)
Chemical sterilisers	Per process	- Biological - Chemical - Physical indicators and external indicators per item
Moist heat (steam sterilisers)	Daily - Per process	- Bowie Dick - Biological - Chemical - Physical indicators and external indicators per item[105]

[104] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[105] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

11.4 Tracking and traceability

Keeping good records of medical devices and their movement is essential to the functioning of an efficient CSSD. If possible, all devices should be labelled and tracked so that it can be followed and recalled in the event of a decontamination failure or similar event.

11.4.1 Tracking

All items processed in CSSD should be logged to ensure:

- Stock control
- Stock rotation
- System of the identification of location of items
- Record of returned items after use
- Logged arrival and dispatch of items into and out of the department

11.4.2 Traceability

Traceability is a system that identifies all stages of the decontamination process and use of medical devices. It identifies the movement of items from the patient through CSSD processes and back to patient areas. It essentially allows the identification of a set (autoclave cycle, packed by, pack name) throughout the whole process of use. It ensures that sets or instruments can be recalled if necessary. It should provide the information in **Table 18** regarding the patient and processes.

Table 18: Information required for a tracing system

Patient	• Name • Unique ID • Location • Date • Instruments used • User/operator
Process	• Sterilisation cycle number • Date of process • Proof of successful process • Proof of validation of washer-disinfector/ steriliser • Operator[106]

11.5 Contaminated supplies

Contaminated supplies are totally unsuitable for use. Items should be closely monitored through visual inspection looking for contamination as part of a quality management programme. Any contaminated or opened packaging should be considered unfit for use and discarded or decontaminated if they are re-usable items.

Items are considered contaminated when:

- They are wrapped incorrectly or inadequately
- Packaging is damaged or opened
- Comes in contact with a wet surface

[106] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

- An item is placed or dropped on a dirty surface like floor or sink
- Has no indication of having been through a sterilising process for example the chemical indicator has not changed colour
- Incorrect or inadequate cleaning procedures in the storage area
- Stored at incorrect temperature
- Excessive exposure to sunlight or ultraviolet light
- Evidence of pests and insects
- Evidence of incorrect handling when transporting items

NOTE: When sterilised devices are transported between wards or facilities, it should be placed in clean containers to prevent contamination and damage to packaging

11.6 Autoclave maintenance

The autoclave should be checked by the operator or supervisor each time it is used to make sure that it is functioning properly. An equipment log should be used to monitor performance, including temperature, time, and cycle. If there is a fault, report it to the supervisor or manager and call out the engineer to correct the fault. A fault log must be recorded and kept for medico legal reasons.

The autoclave is not working correctly if:

- Steam comes out of the safety valve instead of the pressure valve - in such case, the pressure valve must be cleaned and replaced
- Steam comes out from under the lid or around the door - if this occurs, the gasket must be cleaned and dried or replaced
- Items emerge wet indicates the steam is incorrectly delivered - there is condensation along the chamber walls
- Items emerge dry and crisp - steam is overheated
- Water marks on the packs - poor water quality
- Indicators fail - poor air removal, leaks or incorrect processes

NOTE: To ensure that the autoclave is properly maintained, ascertain that regular maintenance is performed and documented according to the manual

11.7 Cleaning of the autoclave

Cleaning of the autoclave should be done according to the manufacture's recommendation.

General points about the cleaning of an autoclave:

- It should be cleaned daily before use
- Clean all external parts, using a soft cloth dampened with regular neutral detergents (do not use corrosive or abrasive products)
- Never use abrasive cloths or wire (or other abrasive) brushes to clean the metal parts
- Before starting each cycle, thoroughly clean the door seals, using a damp cloth
- The formation of white spots at the base of the chamber indicates that poor-quality pure water has been used
- For the inside of the autoclave, remove all the inside structures such as tray holders and baskets
- Use a clean cloth dampened in distilled water (without any detergents or disinfectants) and clean the inside surfaces of the chamber, particularly the bottom, the door and the fold at the opening of the chamber, as this

is where the residues and impurities tend to accumulate

- Clean the seal and the door with a soft cloth, dampened with water to remove limescale
- This cleaning operation must be carried out to remove any impurities that may cause the sterilisation chamber to lose pressure and the seal to be cut[107]

11.8 Record-keeping

Record-keeping helps track what happens during a process. In case a problem arises during the decontamination process or afterwards, records can help analyse what caused the problem as well as assist when devices have to be recalled.

11.1.8 Important points about record keeping:

- Helps to check if sterilisation cycle parameters have been met for every cycle - if a problem is identified, the packs can be recalled
- Helps to monitor processes at the CSSD - failures can be corrected immediately
- If a problem is identified after the packs have been issued, the use of load identification numbers assist to identify faulty packs
- Sterilisation records help staff determine whether reprocessing must be repeated and the extent to which a recall is needed
- Properly maintained records help to verify that the department has met or exceeded quality goals

11.1.8 Types of Records

Regardless of the type of sterilisation methods used, several basic records must be maintained for each sterilisation cycle that is performed. These records will allow the tracking of sterilised items to the patient.

- *Load control number:* must be attached to any item intended for use as a sterile product and must identify the sterilisation date, steriliser equipment used, cycle number and expiry date where applicable
- General contents of the load in each sterilisation cycle
- Biological and chemical indicator test results
- Exposure time and temperature and pressure (if applicable) of the sterilisation process
- Name or initials of steriliser operator

11.1.9 The following autoclave maintenance records must be maintained for all sterilisation:

- Date of service
- Model and serial number
- Reason for maintenance
- Location
- Descriptions of replaced parts
- Biological testing records
- Name and signature of controller
- Scheduled date for re-testing
- Re-testing results
- Model and serial number

[107] Mehtar, S., 2010. Understanding Infection Prevention and control. Juta & Company. Claremont. South Africa

- Reason for maintenance
- Location
- Descriptions of replaced parts
- Biological testing records
- Name and signature of controller
- Scheduled date for re-testing
- Re-testing results

NOTE: Follow the manufacturer's instructions wherever possible since maintenance varies depending on the type of autoclave

More and more diagnostic and therapeutic procedures are performed using rigid or flexible endoscopes. The risk of infection can be classified according to the degree of invasiveness of the procedure. Effective decontamination will reduce the risk of infection, ensure the quality of diagnostic procedures and samples as well as prolong the life of the equipment.

Staff should be aware of the complexities of the endoscopes they are processing to ensure that the design and construction of the endoscope is fully understood. Failures in decontamination, particularly for flexible endoscopes, have been reported due to failure to access all channels of the endoscope. Irrespective of the method of disinfection or sterilisation, cleaning is an essential step in the decontamination procedure and the manufacturers' instructions must therefore always be followed.[108]

Endoscopes are problematic to decontaminate due to the complexity of their design (long narrow channels and complex internal design). They are also expensive and easily damaged. There are two types of endoscopes:

- Rigid endoscopes
- Flexible endoscopes

Table 19 provides an overview of the different types of endoscopes and the level of decontamination required.

Table 19: Examples of endoscopes and level of decontamination required

Types of endoscopes	Rigid endoscope example	Flexible endoscope example	Level of decontamination
Invasive: Enter normally sterile body cavities or introduced into the body through a break in the skin or mucous membrane	Arthroscope Laparoscope Cystoscope	Nephoscope Angioscope Choledochoscope	Sterilisation by steam or a low temperature method e.g., gas plasma
Non-invasive: In contact with intact mucous membrane, but does not enter sterile cavities	Bronchoscope	Gastroscope Colonoscope Bronchoscope	High-level disinfection, e.g., immersion in glutaraldehyde, peracetic acid, chlorine dioxide[109]

12.1 Processing of endoscopes

The complete cycle of endoscope processing includes several steps that have to be adhered to* (Figure 29*):

- Cleaning
- Rinsing
- Disinfection or sterilisation
- Rinsing if only disinfection was done
- Drying

[108] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[109] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

FIGURE 29: STEPS OF ENDOSCOPE REPROCESSING

12.2 Endoscope cleaning

12.1.1 Preparations for endoscopes cleaning and disinfection:

Ensure the following items are in place:

- PPE
- Four basins each containing the following:
  - Enzymatic cleaner (Endozyme) solution (diluted as per manufacturers' instructions)
  - Distilled or sterile water
  - OPA
  - Distilled or sterile water
- Endoscope cleaning brushes
- Syringe 50ml
- Drying/wiping sterile cloths (lint free) according to the manufacturer's instructions
- Lubricating oil
- Leakage test device
- Flushing valves

12.1.2 Cleaning and disinfection of flexible endoscopes

Figure 30 provides a visual summary of the steps to follow to ensure adequately decontaminated flexible endoscopes.

FIGURE 30: DECONTAMINATION CYCLE OF FLEXIBLE ENDOSCOPES[110]

[110] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

The following is recommended:

- **Pre-cleaning (point-of-use):** Immediately on removal of the instrument from the patient, the endoscope should be wiped from control head to distal tip using a clean cloth soaked in clean water and enzymatic cleaning solution (diluted as per manufacturers' instructions)
- It is impossible to adequately disinfect or sterilise an endoscope when organic material has been allowed to dry on the endoscope
- The internal suction channel should be aspirated with enzymatic solution, depressing and releasing suction button to promote debris dislodgement.
- Depress and release air/water buttons to flush water through water channel and air through air channel (where applicable use air/water cleaning adaptors as per manufacturers' instructions)
- **Leak test:** Prior to disassembly and further cleaning of the endoscope **the leak test should be performed as per manufacturer's instructions.** In the case of video endoscopes, the protective cap should be applied prior to leak test
- The flexible endoscope and all reusable accessory items should be disassembled as far as possible
- **Cleaning:** The components should be cleaned with an enzymatic solution.
- Any taps should be opened, and the channels/lumens of the endoscope should be brushed to remove any adherent debris
- If the cleaning brush has obvious debris, it should be washed prior to being withdrawn through the channel
- Sites such as nozzles, flaps, hinges, crevices and joints of accessory items should be cleaned with a soft brush to remove any adherent debris - this cleaning process should continue until the endoscope, its channels, buttons and valves and accessory equipment are completely clean
- Accessory items, including buttons should be placed in an ultrasonic washer according to manufacturers' instructions - important that spiral coiled accessory equipment be thoroughly cleaned in the ultrasonic washer
- Thorough flush rinsing should be carried out to remove any traces of detergent from all channels
- All channels should then be purged with medical air to expel as much water as possible, and the external surface must be dried with a lint free cloth prior to disinfection
- Brushes used in the cleaning process for each endoscope shall be cleaned and thermally **disinfected** after each use, however, single use brushes are preferred.

NOTE: Fibre optic endoscopes should only be subjected to ultrasonic cleaning in accordance with manufacturers' instructions - some accessory instruments have extremely small lumens or are too fine or difficult to dismantle for cleaning, as such it is impossible to ensure thorough cleaning and decontamination - consideration should thus be given to using a single-use accessory

Important points about the cleaning of endoscopes:

- Rinse scope in sterile water, flush through with sterile water - flush with air because water will dilute Othopaldehyde (e.g., CIDEX), and will thus make it ineffective
- Flush Othopaldehyde (e.g., CIDEX) through scope and immerse scope according to the manufacturer's instructions
- Rinse with sterile water, flush scope with water, then air - wipe dry with towel and hang on stand to dry
- Discard disinfectant solutions after 24 hours, or depending on manufacturer's instructions or when becoming visibly soiled during the day

12.1.3 Cleaning of rigid endoscopes

The cleaning steps as for the flexible endoscope above should be followed.

The following should however be noted:

- Rigid endoscopes and accessories, which do not have any fibre-optic light carriers or cables, may be dried in a drying cabinet
- Upon completion of the cleaning, rinsing and drying process, the rigid endoscope and associated instruments

should be reassembled, inspected, and checked to ensure they are not damaged and are in good working order, and then disassembled prior to sterilisation

12.3 Endoscope disinfection

Glutaraldehyde/OPA disinfectant has a wide range of antimicrobial activity and is effective against viruses including HIV, Hepatitis B and C and the majority of bacteria, although spores and mycobacteria species are relatively more resistant.

12.1.4 Factors affecting the efficiency of a disinfectant include:

- Water carried over from the washing and rinsing process reduces the concentration of glutaraldehyde
- Organic matter may inactivate glutaraldehyde
- Repetitive use of the disinfectant may also cause a reduction in the concentration of the solution

The following is recommended during disinfection:

- Instruments soaked in the solution must be cleaned thoroughly and dried prior to immersion
- Manufacturer's recommendations on the management of glutaraldehyde should be followed - the solution is at a 2% concentration initially - it is undesirable for this to fall below 1.5%
- Change of the glutaraldehyde solution will depend on use
- Where endoscopy is being performed infrequently, the glutaraldehyde solution should be disposed of at the end of the day.
- Chemical indicators should be used to ascertain the concentration of glutaraldehyde. These processes must be monitored and documented
- Adherence to IPC principles is important during reprocessing of the endoscope

12.1.6 Disinfection of flexible endoscopes

The following steps should be followed:

- The flexible endoscope must be leak tested, clean and dry prior to placement in the liquid disinfectant solution
- Manual disinfection-totally immerse the endoscope, valves and buttons in the disinfectant solution (diluted as per manufacturer's instructions)
- Use a syringe to flush the disinfectant solution down all lumens and channels, remove airlocks and ensure that all internal surfaces are in contact with the disinfectant
- The endoscope should be soaked as per the manufacturer's guidelines depending on the type of endoscope, strength and temperature of the disinfection solution
- Disinfectant solution should be monitored for concentration levels daily or immediately prior to use
- Flexible endoscopes other than bronchoscopes should be totally immersed in 2% glutaraldehyde/ OPA for a minimum of 10 minutes between cases (**depending on the Manufacturer's instructions**) prior to and at the end of each list
- Bronchoscopes should be totally immersed in 2% glutaraldehyde for a minimum of 20 minutes (depending on the manufacturer's instructions) between cases, prior to, and at the end of each list

NOTE: OPA is not to be used for processing of urological instruments due to the rare risk of anaphylaxis noted in patients with a history of bladder cancer

12.1.7 Automated flexible endoscope reprocessing units

The endoscope is placed into and connected to the machine and the appropriate disinfection cycle chosen in accordance with manufacturer's instructions dependent on the type of endoscope. The reprocessing machine

should be routinely monitored as per manufacturer's instructions.

12.1.8 Disinfection of rigid endoscopes

Disinfection is not a sterilising process and shall not be used to prepare items intended for entry into sterile body cavities, or that penetrate the mucosal barrier. Rigid endoscopes are critical items and **must be steam sterilised prior to reuse**.

12.1.9 Post disinfection rinsing

- Water for the final rinse of all gastrointestinal endoscopes should be of high quality, filtered and free from micro-organisms that cause clinical disease e.g., *Pseudomonas*
- Endoscopes processed in an automated reprocessing unit may not require rinsing on completion of cycle, check manufacturer's instructions and description of cycle used

12.4 Sterilisation of endoscopes

12.1.10 Sterilisation of flexible endoscopes

- **Flexible endoscopes cannot be sterilised in an autoclave**, due to the high temperatures
- Most flexible endoscopes (check manufacturer's instructions) can withstand a process capable of **sterilisation using low temperature** (=<55°C)
- These processes include ethylene oxide, hydrogen peroxide and peracetic acid
- Accessory items capable of withstanding steam sterilisation should be processed by this method

12.1.11 Sterilisation of rigid endoscopes

- A rigid scope with external detachable optics **can and should be** sterilised using steam
- Any scope that the manufacturer declares to be suitable for sterilisation should undergo steam or another appropriate sterilisation method (e.g., ethylene oxide and peracetic acid)
- Where sterilisation is through a wrapped process, the packaging material or system used shall be in accordance with the method of sterilisation used (as per manufacturer's instructions)
- Consideration of the ability of the endoscope to withstand steam/low temperature sterilisation should be given prior to purchase of rigid scopes

NOTE: If items used for surgery are unable to tolerate sterilisation, consideration should be given to the purchase of rigid scopes that can undergo a sterilisation process, or single-use items

12.5 of endoscopes

12.1.12 Storage of Flexible Endoscopes

- Endoscopes must be thoroughly dried before storage - dry clean air should be used to assist forced air-drying of channels that reduces bacterial growth during storage
- Denatured alcohol, e.g., methylated spirits should not be used for drying the channels as it can damage the components of flexible endoscopes
- Endoscope storage is preferably by hanging at full length, with insertion tube as straight as possible, and on appropriate support structures rather than coiled in a case
- The storage conditions should be as recommended in (Chapter 10) for sterile items
- After storage all endoscopes must be disinfected/sterilised prior to use

12.1.13 Storage of rigid endoscopes

Rigid endoscopes that have undergone sterilisation as a wrapped item shall be stored in accordance with **Chapter 10 (storage of sterile items)**.

CHAPTER 13: QUALITY IMPROVEMENT

Quality improvement methodology can be applied effectively in the CSSD to enhance the quality and efficiency of sterilisation processes and ensure patient safety.

13.1 Advantages of QI at the CSSD

- **Patient safety**

  Helps to identify and address any deficiencies in sterilisation processes, reducing the risk of infections and adverse events.
- **Compliance with standards**

  Helps to monitor and improve processes to meet regulatory requirements, accreditation and quality standards such as COHSASSA consistently.
- **Efficiency and cost savings**

  Enable CSSD teams to optimize their workflows and streamline processes, leading to increased efficiency. By eliminating waste, reducing errors, and improving productivity, CSSD can achieve cost savings, such as reducing the need for instrument re-sterilisation or reprocessing due to errors.
- **Monitoring and evaluation**

  Regular audit and monitoring of processes, identifying areas for improvement, and implementing changes, can improve operational efficiency and ensure that best practices are followed consistently.
- **Staff engagement and empowerment:**

  Involving staff in quality improvement initiatives empowers them to contribute to the betterment of their department and creates ownership and accountability.
- **Risk mitigation:**

  Quality improvements assists with risk identification and mitigate by implementing quality control measures, ensuring equipment maintenance, and enhancing staff training and competency assessments.

13.2 Model for improvement

QI consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups. The Institute of Healthcare Improvement (IHI) Model for Improvement (**Figure 31**) recommend the following approach:

- *Three fundamental questions are asked which can be addressed in any order:*

a. What are we trying to accomplish?

b. How will we know that a change is an improvement?

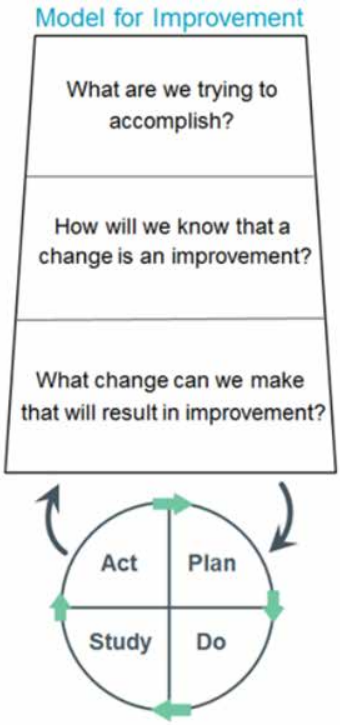
c. What changes can we make that will result in an improvement?[111]

- **The ''Plan-Do-Study-Act (PDSA) cycle"** that is used to test changes in real work settings. The PDSA cycle guides the test of a change to determine if the change is an improvement[112]

[111] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

[112] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

FIGURE 31: MODEL FOR IMPROVEMENT



It is important that problems and risks are identified and that the necessary interventions are implemented to mitigate the risks or solve the problem. For more information about the identification and management of risks in CSSD, consult Chapter 6 of this guideline.

13.3 Steps for quality improvement

The following steps should be followed to implement a quality improvement project after a problem has been identified:

- Forming the team
- Setting an aim
- Establishing measures
- Selecting changes
- Testing changes
- Implementing changes
- Spreading changes

After successful implementation of a change or package of changes for a pilot population or an entire unit, the team can spread the changes to other parts of the organisation or in other organisations.[113]

It is important that the outcomes of quality improvement projects are shared with management teams as well as the HCWs in the units where the project is implemented, and that progress is shared continuously.

*(Refer to the **MoHSS IPC Guidelines 3rd Edition 2023** for more detail on QI)*

Following a multimodal improvement strategy (MMIS) will further assist with sustainable change. The WHO recommends that multiple approaches should be followed in combination to influence behaviour of HCWs.

[113] WHO. 2016. Decontamination and Reprocessing in HCF. https://www.who.int/publications/i/item/9789241549851

Implementation of a multimodal strategies should be linked to the aims and initiatives of QI programmes and accreditation bodies both at the national and facility levels.

The MMIS consist out of the following elements:

1. System change (Built it)
2. Training and education (Teach it)
3. Monitoring and feedback (Check it)
4. Reminders at the workplace (Sell it)
5. Culture of safety (Live it)

FIGURE 32: MULTIMODAL IMPROVEMENT STRATEGY

Targeting only ONE area (e.g., unimodal), is very likely to result in failure. All five areas should be considered, and necessary action taken, based on the local context and situation informed by periodic assessments.

By utilising quality improvement methodologies in the CSSD, healthcare facilities can enhance patient safety, ensure compliance with standards, improve efficiency, empower staff, mitigate risks, and promote a culture of continuous improvement in sterilisation practices.

APPENDIX 1: LAUNDERING OF OPERATING THEATRE LINEN

(See the MOHSS IPC Manual 3rd Edition 2023 for more details - the laundry services for the CSSD are summarised here)

Careful handling and reprocessing of soiled linen prevent the transmission of infectious agents is necessary. Therefore, all reusable gowns and drapes must be washed, disinfected and subsequently sterilised. Where laundry of the OT linen is on site, the CSSD is a significant stakeholder in the standard routinely attained by laundry processes, despite the laundering occurring 'outside' the CSSD. It follows that the CSSD needs to be able to refer to the appropriate guidelines, if available, and the Namibian Standards governing the laundry practices to ensure that all linen products meet the requirements.

Laundering standards

- Wherever operating room linen is laundered on-site, effective liaison and communication between the CSSD and laundry personnel will be of great importance in achieving the necessary standards
- Written protocols for the day-to-day functioning of laundries that process operating room linen need to be established
- Laundries should adopt thorough inspection procedures to ensure that cleaned OT linen has minimum staining and textile damage prior to sterilisation
- Infection control principles should be followed when handling contaminated linen

The following procedure in sorting linen should be followed:

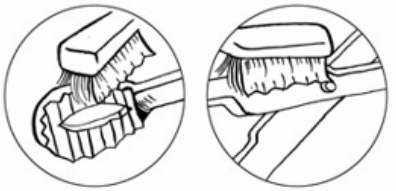
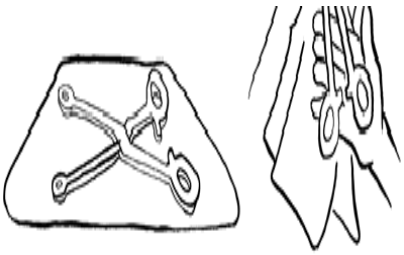
- Follow standard precautions - use PPE
- Handle contaminated linen as little as possible to prevent contamination
- Soiled linen should be sorted before being loaded into washing machines to prevent contamination of other linen and washing machines.

1. Cleaning and sterilisation of theatre linen

- Soaps and detergents are used to loosen soil and remove dirt
- A prewash rinse of 15 minutes will remove gross soilage
- Hot water washing at a temperature of at least 71°C, for a minimum of 25 minutes is recommended - this provides an effective means of destroying vegetative forms of bacteria, but not spores
- Addition of mild acid to neutralise any alkalinity in the water supply - soap or detergent - this is the last action performed during the wash process and helps to decrease skin irritation, overall reducing the numbers of bacteria present
- Hot air drying or drying in sunlight will reduce the number of bacteria present, as will ironing with a hot iron
- Clean linen must be stored and transported in such a manner that cross-contamination is avoided
- Linen to be sterilised must be properly wrapped before being sent to the sterile processing department
- A function check of the sterilisation machine must be performed before the sterilisation process takes place
- A validated process must be used to determine when reusable textiles have to be withdrawn from use

Note: Low linting fabrics are preferred since lint may impair wound healing, because of reaction to foreign bodies - thus non-woven fabrics are recommended

APPENDIX 2: MANUAL CLEANING STEPS

1. Wear heavy-duty rubber gloves, a plastic apron, eye protection, mask and closed shoes dg cleaning 2. **Disassemble** instruments and other items with multiple parts, and be sure to brush in the grooves, teeth, and joints to items where organic materials can collect and stick 3. Immerse the instruments in normal tap water containing a detergent diluted according to manufacturer's guidelines	
4. Scrub instruments and other items vigorously to remove all foreign material completely by using a soft brush, detergent, and water - hold items under the surface of the water while scrubbing and cleaning to avoid splashing	
5. Flush through lumens with an adapted water jet 6. Rinse items thoroughly with clean water to remove all detergent as any detergent left on the items can be toxic and reduce the effectiveness of further processing	
7. Inspect items to confirm that they are clean 8. Allow items to air dry or dry them with a clean towel - this is to avoid diluting the chemical solutions used after cleaning and in preparation for storage or sterilisation	

APPENDIX 3: DISASTER MANAGEMENT POLICY

Purpose

It is important that all CSSD staff are familiar with the emergency plan for internal emergencies to ensure the safety of all staff, patients and visitors.

Disaster Committee

All internal and external disasters are coordinated by the Disaster Committee.

The committee consists of the following people:

- Senior Medical Superintendent (SMS) and Senior Medical Officer (SMO)
- Senior Control Registered Nurse in charge
- Control Administrative Officer
- Community Health Representative
- Environmental Health Officer
- Transport Clerk
- Representative from the local Fire Brigade Department

To cope with a disaster all staff should:

- Be aware of what is required of them
- Know who is in control
- Know the location of all emergency equipment
- Know the emergency exits and evacuation routes
- Be constantly aware of hazards
- Not panic
- Not make statements to the press

Internal disaster:

i) **Important safety rules:**

- Keep all areas neat, especially storerooms
- Discourage loafers and vagrants
- Control visitors
- Ensure that contractors conform to safety regulations
- Ensure all equipment is on a planned maintenance schedule
- Train staff to be aware of hazards and risk in the workplace

ii) **Control of fire**

- It is important that every employee understands the hazards and risks in the hospital as well as the procedures to follow should a fire break out
- All healthcare workers, patients and visitors have a responsibility to ensure the safety of others

❖ **Fire hazards within the hospital**

- High technology equipment (explosions) - autoclaves, computers
- Electrical equipment (electric fires) - polishers, medical equipment
- Linen - foam rubber mattresses
- Building in general - ceilings, oxygen ports and lines, cylinders
- Dangerous substances - theatre gases, cleaning fluid, alcohol

❖ **Techniques for extinguishing fires**

- **Smothering**

A fire is smothered by reducing or cutting off the oxygen by using blankets, sand, foam and dry powder fire extinguishers.

- **Starvation**

A fire can be starved by either removing the source (material burning) or by moving the fire to a safe area

- **Cooling**

Burning material can be cooled to below its combustion point - water is a suitable coolant

❖ **Types of fire**

Type of fire	Description	Method of extinguishing a fire
Class A	General fire of wood, paper, etc.	Water or foam
Class B	Burning, flammable liquid	Dry powder or foam
Class C	Fires where electricity is involved	Dry powder or foam **NEVER WITH WATER**
Class D	Gas fires include products that release gasses when burning	Dry powder or foam

❖ **Using a fire extinguisher**

All staff must be aware of the position of the nearest fire-fighting equipment.

- Remove from the fixture
- Break the seal
- Remove the safety pin
- Press the trigger to test
- Aim at the base of the fire and press the trigger
- Move from left to right

Recommended distance form fire is 3-4 metres

❖ **Important aspects to remember when confronted with a fire**

- Do not panic
- Do not run
- Do not turn your back on the fire
- Move as low as possible
- Contact the switchboard
- Close all windows and doors
- Attempt to control the fire
- Activate the fire alarm if available

iii) **Evacuation procedure**

- **General guidelines**

❖ An evacuation will follow as a result of a fire, flood, bomb or other disaster that requires patients to be moved to a safer environment

❖ An evacuation will only take place on the instruction from the Disaster Committee

❖ It must be done in an orderly fashion

❖ Be familiar with all the possible routes and exits

❖ All staff must move to central points in their units

- ❖ The Area Manager will then allocate tasks
- ❖ All staff not allocated specific tasks must report to the assembly area and await further instructions
- ❖ Patients are the responsibility of the hospital and must be evacuated as a matter of priority
- ❖ Do not panic

- **Responsibilities of the area manager are to ensure:**
  - ❖ Calm evacuation of the area
  - ❖ The safety of all patients
  - ❖ Compliance with procedures
  - ❖ That all persons leave the building
  - ❖ That the second in command is aware of his/her function in the absence of the area manager

- **Specific departmental tasks**
  - ❖ Pharmacy must remove important stock to the assembly area
  - ❖ Emergency unit must set up a first aid post at the assembly area
  - ❖ Laundry staff must take all available bedding to the assembly area
  - ❖ Maintenance department must shut off power and gas supplies and supply portable oxygen
  - ❖ Financial Officer must remove important financial documents
  - ❖ Human Resources Officer must take the current staff list of all staff members on duty
  - ❖ Administrative staff must assist with moving patients to safety
  - ❖ Kitchen staff must assist with moving patients to safety
  - ❖ OPD staff and theatre staff must assist with patients arriving from the wards at the assembly point

NOTES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