Dear Colleagues

The main purpose of the CFSA is to promote national harmonization of decontamination and sterilisation practices with training and sharing of ideas. In doing so the objective is to ensure the basic right of every patient to be treated with a safe to use, appropriately decontaminated medical and or surgical instrument of device.

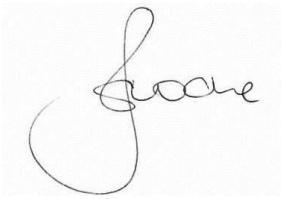
These CFSA Position Statements have been developed to guide and assist all those involved in the decontamination (cleaning, inspecting, assembly, packing, sterilization, and transport) of therapeutic items used on patients in patient care settings.

Care has been taken to ensure they are aligned with relevant South African guidelines, standards, and legislation.

Numerous South African CFSA members, and colleagues have contributed to the development of these Position Statements.

These Position Statements may be uploaded onto Hospital portals and shared.

These Position Statements remain current and will be reviewed periodically.



Xana Jardine
CFSA National Chairperson

CFSA
CSSD Forums of South Africa

V1: 2024

Contents

Abbreviations

BD - Bowie Dick
BI - Biological indicator
CI - Chemical Indicator
CFSA - The CSSD Foundation of South Africa
CSSD - Central Sterilization Services Department
CR - Company Representative
OHSC - Office of Health Standards Compliance
WHO - World Health Organization

Position Statement No 1

Title
Role of Company Representatives in CSSD

Prepared by
CSSD Forums of South Africa (CFSA)

Relevant Guidance
Medical Device Code of Ethical Marketing and Business Practice
SANS 1541 Hospital loan sets

Introduction
The Company Representative (CR) has an educational role to play in the decontamination and reprocessing of items in the CSSD in the hospital setting.
The Company Representatives often have in-depth knowledge with regards to items, be it a surgical instrument, device, or consumable (used in reprocessing) that are sold or promoted by the companies they work for. It is critical that both CSSD staff and CRs do not perform tasks outside of their respective scopes of practice. This document serves as guidance to both parties.

Position Statement
The CFSA therefore endorses the following with regards to the role of the Company Representative in CSSD:

- May only enter the clinical environment (CSSD) in accordance with permission from appropriate members of the staff of the facility.
- Is expected to wear appropriate attire, as provided by/or approved by the facility. It remains the responsibility of the facility to provide appropriate clothing. However, if this is not possible then the facility must provide authorization for the company representative to provide their own appropriate attire.
- Must perform hand hygiene on entering the department.
- Must have completed the CRICE (Company representative in the Clinical Environment) course.
- Has an important role to play in **guiding and training CSSD** staff on the use of their products.
- Should be prepared to advise on technical questions related to the assembly and operational performance of company products consistent with the labelling and instructions for use.
- May not deliver patient care or **perform medical services of any type**, this **includes cleaning, inspecting, assembling, wrapping or sterilization of devices** to be used on patients.

NOTA BENA: Asking or expecting a company representative to clean, inspect, assemble, wrap, or sterilize a device that is be used on a patient, or to clean a device after it has been used on a patient will place the hospital, the company representative, and the patient at risk. This could have medico legal implications for all parties.

The CFSA endorses the statement made in the Medical Device Code of Ethical Marketing that companies should ensure that healthcare representatives have adequate training to ensure sufficient scientific knowledge of the medical devices which they promote to enable the provision of precise and complete information about such products. The product training that they provide must be consistent with the instructions for use of a medical device.

Position Statement No 2

Title
Competency and Knowledge required for working in the CSSD

Prepared by
CSSD Forums of South Africa (CFSA)

Relevant Guidance
World Health Organization. (2016). Decontamination and reprocessing of medical devices for health-care facilities. World Health Organization

Introduction
Poorly decontaminated instruments, devices or items used on a patient could result in poor patient outcomes. It is therefore essential that all staff working in CSSD are trained and that they are competent to perform their assigned tasks. A competent person can be defined as one who has the knowledge, skills, and capabilities necessary to function effectively and efficiently in a given job or when performing specific tasks.

Position Statement
In line with the World Health Organization (WHO) the CFSA acknowledges a distinction between an entry level CSSD operator, an experienced CSSD operator and a CSSD Supervisor.

CSSD staff should undergo training, and complete competency verification activities related to their duties upon initial hire (induction and orientation) annually and at designated intervals. In addition, staff should undergo updated training not only in practices, but also related to new developments in equipment and technology.
All staff should have defined tasks, i.e. tasks listed in their job descriptions.
All staff should also have documented training and competency evaluation records to demonstrate that they are competent at undertaking their assigned tasks.

The CFSA suggests the below example / format for competency evaluations:
3 = outstanding 2 = acceptable 1 = improvement required*
*Needs a documented action plan for improvement including target date for reassessment

No	Task	1	2	3
1	Correct and appropriate use donning / doffing of PPE			

In line with the WHO, the CFSA endorses education and training for CSSD staff as outlined below:

<u>Entry Level Operator</u>
Should understand that a device that has not been decontaminated correctly can transmit disease.
Should have a working understanding of standard (infection control) precautions and correct and appropriate use of PPE.
Should have a basic understanding of the CSSD process.

Course contents should include:
- Introduction to microbiology, types of microbes, routes of transmission and antibiotic resistance.
- Introduction to manual and automated method of cleaning devices.

- Introduction to inspection, assembly and packing of devices to be sterilized.
- Introduction to sterilization of devices, including loading and unloading of sterilizers.
- Introduction to safe transport and storage of sterilized devices.
- Introduction to tests performed for quality control that verify CSSD processes.

Experienced Level Operator

Should understand that a device that has not been decontaminated correctly can transmit disease.
Should understand the principles of infection prevention and control.
Should understand types of instrumentation and instrument management.
Should understand and be able to manage reprocessing failures.
Should understand reprocessing of flexible Endoscopes.

Course contents should include:

- Basic principles of infection prevention and control
- Spaulding's Classification
- Reprocessing chemistries
- Managing cleaning failures
- Instrumentation types, testing and caring for instrumentation
- Managing sterilization failures
    - Failed Bowie Dick
    - Failed BI
    - Failed In pack / External CI
    - Failed Load Control
- Product release and product recall
- Management of loan sets
- Reprocessing of flexible Endoscopes

CSSD Supervisor/Manager

Should have a deeper understanding of the steps in device reprocessing.
Should understand the elements of risk assessment and risk management in CSSD.
Should understand the risks associated with reprocessing of flexible endoscopes.
Should have a working knowledge ISO/SANS standards relating to CSSD.
Should have a basic understanding of Management principles.

Course contents should include:

- Design and flow of a CSSD
- How to choose the correct product / Product manufacturing standards
- Verification of cleaning
- Sterile barrier systems
- Low temperature sterilization
- Water quality
- Reprocessing of flexible endoscopes (Risk Management)
- Loan set standard/management
- Risk assessment and management in line with OHSC audit tool
- Basic management principles including:
    - Leadership
    - Communication
    - Change management
    - Quality improvement
- Induction/orientation and training of staff