SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Sterilisation: Routine Monitoring of Cleaning, Disinfection and Sterilisation Processes
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/548
DATE OF PUBLICATION	May 2020
RISK RATING	Low
LEVEL OF EVIDENCE	National Safety Quality Health Service Standards: Standard 3 – Preventing and Controlling Healthcare Associated Infection Australian/New Zealand Standard AS/NZS 4187:2014
REVIEW DATE	May 2025
FORMER REFERENCE(S)	N/A
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director of Clinical Governance and Medical Services
AUTHOR	SESLHD Sterilising Services Working Party (SSWG)
POSITION RESPONSIBLE FOR THE DOCUMENT	Manager Sterilising Services, The Sutherland Hospital Karolina.Tipevska@health.nsw.gov.au
KEY TERMS	Reusable Medical Device (RMD), Routine Monitoring, Validation, High Level Disinfection (HLD), Preformed Sterile Barrier System (PSBS), Process Challenge Device (PCD), Sterile Barrier System (SBS)
SUMMARY	To ensure processes undertaken by the Sterilising Services Departments consistently produce a result that meets predetermined specifications.

Feedback about this document can be sent to seslhd-executiveservices@health.nsw.gov.au

Sterilisation: Routine Monitoring of Cleaning, Disinfection and Sterilisation Processes

SESLHDPR/548

1. POLICY STATEMENT

The purpose of routine monitoring and control is to provide evidence that the specified and validated cleaning, disinfection, packaging and sterilisation processes for an RMD have been achieved.

2. BACKGROUND

Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Validation has been performed on Washer/Disinfectors, Sterilisers and the associated equipment.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure
- Report any non-compliance to the Sterilising Services Manager.

3.2 Line Managers will:

- Support compliance

3.3 District Managers/ Service Managers will:

- Implement the requirements of this procedure to assure the quality and safety of reprocessed RMDs
- Ensure routine monitoring is performed and recorder.

3.4 Medical staff will:

- NIL

4. PROCEDURE

4.1 Routine Monitoring and Control of the Cleaning Process:

4.1.2 Manual Cleaning

The outcome of the manual cleaning shall be checked at completion of process by visual inspection.

4.1.3 Washer/Disinfectors Employing Thermal Disinfection

Washer/Disinfector shall be tested each day, at the beginning of the day, to ensure that is functioning as intended.

The following parameters shall be verified at completion of each cycle:

- Visual inspection
- Result of process challenge devices
- Process/cycle parameters such as: temperature and exposure time.

4.1.4 Ultrasonic/Irrigator

Following testing shall be performed to ensure Ultrasonic/Irrigator is functioning as intended:

- Cleaning efficacy as per manufacturer's instructions
- Performance of individual transducers as per manufacturer's instructions

4.1.5 Drying Cabinets:

Temperature shall be checked and recorded on daily basis, ensuring within parameters.

4.2 Routine Monitoring and Control of Processes Employing Chemical Disinfection for Thermolabile RMDs

4.2.1 Routine monitoring of the HLD Process as per manufacturer's instructions, including but not limited to:

- Performance of disinfection equipment-water pressure, flow and temperature
- Chemical agent concentration
- Contact time
- Rinse time/volume.

4.3 Microbiological Surveillance of Flexible Endoscopes with channels

- Flexible Endoscopes shall undergo microbiological surveillance in accordance with HSO Procedures and GENCA Guidelines.

4.4 Routine Monitoring and Control of Packaging Processes

- SBS
- PSBS
- Reusable rigid sterilising containers
- Heat sealer temperature shall be recorded daily and visual checks shall be made immediately after each episode of sealing
- One or more samples shall be checked daily to establish seal integrity before and after exposure to a sterilisation process.

4.5 Routine Monitoring and Control of Sterilising Processes

Routine monitoring and control shall demonstrate that the specified and validated sterilisation processes for an RMD have been delivered to that RMD

4.5.1

- Sterilising equipment shall be checked according to Table 8.2 to ensure that it is functioning as intended each day
- Process records shall be checked at the completion of each cycle to verify that the process was delivered in accordance with specifications
- Biological Indicators (BI), Chemical Indicators (CI) and Process Challenge Devices (PCD) may be used as an additional method demonstrating sterilisation processes were delivered in accordance with the validated specifications.

4.5.2 Low temperature Sterilisation Systems

- Performance tests shall be conducted in accordance with the manufacturer's instructions for use.

4.5.3 Moist Heat

- Daily air removal and steam penetration test (Bowie and Dick Type Test) shall be performed on steam sterilisers
- Leak rate/vacuum test and air detector tests shall be performed weekly on steam sterilisers with an air detector, daily for steam sterilisers without air detector
- Requirements for routine monitoring and control of sterilising equipment as per Table 8.2.

5. DOCUMENTATION

- Specific HSO Procedures

6. AUDIT

- Reusable Medical Devices (RMDs) - Packing and Sterilisation of - Daily Audit
- Reusable Medical Devices (RMDs) - Mechanical cleaning of - Daily Audit
- Reusable Medical Devices (RMDs) - Manual cleaning of - Daily Audit

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health services organizations
- ISO 11607 Packing for terminally sterilised medical devices
  ISO11135 Sterilisation of health care products-Biological Indicators (series)
- ISO11140 Sterilisation of health care products-Chemical Indicators (series)
- ISO15882 Sterilisation of health care products-Chemical indicators-Guidance for selection, use and interpretation of results
- ISO17665 Sterilisation of health care products-Moist heat
- ISO17665-1 Part 1: Requirements for the development , validation and routine control of a sterilisation process for medical devices
- ISO25424 Sterilisation of health care products-Low temperature steam and formaldehayde - Requirements for development, validation and routine control of a sterilisation process for medical devices
- ISO14180 Sterilisers for Medical Purposes-Low Temperature Steam Formaldehayde Sterilisers – Requirements and Testing
- EN 285 Sterilisation-Steam Sterilisers - Large Sterilisers

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
November 2016		SESLHD Sterilising Resource Group
November 2016	1	Approved by Executive Sponsor for Draft for Comment

December 2016	1	Approved by Clinical and Quality Council
February 2020	2	SESLHD Sterilising Working Party (SSWG) conducted a minor review. Rewarded to more accurate reflect the current standards. References updated and listed.
May 2020	2	Approved by Executive Sponsor. Published by Executive Services.