Chemical and Biological Indicators and Process Challenge Devices Procedure

1. Purpose

The purpose of this procedure is to provide guidance on the use of chemical and biological indicators, as well as process challenge devices, to support the safe and effective reprocessing of reusable medical devices (RMDs).

This procedure applies to all WA Country Health Service (WACHS) healthcare workers that use or reprocess RMDs.

2. Procedure

Biological indicators (BIs) are used for routine monitoring, qualification and load monitoring in the processing of RMDs.

Chemical indicators (CIs) are used to verify that critical parameters are met in the reprocessing of RMDs.

A process challenge device (PCD) is used to assess the effective performance of a sterilisation process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult RMD routinely processed.

2.1 Biological indicators

BIs used for microbiological performance qualification and routine monitoring and control (as applicable) are to comply with ISO 11138-1:2017 Sterilization of health care products – Biological indicators – Part 1: General requirements.

BIs are to be used:
- according to the manufacturer's instructions for use (IFU) in low temperature sterilisers
- at frequencies determined by the facility for validated moist heat sterilisation process.

2.2 Chemical indicators

CIs are to comply with ISO 11140-1:2014 Sterilization of health care products – Chemical indicators – Part 1: General requirements and be selected according to the sterilisation method used.

CIs are to be:
- used as part of performance qualification (PQ) if internal chemical indicators are to be used routinely on the exterior of each packaged RMD
- used according to the manufacturer's IFU for low temperature sterilisation systems using a liquid chemical sterilising agent
- used in every load where semi-critical RMDs are sterilised unwrapped
- placed at the most difficult-to-sterilise location
- included in loan and/or repair RMDs that are left unwrapped to identify processed from unprocessed loads.

2.3 Process challenge devices

PCDs are to be used in every load to confirm that the equipment is working correctly and operating within specifications.

Note that for pre-vacuum sterilisers without an air detector it is recommended that the use of PCDs is considered to verify the absence of residual air that might affect the sterility of the load.

3. Roles and Responsibilities

Health Service Organisations are responsible for ensuring that adequate resources and support are provided to ensure a safe working environment for all staff**.**

SSD Manager/Supervisor is to implement the requirements of this document to ensure the processing of RMDs is compliant with AS/NZS 4187:2014 and associated normative references and ensure the quality and safety of reprocessed RMDs.

SSD staff must comply with the requirements of this document and report non-compliance to the SSD Manager/Supervisor or Perioperative Services Manager.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

4.1 Monitoring

Regular monitoring will contribute to compliance with relevant Standards, good quality patient outcomes and improved staff satisfaction.

The SSD Manager/Supervisor or Perioperative Services Manager are responsible for ensuring that:

- monitoring of compliance with this document is carried out in line with AS/NZS 4187:2014
- risk assessments are completed, outcomes evaluated, and actions taken as required.

4.2 Evaluation

Review of this document will be coordinated by the Surgical Services Program Team in collaboration with key stakeholders including relevant Advisory Forums.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS/NZS 4187:2014.

Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to Section 26 of the *Health Services Act 2016* (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for

service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies and procedures is mandatory.

6. References

1. AS/NZS 4187:2014 and amendment 2:2019, Reprocessing of reusable medical devices in health service organizations. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
2. ISO 11138-1:2017. Sterilization of health care products – Biological indicators – Part 1: General requirements. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
3. ISO 11140-1:2014. Sterilization of health care products – Chemical indicators – Part 1: General requirements. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
4. ISO 17665-1: 2006. Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
5. ISO/TS 17665-2: 2009. Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
6. St John of God Midland Public and Private Hospitals. Central Sterilisation Services Department Manual, MIC-SSD-OTH-0002.

7. Definitions

Term	Definition
Biological Indicator (BI)	A test system containing viable microorganisms providing a defined resistance to a specified sterilisation process.
Chemical Indicator (CI)	A non-biological test system that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process.
Performance Qualification (PQ)	A process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with the operational procedures, consistently performs in accordance with pre-determined criteria and thereby yields the product meeting its specification.
Process Challenge Device (PCD)	An item designed to constitute a defined resistance to a sterilisation process and used to assess the performance of the process.

Reusable medical device (RMD)	A medical device designated or intended by the manufacturer as suitable for processing and reuse. Clarification notes: 1. This is not a medical device that is designated or intended by the manufacturer for single use only. 2. An RMD is presented for use either as an individually packaged RMD or as more than one RMD assembled and packaged together as a group or set. For the purposes of this document, the term RMD includes a loan RMD and a trial RMD and applies to all reusable devices that require reprocessing.
Sterilisation Services Department (SSD)	Also known as Central Sterilising Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service Organisation that performs cleaning, disinfection and sterilising actions on RMDs and manages storage of sterile stock and consumables.

8. Document Summary

Coverage	WACHS wide
Audience	All WACHS healthcare workers that use or reprocess reusable medical devices
Records Management	Non Clinical: Records Management Policy Clinical: Health Record Management Policy
Related Legislation	*Therapeutic Goods Act 1989* (Cwlth) *Health Services Act 2016* (WA)
Related Mandatory Policies / Frameworks	Clinical Governance, Safety and Quality Policy Framework National Safety and Quality Health Service Standards Accreditation Policy – MP 0134/20
Related WACHS Policy Documents	Environmental Cleaning Policy Infection Prevention and Control Policy Packing, Wrapping and Sealing Reusable Medical Devices Procedure Reprocessing Reusable Medical Devices Policy Reusable Medical Devices on Loan and Instruments on Trial Procedure Tracking and Traceability of Reusable Medical Devices Procedure Validation of Cleaning, Disinfecting, Packaging and Sterilising Processes Procedure
Other Related Documents	WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 1882
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.03, 3.08, 3.10, 3.11, 3.12, 3.14, 3.17
Aged Care Quality Standards	Nil
National Standards for Mental Health Services	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	9 March 2023	9 March 2023	New procedure

10. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing – Perioperative
Business Unit	Nursing and Midwifery – Surgical Services
EDRMS #	ED-CO-22-500939

This document can be made available in alternative formats on request.