Audit of Sterilisation Services Departments Procedure

1. Purpose

The purpose of this procedure is to provide guidance on the requirements for regular auditing of Sterilisation Services Departments (SSDs).

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

2. Procedure

2.1 Auditing

Audits should be undertaken at a minimum as per the site's audit schedule utilising the relevant audit tools. Refer to WACHS Sterilisation Services: Policies, Procedures and Resources List – Quality Assurance section for hyperlinks to relevant audit templates.

Following each audit, any identified issues/concerns should be escalated to the Environmental Cleaning Team Leader/Manager or responsible person to ensure issues are rectified as soon as practicable.

Ongoing identified issues/concerns should be escalated to the Environmental Services Manager, the Infection Prevention and Control Clinical Nurse Specialist (IPC CNS)/team member and tabled at the relevant committee meetings (refer to Section 4.1: Monitoring below).

2.2 Documentation/record keeping

All audits are to be recorded and monitored either through an electronic system or via hard copy documentation.

Completed task lists, cleaning audits and reports will be stored and maintained in Records Manager in a designated folder accessible to relevant key personnel including the Environmental Cleaning Team Leader/Manager, Perioperative Services Manager/SSD Manager and IPC CNS.

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.

All identified issues must be escalated and reported to the local Perioperative Management Committee and Infection Prevention and Control Committee. They are also to be tabled at the Regional Infection Prevention and Control Committee meetings, with any issues escalated to the Regional Safety and Quality Committee.

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 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/.
3. ISO 11607-2:2019. Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes. Available from https://www-saiglobal-com.wachslibresources. health.wa.gov.au/online/.

4. ISO 15883-1:2006. Washer-disinfectors – Part 1: General requirements, terms and definition and tests. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
5. ISO 17664-1:2021. Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices. Available from https://www-saiglobal-com.wachslib resources.health.wa.gov.au/online/.
6. ISO/TS 17665-3:2013. Sterilization of health care products – Moist heat – Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization. Available from https://www-saiglobal-com.wachslib resources.health.wa.gov.au/online/.
7. Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia (GESA), 2021.
8. Women and Newborn Health Service. Hospital Sterile Supply Department Policy and Procedure Manual - HSSD reprocessing activities. King Edward Memorial Hospital Sterile Supply Department (HSSD), 2021.

7. Definitions

Term	Definition
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 or implement SSD audits.
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	Chemical and Biological Indicators and Process Challenge Devices Procedure Cleaning of Reprocessing Equipment Procedure Environmental Cleaning Policy Infection Prevention and Control Policy Packing, Wrapping and Sealing Reusable Medical Devices Procedure Repair and Maintenance of Reprocessing Equipment and Reusable Medical Devices Procedure Reprocessing Reusable Medical Devices Policy Reusable Medical Devices on Loan and Instruments on Trial Procedure Storage, Handling and Transport Requirements for Sterile Stock Procedure Thermal Disinfection of Reusable Medical Devices Procedure Tracking and Traceability of Reusable Medical Devices Procedure Validation of Cleaning, Disinfecting, Packaging and Sterilising Processes Procedure
Other Related Documents	SSD Audit Schedule and Audit Tools WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 2078
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.08, 3.10, 3.11, 3.12, 3.14, 3.15, 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	30 March 2023	30 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-23-121720

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