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Nonconforming Reusable Medical Devices Procedure

1. Purpose

The purpose of this procedure is to outline the requirements and subsequent management of nonconforming reusable medical devices (RMDs).

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

2. Procedure

A RMD is not to be released from reprocessing until all acceptance criteria for release of the device have been met. RMDs that have not met all acceptance criteria are to be quarantined and managed in accordance with this procedure.

All RMDs processed are to be tracked manually or via the electronic tracking system, as per local processes. If a recall is required, this will ensure that affected RMDs can be readily identified. Refer to the Tracking and Traceability of Reusable Medical Devices Procedure.

2.1 Nonconforming RMDs

A nonconforming RMD/other device includes items that do not meet acceptance criteria after completion of cleaning, disinfection or sterilisation processes, and / or packaging, as applicable. i.e. A nonconforming RMD is a RMD that does not fulfil appropriate reprocessing requirements and are not safe to be used on patients.

On detection of a failure at any stage of reprocessing, the resulting nonconforming RMD/s must be removed from use and appropriately managed to reduce the risk of adverse patient outcomes. The table below lists examples of nonconforming RMDs that do not meet acceptance criteria for release during reprocessing, as well as subsequent transportation and storage:

Table 1: Nonconforming RMDs

Component / process step	Examples of a nonconforming RMD/other device include a device that
RMDs/other devices	• is visually dirty after completion of the cleaning process • is non-functional • is damaged, soiled or incomplete • is recalled by manufacturer
Sterile Barrier System (SBS)	• inappropriate SBS was used • incorrect wrapping method was used • incorrect closure or seal used • SBS is damaged or visible moisture or deterioration is present
Labelling	• missing or faulty batch label • incorrectly labelled RMD or tray

	• insufficient proof of process for reprocessing of RMD
Reprocessing process	• machinery/equipment failure • incorrect sterilisation method • external chemical indicator has not changed as per manufacturer's specifications • the processed biological indicator is positive following incubation time/quarantine • cycle records do not confirm achievement of parametric release established during Performance Qualification (PQ)

Transport/handling and storage	• incorrect handling and transport (refer to Storage, Handling and Transport Requirements for Sterile Stock Procedure)
	• transport container is not fit-for-purpose
	• inappropriate environmental conditions in the sterile store, e.g.
	  ○ temperature outside of 18°C - 25°C range
	  ○ humidity outside of 35% - 70% range
	  ○ air conditioning and ventilation systems outside of the requirements outlined in AS 1668.2-2012
	  ○ exposure to excessive sunlight or other sources of ultraviolet (UV) light
	  ○ exposure to vermin and insects during storage
	• RMD is placed or dropped on a dirty surface after reprocessing (e.g., a floor or sink area)

2.2 Recall of nonconforming RMDs

A recall is the removal from service of an individual RMD/other device or equipment until it can be repaired or appropriately reprocessed, following the identification of nonconformance regarding function or noncompliance with a reprocessing cycle. In some instances, the situation will require the recall of a load of RMD/s which requires individual identification of each item's location and retrieval.

A recall of RMDs reprocessed in the Sterilisation Services Department (SSD) must be undertaken whenever there is evidence of sterilisation process failure. This is a significant event and requires immediate attention, appropriate action and documentation. The SSD Manager/Supervisor or delegate is responsible for coordinating all RMD recall activities.

The recall process is to be initiated immediately after notification and/or determination of a sterilisation failure:

- Review all information available in the manual tracking log or electronic tracking system to determine if a recall is required.
  - If using an electronic tracking system, recalling a load from a failed steriliser or washer will automatically attach a recall alert against all trays in the load.
  - When a tray has a recall notice against it, an alert will be issued to the user as the RMD tray is scanned. The alert will stay attached to the tray until it is either cleared by the SSD Manager/Supervisor or sent to the decontamination area to be reprocessed.
- A product recall form must be completed and circulated to the department/s impacted by the recall. The form must include the following information:
  - the department/s for which the recall notice is intended
  - sterilisation batch information
  - items that were included in the load (General tray)

  - action/s to be taken by the department/s when the items are located (e.g. return the RMDs to the SSD)
  - circumstances leading to the recall
  - investigation and corrective action/s taken by the SSD
  - consequences of the recall (e.g. RMD unavailable for a period of time, availability of alternative RMDs).
- Physically remove the nonconforming RMDs from the SSD storage area and from the department/s impacted by the recall.

2.3 Notification of recalled RMDs

The table below outlines the process for notifying relevant staff of an RMD recall:

Table 2: Notification of recalled RMDs

In hours (Monday – Friday 0800 – 1700 hours)	After hours (Monday – Friday 1700 – 0800 hours, Saturday and Sunday)
The SSD Manager/Supervisor is to immediately notify: • Perioperative Services Manager • Director/s Surgical Services • Infection Prevention and Control (IPC) team member/Regional Clinical Nurse Specialist (CNS) as appropriate • Clinical Nurse Managers (CNMs) of affected ward areas and outlying departments (if applicable) • Outside agencies (if applicable). The Director/s of Surgical Services must then notify the Coordinator of Nursing (CON) and Director of Nursing/Health Services Manager (DON/HSM).	The SSD staff is to immediately notify: • The SSD Supervisor • The after-hours Theatre Nursing Coordinator • After Hours Coordinator/s of affected ward area/s who will escalate to the Executive-on-Call as appropriate. The Executive-on-Call must notify the CON and DON/HSM.

3. Roles and Responsibilities

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

The **SSD Manager/Supervisor** is to:
- implement the requirements of this document to ensure the processing of RMDs is compliant with AS 5369:2023 and associated normative references
- ensure the quality and safety of reprocessed RMDs
- coordinate all RMD recall activities.

Sterilisation Technicians 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 and auditing of reprocessing processes will facilitate compliance with relevant Standards, quality patient outcomes and improved staff satisfaction. Results of noncompliance are to be escalated to the local peri-operative/SSD meetings.

Recall incidents are to be reviewed and discussed at local peri-operative/SSD meetings, tabled at regional IPC Committee meetings and escalated appropriately 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 within a five-year period or earlier as relevant to changing standards/guidelines.

This will take into consideration any trends in relation to clinical incidents, the results of ongoing quality monitoring activities that are undertaken at a site/regional level and evidence of appropriate reporting and recall processes.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS 5369:2023.

Failure to comply with this policy 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

AS 5369:2023. Reprocessing of reusable medical devices and other devices in health and non-health related facilities. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

AS 1668.2-2012. The use of ventilation and air-conditioning in buildings – Ventilation design for indoor air contaminant control. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

ISO 11140-1:2014. Sterilization of health care products – Chemical indicators – Part 1: General requirements. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

ISO 11607-2:2019. Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

ISO 15883-1:2006. Washer-disinfectors – Part 1: General requirements, terms and definitions and tests. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

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 Home - WACHS Library - WACHS Library at Western Australia Department of Health

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 Home - WACHS Library - WACHS Library at Western Australia Department of Health

ISO/TS 17665-2:2009. Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1. Available from Home - WACHS Library - WACHS Library at Western Australia Department of Health

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.

7. Definitions

Term	Definition
Nonconforming RMD	An RMD that does not fulfil requirements (i.e. does not meet the required specification).
Performance Qualification (PQ)	A process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.
Recall	Request to return nonconforming RMD/s to the SSD after the discovery of safety issues that might lead to adverse patient outcomes.
Reusable medical device (RMD)	A medical device designated or intended by the manufacturer as suitable for processing and reuse. Clarification notes: • 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.
Sterile Barrier System (SBS)	The packaging around medical devices that allow those devices to be sterilised. Provides a microbial barrier and maintains sterility effectively up to the point of use.

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 sterilisation 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: Corporate Recordkeeping Compliance Policy Clinical: Health Record Management Policy
Related Legislation	• *Therapeutic Goods Act 1989* (Cwlth) • *Health Services Act 2016* (WA)
Related Mandatory Policies / Frameworks	• National Safety and Quality Standards Accreditation Policy – MP 0134/20 • Clinical Governance, Safety and Quality Policy Framework
Related WACHS Policy Documents	• Clinical Audit Policy • Environmental Cleaning Policy • Flexible Endoscope Reprocessing Procedure • Hand Hygiene Policy • Infection Prevention and Control Policy • Managing Risks of Hazardous Chemicals and Dangerous Goods Procedure • Work Health and Safety Policy • Packing, Wrapping and Sealing Reusable Medical Devices Procedure • Quality Management and Validation Procedure (under development) • Reprocessing Reusable Medical Devices Policy • Reusable Medical Devices on Loan and Instruments on Trial Procedure • Storage, Handling and Transport Requirements for Sterile Stock Procedure • Waste Management Policy
Other Related Documents	• WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	• Product Recall Form
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 2215
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.03, 3.06, 3.07, 3.08, 3.09, 3.12, 3.13, 3.14, 3.17
Aged Care Quality Standards	Nil
Chief Psychiatrist's Standards for Clinical Care	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	23 January 2024	23 January 2024	New Procedure

10. Approval

Policy Owner	Executive Director Nursing and Midwifery Services
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing – Perioperative
Business Unit	Nursing and Midwifery – Surgical Services
EDRMS #	ED-CO-23-318736

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