SESLHD POLICY COVER SHEET

NAME OF DOCUMENT	Sterilisation - Reprocessing of Reusable Medical Devices (RMDs)
TYPE OF DOCUMENT	Policy
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RISK RATING	Medium
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standard: Standard 3 – Preventing and Controlling Infections AS/NZS 5369-2023
REVIEW DATE	November 2027
FORMER REFERENCE(S)	Nil
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Clinical Governance and Medical Services
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POSITION RESPONSIBLE FOR THE DOCUMENT	SSD Management Tim.cole@health.nsw.gov.au
FUNCTIONAL GROUP(S)	Infection Control
KEY TERMS	RMDs, Original Equipment Manufacturer (OEM) Instructions for Use (IFU)
SUMMARY	This policy describes the requirements necessary for reprocessing facilities to compliance with National standards in the reprocessing of Reusable Medical Devices within the SESLHD.

Sterilisation – Reprocessing of Reusable Medical Devices (RMDs)

SESLHDPD/338

1. POLICY STATEMENT

The contemporary reprocessing of reusable medical devices (RMDs) is directed by the Australian Commission on Safety and Quality in Healthcare to comply with National and International standards of practice. By default, this means health services shall apply Australian Standard- AS-NZS 5369-2023 “Reprocessing of Reusable Medical Devices”, as the basis for developing all relevant procedures along with a robust governance process relating to the reprocessing of their facilities’ RMD inventory.

2. BACKGROUND

AS-NZS 5369, is based on a comprehensive and constantly evolving folio of 30+ national and predominantly international standards (ISO/EN/BS/AAMI) the majority of, which are specific to the RMD reprocessing sector.

The extensive references and guidance contained in AS-NZS 5369 provides all RMD reprocessing facilities with the means to develop handling processes and procedures specific to the range of RMDs their individual facility relies upon for patient treatment.

All reprocessing conducted within SESLHD shall be conducted following site-specific reprocessing procedures and OEM IFU’s designed for each site. The document folio should align with national and international standards in content and cross-referencing, be agile to changes and updates of these standards, be capable of review and audit by internal and external sources and shall form the basis of ongoing internal training and staff development relative to the skills required of technicians working within the individual facility. Further, the aim of the strategy is enable facilities to respond to and adjust practices to reflect future iterations of all/any standards as they are updated and published and to implement procedures relative to the introduction of new reprocessing technologies.

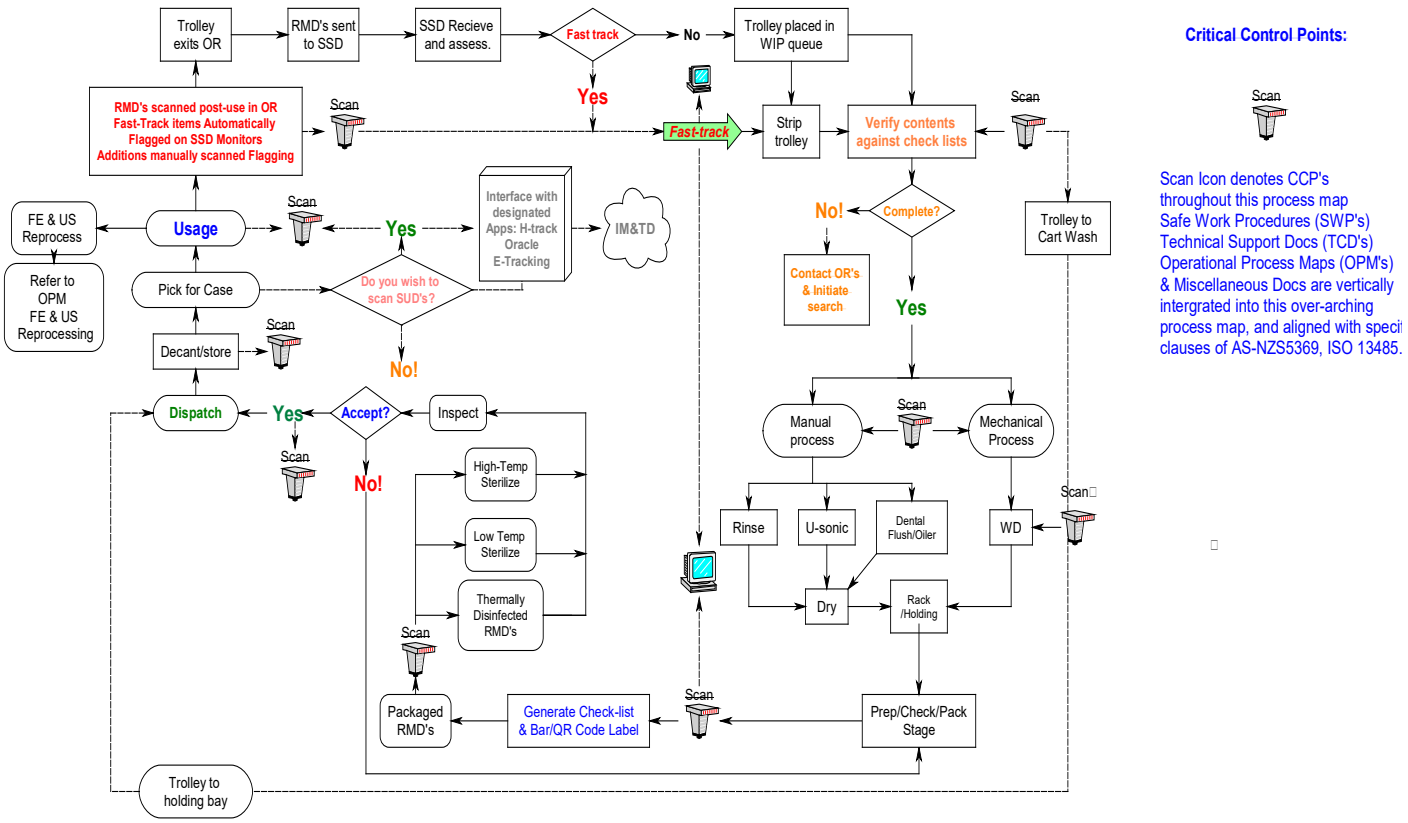
2.D: SESLHD RMD reprocessing process flow chart and compliance reference guide - For reference only - Not site specific.

The sample matrix below lists a banner range of document headings relative to a reprocessing facility with a locally diverse range of reprocessing requirements. The matrix lists the relevant clauses of AS-NZS5369. It is by no means exhaustive, and all sites will need to develop a range of site-specific procedures and support documents relative to the RMD product families handled on their respective sites.

Document Master List: Key; PD- Policy Doc, SWP- Safe Work Procedure.

Doc #	AS-NZS 5369 Clause	Document Type & Description
PD	2/2.3.2	Policy: Reprocessing of RMDs Inclusive of All Product Families
SWP	3.7.1	SWP: PPE & Apparel- Decontamination Areas & Related Satellite Reprocessing Areas
SWP	8.2	SWP: Preparation of Work Area- Decontamination & Related Satellite Reprocessing Areas
SWP	3.7.4	SWP: Safe Use of Chemicals in All Decontamination Areas
SWP	4.2	SWP: Daily Test Procedures: Steam Sterilizer, Washer-Disinfector, Instrument Drying Cabinet, U-Sonic Cleaner, Scope Flusher, Automated Endoscope Reprocessor, UV-C, Hydrogen-Peroxide Nano-Nebulant HLD Units, Disinfecting Cart Washer, Endoscope Drying Cabinets, Battery Charger, Electro-Surgical Test Unit, Luminometer, Road-Case Lifter,
SWP	4.2	SWP: Handling of used RMDs at Point of Receipt Inclusive of Satellite Reprocessing Area's
SWP	6.2.2	SWP: Collection of RMDs from Clinical Areas
SWP	6.2.3	SWP: Handling of RMDs requiring Manual Decontamination Only
SWP	6.2.3	SWP: Washer-Disinfector Operation- All Cart Variants
SWP	6.2.3	SWP: Operation of Ultra-Sonic Cleaner
SWP	6.3.5	SWP: Operation of Automated Endoscope Reprocessor (HLD)
SWP	6.3.5	SWP: Operation of UV-C High Level Disinfector (HLD)
SWP	6.3.5	SWP: Operation of Nano-Nebulant type High-Level Disinfector (HLD)
SWP	6.2.3	SWP: Medical Air & Water -Pistols
SWP	6.2.3	SWP: Operation of Drying Cabinet
SWP	5.6	SWP: Preparation of Workspace in Prep/Pack area
SWP	6.5	SWP: High-Temperature Steam Sterilizer
SWP	6.5	SWP: Low-Temperature Sterilizer

In addition, the following flow-chart maps the entire reprocess pathway for RMDs, establishes typical critical control points to facilitate compliance with mandatory national standards to address a "risk-based" approach to quality assurance, and in tandem with the matrix enables reprocessing units to develop a proactive approach to their respective reprocess activities.



RMD Reprocess Flow

Critical Control Points:

Scan

Scan Icon denotes CCP's throughout this process map
Safe Work Procedures (SWP's)
Technical Support Docs (TCD's)
Operational Process Maps (OPM's)
& Miscellaneous Docs are vertically intergrated into this over-arching process map, and aligned with speci clauses of AS-NZS5369, ISO 13485.

3. RESPONSIBILITIES

3.1 All employees shall:

- Comply with the requirements of this policy
- Report non-compliance to Sterilisation Services Manager.

3.2 Line Managers shall:

- Support compliance and implementation.

3.3 Service Managers / Supervisors shall:

- Implement the requirements of this procedure to assure compliance with the General Retention and Disposal Authority and *State Records Act 1998.*

4. Administration

4.1 Records shall include the following:

- Purchasing records of reprocessing equipment
- Monitoring of reprocessing equipment
- Decontamination process records
- Sterilising process records

- High level disinfection, including chemical and thermal process records
- Microbiological surveillance testing of Flexible Endoscopes
- Staff training and competency to undertake reprocessing activities
- Staff rosters and allocations
- Maintenance records for reprocessing equipment
- Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) for reprocessing equipment
- Process deviation reports and where applicable, records of corrective action or preventative action.

5. DOCUMENTATION

- Not applicable.

6. AUDIT

- As indicated by Infection Prevention Control Committee (IPCC).

7. REFERENCES

- AS/NZS 5369- 2023: Reprocessing of reusable medical devices in health service organization and its normative references
- *State Records Act 1998*
- NSW Health Policy Directive PD2009_057 - Records Management - Department of Health
- SESLHDPD/196 - Records Management
- SESLHDPR/220 - Records Management - Destruction of

8. VERSION AND APPROVAL HISTORY

Date	Version No.	Author and approval notes
6 November 2024	1.0	New governance document to replace existing suite of SESLHD wide sterilisation policy documents. Approved at SESLHD Infection Prevention Control Committee and SESLHD Patient Safety and Quality Committee.