SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Sterilisation: Validation of Washer/Disinfectors
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/524
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)	Nil
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	**RMD** - Reusable Medical Device **OQ** - Operational Qualifications **IQ** - Installation Qualifications **PQ** - Performance Qualifications **Validation** - documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications
SUMMARY	To provide evidence of the level of quality validation and monitoring of the process necessary to ensure patient safety.

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

1. POLICY STATEMENT

Validation of washer/disinfectors is to establish that the washing process developed can be delivered effectively and reproducibly to each load. Validation is considered as a total program which consists of three identified stages: Installation Qualification, Operational Qualification and Performance Qualification carried out on washer/disinfectors for which there is documented evidence from the manufacturer that they comply with requirements of the relevant ISO standards.

2. BACKGROUND

IQ - Installation Qualification is carried out by the manufacturer to ensure washer/disinfectors are correctly installed and safe to operate.

OQ - Operational Qualification is a process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

PQ - Performance Qualification shall demonstrate the obtainment of cleaning efficacy, disinfection conditions throughout the chamber, load carrier and load, drying efficacy and free of process residue.

3. RESPONSIBILITIES

3.1 Employees will:

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

3.2 Line Managers will:

- Support compliance

3.3 District Managers/ Service Managers will:

- Inform the manufacturer of the Washer Disinfectors or qualified service provider of the requirements of this procedure
- Ensure Validation Service Agreements are in place with the manufacturer of the Washer Disinfectors or qualified service provider
- Obtain written service agreement with detailed validation procedure
- Obtain validation report
- Obtain calibration report traceable to international or national measurement standards, this report will include the certification number of the calibration device used.

3.4 Medical staff will:

- Nil

4. PROCEDURE

4.1 Validation of Washers/Disinfectors

- Calibration equipment used in the Validation process shall be certified by a suitable certification body traceable to international or national standard
- PQ can only be performed after completion of IQ & OQ
- Cleaning agents which are intended for use on RMDs have been registered by the ARTG
- In the case where process cycles using the same load configuration only differ by length of the different phases, the cycle being tested could be the shortest cycle proposed for Validation
- Water supply shall be a suitable quality which shall be potable
- RO water maybe be used for at least the final rinse.

4.2 Performance Re Qualification

- Shall be carried out annually or when major engineering changes are carried out which causes deviation from the data determined during initial Validation or if process conditions have changed (Loading/Load configuration/Chemistry).

4.2.1 Tests performed during Re Qualification shall be as followed

- Thermalatric Thermometric testing, carried out on wall chambers and Load
- Cleaning efficacy test
- Chemical dosing test

4.2.2 Cycle Parameter Criteria

- Operating cycles are within predetermined parameters established during initial Validation and confirmed at Performance Requalification.

4.2.2 Validation report

Shall include:

- The equipment specification and any subsequent changes to it
- Location and unique identification eg SN and manufacturer
- Documentation to demonstrate compliance with the safety specifications
- Report of proper installation
- Load configuration.

5. DOCUMENTATION

- Service Agreements
- Validation Report

6. AUDIT

- CEC Audit Tool

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisation and its normative references
- 15883-1 Part 1: General Requirements, term and definitions and test
- 15883-2 Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc
- 15883-4 Part 4: Requirements and tests for washer disinfectors employing chemical disinfection for thermolabile endoscopes.

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
		SESLHD Sterilising Research Group
September 2016	1	Endorsed for Draft for Comment
November 2016	1	Endorsed by SESLHD Clinical and Quality Council
February 2020	2	SESLHD Sterilising Working Party (SSWP) conducted a minor review to list correct documentation for a Validation Report
May 2020	2	Approved by Executive Sponsor. Published by Executive Services.