SESLHD PROCEDURE COVER SHEET

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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director Clinical Governance and Medical Services
AUTHOR	SESLHD Sterilising Services Working Group (SSWG)
POSITION RESPONSIBLE FOR THE DOCUMENT	Karolina Tipevska Manager Sterilising Services, Sutherland Hospital Karolina.Tipevska@health.nsw.gov.au
KEY TERMS	Sterilisers, Validation, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Validation Report, Service Agreement
SUMMARY	The purpose of this procedure is to document the requirements necessary to undertake and demonstrate successful validation of the sterilisation processes.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

Sterilisation: Validation of Sterilisers SESLHDPR/636

1. POLICY STATEMENT

Validation of Sterilisers is to establish that the sterilisation 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 sterilisers for which there is documented evidence from the manufacturer that they comply with requirements of the relevant ISO standards.

2. BACKGROUND

Due to the complexity of the RMD's, the equilibration time, the types of loads and the type and design of the sterilisers there is a need to assure successful sterilisation under pre-set conditions.

Installation Qualification (IQ) is carried out by the manufacturer to ensure sterilisers are correctly installed and safe to operate.

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

Performance Qualification (PQ) shall demonstrate that the steriliser consistently operates in accordance with predetermined criteria and the process yield product that is sterile and meets the specified criteria.

3. DEFINITIONS

Sterilisation process - series of actions or operations needed to achieve the specified requirements for sterility.
Validation - documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined.
Equilibration time – period which elapses between the attainment of the sterilisation temperature at the reference measuring point and the attainment of the sterilisation temperature at all points within the sterilisation load.

4. RESPONSIBILITIES

4.1 Sterilising Services Staff will:

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

4.2 Line Managers will:

- Support compliance.

4.3 Sterilising Service Managers will:

- Inform the manufacturer or qualified service provider of the sterilisers, the requirements of this procedure

- Ensure Validation Service Agreements are in place with the manufacturer of the sterilisers or qualified service provider
- Obtain written service agreement with detailed validation procedure
- Review and approve validation report
- Obtain calibration report traceable to international or national measurement standards, this report will include the certification number of the calibration devices used in the validation process.

5. PROCEDURE

5.1 Validation of Sterilisers

Each stage of validation shall be carried out in accordance with a documented procedure. Each test instrument used for validation shall have calibration traceable to a national standard.

IQ shall verify the equipment to be installed, the installation of the equipment and the function of the equipment.

OQ shall demonstrate that installed equipment will deliver the sterilisation process with defined process parameters and their limits.

5.2 Performance Qualification

- Demonstrates that RMD has been exposed to the specified sterilisation process by the equipment to be used for routine sterilisation
- The test sterilisation load comprises RMDs that will be routinely processed and that are assigned to a product family/ies compatible with the one/s assigned to the sterilisation process or that represents the product families presenting the greatest challenge to the sterilisation process
- PQ shall include a series of at least three consecutive exposures of the sterilisation load to the sterilisation process.

Checks include:

- Documentation that confirms successful IQ and PQ
- The test sterilisation load comprises RMDs that will be routinely processed and that are assigned to a product family/ies compatible with the one/s assigned to the sterilisation process or that represents the product families presenting the greatest challenge to the sterilisation process
- The combination of materials used to construct and package the RMDs should withstand the process parameters and any restriction resulting from the design of the RMD and the materials used should be defined
- The RMDs to be sterilised, including the microbiological quality of the RMDs and the manner in which the RMDs are packaged and presented for sterilisation should be defined
- The packaging system is identical to that intended for routine production or reprocessing
- The load configuration is known to be the most difficult to sterilise

- The sterilisation process and the limiting process values shall conform with ISO 17665-1.

5.2.1 Performance Qualification Report shall confirm:

- The product families that can be processed
- The load configuration
- The size of the sterilisation load and/or its mass
- The procedures for any preconditioning of RMDs
- A description of the packaging system and methods
- The description of the RMDs within a package containing multiple RMDs
- The periodic tests
- The process challenge devices
- The positioning of the data loggers within the RMD's, load and chamber
- The result of the chemical indicators
- The response of biological testing.

5. DOCUMENTATION

- Service Agreement
- Validation Procedure
- Validation Report.

6. AUDIT

Clinical Excellence Commission Audit Tool.

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organization and its normative references
- ISO 17665-1: 2006 Requirements for the development, validation and routine control of a sterilisation process for medical devices

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
September 2018	DRAFT	SESLHD Sterilising Services Working Group (SSWG)
October 2018	DRAFT	Draft approved by Executive Sponsor and was placed on Draft for Comment
November 2018	DRAFT	Processed by Executive Services prior to Clinical and Quality Council approval.
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