

Overview

This document

This document outlines the guidelines for the Validation of Ethylene Oxide Sterilisers for Sterile Services Departments / Units within New Zealand. These guidelines are endorsed by the New Zealand Sterile Services Association (NZSSA).

These guidelines may be used to develop policies and procedures to improve the management of validating Ethylene Oxide Sterilizers within healthcare facilities. This is to assist sterilizing units in providing a quality service to its customers and ultimately the quality of care received by patients.

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Introduction

Purpose

In order to determine the efficacy of ethylene oxide sterilisers it must be monitored and measured against the parameters required to achieve sterilisation. The information in these guidelines can be located in AS/NZS 4187: (2003) *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*; and AS/NZS 4815: (2006) *Office based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*

All Sterile Services Departments / Units should ensure that all ethylene oxide sterilisers are ‘validated’ annually against the above standards. It is the responsibility of the person in charge of the department to arrange for this to happen.

The purpose of validating ethylene oxide sterilisers is to evaluate its reliability and consistent performance and this must occur over three consecutive cycles. This is achieved by challenging the ability of the steriliser to destroy all viable micro-organisms, dry and aerate all load items.

Validation takes into account:

- The performance of the steriliser being validated, including the drying and aeration of load items in ethylene oxide sterilisers
- Packaging Material(s) being used
- Types and numbers of items being sterilised per cycle
- Weight of load items
- Density of load

All aspects of the validation process must be thoroughly documented and verified by the person in charge of the department.

Scope

For use by Sterile Services Departments / Units throughout New Zealand

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Introduction, Continued

Associated documents

The table below identifies associated documents.

Type	Title/Description
Standard	<ul style="list-style-type: none">AS/NZS 4187:2003 – Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.AS/NZS 4815: (2006) Office based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environmentISO 11135: 1994(E) Medical devices – Validation and routine control of ethylene oxide sterilisation

Definitions

The following are definitions with their meanings that relate to the validation process:

Word	Definition
Aeration	<ul style="list-style-type: none"> Part of the sterilisation process during which ethylene oxide and/or its reaction products desorb from the medical device until predetermined levels are reached.
Aeration Chamber separate from steriliser	<ul style="list-style-type: none"> A mechanical chamber where aeration occurs. May be performed within the steriliser and/or in a separate chamber.
Commissioning	<ul style="list-style-type: none"> Documented evidence that equipment has been provided, installed and functions within the predetermined limits. The commissioning of equipment includes installation qualification (IQ) and operational qualification (OQ) processes.
Installation Qualification (IQ)	<ul style="list-style-type: none"> Documented evidence that equipment has been installed in accordance with manufacturer's instructions.
Operational Qualification (OQ)	<ul style="list-style-type: none"> Documented evidence that installed equipment is operating within the predetermined limits during its use.
Performance Qualification (PQ)	<ul style="list-style-type: none"> Demonstrates the sterilisers ability to attain the required sterilising conditions in specified loads which is verified by physical parameters: thermocouples probes, biological chemical indicators and PCD's. Sterilised products meet required specifications.
Re-commissioning	<ul style="list-style-type: none"> Is the repetition of part or all of the commissioning of equipment requirements.
PCD	<ul style="list-style-type: none"> Performance Challenge Device.
Performance Requalification	<ul style="list-style-type: none"> Re-confirmation of data gathered during the performance qualification process.
Validation	<ul style="list-style-type: none"> Documented procedure providing evidence that all equipment will consistently produce a product complying within the predetermined limits and specifications.

Required Resources

Resources

Before beginning the validation process, the following items must be available. All testing indicators used during validation must be the type and kind that are normally used when processing equipment outside of the validation process.

- Chemical Indicators / Integrators (CI) (optional only if not used regularly in packs sterilised daily)
 - Biological Indicators (BI) (identical to those used in the challenge test pack if one is used regularly)
 - Process Challenge Devices (if used regularly)
 - Relevant documentation sheets / records
 - Test load items (Instrument sets, laminate packaged items, medical devices). If possible, keep old unused instruments and medical devices to make validation packs rather than using end user product that may be required.
 - Packaging Materials and tamper proof sealing product, if required
 - BI Incubators (may need more dependant on the number of BI's to be incubated)
 - BI Record Book / documentation form
 - Record of load configuration requirements including the placement of BI's, CI's and thermocouples
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Reference Load Identification

Before beginning either the Performance qualification or Performance requalification processes, a decision must be made on the types and numbers of reference loads that are going to be used. A decision must also be made on the type of cycles that are going to be tested.

Cycle Type

For each type of sterilising cycle whereby the sterilisation parameters are different, three consecutive test cycles must be processed. These must be completed for both hot and cold cycles if both cycles are used.

Examples of cycle types include:

- Wrapped cycle
 - Laminated packaging cycle
 - Mixed wrapped and laminated packaging cycle
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Load Items / Reference Loads

Load items used in reference loads must be relevant to the cycle type and numbers of items sterilised in any particular load every day in the sterilising unit.

Some examples of reference loads are:

- Complex designed items (flexible endoscopes)
- Anaesthetic and Respiratory items
- Minimal invasive items (lumen instruments)
- Combination of any of the above types of loads

The selection of a reference load should ensure that it provides the greatest challenge to the ethylene oxide sterilizer. Cycles and load items processed on a daily basis must never exceed weight or density of the validation reference loads

Service Provider

The Service Provider(s) must be qualified and certified to complete IQ, PQ and OQ Procedures. They are responsible for the use of thermocouple probes and must be competent and qualified in their use.

Selection of Service Provider:

Where possible, the Validation Service Provider(s) must be independent and not provide servicing and maintenance for the same sterilisers they validate.

Where this is not possible, the department manager must ensure that the Service Provider is knowledgeable and has integrity to validate the same steriliser(s) that they service and maintain. Another option is to have two different people from the same company, one for servicing and maintaining the steriliser(s) and another different person to validate the steriliser(s).

The probes must be calibrated and certified yearly by an independent and external company, a copy of that certificate must be included in the validation report from the service provider. A validation report and certificate of the validation process must be provided with the Certificate placed in an area close to the sterilizer that was validated.

Validation Process

Breakdown of tests carried out as part of the validation process

The following tests must be carried out in this order prior to the processing of reference loads.

Leak rate test A leak rate test is processed to check that there is no air, or that an acceptable amount of air is leaking into the chamber during the cycle. This test must be processed at the start and conclusion of the validation process. Results must be compared to previous Leak Rate test results and recorded.

Heat Penetration Test A heat penetration test is run to find the 'cold spots' in the chamber for each type of cycle 37°C and 55°C. Historical 'cold spots' in a Ethylene Oxide steriliser may include the drain line, by the chamber door and the point(s) in the chamber furthest from the ethylene oxide point of entry. The thermocouple probes, BI's, CI's and PCD's are placed in load items at the 'cold spots'. This is to monitor that the required sterilisation parameters are achieved in the 'cold spots' throughout the chamber. The thermocouple probes are attached to the load basket. Ensure that the tips don't touch the metal of the basket or incorrect readings may occur.

A heat penetration test must be run every time a sterilizer is validated. This is to compare results from the previous validation cycles and to ensure that the test components are being placed in the 'cold spots'.

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Validation Process, Continued

Loading reference load items

Items must be loaded as they would be in normal cycles and as per recommended loading practices. The construction of the reference load items must mirror the packs processed in the sterilizing unit daily. Items containing Thermocouple probes, BI's and CI's must be placed in the 'cold spots' determined during the heat penetration test.

Placement of Thermocouple Probes

Thermocouple probes must be placed in the reference load items being placed in the 'cold spots' throughout the chamber. The number of probes placed in each reference load item will be determined by the number of probes available on the equipment by the Service Provider.

The probes must be placed in the reference load items without compromising the seal or integrity of the item, packaging material or container. This could lead to assisting the removal of air and penetration of steam. This in turn would not mirror the sterilizing of these items as would happen normally

Placement of Process Challenge Devices

Process Challenge Devices must be placed in the area where they are normally processed during wrapped goods cycles.

Placement of Biological Indicators

Wrapped cycles, excluding rigid containers

Biological indicators are to be placed alongside the thermocouple probes in the reference load items; which are in turn placed in the 'cold spots' of the chamber.

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Validation Process, Continued

Placement of Biological Indicators, Continued

Specialised containers for Ethylene Oxide sterilisation	Biological indicators are to be placed one in each corner and one in the middle of each container placed in the reference load. Ensure that there are enough incubators available to incubate the BI's as required. The incubators must be maintained, serviced and monitored as recommended by the manufacturer. Incubators requiring temperatures must be monitored weekly to ensure that they are functioning correctly.
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Placement of Chemical Indicators / Integrators

Chemical indicators / integrators are to be placed alongside the biological indicators and thermocouple probes placed in the reference load items. For rigid containers place one chemical indicator / integrator per container.

Drying of Load Items

Part of determining the effectiveness of the Ethylene Oxide steriliser is to check the ability of the steriliser to produce dry load items. Items that are not dry when opened after sterilisation are not considered sterile.

When removing reference load items after allotted aeration time, open the items containing the thermocouple probes, BI's and CI's immediately and process these items as identified above. .

Investigate any wet load items as to why they may have been wet. i.e., Plastic components in a metal container, whereby the plastic components cool quicker than the metal container so condensation is then likely to form.

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Validation Process, Continued

Documentation

All aspects of the validation process must be documented by both the sterilizing unit and the service provider. Generic information that must be documented include:

- Date of testing
- Name of Department & Hospital
- Type of reference cycle
- Start and finish times for each cycle
- Operator ID
- Service Provider ID
- Steriliser Type / Serial number
- Steriliser Parameters
- Cycle type
- Results from tests

(See appendix A: Copy of Documentation Form)

Results

Results must be documented for chemical indicators / integrators and process challenge devices at the time of opening the reference load items. Documentation of the Biological indicators results occur at the end of the required incubation period.

Load configuration information

The configuration of each reference load type must be documented. This can be done by taking a photo of each load, or by documenting on a drawing of the steriliser basket. Information that should be documented:

- Placement of biological indicators
 - Placement of chemical indicators / integrators
 - Placement of thermocouple leads
 - Types and names of packs in each reference load
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Appendix A

Validation Documentation Form

Date of testing
Department & Hospital
Operator ID
Service Provider ID
Steriliser Type / Serial no.
Steriliser Parameters
Type of reference cycle

Name of item	Qty	Placement in steriliser basket (eg, top middle of basket/shelf)	Load placement no.
			1
			2
			3
			4
			5
			6
			7
			8
			9

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Appendix A, Continued

Biological Indicator (BI) Placement

Expiry Date	Lot Number	Type of BI	Corresponding Load Placement No's.

Chemical Indicator / Integrator (CI) Placement

Expiry Date	Lot Number	Type of CI	Corresponding Load Placement No's.

Process Challenge Device (PCD) Placement

Expiry Date	Lot Number	Type of PCD	Corresponding Load Placement No's.

Start Cycle Time:	Finish Cycle Time:
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Results

Biological Indicator (BI) Result

Time of Incubation	Finish Incubation	Pass / Fail

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NZSSA Guidelines: *Maintenance & Validation of Ethylene Oxide Sterilisers*

Appendix A, Continued

Chemical Indicator (CI) Result	Process Challenge Device (PCD) Result
Pass / Fail	Pass / Fail
Attach CI in this box	Attach PCD Strip in this box

Attach to this form the following items:

- Photograph of reference load if available
- Copy of the Chart or printout of the load

Overall Result of load – Pass / Fail

Unit Manager’s Signature: Date: