

Validation of Benchtop Sterilisers

The purpose of this document is to outline the process of conducting the Validation process of benchtop sterilisers in accordance with all relevant Australian Standards, regulations and industry requirements.

The object of Validation is to confirm achievement of a Sterility Assurance Level (SAL) of 10^{-6} .

Definitions

1. **Steriliser**

Reference to a Steriliser in this document is to a bench top sterilising unit. The Class of steriliser is not specific.

2. **Calibration**

The process of calibrating a Steriliser is to measure and ensure that all temperature pressure and time parameters displayed or used within any sterilisation cycle are within allowed deviations as defined under Australian Standards.

3. **Load**

A load is a set of instruments in a defined packing methodology or cassette and is used as a reference in any Calibration, Load Penetration or Validation process. Examples of Load options are detailed in Attachment 1 of this document.

4. **Load Penetration Test**

A test where a defined load of instruments and/or hand pieces in a known pack has a temperature probe within the pack to measure temperature against time during a sterilisation cycle. This test ensures the internal areas of the load reach defined temperatures for defined time periods during a sterilisation cycle.

5. **Validation**

Validation (commissioning and performance qualification) is the process of operating a steriliser over successive cycles to ensure the sterilisation processes is undertaken. This uses known and defined loads that are considered to be the most challenging the clinic is likely to utilise in their clinical activities.

6. **Biological/Enzymatic Indicators**

The Australian Standard requires either a biological or enzymatic indicator to be used during the validation process.

7. **Performance Qualification**

Performance Qualification is the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields a product that meets specification.

Requirements to Undertake Validation

Validation is to be undertaken at least every twelve months and when the most challenging load used within the clinic is increased or altered or if any clinical procedure is amended that may have an impact on the steriliser cycles or equipment used. Alterations to steriliser loads are exemplified by changes to;

- ★ Sterilising parameters
- ★ Load or packaging specifications
- ★ Type and complexity of instruments that would further challenges the sterilisation process

Validation should be undertaken following a recalibration of the steriliser for any reason and is also required after a major repair of the steriliser. Major repair is defined in AAMI ST46, 2002; Steam sterilization and sterility assurance in health care facilities, *“A major repair is a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel, replacement of the chamber door or a major piping assemble, or rebuild or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves, is not considered major repair.”*

Note- A bench top sterilizer does not need to undergo re-validation (performance qualification) if it is moved from site to site.

Timing of Validation

Validation of a steriliser is to be undertaken as soon as practical following calibration but not longer than 14 days from a calibration; unless the steriliser is brand new. However Validation may also be undertaken at any time if clinical staff needs to verify operation following any change in process or equipment.

Validation Process

1. Cycles

For Validation to be completed in accordance with the Australian Standards, the steriliser must be run through three consecutive cycles. The time between cycles must be sufficient for the steriliser to return to operating temperatures, not necessarily to cool completely.

The load used in each cycle must be cool, i.e.: Room Temperature. For efficiency it is therefore suggested three identical loads are utilised to shorten the time between cycles.

2. Sterilisation Cycle Selected

The cycle to be used for the three consecutive cycles is the most challenging cycle available on the steriliser or the most challenging cycle available that the clinic will utilise.

Validation of less challenging cycles is not required to be undertaken.

3. Recommended Process

The steriliser is loaded with the defined load i.e. using the largest and most difficult load and packs for that clinic.

Within any pack used for the Load, temperature sensors (thermocouples) and a biological indicator shall be enclosed in the most challenging pack and or packs prior to being placed in the steriliser.

An additional biological/enzymatic indicator and temperature sensors (thermocouples) will be placed in alternate locations in the chamber of the steriliser. Note; a minimum of 2 biological indicators shall be used for each cycle for sterilizers with a chamber volume less than 0.3m³ less than

A temperature sensor (thermocouple) should be placed adjacent to or within the coldest know area of the steriliser chamber. This is often referred to the drain or chamber reference temperature. Steam penetration can be measured during the sterilisation cycle by measurement and calculation in the difference between the pack and other temperature sensors, and this reference temperature.

In total, three temperature sensor or more should be used within the sterilizer chamber. In addition, pressure measure measurement of the chamber shall be measured and recorded in like manner as the temperature sensors.

An un-processed biological/enzymatic indicator will be used as a control. This indicator will remain outside of the steriliser during the test process.

Following each cycle the biological/enzymatic indicators will be placed in the incubator and the location of each indicator recorded. Note; ensure biological indicators are selected and used in accordance with manufactures recommendations and that Biological indicators are within their indicated “use-by” date. The lot number of the indicator should be recorded on the Validation Record Sheet.

This process shall be repeated three times.

4. Recording of Results

The performance qualification report includes all the following information:

- ★ The identification of the sterilizer
- ★ The cycle selected
- ★ A description of the type of load and its loading pattern within the sterilization chamber.
- ★ The location and position of all temperature sensors and biological/enzymatic indicators. This may be presented diagrammatically or using photos and should be used as a reference by clinic staff when using the sterilizer
- ★ The time and date when each of the three performance cycle qualification cycles were run.
- ★ The results of all process parameters, including biological/chemical indicators (Note: acceptance criteria needs to be set prior to performance qualification. A ‘pass’ result is usually 100% correlation of the results of all parameters monitored)

- ✦ If any cycle failed, the results of the investigation into the failure and the corrective action taken
- ✦ The name and signature of the person undertaking the performance qualification, and the name and signature of the person confirming the results

(This information has been directly taken from AS4185)

5. Persons Permitted to Undertake Validation

Validation is a recording process to verify the sterilisation process is being completed and full sterilisation is being achieved and is to be undertaken by a trained technician only.

References & Related Materials

- ✦ Australian Standard, 2003. "AS ISO11134 Sterilisation of health care products- Requirements for validation and routine control- Industrial moist heat sterilisation". Standards Australia.
- ✦ Australian New Zealand Standards, 2006. "Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, not involved in complex patient procedures and processes- Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of the associated environment", Standards Australia.
- ✦ Dental Health Services Victoria, 2006. "Infection Control Manual"
- ✦ Dental Logistics, 2004. "Steriliser Validation" Dental Health Services Victoria.
- ✦ Dental Logistics, 2004. "Steriliser Calibration" Dental Health Services Victoria
- ✦ European Standard, 2004. "Small steam sterilisers", European Committee for Standardization.
- ✦ International Standard, 2006. "Sterilisation of health care products- moist heat- Part1: requirements for the development, validation and routine control of sterilisation process for medical devices", ISO.
- ✦ Oral Health Unit, 2003 "Oral Health Critical Instrument Tracking Train the Trainer Course". Queensland Health
- ✦ AAMI ST46, 2002; Steam sterilization and sterility assurance in health care facilities