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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Installation Qualification, Operational Qualification and Requalification for Table-Top Steam Sterilizers

IPAC Program Template

Infection Prevention and Control (IPAC) Program

Last updated January 2025

PURPOSE

This document outlines the process for conducting installation qualification (IQ), operational qualification (OQ) and requalification (RQ) of your medical clinic's table-top steam sterilizer to ensure compliance with CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics and safe operation.

For assistance or more information, please contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5004.

QUALIFICATION/REQUALIFICATION FREQUENCY

Installation qualification (IQ)

- ☐ Must perform IQ immediately after installation or if the sterilizer is moved. Please refer to section 8.3 of CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics for IQ testing requirements.

Operational qualification (OQ)

- ☐ Must perform OQ after installation qualification (IQ) and prior to use. Please refer to section 8.4. of CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics for OQ testing requirements.

Requalification (RQ)

- ☐ Must perform and document RQ annually. Please refer to section 8.4 of CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics for RQ testing requirements.
- ☐ Additional triggers for requalification include:
  - Following any significant repair.
  - Sterilizer relocation.
  - Unexplained sterility failure.
  - Any disruption to steam supply or change to steam pressures.

Installation qualification (IQ)

General information

Clinic name: _____

Sterilizer model and serial number: _____

Location of sterilizer: _____

Date of installation qualification: _____

Installation qualification (IQ) process

- ☐ Confirm the sterilizer is installed according to the manufacturer's instructions for use (MIFU).
- ☐ Verify all connections (e.g., power, water supply) are secure.
- ☐ Verify clearances.
- ☐ Verify orientation and appropriate surface.
- ☐ Complete installation qualification sign-off.

Documentation and records

- ☐ Attach all relevant and supporting documentation to this form. Retain records.

Installation qualification sign-off

Performed by: _____ _____

Name Signature

Date: _____

References

- Sterilizer Manufacturer's Instructions for Use (MIFU)
- CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics
- CPSA Qualification of Table-Top Sterilizers

Operational qualification (OQ) and requalification (RQ)

General information

Clinic name: _____

Sterilizer model and serial number: _____

Location of sterilizer: _____

Date of operational qualification and requalification: _____

The following tests must be conducted and the results documented:

1. **Dynamic air removal test/Bowie Dick (if applicable)**
   - Purpose: To verify air removal and steam penetration.
   - Applicability: Only for pre-vacuum sterilizers.
   - Criteria: Test sheet must show uniform colour change with no unprocessed areas.
     Results: _____

2. **Biological indicator (BI) process challenge device (PCD) test**
   - Purpose: To verify sterilization efficacy.
   - Procedure: Conduct three consecutive cycles using a BI PCD and record results and ensure the chamber is fully loaded during each test.
   - Criteria: No growth observed in the biological indicators.

   Test 1
   Cycle number: _____
   Load contents: _____
   Test 1 result: _____

   Test 2
   Cycle number: _____
   Load contents: _____
   Test 2 result: _____

   Test 3
   Cycle number: _____
   Load contents: _____
   Test 3 result: _____

   Control BI test result: _____

3. **Physical parameters verification**
   - Purpose: To confirm the sterilizer operates within specified temperature, pressure and time ranges.
   - Documentation: Record cycle parameters from sterilizer printouts.

   Test 1
   Cycle temperature: _____
   Cycle time: _____

   Test 2
   Cycle temperature: _____
   Cycle time: _____

   Test 3
   Cycle temperature: _____
   Cycle time: _____

4. **Chemical indicator test**
   - Purpose: To ensure the parameters to achieve sterilization have been met.
   - Criteria: All indicators must pass as outlined in the indicator MIFU.

   Test 1
   Results: _____

   Test 2
   Results: _____

   Test 3
   Results: _____

Qualification/requalification acceptance criteria

The sterilizer is considered operationally qualified/requalified if all the following conditions are met:

- ☐ Uniform colour change in the Bowie-Dick test (if applicable).
- ☐ Three consecutive passing BI PCD test results with fully loaded chambers.
- ☐ Physical parameters are within acceptable ranges.
- ☐ All chemical indicators demonstrate the required changes.

Corrective actions

If any tests fail, the following actions should be taken, at minimum:

- ☐ Identify the cause of failure.
- ☐ Perform maintenance or calibration as needed.
- ☐ Retest and document results.
- ☐ Record corrective actions taken: _____

Documentation and records

- ☐ Attach all relevant test results, printouts and logs to this form. Retain records.

Qualification/requalification sign-off

Performed by: _____ _____

Name Signature

Date: _____

References

- Sterilizer Manufacturer's Instructions for Use (MIFU)
- CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics
- CPSA Qualification of Table-Top Sterilizers