cpsa
COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Qualification of Table-Top Sterilizers

IPAC Program Guidance

November 2022

Background

Today's table-top sterilizers are user-friendly. While relatively simple to use, they are also complex machines within which critical, intricate processes occur. Each sterilizer has unique temperature and pressurization set points, steam and air evacuation methods and drying times. For sterilization to be successful, these conditions must be uniform throughout the chamber and across all load contents. Sterilizer qualification processes provide the necessary confidence that these important parameters are met reliably and as intended.

What has changed?

CPSA's requirements for the documentation of installation and operational qualification were updated in the Reusable & Single-use Medical Device Requirements for Medical Clinics (Jan. 2022). To reflect the importance of these processes, the level of detail required to perform and document these procedures has increased. For most clinics, these procedures will be new.

Purpose

This guidance is intended to assist physicians and medical clinic staff in understanding these amended requirements by describing the steps for installation and operational qualification of table-top sterilizers.

Qualification requirements are set out in CPSA's Reusable and Single-Use Medical Device Requirements for Medical Clinics. Installation qualification requirements can be found in Section 8.3 and Operational qualification requirements are in Section 8.4. Requirements for documentation of these processes is located in Section 11.5.2.

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

Why is sterilizer qualification necessary?

Sterilizers are essential to the reprocessing of reusable semi-critical and critical medical devices. Even though each sterilized load is monitored, additional evaluations are required to provide assurance that the sterilizer is operating in a reliable and consistent manner. These evaluations are called qualification.

Qualification is performed at critical times, such as when a sterilizer is first installed, annually and after significant repairs are made to the sterilizer. There are two types of qualification required by CPSA: Installation Qualification and Operational Qualification/Requalification.

Without documented qualification, the assurance of sterility is considered to be sub-standard. While important in its own way, performing preventative maintenance on a sterilizer is not the same as conducting qualification.

Installation qualification

A new sterilizer cannot simply be plugged-in, turned on and used—it must be "qualified" upon installation to provide assurance of its effective operation. Installation qualification requirements are set out by the sterilizer manufacturer, and are typically found in the operating manual. Installation qualification involves proper orientation of the sterilizer (e.g., secure location, overhead clearance), filling with the correct water type, pre-cleaning and matching with a compatible power supply.

Installation qualification can be performed by clinic staff or a manufacturer-authorized technician. Any deficiencies noted during the installation process must be corrected immediately and before the sterilizer is put into routine use.

Written documentation must be available to verify installation qualification has been successfully completed in accordance with the sterilizer manufacturer's instructions. If verification of installation qualification cannot be produced, clinic staff will be asked to obtain it, regardless of how long the sterilizer has been in use.

Operational qualification and requalification

Operational qualification and requalification verify that the sterilizer's processes occur after the sterilizer has been correctly installed. The required steps of operational qualification and requalification are described in more detail below. These steps can be performed by clinic staff or a sterilizer technician.

Operational qualification must also occur at the same time as installation qualification. Requalification must then be performed and documented annually, **and** following any significant repair, sterilizer relocation, unexplained sterility failure, and following any disruption to steam supply or change to steam pressures.

Each sterilization cycle type used by clinic staff must be qualified.

Steps of operational qualification and requalification

1. Assemble a process-challenge device (PCD), also known as a test pack, containing a biological indicator (BI) and an internal chemical indicator (CI). The PCD should represent the most challenging instrument set that is routinely sterilized. **A new PCD must be prepared for each of the three loads run.**

2. Place the PCD in the sterilizer chamber's cold spot, if the manufacturer indicates one exists.

3. The sterilizer chamber must be fully loaded. Emulate the contents and configuration of a typical load run in your clinic. (See Note ii. below)

4. Run the cycle. After completion, check and document the CI result then retrieve the BI from the PCD and incubate it. Check the result of the BI after incubation and document the result as Operational Qualification/Requalification #1.

5. Repeat steps 1-4 two more times using the same cycle type. There must be **three consecutive tests** run in full chambers, each with its own newly prepared PCD. Record the BI results as Operational Qualification/Requalification #2 and #3.

   Once all three BI results are satisfactory, operational qualification/requalification is complete and successful.

Important notes

i. **Operational qualification/requalification must be done for each type of cycle used by the clinic.** So, if a clinic typically runs a "pouches" cycle at 132° C and a "wrapped" cycle at 121° C, both cycle types require qualification.

ii. If functional medical devices are packaged and used to fill the chamber, those packages shall not be released for use on patients when the cycle is complete. They must remain packaged and quarantined until all biological, physical and chemical monitors are confirmed to be satisfactory.

iii. Remember that packing used in clinic settings (e.g., peel pouches, non-woven wraps) are single-use products and cannot be reused or re-sterilized.

iv. Dynamic air removal sterilizers with pre-vacuum cycles must also be tested annually for air leaks or inadequate air removal/steam penetration. In addition to the steps above, clinic staff will perform and document three consecutive air removal tests (e.g., Bowie-Dick Test Packs) in an otherwise empty sterilizer.

v. Operational qualification/requalification can be recorded either on the clinic's sterilization tracking log, or on a dedicated qualification tracking log.

Terms to know

Installation qualification: The process of obtaining and documenting evidence that the sterilizer has been provided, installed and connected as intended by the manufacturer.

Operational qualification & requalification: The process of obtaining and documenting evidence that the sterilizer consistently operates within predetermined limits when used as intended by the manufacturer.

Preventative maintenance: Procedures set out by the sterilizer manufacturer to be performed on a planned, recommended frequency (e.g., daily, weekly, monthly). This typically involves inspection of fluids and surfaces, minor cleaning, and replacement of filters and gaskets. The intent is to prevent the need for significant repairs and keep the sterilizer in good working condition. This differs from installation and operational qualification in that it does not generate evidence of the sterilizer performance.

Process challenge device (PCD): Also often referred to as a test pack, a PCD provides resistance (i.e., a challenge) to the sterilization process. In the context of sterilization in medical clinic settings, a PCD is typically composed of a biological indicator inserted into a package alongside typically used medical devices.

Significant repairs: Anything done to the sterilizer outside normal operation and preventative maintenance. Significant repairs can include, but are not limited to, replacing controls and plumbing packages; installing new components; or welding of the pressure vessel. These repairs are typically undertaken to correct issues observed during preventative maintenance or to rectify the intended operation or performance of the sterilizer after unexplained sterility failure.

Test pack: See "Process Challenge Device (PCD)"

References & resources

1. CPSA Reusable & Single-Use Medical Device Requirements for Medical Clinics
2. Guidance for Medical Clinics: CPSA Reusable & Single-Use Medical Device Requirements
3. Government of Alberta. Reusable & Single-Use Medical Devices Standards. 2019.
4. CSA Group. CAN/CSA-Z314-18. Canadian Medical Device Reprocessing. February 2018. Pages 27 and 29.