POLICY:	**Operational Qualification and Requalification of Steam Sterilizer**
Program Area:	**Medical Device Reprocessing**
Section:	**General**
Reference Number:	**CLI.5510.PL.010**
Approved by:	**Regional Lead - Acute Care & Chief Nursing Officer**
Date:	Issued 2024/Nov/03
	Revised yyyy/mmm/dd

PURPOSE:

The process of obtaining and documenting evidence to verify that the manufacturer's process parameters are being achieved.

BOARD POLICY REFERENCE:

Executive Limitation (EL – 02) Treatment of Clients
Executive Limitation (EL – 07) Corporate Risk

POLICY:

Operational Qualification are performed by the sterilizer manufacturer at installation and include a verification of each cycle used by the health care setting.

Requalification takes place annually and may be performed by the health care setting or the sterilizer manufacturer.

Requalification testing is also performed in response to any one of the following events:

1) Replacing sterilizer controls,
2) Replacing plumbing,
3) Major rebuilding, and
4) Installation of chamber door, a vacuum pump, major piping.

Normal preventative maintenance such as rebuilding solenoid valves or replacement of gaskets is not considered major repair.

DEFINITIONS:

Process Challenge Device (PCD) – an item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess the performance of the process.

IMPORTANT POINTS TO CONSIDER:

- An air removal test (Bowie-Dick) is completed and documented daily. The leak-rate test is to be completed and documented weekly.

PROCEDURE:

1. For dynamic air removal sterilizers using pre-vacuum cycles the steam sterilizer is tested with three consecutive air removal tests (Bowie-Dick) in an empty chamber to ensure proper function of the air removal system.
   - The air detection test procedure as follows:
     - If the sterilizer requires preheating, run a warmup cycle.
     - Place the air-detection PCD in the lower portion of the sterilizer nearest the chamber drain opening in an empty chamber.
     - Run a pre-vacuum air removal cycle.
     - The chemical indicator of the air-detection test is interpreted according to the test manufacturer instructions (uniform colour change). Test results are assessed by Medical Device Reprocessing (MDR) staff and documented.
2. Operational qualification and requalification is to be conducted by running three consecutive cycles in an empty chamber using PCDs with biological indicators.
   - Qualification testing is performed on all cycles being used in the health care setting.
   - The PCD is validated for the sterilization cycle to be tested.
   - The PCD contains a biological indicator and an internal chemical indicator.
   - Each of the three biological indicator tests is performed as follows:
     - The PCD is placed on the lowest shelf of the loading cart in the steam sterilizer nearest to the chamber drain opening.
     - A standard sterilizer cycle is performed.
     - For dynamic air removal sterilizer, the test runs in an empty chamber.
     - Following the cycle, the chemical indictor is checked to ensure a passing condition, and the biological indicator removed from the PCD and incubated according to MIFU.
     - Each test is documented. The documentation includes the date and time of sterilization, sterilizer number, cycle number and name of person conducting the test.
3. The leak-rate test in a steam sterilizer exhibits an average leak rate that meets the manufacturers specifications. Results of the leak test are documented using CLI.5510.PL.010.FORM.01 Sterilization Requalification Record.

EQUIPMENT/SUPPLIES:

PCD biological packs
PCD air-detection packs (Bowie-Dick)

Supporting Documents:

CLI.5510.PL.010.FORM.01 Sterilization Requalification Record

REFERENCES:

CSA Standards Z314:23 Canadian Medical Device Reprocessing
Section16.4.4.3.1