POLICY:	**Performance Qualification of Surgical Instrument Sets and Medical Devices**
Program Area:	**Medical Device Reprocessing**
Section:	General
Reference Number:	**CLI.5510.PL.009**
Approved by:	**Regional Lead - Acute Care & Chief Nursing Officer**
Date:	Issued 2024/Nov/03 Revised yyyy/mmm/dd

POLICY SUBJECT:
The program of tests that demonstrates that the medical devices and instrument sets meet the conditions necessary for sterilization at the health care setting.

PURPOSE:
The process of obtaining and documenting evidence that the equipment is installed, operated and consistently performs according to predetermined criteria to meet its product specification.

BOARD POLICY REFERENCE:
Executive Limitation (EL- 02) Treatment of Clients
Executive Limitation (EL- 07) Corporate Risk

POLICY:
Performance qualifications of surgical instrument sets and medical devices.

IMPORTANT POINTS TO CONSIDER:
1. Different products are grouped into product families.
2. Product families are evaluated with the following:
   - multiple layers,
   - close tolerances between the layers,
   - accessory items,
   - lumens,
   - weight,
   - material of construction and
   - density/metal mass of the items.

PROCEDURE:
1. a) Ensure that the products to be sterilized have been validated by the sterilizer manufacturer.
   b) One or more product groups are established, each of which represents devices or instrument sets with similar sterilization process requirements and limitations.
   c) Each medical device or instrument set that the health care setting intends to process is assigned to the appropriate product group.
   d) Within each product group, the product that presents the greatest challenge to sterilization is selected as a test set.
   e) For the devices selected in item d), three consecutive tests are run in the appropriate

sterilization cycle to ensure that they can be sterilized with the equipment and processes used in the health care setting.

2. The test sets used for performance qualification contain internal and external chemical indicators and biological indicators at the points considered to be the most difficult to sterilize. Place indicators in every corner and in the centre of every layer.
3. If the health care setting has more than one sterilizer of the same type, three tests for performance qualification of products are conducted in each sterilizer used.
4. Test sets are reprocessed (decontaminated, prepared and repackaged) between tests.
5. Performance qualification are done every time there are changes to sets or trays.
6. Testing of new types of packaging or wrap materials are performed using test sets containing biological and chemical indicators.
7. In a steam sterilizer, the test set is placed in a normally loaded sterilizer at the location nearest the drain.
8. Results of the cycle, chemical indicators, and Biological Indicator (BI) tests from the 3 consecutive test cycles is documented on CLI.5510.PL.009.SD.01 Performance Qualification Record.
9. Failure of any of the biological or chemical indicator tests within a set is considered a failure to sterilize the set. In the event of a failure the following steps apply:
   a) Similar sets of packages from the same family product are not used until it is demonstrated that the designated test package can be sterilized.
   b) Health care setting verifies that the devices, packaging and cycle conditions are compatible.
   c) The set may be divided into smaller packages and retested.
10. Process for Performance Qualification:
    a) Fill container or tray(s) with medical devices, it would hold in use, to create Tray Set.
    b) All test sets are exposed to the same sterilization process in 3 separate full load cycles to demonstrate reproductivity.
    c) Place a BI and chemical Integrator in every corner and in the centre of every layer.
    d) Every test set encompasses variations such as time of day tested, operator, and package content (always include worst case scenario packages).
    e) Tests are processed – decontaminated, prepared and repackaged – between tests.
    f) Performance qualification are done every time there are changes in sets or trays.

EQUIPMENT/SUPPLIES:

Biological spores
Chemical integrators

SUPPORTING DOCUMENT:

CLI.5510.PL.009.FORM.01 Performance Qualification Record

REFERENCES:

CSA Standards Z314:23 Section 16.4.4.1.3