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Policy: Monitoring of Steam Sterilization

Date:

Revised Date:

Purpose: Sterilization is the elimination of all disease-producing microorganisms, including spores. Sterilization is used on critical medical equipment/devices and, whenever possible, semi critical medical equipment/devices.

Routine monitoring verifies that the sterilization process is working as expected and that medical equipment/devices achieve sterility.
Routine monitoring shall include assessment of:
a) physical parameters of the sterilizer cycle (e.g., time, temperature, pressure), shown on gauges and displays during each cycle and recorded on a graph, printout, or electronic record at the end of each cycle;
b) chemical indicators (i.e., external indicators on each package and internal indicators that are visible through packaging materials or are part of the PCD); and
c) biological indicators.

- Autoclaves must be installed according to the manufacturer's instructions.
- Physical parameters must be checked and signed for each sterilizer cycle by the person sterilizing the instrument.
- Biological (BI) and chemical indicators (CI) must be checked and results recorded for each load.
- A logbook entry must be made for each sterilizer load.
- Following installation of a new sterilizer, sterilizer maintenance or relocation the sterilizer must pass at least three consecutive cycles with BIs placed in an empty sterilizer before the sterilizer can be put into routine service. A sterilizer shall not be approved for use if the BI yields a failed test on any of the three consecutive cycles.

Chemical Indicators: External indicators on the outside of each wrapped package and internal chemical indicators inside each package, which change color when exposed to the right conditions for sterilization;

- CIs do not indicate that a device is sterile and do not replace the need to use a BI.
- The class of CI chosen is based on the parameters being measured and the degree of precision that is needed.
- If a dynamic air removal-type sterilizer is used, an air removal test with a Class II CI (Bowie-Dick test) shall be performed every day the sterilizer is used.

Classes of Chemical Indicators

Class I Process indicator	Usually applied to the outside of packages Respond to one or more critical process variables
Class II Indicator for specific Tests	Indicator for use in specific test procedures Bowie-Dick test
Class III Single variable indicator	Reacts to a single critical variable in the sterilization process to indicate when a specified value has been reached (e.g., temperature at a specific location in the chamber)
Class IV Multi-variable indicator	Reacts to two or more critical variables in the sterilization cycle May be used for process control

Class V Integrating indicator	Reacts to all critical variables in the sterilization process (time, temperature, presence of steam) Equivalent to, or exceeds, the performance requirements of BIs **May be used as an additional monitoring tool to release loads that do not contain implants**
Class VI Emulating Indicator	Reacts to all critical variables (time, temperature, presence of steam) Used as internal CI for process control **Cannot be used as an additional monitoring tool to release loads that do not contain implants**

Biological Indicators: confirm the actual killing of microbial spores.

- A biological indicator (BI) shall be used to test the sterilizer once each day the sterilizer is used and for each type of cycle that is used.
- Items in the processed load should not be released until the results of the BI test are available; if quarantine pending BI results is not possible, evaluation of a Class V chemical indicator and the specific cycle physical parameters may be used to justify the release of routine loads.
- There must be a written recall procedure (shall include patient notification) that is followed in the event of a failed biological indicator.

References:

1. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Infection Prevention and Control for Clinical Office Practice. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015. https://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_2013.pdf

2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices.3rded.Toronto,ON:Queen's Printer for Ontario; May 2013 https://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf