Standard Operating Procedure

Sterilization and Sterility Assurance

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OBJECTIVES

Devices shall be prepared for steam sterilization in such a way that steam can move through the device and contact all surfaces. Preparation of the reusable medical devices for sterilization shall include the following as they apply to each device.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing.

ELEMENTS

1. Critical medical devices: medical devices which enter sterile body spaces including the vascular system
   - 1.1 All Critical medical devices shall be sterilized in accordance with the validated Manufacturer's Instructions for Use (MIFU) for each device, utilizing the recommended method of sterilization. Sterilization methods include:
     - a) Steam;
     - b) Gas Plasma (e.g., Sterrad®, Steris V-Pro®);
     - c) Ethylene Oxide (ETO).
2. Sterilizers
   - 2.1 Are to be operated following manufacturer's instructions.
   - 2.2 Shall be tested regularly following manufacturer's instructions, and following any malfunction or disruption to service.
   - 2.3 Shall have operational qualification or requalification testing performed after any new installation or after any major repairs are performed. Operational re/qualification testing shall be based on manufacturer's instructions and site based procedures.
3. Devices
   - 3.1 Shall have a written procedure detailing the sterilization required in accordance with the MIFU.
   - 3.2 Are to be packaged, sealed and labelled with materials approved for use in the designated sterilization system.

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3.3 Shall undergo performance qualification and requalification as per “Canadian Medical Device Reprocessing, Canadian Standards Association (CAN/CSAZ314-18) and documented.

4. Sterility assurance for steam sterilization

4.1 Steam sterilization has 2 difference cycle types, Dynamic Air Removal (Pre-Vacuum), and Gravity Displacement.

4.2 For steam sterilization the following shall be completed and documented to provide the assurance of sterility;

a) Monitoring for each cycle including documentation of any malfunction and actions taken.

b) All printouts or records shall be signed and maintained in department documentation as per AHS policy.

c) Daily air removal testing (Bowie-Dick type)

d) Weekly leak testing as per manufacturer instructions and local procedures.

e) Mechanical monitoring of cycle parameters.

f) Chemical monitoring including internal and external chemical indicators.

g) Biological monitoring using a biological indicator daily, in each sterilizer used, and for each cycle type. A biological indicator shall also be included in any cycle containing implantable items.

5. Sterility assurance for gas plasma sterilization

5.1 For gas plasma sterilization the following shall be completed and documented to provide the assurance of sterility;

a) Monitoring for each cycle including documentation of any malfunction and actions taken.

b) All printouts or records shall be signed and maintained in department documentation as per AHS policy

c) Mechanical monitoring of cycle parameters, and all printouts or records signed and maintained in department documentation.

d) Chemical monitoring including internal and external chemical indicators

e) Biological monitoring using a biological indicator daily, in each sterilizer used, and for each cycle type. A Biological Indicator shall also be included in any cycle containing implantable items.

6. Sterility assurance for Ethylene Oxide (ETO) Sterilization

6.1 For ETO sterilization the following shall be completed and documented to provide the assurance of sterility:

a) Monitoring for each cycle including documentation of any malfunction and actions taken.

b) All printouts or records shall be signed and maintained in department documentation as per AHS policy.

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c) Mechanical monitoring of cycle parameters, and all printouts or records signed and maintained in department documentation.

d) Chemical monitoring including internal and external chemical indicators.

e) Biological monitoring using a biological indicator daily, in each sterilizer used, and for each cycle type. A biological indicator shall also be included in any cycle containing implantable items.

DEFINITIONS

None

REFERENCES

- Non-Alberta Health Services documents
  - *Reusable & Single-Use Medical Devices Standards.* (Government of Alberta-Alberta Health) (September 2019).
  - *Canadian Medical Device Reprocessing.* (Canadian Standards Association) (CAN/CSA Z314-18)

VERSION HISTORY

Date	Action taken
October 2017	Initial approval
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