Purchase and Evaluation of Reprocessing Supplies

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OBJECTIVES

- To provide safe patient care by ensuring applicable standards are adhered to for Medical Device Reprocessing (MDR).
- To develop a standard procedure for the evaluation and purchase of reusable medical devices, single-use devices and general reprocessing supplies such as, wrapping materials, sterilization indicators, and Process Challenge Devices (PCDs).

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staff, 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. When purchasing or evaluating a medical device, the health care facility shall confirm that:
   - It is authorized for use by Health Canada through an Establishment License for Device Risk Class I Devices, or for Risk Classes II-IV, an active Device License, or Special Access Program authorization or Investigational Testing Authorization.
   - Meets applicable Canadian standards (e.g., written manufacturer's instructions for use (MIFU)).
   - Devices not manufactured or licensed for medical use shall not be used on a patient for the purposes of diagnosis, investigation, prevention, monitoring, treatment, replacement, modification or alleviation of pregnancy, disease, injury, handicap, disorder or symptoms.
2. Purchasing decisions for reusable medical devices and reprocessing supplies and equipment shall involve representatives from the departments in the healthcare facility that will use, reprocess, and maintain the devices. The following departments should be involved as appropriate to the complexity, risk class, and intended use of the device:
   - 2.1 Medical Device Reprocessing;
   - 2.2 Contracting, Procurement, and Supply Management (CPSM) and/or Equipment Sourcing (as appropriate);
   - 2.3 End user department;
   - 2.4 Infection Prevention and Control;
   - 2.5 Workplace Health and Safety;
   - 2.6 Clinical Support Services e.g., Linen & Environmental Services;
   - 2.7 Clinical Engineering; and

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2.8 Facilities, Maintenance and Engineering.

Note: Input from WHS is particularly important to ensure reusable devices do not pose risk to workers during reprocessing (e.g., sharps and devices with narrow lumens).

Input from IPC and MDRD is particularly important to ensure reusable devices can be effectively cleaned.

3. Single-use devices or components shall be considered when purchasing devices with sharp components and devices with narrow lumens that cannot be cleaned safely or effectively.
4. Prior to purchasing or evaluating a new reusable medical device, healthcare facility personnel shall review the manufacturer's instructions to ascertain that the recommended reprocessing procedures:
   - 4.1 are device-specific, legible, and understandable;
   - 4.2 specify the necessary materials and equipment for sterilization of the device;
   - 4.3 can be achieved, given the resources of the facility including but not limited to:
     - i. cleaning (ensure method used is compatible with manufacturer's instructions for use);
     - ii. disassembly (if required);
     - iii. cleaning (ensure method used is compatible with the manufacturer's instructions for use);
     - iv. inspection;
     - v. reassembly;
     - vi. disinfection (ensure method used is compatible with the manufacturer's instructions);
     - vii. sterilization (ensure method used is compatible with the manufacturer's instructions).
   - 4.4 are in accordance with the intended use of the device;
   - 4.5 clearly indicate which parts need to be disassembled and provide clear disassembly instructions (including illustrations where necessary);
   - 4.6 state whether or not the device is immersible;
   - 4.7 specify if there is a limit to the number of times the device can be reprocessed or if reprocessing will contribute to degradation of the device.
   - 4.8 identify reposable components, number of reprocessing cycles, and tracking method (if indicated).
   - 4.9 provide a list of single-use components.
5. Follow the CPSM Evaluation of Medical Device process for pre-purchase evaluation requests. Complete, submit, and receive approvals as per the CPSM Evaluation of Medical Device process.
6. Medical devices supplied to the facility under a leasing, loaning, or sharing arrangement shall be managed in accordance with Management of Loaned, Reusable Medical Devices (CAN/CSA-Z314.22-16).
7. Medical devices reprocessing before initial use, unless packaged and sterilized by the manufacturer.

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DEFINITIONS

None

REFERENCES

- Non-Alberta Health Services documents
  - *No. 60601 series of Standards and Health Canada's listing of active medical device licenses*. (Health Canada) (CAN/CSA-CSS.2).
  - *Canadian Medical Device Reprocessing*. (Canadian Standards Association) (CAN/CSA-Z314-18).

VERSION HISTORY

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