Purchasing Medical Devices – Pre-purchase Criteria for End-Users

Note: This best practice recommendation was developed by the Infection Prevention and Control Equipment Purchasing Working Group in consultation with Workplace Health and Safety (WHS), Contracting, Procurement and Supply Management (CPSM), Capital Management and Medical Device Reprocessing Department (MDRD) representatives to help Infection Control Professionals understand the complexity of purchasing medical devices. This recommendation is a part of suite of documents.

The aim of this document is to support patient safety by outlining key elements of the purchase process: pre-purchase criteria for end-users of critical and semi-critical medical devices and reprocessing equipment.

Best practice recommendations

If the reusable medical device is new or updated, uses new technology, introduces additional component, or requires changes in reprocessing, the **end-user**, i.e., unit manager, requester, purchaser, or decision maker authorizing the purchase.

1.1 Collects the necessary documentation and information to evaluate the purchase.

1.2 Requests manufacturer's instructions for use – reprocessing (MIFU-R) and licensing information from the vendor.

1.3 Confirms with the vendor that the device meets Health Canada licensing requirements.

1.3.1 If the vendor does not readily supply the information described in the note below, the end-user, i.e., unit manager, requester, purchaser, or decision maker authorizing the purchase, may request assistance from Contracting Procurement and Supply Management (CPSM) by phone at this toll free number: 1-877-595-0007 or by email at cpsm.customersupport@ahs.ca.

1.3.2 If CPSM cannot obtain the information requested by the end-user as described in the note below, the device cannot be purchased.

1.3.3 For further detail about Health Canada licensing requirements refer to these resources:

a) Health Canada. 2015. Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs).

b) Health Canada 2020 Guidance Documents for Medical Devices.

Note: Manufacturers are responsible to supply[1]

a) details about the device design and intended use;

b) directions for use;

c) information on single-use components; and

d) device-specific recommendations for reprocessing including:

- **Manufacturers instructions for use- reprocessing** (MIFU-R) for all device components;
- Personnel training materials e.g., photos or graphics on correct device reprocessing;
- Specifications for reprocessing parameters and their tolerances; for example:
  - The number of times the device can be reprocessed if the device is deemed to be limited use i.e., reposable with appropriate tracking method;
  - Recommendations for checking device integrity when applicable e.g., sheath testing, sharpness of cutting edges, etc.;
  - Possible degradation from reprocessing.

[1]Canadian Standards Association R2016 Sterilization of Medical Devices-Information to be provided by the Manufacturer for the Processing of Resterilizable Medical Devices, Mississauga, Ontario, Canada.

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2. The end-user, i.e., unit manager, requester, purchaser, or decision maker authorizing the purchase, confirms the purchase supports provision of quality healthcare and necessary resources are in place by considering the following in consultation with infection prevention and control (IPC), medical device reprocessing department (MDRD), Linen and Environmental Services (LES) etc. as necessary.
   - 2.1 Is the purchase part of an AHS initiative, standardization or a single device?
   - 2.2 Are there minimum technical requirements?
   - 2.3 Will the proposed equipment meet the requirements for Information Technology (IT) Connectivity (Connect Care)?
   - 2.4 Are there installation limitations or requirements, e.g., dimensions, weight, electrical and other utilities, environmental control? If yes, consult with Capital Management which includes Clinical Engineering, Facilities Maintenance and Engineering (FME).
   - 2.5 Are facility modifications required? If yes, consult with Capital Management.
   - 2.6 Will the proposed equipment be used in conjunction with other equipment in the facility? If so, is the equipment compatible?
   - 2.7 Do employees know how to use the device or is additional training required?
3. The end-user, i.e., unit manager, requester, purchaser, or decision maker authorizing the purchase, confirms resources in place to meet reprocessing e.g., cleaning, disinfection or sterilization, service and maintenance requirements, for example:
   - 3.1 Who will be responsible for cleaning and disinfecting the device?
   - 3.2 Will the device be reprocessed in a central reprocessing area? If yes, consult with the medical device reprocessing department.
   - 3.3 If so, how will the device be transported?
   - 3.4 Has the medical device reprocessing department (MDRD) manager or designate agreed to reprocess the device?
   - 3.5 What are the storage requirements for clean and sterile devices?
   - 3.6 Are enough devices being purchased to accommodate reprocessing time?
   - 3.7 Are all required components/consumables factored into the purchase?
   - 3.8 Who will be performing preventative and routine maintenance and are there associated costs to be factored into the purchase?

Background

1. Before purchase, the end-user must confirm the device or reprocessing equipment is suitable and safe for the intended use.
2. Replacement of existing devices or equipment does not usually require evaluation unless the device or manufacturer's instructions have changed significantly, e.g., updated/revised to include additional components or require changes in reprocessing methods.
3. For medical devices on loan or trial follow the AHS Policy for Management of Loaned and Reusable Medical Devices.
4. Foundations and Trusts follow AHS 2017 Insite Home > Teams > Community Engagement & Communications > About > Foundations and Health Trusts Strategic Alignment and Procurement Guidelines.
5. CPSM 2019 documents are available on AHS Insite Home > Teams > CPSM > Medical Device Safety

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including:

- Medical Device Incident or Problem Reporting Procedure
- Medical Device Safety Policy. Refer to this policy for details if validated manufacturer's instructions are not available, appear to be inadequate or non-compatible with accepted standards, policies, processes, or reprocessing options, particularly for a unique medical device.
- Medical Device Recall Procedure
- Medical Device Safety – Preparing and Shipping for Investigations.

Definitions

Term	Meaning
End-user	Means the requester, purchaser, decision maker authorizing the purchase.
Manufacturer's instructions for use – reprocessing (MIFU-R)	Means the validated, written directions provided by the manufacturer or distributor of a medical device or product that contain the necessary information for cleaning, disinfection/sterilization (reprocessing) of the medical device or product.
Reprocessing equipment	Means equipment used to sterilize or disinfect critical and semi-critical medical devices including sterilizers, autoclaves, washer-disinfectors, endoscope reprocessors, and thermal high-level disinfection equipment such as pasteurizers or washer disinfectors with a validated thermal disinfection cycle..
Validated	Means a documented procedure for obtaining, recording, and interpreting the results required to establish that a process for cleaning, disinfection or sterilization of a medical device will consistently yield safe products complying with the CSA Standard Z17664.

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