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 one of four in a suite of documents to support the pre-purchase approval process of medical devices: Purchasing Medical Devices – Spaulding Risk Classification for End-Users; Purchasing Medical Devices – Forms and Documentation; Purchasing Medical Devices – Pre-purchase Criteria for End-Users; and Purchasing Medical Devices – Roles and Responsibilities.

Terms are defined in the **Definitions** section.

If you have any questions or comments contact IPC at ipcsurvstdadmin@ahs.ca.

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

Best practice recommendations

1. If the reusable medical device is new or updated, uses new technology, introduces additional component, or requires changes in reprocessing, the **end-user** (defined as 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 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 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:

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

       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;

   d) device-specific recommendations for reprocessing including:
   - Reprocessing instructions 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.
2. The end-user confirms the purchase supports provision of quality healthcare and necessary resources are in place by considering the following:
   - 2.1 Is the purchase part of an AHS initiative, standardization or a single device?
   - 2.2 Are there minimum technical requirements?

For more information contact
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[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.

2.3 Will the proposed equipment meet the requirements for 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 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?

Definitions

End-user means the requester, purchaser, decision maker authorizing 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 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.

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