Purchasing Medical Devices – Roles and Responsibilities

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 part of a suite of documents.

The aim of this document is to support patient safety by outlining key elements of the purchase process: roles and responsibilities for purchasing medical devices and reprocessing equipment.

Best practice recommendations

1. Reporting medical device incidents or problems

   1.1 All staff, end-users, i.e., unit manager, requester, purchaser, or decision-maker authorizing the purchase and departments are responsible to report medical device incidents or problems (MDIPs) experienced, e.g., devices with inadequate labelling specifically instructions for cleaning, disinfection or sterilization, as per the AHS Patient Safety and Medical Device Safety Policy Suites, and Health Canada Medical Devices Regulations. Refer to: https://share.albertahealthservices.ca/teams/CPSM/ClinicalSupportEngagement/AHSMDIPReporting/SitePages/Home.aspx.

2. **End-user** i.e., unit manager, requester, purchaser, or decision-maker

   2.1 Roles and responsibilities

   - Collects the necessary documentation and information to evaluate the purchase. Refer to Information Sheet Purchasing Medical Devices – Pre-purchase Criteria for details.
     - Determines the device risk category using Spaulding's Classification i.e., non-critical, semi-critical or critical; and engages subject matter experts as required. Refer to Information Sheet Purchasing Medical Devices – Spaulding Risk Classification.
     - Consults subject matter experts (refer to Section 3.0) based on factors such as device complexity; intended use; reprocessing area; technical, maintenance and infrastructure requirements; safety; and state of technology, e.g., new, emerging or in-use and well-accepted. Consultation with multiple experts may be required depending on the purchase.
     - Clinical experts and frontline personnel who will use the device or equipment provide key input about the suitability of the purchase for the specific location; intended use and training needs.
     - Consults with, and provides necessary information to, subject matter experts to confirm the device can be cleaned, high-level disinfected or sterilized with existing resources, protocols and AHS provided products.
   - Completes a purchase request form. Refer to Information Sheet Purchasing Medical Devices Forms and Documentation.

3. Subject matter experts include any departments impacted by the outcome of a medical device purchase.

   3.1 Contracting, Procurement and Supply Management (CPSM)

   - Roles and responsibilities
     - Accountable for procuring and contracting essential goods, legal purchasing and financial processes.

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Version	Date (YYYY-MM-DD)
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- Main vendor and manufacturer contact. Obtains required documentation for contracted purchases e.g., Health Canada medical device licensing for contracted purchases.
- Leads the competitive bid processes, i.e., Request for Information, Request for Proposal, group purchasing, i.e., through Health Pro and Capital Equipment Annual replacement.

- Consult when
  - Information is not readily available from the vendor request manufacturer's instructions for use and Health Canada licensing information.
  - Equipment and capital sourcing process >$5000 and annual equipment replacement.
  - Questions about whether or not device or equipment is available through AHS contract.

3.2 Capital Management including Clinical Engineering (CE), Furnishings and Equipment, Facilities Maintenance and Engineering (FME), Project Management (PM).

- Roles and responsibilities:
  - Provides clinical expertise for furnishings and equipment; installation; and integration of medical and non-medical devices.
  - The Furnishings and Equipment Team consults with necessary subject matter experts to ensure that the equipment is adequate for use.
  - FME/PM reviews **reprocessing equipment** and electrical medical device requests related to:
    - Existing infrastructure and utilities;
    - Maintenance, training, and service agreements; and
    - Compliance with relevant standards, e.g., Canadian Standards Association.
- Consult when
  - Technical (CE) or maintenance (FME) expertise is required
  - Infrastructure and utility requirements (FME):
    - Installation;
    - Monitoring;
    - Integration of medical and non-medical devices;
    - Testing of electrical medical devices.
  - Equipment purchase is part of a project (PM), e.g., equipment and furnishings for capital projects (new builds and renovations); requires infrastructure changes (FME); or is reprocessing equipment (FME, CE).

Note: specific responsibility may vary by zone.

3.3 Environmental Public Health (EPH)

3.4 Medical Device Reprocessing Department (MDRD)

- Roles and responsibilities
  - Confirm suitability of purchase for critical and semi-critical medical devices and reprocessing equipment based on device standards such as Canadian Standards Association (CSA) and **manufacturer's instructions for use-R (MIFU-R**) including:
    - Reprocessing instructions;
    - Characteristics that make the device difficult to clean;

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        - **Reposable** components;
        - Methods for cleaning and disinfection or sterilization;
        - Compatibility with existing resources and processes e.g., protocols and implementation requirements, such as additional equipment or staff training.
    - May recommend consultation with other subject matter experts if new implementation processes, protocol development or extensive staff retraining requirements.
- Consult when:
    - Purchasing reusable critical or semi-critical medical devices or reprocessing equipment that will be reprocessed or used in MDRD.
    - Questions about MIFU-R for cleaning, disinfection or sterilization and compatibility with current standards and protocols.

3.5 Infection Prevention and Control (IPC)

- Roles and responsibilities
    - Confirms with the end-user the intended use of a critical or semi-critical medical device matches the manufacturer's intended use of the device.
- Consult when
    - General questions about cleaning and disinfection or sterilization.
    - IPC does not sign-off or give approval on the manufacturer's instructions for use cleaning, disinfection or sterilization instructions; however, end-user may consult with IPC as needed.
    - IPC may use the IPC Optional Tracking Checklist to record their participation and stated recommendations.

3.6 Workplace Health and Safety (WHS)

- Roles and responsibilities
    - Confirms device and accessories meet occupational standards.
    - Consult for questions about staff safety.

3.7 Information Technology (IT)

- Consult when the device or accessories need to be on a network.
- Consult when the device or accessories send or receive data.

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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.
Reposable	Means limited use medical devices.
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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