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. End-user
   1.1 Roles and responsibilities
   - Collects the necessary documentation and information to evaluate the purchase. Refer to [Information Sheet Purchasing Medical Devices – Pre-Purchase Criteria](#).
   - Determines the device risk category using Spaulding’s Classification i.e. non-critical, semi-critical or critical; and engages stakeholders and subject matter experts as required. Refer to [Information Sheet Purchasing Medical Devices – Patient Safety](#).
   - Consults stakeholders 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 stakeholders 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 stakeholders 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](#).

2. Contracting, Procurement and Supply Management (CPSM)
   2.1 Roles and responsibilities:
   - Accountable for procuring and contracting essential goods, legal purchasing and financial processes.
   - 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.

2.2 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. Capital Management including Clinical Engineering (CE), Facilities Maintenance and Engineering (FME), Project Management (PM).
3.1 Roles and responsibilities:

- Provides clinical expertise for equipment; installation; and integration of medical and non-medical devices.
- FME/PM reviews reprocessing equipment and electrical medical device requests related to:
  - existing infrastructure and utilities;
  - maintenance, training, and service agreements are in place; and
  - compliance with relevant standards.

3.2 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); requires infrastructure changes (FME); or is reprocessing equipment (FME, CE).

Note: specific responsibility may vary by zone.

4. Medical Device Reprocessing Department (MDRD)

4.1 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 including:
  - written, validated instructions;
  - characteristics that make the device difficult to clean;
  - 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.

4.2 Consult when:

- Purchasing critical or semi-critical medical devices or reprocessing equipment that will be reprocessed or used in MDR.
- Questions about manufacturer’s instructions for cleaning, disinfection or sterilization and compatibility with current standards and protocols.

5. Infection Prevention and Control

5.1 Roles and responsibilities:

- Confirms the critical or semi-critical medical device or equipment will be used according to the manufacturer’s intended use.

5.2 Consult when:

- General questions about cleaning and disinfection or sterilization.
6. **Workplace Health and Safety**

   6.1 Roles and responsibilities:
   
   - Confirms device and accessories meet occupational standards.

   6.2 Consult for questions about staff safety.

**Definitions**

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

**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.