Purchasing Medical Devices – Forms and Documentation

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.

Bolded 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. For purchases under $5000 the **end-user** completes:
   - Purchase Requisition 02089 found at Home > Employee Tools > Insite Search > purchase requisition, and submits the completed form to CPSM.customerSupport@ahs.ca.
2. For purchases over $5000 the end-user selects and completes the most suitable form for their request:
   - 2.1 Evaluation of Medical Device Request 09801 which includes a requirement for IPC sign-off.

     Note: Form 09801 is a CPSM form currently under review/revision. IPC does not provide final sign-off or give approval for the device purchase; however, the end-user may consult with IPC as needed. Following consultation, infection control professionals may provide this response, or similar, if they are asked to sign-off: *IPC verified with the end-user that the intended use of a critical or semi-critical medical device matches the manufacturer's intended use of the device. IPC has also recommended the end-user consult with medical device reprocessing department (MDRD) when applicable*. In lieu of signing the existing CPSM form, ICPs may provide a completed Optional Tracking Checklist for Infection Control Professionals.
   - 2.2 Emergency Equipment Replacement Requisition 09654 used where funding is not available for emergent equipment replacement requests. The emergency equipment replacement process requires documented IPC consultation based on Spaulding Classification and the Purchasing Medical Devices – Roles and Responsibilities per a Capital Management checklist. Infection control professionals may complete their role in the process by providing email correspondence including confirmation of the following: *IPC verified with the end-user that the intended use of the medical device matches the manufacturer's intended use of the device. For critical and semi-critical medical devices, IPC recommends the end-user consult with MDRD when applicable.*
   - 2.3 Equipment Requisition 00483 for equipment requests used where funding is available through 103 capital account or Foundation, Donation, Trust or Grant. Refer to processes outlined in Insite Home > Teams > CPSM > Support Centre > Directives, Guides, Policies & Processes > Processes > Equipment Ordering.
   - 2.4 Construction, Renovation and Space Request (CRSR) 09744 found at Insite > Home >Teams > Capital Management > Capital Management Forms > Construction, Renovation & Space Request for service requests for renovation projects or capital equipment e.g., for reprocessing equipment, sterilizers, washer disinfectors, thermal disinfection equipment and automated reprocessors.
     Submit through the Customer Service Request e-Facilities portal:
     Home > Teams > Capital Management > About e-Facilities > e-Facilities Service Request Portal.
3. The end-user documents and maintains a record of the purchase process, e.g., copy of request, completed forms, Medical Device Reprocessing Department (MDRD) sign-off, manufacturer's instructions for use, and email correspondence.

For more information contact
ipcsurvstdadmin@ahs.ca

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3.1 Although not required, infection control professionals (ICPs) may maintain records, i.e., electronic or print, with details of their participation and review in the pre-purchase using the Optional Tracking Checklist for Infection Control Professionals or another mechanism, e.g., email string.

Definitions

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

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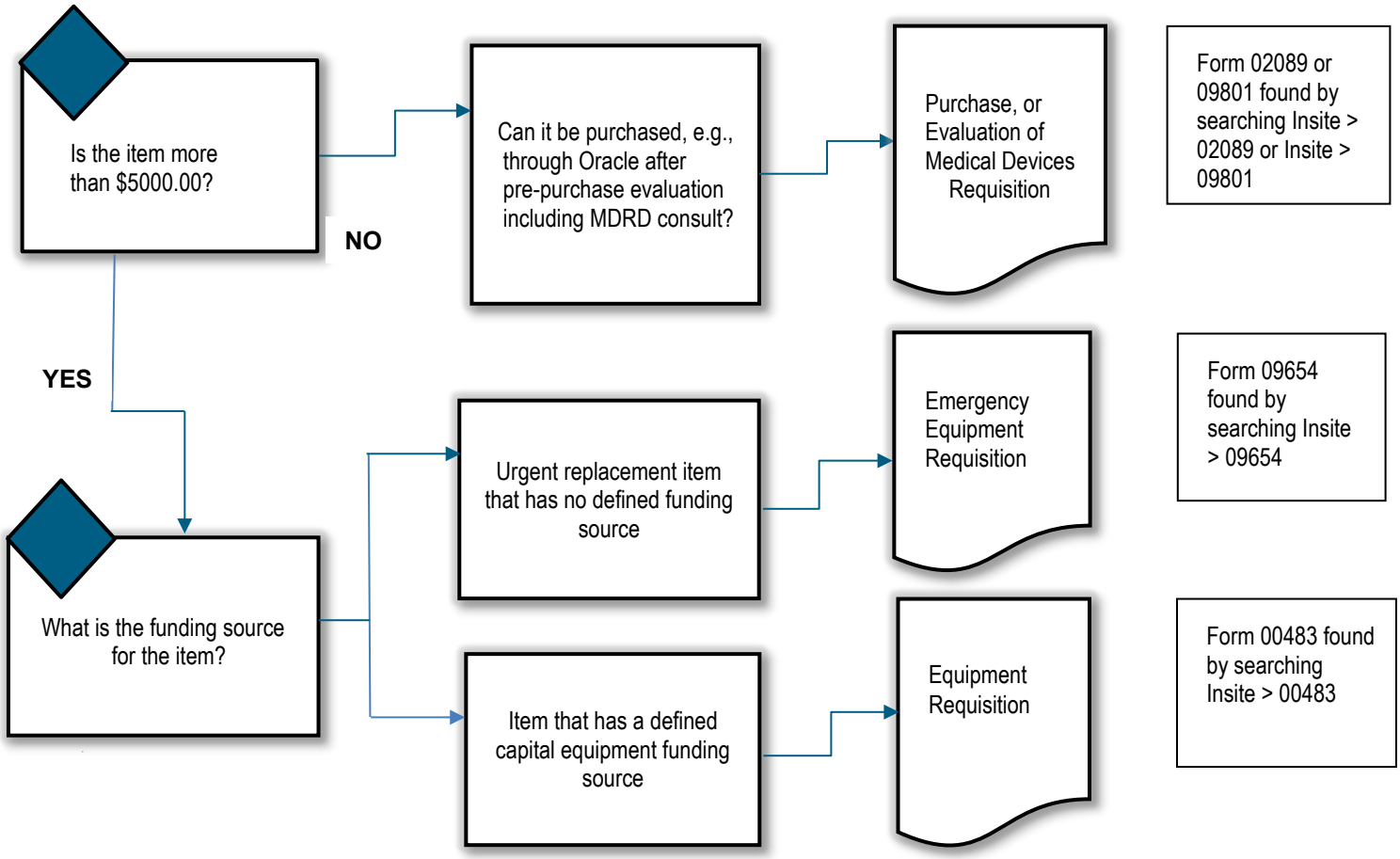
Example of funding & purchase request



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