IPC Staff Resource for IPC/CPSM Collaboration Activities

Purpose

Developed by Contracting, Procurement and Supply Management (CPSM) and IPC Leadership as a resource for infection control professionals (ICPs) participating in CPSM procurement processes.

1. Infection control professionals (ICPs) may be invited to participate in CPSM procurement processes including:

Request for Information – A request for information regarding a vendor's capability, operations, supply, and pricing.

Request for Proposals – A process where a number of factors are evaluated, which may or may not include price.

Competitive Bid (RFP process) – For large contracts with potential substantial savings that cannot be obtained through Group Purchasing Organization (GPO) and/or price harmonization, CPSM may choose to go to RFP to achieve best pricing, service and quality.

Note: CPSM integrated specifications for IPC general and mandatory requirements into their RFP Technical Requirements for purchases of medical devices. Mandatory Requirements are Pass/Fail; if vendors do not have these, they are disqualified, e.g., applicable current or pending Health Canada licensing and device adheres to IPC standards and policies.

Applicable CPSM documents/processes

Doing Business with AHS | Alberta Health Services

Basic Procurement Process and Competitive Bid Thresholds (Procedure Document #1152-02) – The objective of this procedure is to ensure that goods and services are acquired by AHS in manner that:

- Results in a safe and clinically acceptable product or service for the delivery of patient care; uses public funds in a prudent manner which ensures optimal cost, quality, and service; and ensures the procurement process is fair and equitable in the context of transparency and efficiency.

CPSM

- Offers an orientation process for the RFP requirements including meeting schedule and approximate time requirements.
- Adheres to the most current versions of IPC Standards, including the following:
  - The Alberta Health Infection Prevention and Control standards:
    - Standards for Infection Prevention and Control Accountability and Reporting
    - Standards for Reusable and Single-Use Medical Devices: standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all healthcare facilities and settings,

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Alberta Health Services
Infection Prevention & Control

all of which can be accessed at: https://www.alberta.ca/infection-prevention-and-control.aspx.

- AHS Policies:
  - Medical Device Safety available at AHS Insite Home > Teams > CPSM > Medical Device Safety
  - Critical and Semi-Critical Single-Use Medical Devices
  - Management of Loaned, Reusable Critical and Semi-Critical Medical Devices.

Infection control professional (ICP) role is to represent the IPC program; contribute IPC expertise and evidence-informed recommendations are considered before purchase, e.g., cleaning and disinfection/sterilization instructions that align with AHS processes; and the purchase results in a safe and clinically acceptable product or service for delivery of patient care. ICP informs IPC director of general timelines (to estimate ICP's time/FTE commitment) and any IPC related challenges.

ICP considerations may include

1.1 Questions such as:

- Are there appropriate sizes and volumes to the intended use, e.g., small volume single-patient use containers vs. bulk dispensing, single-patient use or single-use eye drops, wound care dressings in sizes to avoid cutting sterile supplies for reuse in accordance with IPC principles?
- Are there significant safety concerns that have been identified and not yet addressed?
- Does the device/equipment require extensive staff training or new processes?

1.2 Applicable IPC BPR recommendations and relevant CSA Standards: KRS Website > Subject Guides > Infection Prevention & Control > CSA Standards, e.g., CSA Z317.12:20, Cleaning and disinfection of health care facilities, 5.1.3. Refer to IPC resources, p. 5.

2. The ICP may be invited to participate in HealthPRO Contracts (national) website.

"HealthPRO uses a unique collaborative model for knowledge-gathering, deploying advisory committees designed to improve national decision-making. We led the establishment of the Clinical Contract Advisory Committee (CCAC)—the first national body of its kind – to optimize engagement between clinicians and procurement professionals, who together design even better contracts for the Canadian healthcare market."

Group Purchasing Organizations (GPO) – AHS currently has an agreement in place with HealthPRO. Work is currently underway to standardize like items around the province to achieve optimal pricing without compromising clinical requirements.

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The Infection control professional role in a HealthPRO contract is to represent the IPC program; contribute IPC expertise and evidence-informed recommendations so that infection prevention and control requirements are confirmed before purchase, e.g., cleaning and disinfection/sterilization instructions that align with AHS processes and are sufficient to support quality purchases and safe patient care.

Refer to IPC Best Practice Recommendations and CSA standards as described on page 1.

3. The ICP may be consulted about medical device safety.

Refer to Product Quality & Safety | Clinical Engineering Safety available at AHS Insite Home > Teams > CPSM > Medical Device Safety.

Our goal is to prevent unexpected medical device-related harm and promote device and safety improvements through best practices in detection, reporting, traceability, monitoring, analysis, and through industry and regulatory collaboration.

Best Practices in Medical Device Safety available at AHS Insite Home > Teams > CPSM > Medical Device Safety > Best Practices in Medical Device Safety.

Device users and managers minimize medical device risk by:

- Ensuring devices are approved by Health Canada and meet site and program infrastructure, maintenance, cleaning and use capabilities, and are compatible with other required devices, before requesting
- Reading, understanding, and following manufacturers' labelling and Instructions for Use (IFU) before use
- Confirming labels and expiry dates, and examining packaging and devices for evidence of defect or failure before use
- Following the actions provided in Equipment & Product Advisories, about recalls and other official safety notifications
- Reporting medical device incidents or problems experienced at the point of use to AHS Medical Device Safety Teams through the online Medical Device Incident or Problem (MDIP) Report form (formerly Product Feedback/Equipment Feedback)
- Following the PLEASE Quarantine process for medical device-related harm or potential for serious harm.

Medical Device Incident or Problem Reporting procedure

Reporting medical device incidents or problems (MDIPs) experienced at the point of use is an important AHS risk management strategy and is required as described in the AHS Patient Safety and Medical Device Safety Policy Suites, and Health Canada Medical Devices Regulations.

Infection Control Professional role: ICPs are often consulted when problems are identified with manufacturer instructions or medical device issues. Depending on the issue, follow-up actions may include advising the user to report the issue through the Reporting and Learning System and/or to complete an MDIP form.

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4. The IPC may be consulted about purchasing medical devices.

Refer to above CPSM resources as well as Medical Device Safety policy and IPC BPR Purchasing Medical Devices suite of documents:

- Forms and Documentation
- IPC Optional Tracking Checklist
- Roles and Responsibilities (including the infection control professional role)
- Decision Support Algorithm
- Spaulding Risk Classification for End-Users
- Pre-purchase Criteria for End-Users.

Unit sponsored trials for vendor items not currently on CPSM contract.

Follow the above IPC Purchasing Medical Devices suite of documents. For example, before trialing the item complete an Evaluation of Medical Device Request form 09801. This step informs CPSM by making them aware of trials so they can track progress and evaluate outcomes.

5. All AHS staff including ICPs are required to follow policy requirements.

IPC Policies

Management of Loaned, Reusable Critical and Semi-Critical Medical Devices Policy

Critical and Semi-Critical Single-Use Medical Devices Policy.

CPSM developed an inventory of single-patient use devices to meet Alberta Health requirements.

6. ICPs may be consulted about supply issues (ABHR and Disinfectant WG) examples include:

Infection Control Professional role: Zone representatives participate in regular working group meetings, provide Zone updates, collaborate with the multidisciplinary members, and develop, review and update documents as required related to supply shortages during COVID pandemic.

Consult with the ABHR and Disinfectant WG including the CPSM representatives regarding supply issues.

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Resources / further reading

1. **CPSM resources**

   Directives, Guides, Policies & Processes (Home > Teams > CPSM > Support > Centre > Directives, Guides, Policies & Processes) including:

   - Basic Procurement Process and Competitive Bid Thresholds
   - Competitive Bid Process Procedure
   - Strategic Sourcing & Supply Management.

2. **IPC resources**

   IPC Best Practice Recommendations, CSA Standards and table on Emerging Issues page as applicable.

Furniture and Other Non-medical items in patient care areas and Family and Patient Tip Sheet for Personalizing Spaces in Continuing Care	Manufacturer instructions confirm the item can be cleaned and disinfected with AHS disinfectants and processes. Select surfaces that are: • Easy to clean, maintain and repair • Non-absorptive • Non-porous • Fluid-resistant • Smooth with no crevices, rough textures, folds or seams • Durable enough to withstand repeated cleaning and disinfection with AHS provided products • Resistant to breakage, punctures or tears, stains, damage and wear. Consider relevant CSA Standards: KRS Website > Subject Guides > Infection Prevention & Control > CSA Standards, e.g., CSA Z317.12:20, Cleaning and disinfection of health care facilities, 5.1.3.
Patient Care Tubs	Choose tubs that meet these IPC criteria: • Designed and intended for use in a healthcare setting • Constructed of a smooth, cleanable, and durable surface • Manufacturer's instructions provide details on cleaning, disinfection and maintenance requirements • Compatible with AHS cleaning and disinfection products • Without jets or whirlpools. Assess chemical/product dispensing systems and select those: • With replaceable bottles or cartridges. • Without reservoirs to eliminate topping up of product.

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Patient Lifts and Handling Aids – review and follow Section 8 (excerpts only provided here)	Select mechanical patient lifts constructed with smooth, non-porous material and clean lines that permits appropriate cleaning and disinfection.
	• Hand controls must be resistant to moisture damage and easily cleaned and disinfected.
	Select handling aids, e.g., transfer slings, belts, sliders and restraints, constructed of materials that are easily laundered or cleaned and disinfected.
	Evaluate manufacturer's instructions for use and ensure they include:
	• Detailed written cleaning, disinfection procedures and preventative maintenance information for all components
	• Disinfection products with a Health Canada drug identification number (DIN)
	• Recommended service life and inspection specifications
	• Labels with:
	  ○ An area on the label to record patient name (required for some handling aids)
	  ○ Indications for use, i.e., disposable or reusable
	  ○ Cleaning, disinfection, and/or laundering instructions for reusable devices
	  ○ A symbol for cleaning with maximum temperature for washing and drying
	  ○ A place to document "date of first use"
	  ○ A warning not to use a damaged or eroded/threadbare sling.

Principles for Environmental Cleaning and Disinfection.	Choose cleanable materials and finishes that are smooth, non-porous, water-resistant, durable, and compatible with AHS cleaning and disinfection products.
Hand Hygiene Sink Requirements	Product evaluation AHS and Covenant Health staff responsible for purchasing new sinks and faucets for handwashing should follow these recommendations. Infection Prevention and Control should be consulted when evaluating and purchasing new sinks and faucets. Refer to Section 4, Selection Criteria for Basins and Section 5, Selection criteria for faucet fixtures

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Medical gels	If multiuse containers are used, follow these recommendations, in order of preference: • Choose the smallest suitable size and dedicate the medical gel to a single patient with ongoing medical gel needs within the patient care area. Discard the container when it is no longer being used for that patient. • Choose the smallest suitable size. With the use of Routine Practices, the container can be used on multiple patients within the diagnostic setting. Discard the container when empty or if there is evidence of contamination.
Selection and Management of Isolation Carts	Follow Section A details for selecting.

3. RFP specifications

CPSM reviews vendor licences for medical devices including medical device reprocessing equipment for RFPs and designates Pass/Fail on these mandatory requirements. If vendors do not have these, they are disqualified.

- For all medical devices: Does the manufacturer, importer (if applies) and distributor have a Health Canada Medical Device Establishment Licence? (Y/N)
  - Regulatory references
    - Medical Devices Regulations (justice.gc.ca)
    - Guidance on Medical Device Establishment Licensing (GUI-0016): Summary - Canada.ca
    - Medical Devices Establishment Licence (MDEL)Listing (canada.ca).

- For Health Canada Class II-IV devices: Has the vendor provided active Health Canada Licence Numbers and Names for all devices, including components, accessories and consumables, before contract execution*? (Y/N))
  - Refer to Medical Device Safety Policy Section 1 for details.
  - Regulatory references
    - Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs) - Canada.ca
    - Guidance Document: Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs) - Canada.ca
    - Medical Devices Active Licence Listing (MDALL) - Your reference tool for licensed medical devices in Canada.

*Note: The manufacturer may be in the process of obtaining Health Canada licence during the RFP; however, before contract execution, i.e., before AHS acquires a medical device, the device must be authorized by Health Canada.

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- For all medical devices: Has the vendor provided complete labelling and manufacturer's directions for use? (Y/N)
    - Regulatory references
        - Guidance Document: Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices - Appendices for the Labelling of Soft, Decorative, Contact Lenses and Menstrual Tampons - Canada.ca
        - Guidance Document - Labelling of In Vitro Diagnostic Devices - Canada.ca.
- For reusable medical devices, including single-patient reuse: Has the vendor provided cleaning and reprocessing instructions appropriate to Spaulding's Classification for each reusable device, including components and accessories)? (Y/N)
    - Regulatory reference
        - Guidance Document: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices - Canada.ca

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Definitions

Critical medical device means a medical device that enters sterile tissues/vascular system or enters normally sterile cavities and therefore presents a high risk of infection if the medical device is contaminated with any organisms, including bacterial spores. Examples include but are not limited to needles (including acupuncture needles), lancets, syringes, suture removal kits, urinary catheters, biopsy forceps, infusion supplies and devices, such as catheters, lines, e.g., intravenous administration tubing and access ports**.**

Manufacturer means a person, including a partnership, firm or association, who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and with respect to the medical device, is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing, modifying, or assigning the medical device an intended purpose, whether those tasks are performed by that person or on their behalf.

Manufacturer's instructions (directions) for use (MIFU) mean validated, written directions provided by the manufacturer or distributor of a medical device or product, which contains the necessary information/labelling for the safe and effective use of the medical device or product. The MIFU does not include cleaning or reprocessing requirements.

Manufacturer's Instructions for Use – Reprocessing (MIFU-R) includes instructions for cleaning and disinfection/sterilization (reprocessing).

Medical device means any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for a human being for any of the following purposes:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap
- Investigation, replacement, or modification of the anatomy, or of a physiologic process
- Control of conception, and that does not achieve its principal intended purpose in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

Note: For the purposes of RFP medical device includes equipment, consumables, accessories, and components.

Medical device reprocessing (MDR) means an area where the reprocessing of reusable critical and semi-critical medical devices occurs. This includes centralized MDR departments, or any area where reprocessing of reusable critical and semi-critical medical devices takes place.

Non-critical medical device means a medical device, which either touches only intact skin but not mucous membranes or does not touch the client.

Reusable medical device means a device that has been designed by the manufacturer, through the selection of materials and/or components, to be reprocessed and reused.

Semi-critical medical device means a medical device that comes into contact with mucous membranes or nonintact skin but does not penetrate them.

Single-use (disposable) medical devices means a medical device that comes into contact with mucous membranes or non-intact skin but does not penetrate them.

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Single-use medical devices mean critical and semi-critical devices labelled by their manufacturers to be used only once. The manufacturer may use terms including but not limited to the following, to designate a device for single-use only:

- Disposable
- Consumable, not for re-use or do not re-use
- Discard after single-use
- Do not use twice, or
- A symbol such as  .

Note**:** AHS may purchase single-use medical devices that are reprocessed and redistributed by a commercial reprocessor in accordance with Health Canada requirements and the Reusable & Single-Use Medical Devices Standards (Alberta), i.e., meets the same requirements as a manufacturer of new devices, as per SUMD policy.

Single-patient use medical devices means a semi-critical medical device that is labelled by its manufacturer for use on a single patient as described in the manufacturer's instructions, and not for reuse on another patient. The manufacturer instructions may:

- Allow an extended episode of use on a single patient
- Allow reuse on a single patient.

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