



TITLE

MEDICAL DEVICE RECALL

SCOPE

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Clinical Operations Executive Committee

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SPONSOR

Contracting, Procurement & Supply Management;
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Not applicable

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Medical Device Safety Policy (#PS-103)

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NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To facilitate effective management of **medical device** safety notifications including **recalls** to enhance safety for **patients, Alberta Health Services (AHS) representatives** who use medical devices, and AHS.
- To set out standards for efficient and effective use of resources when handling medical device recalls.
- To ensure medical device recall regulatory requirements are met.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. **Centralized Intake and Triage of Medical Device Recall and Safety Information**
 - 1.1 AHS **medical device safety (MDS) responsible departments** shall request medical device manufacturers, importers, and distributors send all medical device safety notifications (which includes recall notifications) that affect AHS and **medical device-related entities** to the AHS Safety Alerts Coordinator at EP.Advisory@ahs.ca.

- 1.2 AHS, its subsidiaries, and medical device-related entities personnel should immediately forward any medical device safety notifications received locally to EP.Advisory@ahs.ca.
- 1.3 The AHS Safety Alerts Coordinator shall monitor EP.Advisory@ahs.ca and triage incoming notifications to the appropriate AHS MDS responsible department to review and coordinate appropriate actions.
 - a) AHS Medical Device Safety – **Product** – Product Quality and Safety shall handle safety notifications about non-maintained medical devices including single-use devices and reusable instruments, commodities distributed from AHS' warehouses, and any medical device not otherwise triaged to MDS – **Equipment** or an AHS **designated specialty area**.
 - b) AHS Medical Device Safety – Equipment – Clinical Engineering Safety shall handle safety notifications about maintained medical devices (equipment), unless triaged to a designated specialty area.
 - c) Certain AHS designated specialty areas independently handle safety notifications about medical devices that are exclusive and specific to that specialty area (e.g., Laboratory-only devices, Pharmacy-only devices). Designated specialty areas collaborate with AHS MDS responsible departments as required to ensure no areas within the organization are overlooked.

2. Risk Assessment and Developing Organization-Wide Mitigation Plans

- 2.1 The AHS MDS responsible department requests and/or confirms all information required to develop a plan of response to the recall/safety information, including but not limited to the following:
 - a) risk to patients or others associated with the **medical device problem (MDP)** including:
 - (i) the **vendor's Health Hazard Classification** and Health Canada's defined type of recall, where possible;
 - (ii) actual frequency and/or estimated likelihood of the problem;
 - (iii) potential severity of effect if the problem occurred;
 - (iv) detectability of the problem before or during use;
 - (v) availability of unaffected replacement devices (for a physical recall) and/or the potential requirement for substitute medical devices;
 - (vi) timing of field corrections or acquiring replacements/substitutes;
 - (vii) the risk of having no devices available for use; and

- (viii) identifying the location of recalled medical devices through AHS using purchase history, delivery information, and the vendor's distribution records;
- b) potential mitigating factors such as:
- (i) the availability of exact match or close substitute medical devices from another vendor;
 - (ii) requirements or limitations associated with the use of substitute medical devices; or
 - (iii) other potential opportunities for risk mitigation, such as visual inspections or vendor-prescribed alternate procedures.
 - If mitigation requires change to clinical practice, the AHS MDS responsible department shall refer the matter to clinical experts familiar with the device and its use (typically Patient Safety or Health Professions Strategy and Practice [HPSP]); and
 - coordinate with clinical experts and the AHS MDS responsible department to determine the most appropriate practice changes and to communicate these changes, as required; and
- c) the risks to patients and others associated with the various options available, including the risks and benefits of delayed communication about the MDP, if there is a delay receiving replacement or substitute devices, or field corrections.
- 2.2 The AHS MDS responsible department shall consult with stakeholders as required when developing AHS' response plan, including but not limited to:
- a) Infection Prevention & Control (IPC) about sterility/contamination issues;
 - b) clinical experts with sufficient experience and training for substitute medical device questions and clinical risk-benefit assessment (e.g., determining the risk of using an affected device and its associated benefits compared to the risk of not having the device available and/or using an alternate or substitute device);
 - c) Legal Services about liability, wording, and decision-making when performing risk-benefit analysis, and about special regulatory circumstances;
 - d) Contracting, Procurement & Supply Management (CPSM) about warehouse matters, supply issues, logistics and timing factors, and substitute medical devices available on or off contract; and

- e) Health Canada and/or the United States Food and Drug Administration about special regulatory circumstances.

2.3 The AHS MDS responsible department shall finalize the response plan and document in accordance with the AHS *Records Management* Policy.

3. Communicating the Response Plan and Mitigating Actions

3.1 The AHS MDS responsible department communicates the device problem information and mitigation action(s) (as per Section 2 above) to be taken by affected clinical area managers, AHS representatives, and others who use the devices using standardized communication formats and processes including but not limited to Equipment and Product Advisories (E&P Advisories). As appropriate, a memo or alternative communication mechanism may be used.

3.2 The majority of medical device safety notification/recall response plans are developed through AHS MDS responsible departments. Communications include the following:

- a) a specific E&P Advisory type:
- (i) Information Advisory to communicate the problem, risk, and mitigation actions to be taken by AHS representatives using medical devices (and others if appropriate) but there is no physical withdrawal of medical devices;
 - (ii) Recall Advisory to communicate the problem, risk, and mitigation actions including removing the medical devices from inventory and point of use areas, and providing instructions to front-line clinicians about replacement and/or substitute medical devices;
 - (iii) Recall Advisory – Quarantine on your Unit to communicate the problem, risk, and mitigation actions but leaves the medical devices available to front-line clinicians using medical devices;
 - A Physician or other **most responsible health practitioner (MRHP)** may determine that the benefit of using a recalled medical device outweighs the risk associated with the reported problem or the risk of using no device. If a recalled medical device is used, then the justification for the decision and medical device information shall be documented in the patient's **health record**.
 - Once replacement or substitute medical devices arrive, the unit shall return any quarantined medical devices as instructed in the recall advisory.
 - (iv) Field Correction Advisory to communicate the problem, risk, and mitigation actions to be taken by AHS representatives and

patients using medical devices until a Field Correction is completed;

- Field Corrections are performed at AHS facilities by equipment vendor representatives or internal equipment experts as directed by the vendor.

(v) Update Advisory to communicate additional information and actions to AHS representatives and patients using medical devices, as required. An update advisory may take the form of another specific advisory type;

- b) **effectiveness checks** (E&P Response Form) that the affected clinical area manager completes and returns to the Safety Alerts Coordinator; and
- c) other information as appropriate, for example, the vendor recall/safety notification, Health Canada information, or detailed product distribution records.

3.3 E&P Advisories are distributed to clinical managers of affected locations at AHS and medical device-related entities, using a standardized process:

- a) E&P Advisories are distributed from EP.Advisory@ahs.ca, to CPSM Site Services Supervisors at affected AHS and medical device-related entities' facilities. Other areas, such as AHS Distribution Centres and Procurement Teams, shall be included in the distribution of E&P Advisories as applicable.
- b) CPSM Site Services Supervisors and Site and/or Zone Leadership shall determine the most appropriate local E&P Advisory distribution practices for their sites and programs, and review these practices annually.
- (i) Local practices shall consider 'alert fatigue' and the risk associated with AHS representatives deleting an advisory before reading, compared to the risk of an E&P Advisory not being distributed to an affected AHS facility or applicable contracted service provider.
- (ii) The most common methods of site E&P Advisory distribution are:
- to a targeted list, determined by CPSM cross-referencing the E&P Advisory information with site purchase, receiving, and delivery history; or
 - to a standardized site list each time, usually all Unit or Program Managers and educators.

- c) Managers of areas receiving an E&P Advisory that have sent recalled medical devices elsewhere are responsible for sending the E&P Advisory to the AHS site(s) where the medical devices were sent and ensuring the affected site(s)' receiving area Manager is aware.
 - d) CPSM Site Services staff and managers of areas that have sent recalled medical devices elsewhere shall always copy EP.Advisory@ahs.ca when distributing E&P Advisory emails, as a record of distribution of the communication to sites or programs.
 - e) Special circumstances: Occasionally, additional communication distribution mechanisms may be used. The most appropriate mechanism(s) shall be determined by the MDS responsible department in consultation with the involved AHS facilities and AHS representatives using medical devices.
 - f) E&P Advisories are posted on Insite.
- 3.4 Internal Field Correction – Clinical Engineering Safety, Facilities Maintenance & Engineering (FM&E), or designated specialty area technical staff may determine that a field correction is appropriate without an E&P Advisory being communicated.
- 3.5 Designated Specialty Area Communication – Certain areas or programs with exclusive use of a medical device may communicate about exclusive-use MDPs, risks, and mitigation actions as appropriate for that area or program. Examples include Laboratory Services-exclusive medical devices and Pharmacy Services-exclusive medical devices.
- 4. Affected Areas Complete the Recall or Safety Mitigation Actions and Effectiveness Checks**
- 4.1 Accountable leaders of affected areas, typically clinical Unit Managers, are responsible for ensuring the mitigating actions (as per Section 3 above) are completed as appropriate, including but not limited to:
- a) ensuring all appropriate AHS representatives and patients using devices are aware of the MDP and actions;
 - b) completing non-recall safety actions;
 - c) completing recall actions:
 - (i) assisting AHS or medical device-related entities CPSM Site Services staff with the locating, quarantine, replacement, return, or other actions as required for recalled medical devices supplied through AHS or medical device-related entities' inventory services; and

- (ii) ensuring the locating, quarantine, replacement, return, disposal or other actions are completed as required for recalled medical devices not managed by CPSM Site Services staff; and
- d) submitting completed internal and vendor effectiveness checks.
 - (i) Internal Effectiveness Checks – Managers of clinical areas that use affected devices shall complete and return the AHS *Equipment and Product Advisory Response Form* to EP.Advisory@ahs.ca.
 - (ii) Vendor Effectiveness Checks – vendors typically request AHS representatives using medical devices complete and return a *Vendor Response Form* (Health Canada). This form is used by the vendor and Health Canada to verify safety communication with AHS facilities and AHS representatives who use medical devices. Health Canada requires vendor response forms to be completed for higher-risk situations.
 - Managers of clinical areas that use affected devices shall complete and return vendor response forms, unless there are circumstances for another person or role to do that function.
 - A warehouse representative may complete and send the form on behalf of all sites receiving product from that warehouse when returning recalled warehouse items returned from sites.
 - An AHS MDS responsible department member may complete and send the form on behalf of AHS, to confirm that field notice communications have taken place.
 - AHS representatives using medical devices may add comments or strike out words on vendor response forms so the content is accurate for the person completing the form. Assistance is available from the MDS responsible departments.
 - The vendor and/or Health Canada may follow up with AHS MDS responsible departments, who may in turn follow up with Managers of clinical areas that use affected devices to confirm information was received and to ensure response forms are completed and sent, as required.

5. Records of Communication and Effectiveness Checks

5.1 The AHS MDS responsible department shall maintain a record of:

- a) information used to prepare the response plans;

- b) all communications about the recall/safety information;
 - c) medical device location information;
 - d) communication distribution information;
 - e) internal effectiveness checks; and
 - f) follow-up communication/information.
- 5.2 All records shall be maintained in accordance with the AHS *Records Management Policy*.
- 5.3 The AHS MDS responsible department shall answer questions from the vendor or Health Canada about communication distribution and effectiveness checks, and facilitate completion of response forms by Managers of areas that use affected devices as required.

DEFINITIONS

AHS representative means Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

Designated specialty area means Laboratory Services, Pharmacy Services, Medical Physics, and other specialty areas with medical device use that is exclusive to only that department. In consultation with AHS MDS responsible departments, they may implement safety notification procedures for medical devices that are specific to that device and area.

Effectiveness check means a survey of those affected by the recall in order to verify they have received the recall information, are aware of any appropriate action to be taken, and may include verification of the action taken. The party conducting the recall is responsible for implementing effectiveness checks which may also be undertaken or verified by the Health Products and Food Branch Inspectorate.

Equipment means medical devices that are supported by a responsible AHS service group such as Clinical Engineering, Facilities Maintenance and Engineering, a specialty area qualified technician such as Laboratory Services or Diagnostic Imaging, or contracted service provider(s).

Health hazard classification means the numerical designation assigned to a particular device recall demonstrating the relative risk presented by the recalled device, specifically, there is the reasonable probability that the use of or exposure to the recalled device:

- will cause serious adverse health consequences or death (Type I); or;
- may cause temporary adverse health consequences, or there is not a significant probability of serious consequences/death (Type II); or,
- is not likely to cause any adverse health consequences (Type III).

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

Medical device means an item, whether used alone or in combination, including software, intended by the manufacturer for use on patients, for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of, or compensation for a disease, an injury, or handicap;
- investigation, replacement, or modification of the anatomy or of a physiologic process; and/or
- control of conception.

At AHS, and related entities, “Medical Devices” are generally referred to as either “equipment” or “product” to correspond with the functional work streams (acquisition, maintenance, and risk management processes) associated with equipment (maintained medical devices) or product (consumable medical devices and surgical instruments).

Medical device problem (MDP) means, according to Health Canada, an actual or potential deficiency that may affect product performance or safety, a defect, malfunction or fault, a failure of the medical device to perform in accordance with its intended purpose when used in accordance with the manufacturer’s instructions for use (MIFU), or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use. This includes any medical device, labelling, or packaging quality issue or safety hazard, whether or not the medical device affected a patient or other person.

Medical device-related entities means any other entity to which AHS provides medical device supply chain and/or Product Quality & Safety services pursuant to standard CPSM processes and/or Clinical Engineering Safety services pursuant to standard Capital Management processes.

Medical device safety (MDS) responsible department means the department that has responsibility to ensure medical device risk management and post-market surveillance activities are completed, such as internal and external reporting and device problem and clinical adverse event investigation, or refers or delegates those activities to another area or department. At AHS, the Medical Device Safety responsible departments are Product Quality & Safety and Clinical Engineering Safety, who may refer or delegate certain MDS activities to another area or department.

Most responsible health practitioner (MRHP) means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Alberta Health Services to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Patient means an adult or child who receives or has requested health care or services from Alberta Health Services and its health care providers or individuals authorized to act on behalf of Alberta Health Services. This term is inclusive of residents, clients and outpatients.

Product means medical devices that are not maintained, such as clinical consumables or reusable surgical instruments.

Recall means the actions taken to physically remove or withdraw an item from use, availability or the market, due to a defect, problem or hazard. This is the common meaning used in this policy suite. In contrast is the Health Canada definition, which includes “any action taken by the manufacturer, importer, or distributor of a device to recall or correct the medical device, or to notify its owners and/or medical device users of its defectiveness or potential defectiveness...” Health Canada's definition of recall does not only mean removal or withdrawal of a problem device, it includes corrections and information-only notifications.

Vendor means an individual or company that supplies, or seeks to provide, goods and/or services to AHS, and includes manufacturers, importers, and distributors.

REFERENCES

- Alberta Health Services Governance Documents:
 - *Medical Device Incident or Problem Reporting Procedure* (#PS-103-03)
 - *Medical Device Safety Policy* (#PS-103)
 - *Medical Device Safety – Preparing and Shipping for Investigation Procedure* (#PS-103-01)
 - *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy and procedures* (#PS-95)
 - *Records Management Policy* (#1133)
- Alberta Health Services Forms:
 - *Equipment and Product Advisory Response Form*
- Non-Alberta Health Services Documents:
 - *Vendor Response Form* (Health Canada)

VERSION HISTORY

Date	Action Taken
	Optional: Choose an item