

TITLE

MEDICAL DEVICE SAFETY - PREPARING AND SHIPPING FOR INVESTIGATIONSCOPE

Provincial

DOCUMENT

PS-103-01

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Contracting, Procurement & Supply Management;
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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 direct safe preparation, reporting, packaging, and shipping of **medical devices** being sent for **investigation** following a **medical device incident (MDI)** or **medical device problem (MDP)** experienced at the point of use.
- To preserve evidence within medical devices being prepared and sent for investigation.

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. Initial Preparation and Quarantine**

- 1.1 The **accountable leader** shall ensure **suspect medical devices** requiring investigation following a medical device incident or problem (MDIP) are identified and undergo initial preparation and **quarantine**, as appropriate, and assist with designating appropriate **Alberta Health Services (AHS) representatives** as required.
- 1.2 If there was **harm** or there is the potential for serious harm or death if the situation were to recur, then refer to the AHS *Medical Device Incident or Problem Reporting Procedure* and AHS *PLEASE Quarantine Resource* for additional required steps.

- a) For more information regarding harm and reporting refer to the AHS *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy and procedures.
- 1.3 As close in time to the identified MDIP as possible, the AHS representative using the medical device shall prepare the medical device as follows:
- a) Clean external surface as follows:
- (i) Before commencing, follow **routine practices** including appropriate use of **personal protective equipment (PPE)**.
 - (ii) Ensure there is minimal impact on the external condition and structural integrity of the medical device. Do not disassemble the medical device or pull off a partially broken component.
 - (iii) Drain any free liquid that may leak during movement, to the extent practicable.
 - (iv) Wipe off visible blood, tissue, and body fluids from external surfaces of the medical device, including integral accessories/components, using manufacturer-recommended and facility-approved disinfectant wipes as per **manufacturer's instructions for use (MIFU)**.
 - (v) Depending on circumstances, follow additional safe handling procedures (e.g., procedures for handling **hazardous medications**).
 - For additional information, refer to the AHS *Hazardous Medication List*.
- b) Decontaminate external surface to the greatest level possible as follows:
- (i) Continue to wear PPE, follow routine practices and any additional precautions, and observe safe handling procedures as required.
 - (ii) Use manufacturer-recommended and facility-approved disinfectant wipes, following manufacturer's instructions, to carefully wipe the external surfaces of the medical device again, ensuring that the condition and structural integrity of the medical device is impacted as little as possible; let dry completely.
 - Do not subject the medical device to **sterilization** or immersion in a **decontamination** agent (unless expressly instructed to do so by the AHS **Medical Device Safety (MDS) responsible department**. Refer to the AHS *Medical Device Incident or Problem Reporting Procedure*.

- (iii) In general, continue to handle the medical device as **contaminated** since it may continue to be a biohazard prior to decontamination processing.
- There may be occasional exceptions to this (each situation shall be reviewed on an individual basis by AHS MDS responsible department staff to determine whether an exception applies).
- c) Inspect medical device and document any missing components as follows:
- (i) Continue to wear PPE, follow routine practices and safe handling procedures while handling contaminated medical devices.
- (ii) Ensure that all known components of the medical device are present.
- (iii) Document any known components or pieces that are missing, on the corresponding *AHS Medical Device Incident or Problem (MDIP) Report Form*.
- d) **Contain** contaminated medical device(s) as follows:
- (i) Seal medical device within two (2) nested (one inside the other) impermeable **containers**.
- (ii) If the medical device holds liquid, then ensure an absorbent material is placed in the external container.
- (iii) If the medical device is sharp and may penetrate the container and/or skin, then, at minimum, choose a puncture-proof external container.
- (iv) For **product(s)** – choose sealable biohazard bags or bins.
- (v) For **equipment** – seal before transport to the local Clinical Engineering (CE) area (e.g., a flexible endoscope can be contained within one sealable bag prior to being placed in a box or endoscope suitcase as the outer containment device).
- Reporter may consult with local Infection Prevention and Control (IPC) and CE representatives for assistance in containing the contaminated equipment.
- (vi) Clearly label containers “Biohazard.”
- e) Label the medical device as follows:

- (i) Attach a label to the outside of the containers (or medical device, if considered completely de-contaminated with no risk of biohazard) to:
 - assist with tracking the medical device to foster a secure chain of evidence; and
 - ensure it does not inadvertently get returned to service.
- (ii) The label may be:
 - the *Quarantine & Hold label* (as per PLEASE Quarantine process);
 - *AHS MDIP Report Form*; or
 - any other label stating “Quarantine & Hold for Investigation.”

2. Report Medical Device Incident or Problem

- 2.1 The reporter shall complete the *AHS MDIP Report Form*, in accordance with the *AHS Medical Device Safety Incident or Problem Reporting Procedure*.
- a) For assistance contact the central Medical Device Reporting line: 1-877-390-2330.
 - b) The MDIP submitter and Person/Group Holding Device (PGHD) named in the report will receive an automatic email with the AHS MDIP reference number used in all follow-up communication (even if a Product Feedback Form is submitted).

3. Quarantine and Hold the Medical Device

- 3.1 The accountable leader shall designate an AHS representative responsible to ensure the medical device is stored in a secure location while reporting the MDI or problem and awaiting instructions. An appropriate location includes:
- a) a locked drawer; or
 - b) a lockable office with controlled access.
- 3.2 Whoever has custody of the medical device at the time of storage becomes the PGHD.
- a) The PGHD shall print the MDIP auto-response email and attach it to the container/wiped device.
 - b) If both product and equipment are involved in the MDIP and quarantined, then ensure both receive a copy of the automatic email with the AHS

MDIP reference number. There may be two (2) steps to the investigation - an internal investigation on the equipment with attached product and a subsequent external investigation on both the equipment and product or on the product or equipment alone.

- c) Ensure biohazard symbols remain visible, as applicable.
- d) Add labelling if the medical device may contain a hazardous substance (e.g., "hazardous medication remains within tubing").

3.3 Suspect medical devices involved in a MDI (i.e., with harm or the potential for serious harm/death) shall have mandatory secure Quarantine & Hold.

- a) Stand-alone products involved in an MDI shall be placed under secure Quarantine & Hold as directed by the local clinical manager or designate.
- b) Suspect equipment and any attached product involved in an MDI shall be sent for secure Quarantine & Hold by the local **AHS service group** (e.g., CE, Facilities Maintenance & Engineering [FME]) or designate, as directed by the local clinical manager or designate. The designated Quarantine & Hold area shall:
 - (i) confirm the suspect medical device has been reported through the MDIP reporting process, and if not, report it through completing the AHS *MDIP Report Form*;
 - (ii) document the quarantine and AHS *MDIP Report Form* confirmation or completion in e-Facilities; and
 - (iii) continue the Quarantine & Hold (but do not service or maintain the medical device/equipment) while awaiting follow-up from the AHS MDS responsible departments.
- c) If the suspect medical device is typically serviced by an external service group, then it shall not be reported or sent to an external service group at this stage.
 - (i) If the usual process is service by an external group, then the local clinical manager or designate shall assign a local AHS service group (e.g., CE, to be temporarily assigned the Quarantine & Hold responsibility).
 - (ii) The AHS MDS responsible departments, in consultation with AHS Legal Services (and others as appropriate), shall determine if and when equipment usually serviced externally shall be reported and sent to the external service group for investigation.

3.4 Suspect medical devices with reported MDPs (i.e., suspect medical devices not involved in a MDI) shall be quarantined by the local clinical manager or

designate, as appropriate, while reporting processes take place (see AHS *Medical Device Incident or Problem Reporting Procedure*).

- a) This quarantine applies to any suspect medical device where a visual inspection or physical investigation by **vendor**-designated or other medical device experts may be appropriate. Such an inspection or investigation may detect or confirm a manufacturing defect or design flaw, and/or lead to manufacturing corrections, design improvements, or other risk mitigation actions.
- b) This quarantine does not apply to maintained medical device(s) not involved in an MDI displaying normal or expected signs or signals for routine maintenance and these devices should be referred to the appropriate AHS service group according to site or program processes, rather than be placed under quarantine and hold.

4. Device Investigation Arrangements

4.1 The AHS MDS responsible department shall:

- a) gather information and report internally and externally as required;
- b) facilitate an internal and/or external medical device investigation with appropriate stakeholders; and
- c) communicate the investigation location, packaging, documentation, shipping instructions, and authorization to the AHS MDIP primary clinical contact, and the PGHD via email as appropriate.

5. Packaging and Documentation for Transport

5.1 The PGHD shall ensure the medical device is securely transported from the quarantine location to the shipping or investigation location in a manner that minimizes the impact of transportation on the condition and structural integrity of the medical device.

5.2 Determine the appropriate outer packaging for the medical device to be transported based on the options below, with consideration of the destination and method of transportation.

- a) Packaging includes padding and outer shipping/transport carton/case.
- b) Packaging should minimize the impact of transportation on the condition and structural integrity of the medical device.
- c) For an internal investigation, the PGHD shall ensure delivery to, and confirm receipt of the medical device at, the designated AHS investigation location, including:

- (i) same-site porter delivery; or
 - (ii) inter-site delivery via AHS transportation services. At the PGHD discretion, inter-site delivery arrangements may include packaging the medical device in the same manner as for an external investigation (refer to Section 5.2 d]).
- d) For an external investigation, the PGHD shall ensure appropriate packaging, documentation, labelling, and shipping to the designated investigation facility:
- (i) Determine if there are special circumstances that may require special handling (e.g., sharps, batteries, or presence of dangerous substances as defined by Transport Canada's *Transportation of Dangerous Goods Regulations*).
 - Properly cleaned and disinfected, contained, and labelled medical devices do not require special handling beyond what is described (Section 4.3 a] i]).
 - The AHS MDS responsible department shall communicate vendor or medical device-specific packaging requirements to the PGHD as required.
 - Vendor-supplied or medical device-specific packaging should be used whenever possible; follow any additional preparation or packaging instructions provided.
 - (ii) Ensure the medical device is in container with attached AHS *MDIP Report Form* and additional documentation, as required, in the shipping case with appropriate packing and seal.
 - (iii) Print shipping instructions and vendor authorizations for use of the vendor's designated courier.
 - (iv) Transfer the contained device, AHS *MDIP Report Form*, shipping instructions and authorizations to the local AHS Shipping & Receiving Area.
 - (v) AHS Shipping & Receiving shall package, label and ship the medical device according to site and AHS protocol, using shipping instructions and courier authorizations as arranged by the AHS MDS responsible department.
 - (vi) Ensure AHS Shipping & Receiving Area will supply tracking information to the AHS MDS responsible department and the PGHD.

- 5.3 The AHS MDS responsible departments shall follow the investigation process, coordinate additional actions as required, and report the investigation outcome to the primary clinical contact and other stakeholders as appropriate.

DEFINITIONS

Accountable leader means the individual who has ultimate accountability to ensure the consideration and completion of the listed steps in the management of the Alberta Health Services *Immediate Management of Clinical Adverse Events* Procedure. Responsibility for some or all of the components of management may be delegated to the appropriate level responsible administrative leader, but the accountability remains at the senior level.

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).

AHS service group means the group designated as responsible for service and maintenance of equipment (e.g., Capital Management) or a specialty area (e.g., EMS, Laboratory Services, Diagnostic Imaging, etc).

Contain means, for the purposes of this document, to fully enclose an item that may be contaminated, to prevent potential biohazards from coming in contact with people or the environment, which should be free of leakages during handling, storage or transport.

Container(s) means, for the purposes of this document, a sealable device used to contain potentially biohazardous items. In this document, container does not refer to packaging used for shipping items.

Contaminated means used or potentially used medical devices that have not been decontaminated i.e., cleaned, followed by the inactivation of pathogenic microorganisms, in order to render an object safe for handling. All used (and potentially used) medical devices are assumed to be contaminated. These devices shall be handled using appropriate routine practices, including:

- hand hygiene;
- PPE for contaminated contact;
- safe sharps management; and
- biohazardous waste management.

Decontamination means cleaning, followed by inactivation of pathogenic micro-organisms, to render an object safe for handling.

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).

Harm means an unexpected outcome for the patient, resulting from the care and/or services provided, that negatively affects the patient's health and/or quality of life.

Hazardous medication means a medication for which research on humans or animals has shown that any exposure to the substance has the potential to cause cancer, lead to a developmental or reproductive toxic effect or damage organs. Such medication are considered hazardous because their effects present risks for personnel.

Investigation means, for the purposes of the *Medical Device Safety Policy Suite*, all activities carried out from the time of first awareness of a problem involving safety or performance of a medical device to its closure. Reported problems include:

- problems involving the medical device itself, its packaging and labelling;
- compliance with regulatory requirements, among the medical device “performance characteristics”; and
- other complaints or medical device incidents reported by patients or users of the medical device.

Manufacturer’s instructions for use (MIFU), also known as Instructions for Use (IFU), means the validated, written directions provided by the manufacturer or vendor of a medical device or product that contain the necessary information for the safe and effective use of the medical device.

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 incident (MDI) means, according to Health Canada, a medical device problem that has led to the death or a serious deterioration in the state of health of a patient, medical device user, or other person, or could do so were it to recur; serious deterioration in health means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. MDIs include any that occur as a result of an off-label/abnormal use. This is the equivalent of a Serious Clinical Adverse Event (CAE) or Near-Miss Serious CAE, or a worker incident with serious harm, at AHS.

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 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.

Personal protective equipment (PPE) means any specialized clothing or safety items worn by individuals prior to contact with potential or identified hazards, such as from a direct exposure to blood, tissue, and/or body fluids.

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

Quarantine means, for the purposes of the *Medical Device Safety Policy Suite*, effective restriction of the availability of a device for use, until released by a designated authority.

Routine practices means, for the purposes of the *Medical Device Safety Policy Suite*, a comprehensive set of infection prevention and control measures that have been developed for use in the routine care of all patients, at all times to minimize or prevent health care associated infection health care settings.

Sterilization means the validated process used to render a product free from viable microorganisms.

Suspect medical device means a medical device that is suspected to have failed 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.

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 Recall Procedure (#PS-103-02)*
 - *Medical Device Safety Policy (#PS-103)*
 - *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy and procedures (#PS-95)*
- Alberta Health Services Forms:
 - *Medical Device Incident and Problem Report (MDIP) Form*
 - *Product Feedback Form (#09570)*
- Alberta Health Services Resources:
 - *Hazardous Medication List*
 - *Infection Prevention and Control Routine Practices*
 - *Medical Device Incident and Problem Reporting Process*
 - *PLEASE Quarantine*
 - *WHS Worker Incident Report*
- Non-Alberta Health Services Documents:
 - *MEDEC Best Practice Guidelines*
 - *Transportation of Dangerous Goods Regulations (Canada)*

VERSION HISTORY

Date	Action Taken
	Optional: Choose an item