Alberta Health Services

POLICY

**TITLE**
# MEDICAL DEVICE SAFETY

**SCOPE**
Provincial

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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 promote the safety of **patients** and **Alberta Health Services (AHS) representatives** who use **medical devices** by ensuring:
    - appropriate acquisition, operation, training, reprocessing, support, and maintenance of medical devices authorized by Health Canada at AHS;
    - robust medical device **post-market surveillance** and **investigation** practices to enhance patient safety and Workplace Health and Safety (WHS) practices; and
    - timely and effective responses to medical device **safety notifications** including **recalls**.

## PRINCIPLES

Medical device safety is a shared responsibility between the federal and provincial governments, **manufacturers**, **importers**, **distributors** (**vendors**), health care organizations, and patients.

Health and safety risks to patients and AHS representatives may arise directly through the use of medical devices. Patient treatment decisions are based on an understanding of known risks and expected benefits of the use of medical devices. Risks to patients and AHS representatives may also arise indirectly through **medical device problems (MDP)** or other circumstances that compromise the effectiveness, benefits, performance characteristics, or safe use of a medical device. AHS is committed to improving patient safety by promoting practices that identify, manage, and reduce the direct and indirect risk associated with medical devices.

AHS is committed to a culture of safety and learning that includes detecting, reporting, tracking, and monitoring **close calls**, **hazards**, and **medical device incidents (MDI)** in which AHS representatives using medical devices may have been a factor.

## 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. Acquisition, Training, Use, Reprocessing, and Maintenance

1.1 AHS **program group** acquisition decision-makers, in accordance with approval levels set out in the AHS *Delegation of Approval Authority* Policy, shall only acquire medical devices that are authorized by Health Canada which includes the following:

a) Establishment Licence (for Class I medical devices);

b) Medical Device Licence (for Classes II-IV medical devices);

c) Special Access Programme authorization for patient-specific use of an otherwise unlicensed medical device; or

d) Investigational Testing Authorization for human clinical studies.

1.2 Medical devices that do not meet the requirements as outlined by the *Medical Devices Regulations* (Canada) shall not be acquired within AHS unless there has been a **risk-benefit assessment** and documented approval by the appropriate level of program group leadership according to the scope of the decision.

1.3 Medical device acquisition decision-makers shall review the **manufacturer's instructions for use (MIFU)** for medical devices under consideration and ensure that the device and its MIFU requirements are compatible within AHS and the site/program. This review may include consultation with:

a) AHS representatives who use medical devices;

b) Infection Prevention & Control (IPC);

c) Medical Device Reprocessing (MDR);

d) Clinical Engineering;

e) Facilities Maintenance & Engineering (FM&E);

f) Information Technology (IT);

g) eSafety;

h) Human Factors; and

i) other clinical, medical device, and support experts, as appropriate.

1.4 Medical device safety, effectiveness, and intended performance throughout the life of the medical device are the responsibility of the manufacturer, when the manufacturer's labelling and MIFU are followed. AHS representatives shall follow medical device manufacturers' labelling and MIFU to minimize risks to health and safety.

a) AHS representatives using medical devices shall be trained (e.g., by the vendor, internal clinical education) to use medical devices safely and effectively according to MIFU and applicable professional regulations and standards.

1.5 AHS representatives using medical devices shall routinely avoid **abnormal use** ('off-label' use).

a) In urgent or emergent situations where device or other patient management options are limited, the **most responsible health practitioner (MRHP)** may review individual circumstances and use appropriate judgement to determine if the best options for patient management include abnormal use of a medical device. The MRHP may determine, based on individual circumstances, that using an available device outside of labelling or MIFU is the best option for that patient at that time. Document the situation in the patient's **health record** and proceed accordingly.

b) If ongoing and/or routine abnormal use of a medical device is requested, then the requestors shall provide a Briefing Note including risk-benefit assessment and seek approval from the appropriate level of program group leadership according to the scope of the decision (site, program, Zone, provincial).

1.6 AHS medical devices shall be reprocessed according to MIFU and applicable standards, including but not limited to, the Canadian Standards Association (CSA), Alberta Health standards, and appropriate AHS reprocessing policies and processes.

a) Exceptions: In certain circumstances where MIFU appear to be inadequate or non-compatible with accepted standards, policies, processes, or reprocessing options, particularly for a unique medical device, it may be appropriate to consider alternate evidence-based reprocessing procedures rather than the MIFU-recommended procedures.

(i) Alternate evidence-based reprocessing procedures should be assessed for health and safety risk/benefit, and compared to the risks and benefits of other options. At minimum, the following options shall be considered:

- following the MIFU procedures;
- using a different medical device; or
- using no medical device.

(ii) If alternate evidence-based reprocessing procedures are determined to be the best option based on the outcome of the risk-benefit assessment, the decision-making group (at minimum, representatives from the corresponding level of clinical program [site, Zone, provincial], IPC, and MDR departments) shall attempt to secure vendor approval or validation of the preferred alternate evidence-based reprocessing procedure before implementing the alternate reprocessing procedures. The vendor's input shall be considered prior to the final decision by the decision-making group.

(iii) Any approval decisions for alternate evidence-based reprocessing shall be reviewed at regular intervals by the original decision-making group. The assessment, approval, and review documents shall be available to reviewers at the level of clinical, IPC, and MDR leadership according to the scope of the decision (site, Zone, provincial), as well as the MDR Quality Committee, and other oversight groups (such as Accreditation Canada) as required.

1.7 AHS medical devices shall be supported and maintained according to MIFU and applicable standards by the responsible **AHS service group**.

a) **Equipment** shall be serviced only by qualified personnel.

b) In circumstances where the cost of MIFU-defined service or maintenance is prohibitive and qualified service and maintenance personnel exist within AHS, it may be appropriate for medical device service and maintenance to be performed by qualified personnel in a way that is not included in the MIFU (e.g., by 'non-vendor' qualified personnel).

(i) Site, Zone, or program group leadership shall attempt to secure vendor approval of the non-vendor qualified personnel prior to the decision.

1.8 Medical devices that are not owned or issued by AHS are the responsibility of the owner or operator to use, clean, and maintain safely and effectively according to labelling and MIFU.

## 2. Medical Device Incident or Problem Reporting – Post-Market Surveillance

2.1 AHS representatives using medical devices shall promote patient safety by reporting actual or potential MDIs and MDPs to AHS **Medical Device Safety (MDS) responsible departments** through established mechanisms.

2.2 Reporting MDIs or MDPs to AHS MDS responsible departments, regardless of suspected root causes, is required for AHS compliance with Health Canada regulations and for improvements in safety and medical devices.

a) AHS MDS responsible departments shall report MDIs or MDPs internally and externally, including to Health Canada.

b) AHS MDS responsible departments shall use AHS post-market surveillance reports to minimize risk to patients, AHS representatives using medical devices, and to improve medical device safety and effectiveness by:

(i) managing and investigating individual MDI or MDP reports;

(ii) monitoring aggregated report information for trends and opportunities for mitigation and improvement;

(iii) developing mitigation and improvement plans prioritized based on risk; and

(iv) coordinating mitigation and improvement actions.

## 3. Medical Device Safety Notifications Including Recalls

3.1 AHS shall follow established mechanisms to receive, retrieve, review, and respond to medical device safety notifications including recalls, which may affect AHS or **medical device-related entities**.

3.2 AHS MDS responsible departments shall promote timely acquisition of information and an organization-wide, coordinated response to medical device safety notifications through province-wide mechanisms wherever possible, including centralized intake and screening as per the AHS *Medical Device Incident or Problem Reporting* Procedure.

3.3 AHS MDS responsible departments and **designated specialty areas** handling specialty-only safety notices shall:

a) determine the most appropriate response to safety notifications through risk-benefit assessment and collaboration with stakeholders such as the vendor, clinical experts, supply chain experts (Contracting, Procurement & Supply Management [CPSM]), Legal Services, Clinical Engineering, and others as required;

b) identify potentially affected clinical areas through internal and external validation procedures (see AHS *Medical Device Recall* Procedure);

c) notify AHS representatives using or potentially using affected medical devices and others as required about the MDP and mitigation actions to be taken, using standardized communication and communication distribution mechanisms (e.g., an Equipment & **Product** [E&P] Advisory); and

d) target communication as much as possible, balancing the risk of over-distribution (alert fatigue) with the risk of under-distribution (missing a location where AHS representatives might be using an affected medical device).

3.4 The AHS MDS responsible department shall monitor the effectiveness of communication through an **effectiveness check** mechanism.

3.5 Managers of clinical areas affected by medical device recalls shall ensure all actions as described in the safety communication (e.g., E&P Advisory) are completed, including effectiveness checks.

3.6 CPSM and Capital Management shall facilitate fulfillment of AHS' or medical device-related entities' recall actions, vendor recall contractual obligations, and AHS recall documentation requirements through standard CPSM and Capital Management processes.

## DEFINITIONS

**Abnormal use** means an act, or omission of an act, by the user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted. Abnormal use includes intentional use for a non-approved purpose ("off-label" use) or that is not covered by the terms of its licensing. Health Canada states that "abnormal use should be managed by the health care facility and the appropriate provincial or territorial departments of health." Examples of abnormal use include the following:

- Failure to follow clinical instructions for use due to inadequate training.
- Failure to conduct medical device inspection prior to each use as defined by the manufacturer.
- Failure to follow reprocessing instructions due to unavailability of recommended cleaning products or due to insufficient human resources.
- Continued use of a medical device beyond the manufacturer-defined, planned maintenance interval as a result of user's failure to arrange for maintenance.
- Use of a device for a different indication, or in a different environment or or under different conditions than indicated.

**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).

**Close call** means an event that has potential for harm and is intercepted or corrected prior to reaching the patient.

**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.

**Distributor** means a person other than a manufacturer, an importer, or a retailer who sells a medical device in Canada for the purpose of resale or use other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.

**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).

**Hazard** means a situation that has potential for harm and does not involve a patient.

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

**Importer** means a person, other than the manufacturer of a medical device, who causes the medical device to be brought into Canada for sale.

**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** means a person (including a partnership, firm, or association) who sells a medical device under their own name, or under a trade-mark, design, trade name, or other name or mark, owned or controlled by the person, and with respect to the medical device, is responsible for the following: 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 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-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.

**Post-market surveillance** means an integrated set of activities for the monitoring, assessment (evaluation), and risk management of marketed health products, and is a continuation of the regulated health product review process initiated in the pre-approval areas of the product development process.

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

**Program group** means and includes, but is not limited to, a portfolio, department, division, sector or group within the AHS organizational structure.

**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.

**Risk-benefit assessment** means a mechanism that weighs the potential risks or hazards associated with a medical device against the benefits of that product to a specific individual or population. It is used to determine whether or not the overall benefits of treating the individual or population with that device outweigh the risks. For example, in the recall context, it is used to determine whether or not a device under recall should continue to be used at AHS and under what circumstances. In a reprocessing-related context, when manufacturer’s instructions for use (MIFU) for reprocessing do not meet AHS, Alberta Health and/or CSA standards, the risks and benefits of three options are typically compared: (1) reprocessing a device according to MIFU; (2) reprocessing that device another way (e.g., according to CSA standards that are not included in the MIFU), and (3) using a different device for the same population.

**Safety notifications** are safety notices generated and circulated by vendors or regulatory agencies due to potential hazards, non-conformance to claims made about the medical device, or non-conformance to regulations, and describe the required actions medical device users must take in response to the medical device problem, to mitigate risk.

**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

- Appendix A: *Medical Device Safety Suite Overview Diagram*
- Alberta Health Services Governance Documents:
  - *Delegation of Approval Authority* Policy (#1168)
  - *Medical Device Incident or Problem Reporting* Procedure (#PS-103-03)
  - *Medical Device Recall* Procedure (#PS-103-02)
  - *Medical Device Safety – Preparing and Shipping for Investigation* Procedure (#PS-103-01)
- Alberta Health Services Forms:
  - *Product Feedback* Form (#09570)
- Alberta Health Services Resources:
  - *IPC Best Practice Guideline: Pre-Purchase Evaluation of Reusable Medical Devices*
  - *Reporting & Learning System for Patient Safety*
  - *Workplace Health & Safety Incident Management Process*
- Non-Alberta Health Services Documents:
  - *Medical Devices Regulations* (Canada)
  - *Health Canada Guidance on Investigation of Reported Medical Device Problems*
  - *Health Canada Purchase of Licensed Medical Devices for Use in Healthcare Facilities and Requests for Proposal/Information Processes*
  - *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* (Canada)

## VERSION HISTORY

| Date | Action Taken |
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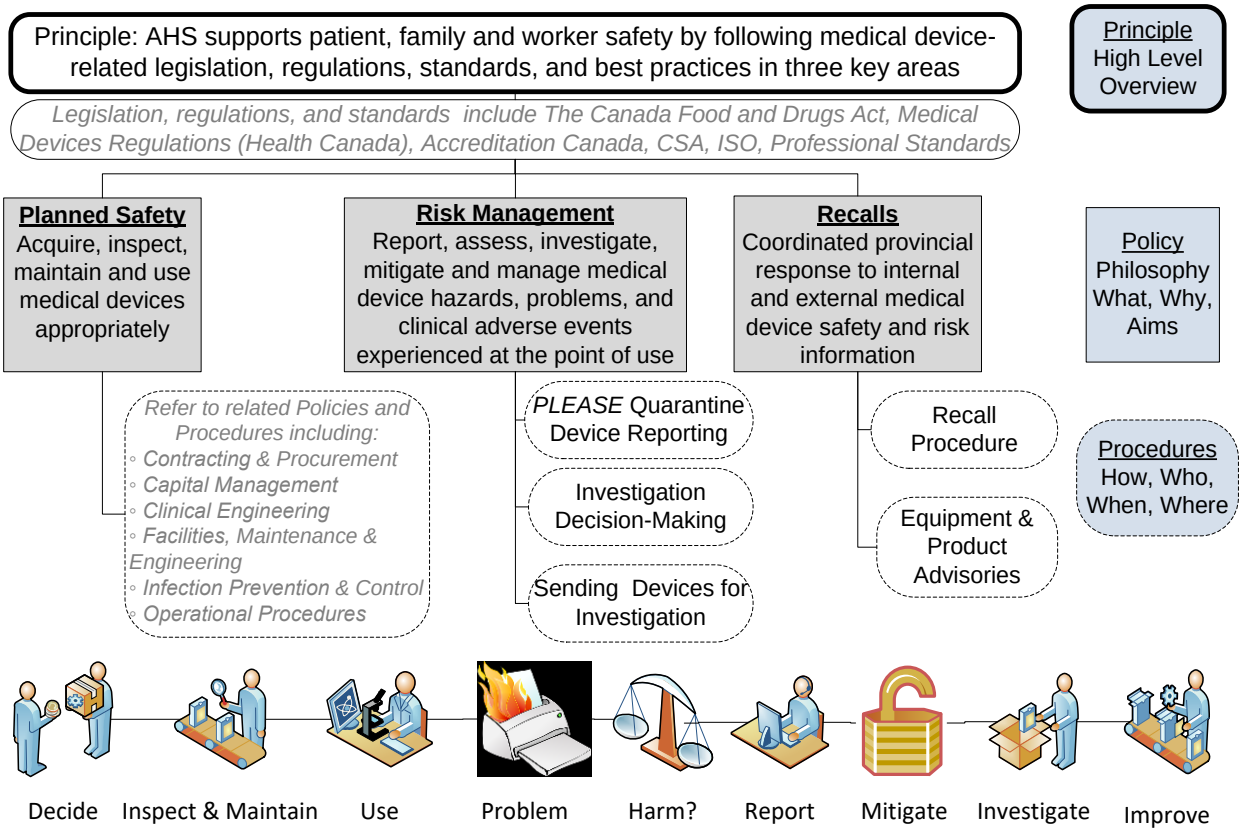
**APPENDIX A**

## Medical Device Safety Suite Overview Diagram




**Note:** Shading indicates the location of this Policy in the suite.