Emergency Health Services – Medical First Responder Provincial Policy

Division	EHS Medical First Responder Program			
Policy Title	EHS MFR Medical Device Recall			
Policy Number	MFR011.00		Retired Number	
Effective Date	Approval Date	Last Review	Approved By	
June 2023	June 2023		J. Walker, MFR Manager	

1.0 Intent:

To set out standards for efficient and effective use of resources when handling medical device recalls and to ensure medical device recall regulatory requirements are met.

2.0 Policy Statement:

2.1 To set out standards for efficient and effective use of resources when handling medical device recalls.

2.2 To facilitate effective management of EHS MFR provided medical devices and recall notifications for equipment used by Medical First Responders.

3.0 Definitions: N/A

4.0 Equipment:

4.1 Zoll AED

4.2 Phillips AED

5.0 Procedures:

5.1 EHS MFR shall request medical device manufacturers, importers, and distributors to send all medical device safety notifications (which includes recall notifications) that affect EHS MFR medical devices to the EHS MFR Coordinator at EHSMFR@emci.ca.

5.2 EHS medical device-related distributors should immediately forward any medical device safety notifications received locally to EHSMFR@emci.ca

5.3 The EHS MFR Coordinator shall monitor EHSMFR@emci.ca and triage incoming notifications to the appropriate EHS MFR Agencies to review and coordinate appropriate actions.

5.4 The EHS MFR Coordinator shall handle safety notifications about medical devices including AEDs, single-use devices, and consumables distributed from EHS MFR.

5.5 The EHS MFR Coordinator confirms all information required to develop a response plan to address the recall/safety information, including but not limited to the following:

1. Identify risk to patients or others associated with the medical device problem (MDP) including:
    a. Establish vendor's Health Hazard Classification and Health Canada's defined type of recall, if possible.

b. Establish frequency and/or estimated likelihood of the problem.
c. Estimate the potential severity of effect if the problem occurred.
d. Gather information about the detectability of the problem before or during use.
e. Establish availability of unaffected replacement devices (for a physical recall) and/or the potential requirement for substitute medical devices.
f. Determine the timing of field corrections or acquiring replacements/substitutes.
g. Consult the EHS Provincial Medical Director to determine the risk of having no devices available for use.
h. Identify the location of recalled medical devices through EHS MFR using purchase history, delivery information, and the vendor's distribution records.

2. EHS MFR Coordinator will determine potential mitigating factors such as:
    a. The availability of exact match or close substitute medical devices from another vendor or EHS stores
    b. Requirements or limitations associated with the use of substitute medical devices.
    c. Other potential opportunities for risk mitigation, such as visual inspections or vendor-prescribed alternate procedures
    d. A requirement of change to clinical practice, the EHS MFR shall refer the matter to clinical experts familiar with the device and its use.
    e. Coordinate with clinical experts and EHS PMD to determine the most appropriate practice changes and to communicate these changes, as required.
    f. The risks to patients and others associated with the various options available, including the risks and benefits of delayed communication about the recall and response plan to the recall including replacement or substitute devices, or corrections.
3. The EHS MFR Coordinator shall consult with stakeholders as required when developing EHS MFR Communications an Response plan, including but not limited to:
    a. EHS Safety
    b. EHS Clinical Development Team to determine clinical-risk assessment.
    c. EHS Systems Support
    d. Health Canada and other regulatory bodies
4. EHS MFR Coordinator will finalize a response plan and execute the communications plan to distribute response plan.

5.6 Communicate the Response Plan and Mitigating Actions

1. The EHS MFR Coordinator communicates the device problem information and mitigation action(s) (as per Section 2 above) to be taken by MFR Agencies and responders that use the devices using standardized communication formats and

processes. As appropriate, a memo or alternative communication mechanism may be used.

2. The medical device safety notification/recall response plans are developed through EHS MFR and EHS Corporate Communications departments. Communications includes:
    a. Clinical Information Advisory to communicate the problem, risk, and mitigation actions to be taken by EHS MFR Agencies using medical devices when there is no physical withdrawal of medical devices.
    b. Clinical Equipment Recall Advisory to communicate the problem, risk, and mitigation actions including removing the medical devices from inventory and providing instructions to MFR Responders about replacement and/or substitute medical devices.
    c. MFR Agency Correction Advisory to communicate the problem, risk, and mitigation actions to be taken by MFR Agencies and responders until a Field Correction is completed. Field Corrections are performed by equipment vendor representatives or internal equipment experts as directed by the vendor.
    d. EHS MFR Update Advisory to communicate additional information and actions to EHS MFR Agencies and responders using medical devices, as required.

5.7 Affected EHS MFR Agencies Complete the Recall Actions. The EHS MFR Agency Coordinators of affected agencies are responsible for ensuring the mitigating actions are completed as appropriate, including but not limited to:
    a. Ensuring all appropriate EHS MFR Responders within the agency that use the device(s) are aware of the device issue and necessary actions.
    b. Completing non-recall safety actions
    c. Completing recall actions by assisting the EHS MFR Coordinator complete the necessary actions.

5.8 The EHS MFR Coordinator shall maintain a record of:
    a. information used to prepare the response and communications plans
    b. all communications about the recall/safety information
    c. communication distribution information

5.9 All records shall be maintained in accordance with the EHS Policy

7.0 Related Policies:

8.0 Policy History:

8.1 Created May 2023.

9.0 References: N/A

10.0 Appendices: N/A