
HAZARD REPORTS AND SAFETY ALERTS

1. Introduction

1.1 Purpose

1.1.1 This policy defines and describes the procedures that ensure LMBME meet the policy objectives and guidelines.

1.1.2 Policy Objective: Risk Management – (CESOP, **Objective 7.9**):

- To minimize device-related risk to patients and staff and on the financial, physical resources and reputation of the organization.

1.1.3 LMBME interpretation of Policy Objective **1.1.1**:

- To minimize device-related risk to:
 - Staff of LMBME.
 - Patients and staff of related groups.
 - The financial and physical resources of LMBME and our funding health organizations.
 - The reputation of LMBME.

1.1.4 Policy Guideline: Hazard Reports and Safety Alerts – (CESOP, **Requirement 7.9.1**):

- The service is involved in processes for managing medical device related hazard reports, alerts, and recalls received by the organization.
- This includes notifying relevant staff of action required and organizing service follow-up to confirm that proper actions are taken.

1.2 Scope

1.2.1 Included:

- **Process:** Hazard Reports and Safety Alerts (CESOP, **Requirement 7.9.1**).

1.3 Exceptions:

- None

2. Policy

2.1 Hazard Reports and Safety Alerts

2.1.1 The Hazards Reports and Safety Alerts process follows policy guidelines:

- CESOP Requirement 7.9.1 – Hazard Reports and Safety Alerts.

Hazard Reports and Safety Alerts

Policy # ABCD-14-11-40003

2.1.2 The Hazard Reports and Safety Alerts process is controlled by standard operating procedures:

- ABCD-14-16-40002 – Hazard Reports and Safety Alerts SOP.

2.1.3 LMBME receives alerts from the **Provincial Alert Coordinator**.

2.1.4 LMBME may discover alerts from other sources such as:

- ECRI – Emergency Care Research Institute.
- Vendor Letters received by LMBME.

2.1.5 LMBME assesses alerts to determine if an alert response is needed:

- An alert response is needed if an asset managed by LMBME is affected.

2.1.6 If an alert response is not needed, LMBME notifies the **Provincial Alert Coordinator** that LMBME is not responding to the alert.

2.1.7 If an alert response is needed, LMBME responds to the alert including:

- LMBME notifies the **Provincial Alert Coordinator** that LMBME is responding to the alert.
- LMBME evaluates the alert information in the context of local considerations.
- LMBME determines corrective actions related to LMBME's scope of service.
- LMBME completes corrective actions.

3. Responsibility

Responsibilities are defined in SOP ABCD-14-16-40002 – Hazard Reports and Safety Alerts.

4. Compliance

All LMBME staff members are responsible for adhering to this policy and monitoring their activities in accordance with the policy. LMBME staff members may warn others if they observe a violation of this policy. Failure by LMBME staff to comply with this policy may result in disciplinary action up to and including termination of employment, services or privileges.

5. Supporting Documents

The Hazard Reports and Safety Alerts process is controlled by standard operating procedures:

- ABCD-14-16-40002 – Hazard Reports and Safety Alerts SOP.

6. Definitions

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Acronym or Word	Definition
Provincial Alert Coordinator	A provincial role: <ul style="list-style-type: none"> Monitors alert sources for new alerts, hazards, and recalls. Distributes alerts, hazards, and recalls to affected groups within the British Columbia Health System.
LMBME	Lower Mainland Biomedical Engineering
VCH	Vancouver Coastal Health
FHA	Fraser Health Authority
PHC	Providence Healthcare
PHSA	Provincial Health Services Authority
Related Groups	VCH, FHA, PHC, PHSA
LMBME's Scope of Service	Services provided by LMBME to related groups within the British Columbia Health System.
Alerts	Alerts, hazards, and recalls.
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
Health Canada	Health Canada
CESOP	Clinical Engineering Standards of Practice for Canada (3 rd Edition)
Alert Response	All consideration and action taken by LMBME to respond to an alert.

7. References

Document No.	Comment
ABCD-14-16-40002	Standard Operating Procedure – Hazard Reports and Safety Alerts
<i>External</i> CESOP	<i>The Canadian Medical and Biological Engineering Society</i> Clinical Standards of Practice for Canada (3 rd Edition)

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Owners:	Engineering Team			
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	1.1	14-SEP-2018	Established requirements for the current practice of the Hazard Reports and Safety Alerts process as per LMBME SOP010 Revision 1.3.	Engineer
	1.2	24-JUL-2019	Revised based on new template requirements.	Engineer

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