**TITLE**

EMS Roles: Medical Device Problems

**SCOPE**

Provincial Emergency Medical Services

**DOCUMENT #**

PS-EMS-03-01

**APPROVAL AUTHORITY**

EMS Senior Provincial Director and Chief Paramedic

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**SPONSOR**

EMS Business Standards and Operations Support

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**PARENT DOCUMENT TITLE, TYPE, AND NUMBER**

Not applicable

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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 support identification and systematic communication regarding medical device (clinical equipment and products) problems identified within Emergency Medical Services (EMS) in a manner that aligns with Alberta Health Services Processes.

- To enhance communication between EMS Clinical Operations, EMS Business Standards & Operations Support (BSOS), EMS Quality & Patient Safety, and appropriate areas of Alberta Health Services (e.g. Contracting, Procurement and Supply Management).

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**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).

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**ELEME NTS**

1. **Role of EMS Staff**

   1.1 Problems with medical devices can be identified at any time by any EMS Staff member. Regardless of whether or not there was a clinical adverse event, EMS Staff shall take the following steps:

   a) Do not discard single use, disposable and/or contaminated medical device in question; keep original packaging and obtain the name of the manufacturer, lot number, expiry date, and serial number as applicable. This information may need to be forwarded on to the Operations Supervisor (Section 2).
b) Consider submission of a Reporting and Learning System (RLS) report for patient safety.

1.2 If the problem resulted in a clinical adverse event, manage the immediate medical needs of patient(s) and EMS Staff, in addition:

a) Refer to the Alberta Health Services (AHS) Immediate Management of Clinical Adverse Events Procedure. Section 4 ("Environmental Safety") can help determine how to proceed with the medical device involved.

b) Prepare the medical device for the PLEASE Quarantine process (Appendix A) and shipping, as required. Refer to the AHS Medical Device Investigation Preparing, Reporting, Packaging and Shipping Procedure.

c) Ensure the PLEASE Quarantine Process (Appendix A) is followed and use the EMS Medical Device Quarantine Label (Appendix B) as applicable.

   (i) EMS Medical Device Quarantine Labels are accessed through zone based EMS Support Services Supervisor(s).

1.3 EMS Staff shall inform the Operations Supervisor of a medical device problem as soon possible. Some examples of problems that must be communicated include, but are not limited to:

   a) medical device defects;
   
   b) failure / malfunction;
   
   c) recall;
   
   d) labelling;
   
   e) contamination;
   
   f) storage environmental issues (e.g., temperature); or
   
   g) limited storage space.

2. Role of the Operations Supervisor

2.1 Refer to AHS Immediate Management of Clinical Adverse Events Procedure to help determine how to proceed with the medical device involved as well as adverse event management, as applicable.

2.2 Notify AHS EMS Operations Management (e.g. Manager on Call) as appropriate.

2.3 Confirm that the PLEASE Quarantine (Appendix A) process and EMS Medical Device Quarantine Label are used, as applicable.

2.4 Complete an AHS Product Feedback Form, as applicable.
2.5 Contact the zone based EMS Support Services Supervisor and, as required, provide;
   a) medical device, relevant packaging, data and/or print outs or materials/information captured in Section 1.1(a),
   b) a copy of the completed AHS Product Feedback Form, and
   c) any other relevant information upon request.

2.6 Await further instruction from the Zone based EMS Support Services Supervisor or the Provincial Manager of EMS Support Services.

3. **Role of the Zone Based EMS Support Services Supervisor**

   3.1 Confirm that the PLEASE Quarantine process and EMS Medical Device Quarantine Label are used, as applicable.

   3.2 In consultation with the Provincial Manager of EMS Support Services, contact the appropriate Zone based EMS Quality & Patient Safety department to help determine if additional AHS departments or programs should be made aware of the problem. These areas may include, but are not limited to:
      a) Patient Safety;
      b) Clinical Engineering Safety (CES);
      c) Contracting Procurement & Supply Management (CPSM);
      d) Product Quality & Safety (PQS).

   3.3 Forward materials gathered as per Section 1 and 2 to the Provincial Manager of EMS Support Services, as requested.

4. **Role of the Provincial Manager of EMS Support Services**

   4.1 Confirm that the PLEASE Quarantine (Appendix A) process and EMS Medical Device Quarantine Label (Appendix B) are used, as appropriate.

   4.2 Identify and communicate with all areas of EMS (operational and non-operational) impacted by the medical device problem.

   4.3 Collaborate with AHS CES and PQS to determine how to manage the problem and the quarantined medical device(s), if any, prior to contacting the vendor.
      a) AHS CES and PQS shall help determine how to manage the problem, and, as applicable, the quarantined medical device(s).
      b) CES and PQS report medical device-related harm to Health Canada, as required, on behalf of EMS.
4.4 Help coordinate sharing of information and corrective actions (if any) to impacted areas within EMS by contacting the most appropriate zone based EMS Quality & Patient Safety department. Consider use of:
   a) AHS Patient Safety Alert or Safer Practice Notice as per the AHS Patient Safety Alerts and Safer Practice Notices Procedure.
   b) AHS Equipment & Product Advisory by contacting the AHS Product Quality & Safety Department.
   c) EMS specific communication (i.e., Frontline Notification, memo) if the problem does not meet requirements to use the established AHS communication processes mentioned in (a) and (b) above.

4.5 Consult with subject matter experts and stakeholders to develop the content of the notification / communication and help determine the distribution mechanism(s).
   a) Submit the resulting communication to AHSEMS.com for posting in the ‘Advisories & Alerts’ section and banner on the home page.

4.6 Update the existing RLS report, or submit a new RLS report, regarding the medical device problem.

DEFINITIONS

Clinical adverse event means an event that reasonably could or does result in an unintended injury or complications arising from health care management, with outcomes that may range from (but are not limited to) death or disability to dissatisfaction with health care management, or require a change in patient care.

Equipment means medical devices that are supported by a designated AHS Department 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.

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

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:
   a) diagnosis, prevention, monitoring, treatment, or alleviation of, or compensation for of a disease, an injury or handicap;
   b) investigation, replacement, or modification of the anatomy or of a physiologic process; and/or
   c) control of conception.
**Note:** At AHS, Covenant and subsidiaries, “Medical Devices” are generally referred to as either “Equipment” or “Product” to correspond with the associated functional work streams (acquisition, maintenance, and risk management processes) associated with Equipment (maintained medical devices) and Product (consumable medical devices and surgical instruments).

**Problem(s)** means, for the purposes of the Medical Device Safety Policy suite, issues attributed to medical device, labelling, or packaging, and include defects, failures, hazards, or malfunctions whether or not the device affected a patient or user.

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

**Quarantine** means effective restriction of the availability of a device for use, until released by a designated authority.

**Reporting & Learning System for Patient Safety (RLS)** means the electronic software program designated by Alberta Health Services to report patient related events resulting in adverse events, close calls, or hazards.

**REFERENCES**

- Appendix A: *PLEASE Quarantine Process*
- Appendix B: *EMS Medical Device Quarantine Label*
- Appendix C: *Managing EMS Medical Device Problems: Process Map*
- Alberta Health Services Governance Documents:
  - Emergency Medical Services Cleaning and Disinfecting, Medical Equipment and Vehicles Procedure (#PS-EMS-02-01)
  - Immediate Management of Clinical Adverse Events Procedure (#PS-95-02)
  - Medical Device Investigation Preparing, Reporting, Packaging and Shipping Procedure (#PS-103-01)
  - Medical Device Problem and Adverse Event Reporting Procedure (#PS-103-03)
  - Medical Device Recall Procedure (#PS-103-02)
  - Medical Device Safety, Risk Management and Recalls Policy (#PS-103)
  - Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy (#PS-95)
- Alberta Health Services Forms:
  - Product Feedback Form

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APPENDIX A

PLEASE Quarantine Process

This AHS process has been modified to meet the needs of the EMS environment.

1. **Preserve** evidence by not changing settings or disconnecting parts unless necessary to do so. In the case of a serious clinical adverse event, consider photographing equipment in place prior to quarantining.
   
a) Ensure identifiable people and/or personal health information is not included within the photo.

2. **Label** the involved medical devices for quarantine and store it locally (e.g. with the EMS service that identified the problem) until further notice from the Provincial Manager of EMS Support Services or EMS Support Services Supervisor.
   
a) *EMS Quarantine* labels must be securely affixed to the medical device and clearly denote that the medical device is removed from service until further notice.

3. **Ensure** the medical device problem is reported to the Provincial Manager of EMS Support Services. The Provincial Manager of EMS Support Services will contact local AHS Clinical Engineering / AHS Medical Device Safety Information Line for assistance.
   
a) Contact the Provincial Manager of EMS Support Services at ems.equipmentandmedicalsupplies@ahs.ca.

4. **Apply** surface disinfection and biohazard containment.
   
a) Refer to the *Emergency Medical Services Cleaning and Disinfecting, Medical Equipment and Vehicles* Procedure.

5. **Send** the quarantined medical device to the designated recipient as per the Provincial Manager of EMS Support Services (or Designate) for quarantine and storage at a zone or provincial level.

6. **Establish** a secure chain of evidence by maintaining product under quarantine until next steps have been determined in consultation with Clinical Engineering and/or Product Quality & Safety.
   
a) If patient harm occurred due to the medical device problem do not release items or information to the vendor until authorized by the appropriate department.
APPENDIX B

EMS Medical Device Quarantine Label

Date: ____________________

Reporter’s name: ______________________________ Reporter’s zone: __________

Type of Medical device:

- [ ] Cardiac monitor
- [ ] IO driver
- [ ] Infusion pump
- [ ] Thermometer
- [ ] Ventilator
- [ ] Point of care testing device
- [ ] Suction unit
- [ ] Other: ____________________________________________

Medical device serial number: _____________________________

1. Notification
   a) Operations Supervisor: [ ]
      - Name of Operations Supervisor: ____________________________
      - Date Notified: ____________________
   b) Zone based EMS Support Services Supervisor: [ ]
      - Name of zone based EMS Support Services Supervisor: __________
      - Date Notified: ______________
   c) Provincial Manager of EMS Support Services: [ ]
      - Contact via email at EMS.EquipmentandMedicalSupplies@ahs.ca
      - Date Notified: ______________

2. Report EMS Staff injury or near misses via MySafetyNet

3. If there was patient involvement, was an RLS created?
   Yes: [ ] Report #__________
   No: [ ]
   Not Applicable: [ ]

4. Provide the reason for quarantine:

____________________________________________________________________
Managing EMS Medical Device Problems: Process Map

Problem with EMS medical device identified.

Roll of EMS Staff:
1. Manage the immediate needs of patients / EMS Staff if problem results in harm.
   - Refer to the AHS Procedure Immediate Management of Clinical Adverse Events (PS-95-02)
   - Refer to the “PLEASE Quarantine” process (Appendix A).
2. Inform the responsible supervisor as soon as possible.

Roll of the Operations Supervisor:
1. Refer to the AHS Procedure Immediate Management of Clinical Adverse Events (PS-95-02).
2. Notify AHS EMS Operations Management (e.g. Manager on Call) as appropriate.
3. Confirm that the “PLEASE Quarantine” process (Appendix A) is followed, as appropriate.
4. Complete an AHS Product Feedback Form, as applicable.
5. Contact the zone based EMS Support Services Supervisor and, as applicable, to provide;
   - relevant packaging, photos and data/print outs, and
   - a copy of the completed AHS Medical/Surgical Product Feedback form
6. Await further instruction from the zone based EMS Support Services Supervisor or the EMS Provincial Manager of EMS Support Services.

Roll of the zone based EMS Support Services Supervisor:
1. Confirm that the ‘PLEASE Quarantine’ process and EMS Medical Device Quarantine Label are used, as applicable.
2. Consult with the Provincial Manager of EMS Support Services and contact the appropriate zone based EMS Quality & Patient Safety (QPS) department to help determine if additional AHS departments/programs should be made aware of the problem.
3. As requested, forward materials gathered/obtained (see sections 1 and 2) to the Provincial Manager of EMS Support Services.

Roll of the Provincial Manager of EMS Support Services:
1. Confirm that the “PLEASE Quarantine” process for medical devices (Appendix A) was followed, as appropriate.
2. Identify and communicate with all areas of EMS impacted by the medication and/or medical device problem.
3. Collaborate with AHS Clinical Engineering and Product Quality & Safety to determine how to manage the problem, and as applicable, the quarantined medical device(s).
4. Help coordinate sharing of the information and corrective actions (if any) to impacted areas within EMS.
5. Consult with subject matter experts and stakeholders to develop the notification / communication, as applicable.
6. Update an existing, or submit a new, RLS report regarding the medical device problem.

EMS medical device problem identified, resolved and communicated to impacted areas within EMS (and AHS as applicable).