MEDICAL DEVICE INCIDENT REPORTING: EQUIPMENT STANDARDS AND PRACTICE

Summary of Changes

	NEW	Previous
BC Cancer		

1. Introduction

1.1. Purpose

This BC Cancer medical device incident (MDI) reporting procedure is to identify medical device incidents and determine the cause so that corrective action can be taken to prevent recurrence working in conjunction with PHSA Risk and Quality Directors.

1.2. Scope (medical device incident/reprocessing failure)

This procedure applies to all BC Cancer/Provincial Health Services Authority (PHSA) staff, employees, contractors, medical staff and students within all BC Cancer programs and services, as well as employees of academic institutions with whom BC Cancer is partner.

This procedure only applies in the event of a serious medical device incident (SMDI) for medical devices that are used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal condition within a BC Cancer program , service or shared care scenario within a host hospital or a breach in reprocessing steps are identified . I.e. an infusion device on a host hospital inpatient is stopped while patient undergoing radiation treatment and the infusion device results in a MDI.

All medical devices must be Health Canada licensed in order to be accepted for use and must have manufacturer written device-specific instructions. Medical devices that have been modified or repaired in-house are not approved for use with patients.

1.3. Exceptions (if necessary)

This program specific procedure does not apply to the following situations:

1) Serious MDIs that occurred outside of Canada

2. Procedure

2.1. Conducting an Incident Investigation

Incident investigations must be conducted immediately upon notification. While conducting an investigation the following priorities should be kept in mind:

- Remove the possibility of further injury to patient
- Attend to the immediate needs of the patients
- Prevent further damage to medical devices and the facilities
- Impound equipment that may be hazardous
- Determine the sequence of events that took place during the incident

- It is not necessary to confirm a causal relationship prior to reporting
- Liaison and notify host health authority if appropriate based on operating agreements and biomedical support provider

3. Responsibilities

3.1. BC Cancer Operations Managers/Leaders and Biomedical Engineering Leads/Handler

- Develop program-specific reporting procedures
- Handle PSLS and notify PHSA Quality and Risk Directors
- Implement and educate relating to the process for reporting, managing, following up and submitting serious MDIs to Health Canada
- Complete follow-up of serious MDI reports
- Monitor and evaluate serious MDI reporting data
- Comply with the PHSA Use and Reprocessing of Critical and Semi-critical Medical Devices policy #C-99-11-20500

http://shop.healthcarebc.ca/_layouts/15/DocIdRedir.aspx?ID=SHOP-1370806636-102

3.2. BC Cancer Staff

- Report serious MDIs per program procedure. (Appendix 7.2)
- Be accountable for their own performance as established by job performance requirements and, if applicable, professional practice standard
- Participate in review, follow-up and planning initiatives relating to serious MDI reports as appropriate
- Will support other staff to locate and understand this procedure and/or advise leadership of the need for education and support regarding the procedure
- All staff members are responsible for adhering to this procedure and monitoring their activities in accordance with the procedure. Staff members may warn others if they observe a violation of this procedure

3.3 PSLS Central Office

- Manage and review the serious MDI reporter form
- Provide serious MDI reports to Health Canada per the Medical Device Regulations

4. Supporting Documents

4.1 Related Policies

The following policies are located on SHOP: http://shop.healthcarebc.ca/

Serious Adverse Drug Reactions: Reporting to Health Canada

PHSA Use and Reprocessing of Critical and Semi-critical medical devices C-99-11-20500

4.2 Forms

PHSA On-Line PSLS MDI Reporter Form

5. Definitions

5.1 Definition of a medical device

Any article, instrument or apparatus which is sold or represented for use, in the diagnosis, treatment or prevention of disease or abnormal physical state, or for correcting human body functions.

- **"Medical Device"** covers a wide range of health and/or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Medical Devices are classified into Class I (lowest risk) to Class IV (highest risk). Examples are:
    a) Class I: hospital beds, wheelchairs, leg prosthesis
    b) Class II: Infusion sets, syringes, tracheostomy tubes, urethral catheters
    c) Class III: Infusion pumps, anesthesia gas machines, intrauterine devices
    d) Class IV: Pacemakers, defibrillators, breast implants, bone grafts

The use of a medical device or medical equipment within the BC Cancer shall be used in such a manner that ensures the following requirements are met:

- All medical devices/equipment must be on a preventative maintenance program as determined by priority (appendix 7.1), and cleaned between patient use following manufacturer's instructions for use (MIFU)
- Employees shall receive necessary training and education to use, operate, and reprocess any medical devices/equipment
- In the event biomedical equipment used within a BC Cancer facility, in relation to a host health authority and an operating agreement, the BC Cancer shall use the biomedical equipment and any necessary protocols, records, and /or documentation

in accordance with the health authority's policy and procedure in order to ensure standardization, and to minimize possible adverse events

- BC Cancer will only use health authority loaned equipment in an emergent patient care situation and only staff that receive annual recertification or have the necessary training may operate the equipment

5.2 Definition of an "incident involving a medical device"

- Any failure, apparent malfunction, poor design or possible error in the use of a medical device or electrical facility: has, may have or has the potential to have adversely affected the quality of patient care, or caused injury to patients or staff
- Any event in which a patient is unexpectedly seriously injured or dies while connected to a medical device
- Any event involving a medical device which results in a PSLS incident report

NOTE: Sometimes while doing routine work, a person becomes aware of a non-reported incident. In this case contact the clinical area and discuss the event and recommend that it be reported as an incident. Do as much of a follow-up as is possible and where possible report the findings and recommendations to the appropriate people.

5.3 Other definitions

"Medical Device Incident (MDI)" implies that there is a suspected relatedness to the failure of a Medical Device. Health professionals and consumers report MDIs because of their suspicion of the relatedness of an incident to the medical device. The description of experiences in these reports should therefore be considered MDI

"Handler" is a person responsible for follow-up activities following submission of a report in PSLS

"Serious Medical Device Incident" is an incident related to a failure of a medical device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to occur. Serious MDIs also include those suspected of being the result of the deterioration of effectiveness or an inadequacy of its labelling

6. References

Accreditation Canada (2016). Qmentum program: Leadership standards (version 11). Retrieved from http://www.accreditation.ca/standards/

BC Ministry of Health (2011) *Best Practice Guideline for cleaning, disinfection and sterilization of critical and semi-critical medical devices in BC Health authorities*

Health Canada (2014) Instructions for Medical Device Problem Report Form for Health Professionals to Canada Vigilance. Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-medical-device-problem-reporting-form-industry-adverse-reaction-reporting.html

Health Canada (2018). Reporting Adverse Reactions to Marketed Health Products: Guidance Document for Industry. Retrieved from https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry/reporting-adverse-reactions-marketed-health-products-guidance-industry.pdf

International Council on Harmonisation. (1994) Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (ICH E2A). Retrieved from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2A/Step4/E2A_Guideline.pdf

7. Appendices

7.1 Priority schedule of medical devices

Class IV = Highest Risk/Highest Priority and is considered mandatory
Class III = High Risk/High Priority maintenance is not possible
Class II = Medium Priority and is considered recommended
Class I= Low Priority

Class IV Devices- A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system

Anesthesia Machines	Defibrillator
Blood Warmer	Hypo/Hyperthermia Unit, Water
Pacemaker, Cardiac	Defibrillator, AED
Monitor, End Tidal CO2	Linear Accelerators
Continuous Passive Airway Pressure Unit	Uninterruptible Power Supply, Mandatory Device
HDR Unit	

Level III Devices- A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days

Pacemaker, Cardiac	Renal dialysis
Blood transfusion machine	Cardiopulmonary bypass

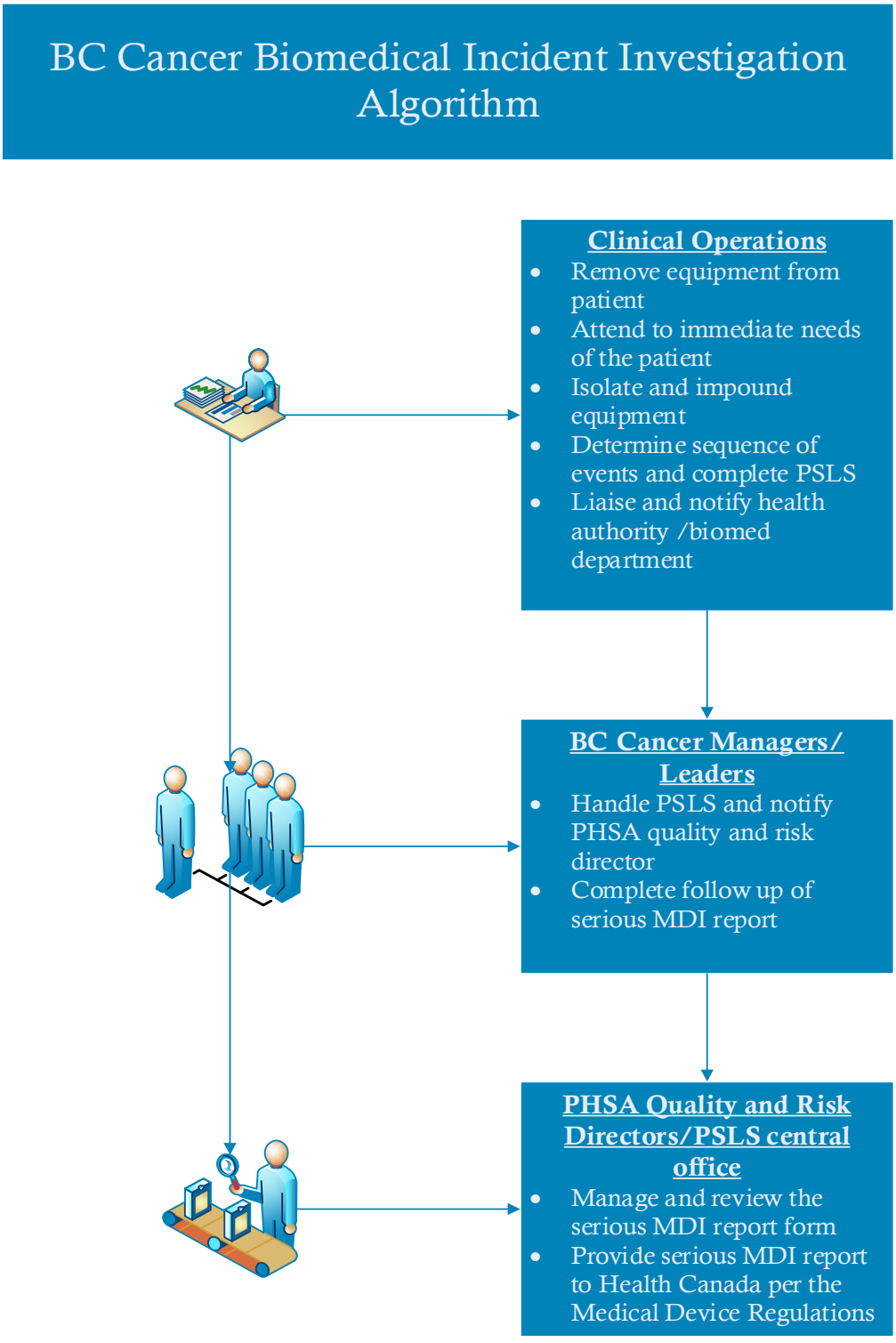
Level II Devices- All non-invasive devices that are intended to come into contact with injured skin, all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye

Electrosurgical Unit	Denture and Orthodontic appliances
Laser, Surgical	Latex condoms
Endoscope, Flexible	Pump, Suction
Pump, Infusion	Pump, Infusion, Syringe
Pump, PCA	Monitor, NIBP
Smoke Evacuator	Uninterruptible Power Supply
Pulse Oximeter/ Vital Signs	Suction, Tracheal
Scanner, Bladder	

Level 1 Devices

Surgical and Dental Instruments	Hospital Bed/Stretcher
Scale, Adult	Microscope, Operating
Thermometer, Patient	

7.2 Incident Investigation Procedure Algorithm



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First Issued:	19-April-2021		
Approving Body:	BC Cancer Quality Council		
Final Sign Off:	**Name**	**Title**	**Date Signed**
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Owner(s):	e.g. name, title/position		
Posted Date:	DD-MMM-YYYY		
Version:			
Revision:	**Name of Reviser**	**Description**	**Date**
	Alannah Bowes	Updated format	03-MAR-2020