PSLS AND MDI REPORTING PROCESS: BIOMEDICAL ENGINEERING

1. Purpose

1.1.1 To define LMBME's (Lower Mainland Biomedical Engineering) methodology for reporting PSLS Events involving medical devices managed by LMBME.

1.1.2 To outline the roles and responsibilities of LMBME in meeting the hospital requirements for mandatory reporting of Medical Device Incidents to Health Canada under Vanessa's Law regulation.

2. Definitions

Acronym or Word	Definition
BCPSLS	British Columbia Patient Safety & Learning System is a web-based tool used by healthcare providers across BC to report patient safety concerns such as actual adverse events, good catches (near misses), and hazards. PSLS helps healthcare providers and leaders collect and analyze information crucial for patient safety and quality improvement. The system is in use across all BC health authorities and in all types of healthcare settings in the province.
Health Authority PSLS Coordinator	Individual responsible for the implementation and support of all modules of the BCPSLS software. Key responsibilities include promoting a patient safety culture through BCPSLS and responding to requests for changes to system configuration to meet the needs of users and maintaining accurate documentation of changes, supporting staff in the use of the system as it evolves, providing reports, analysis and consultation to managers and senior leaders, coordinating the delivery of training in the use of the application and related patient safety practices for healthcare providers across BC and promoting the adoption and application of the software.
BCPSLS Central Office Health Information Specialist	Individual responsible for reporting to Health Canada all PSLS events deemed reportable by relevant hospital staff. This reporting is typically done every Friday.
BMET	Biomedical Engineering Technologist
CMMS	Computerized Maintenance Management System
ECN	Equipment Control Number (LMBME's device identifier/asset number)
Event Handler	Individual managing follow-up activities for PSLS Events. The Event Handler is most often an individual from the department where the Event occurred. Typically, LMBME staff should only be assigned as Event Handlers when LMBME staff under their supervision reports a PSLS Event.
LMBME	Lower Mainland Biomedical Engineering
MDI	Medical Device Incident: 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 another person, or could do so were it to recur.

PSLS Engineer	Responsible for reviewing all PSLS Events involving medical devices managed by LMBME. Determines if these PSLS Events meet the criteria for mandatory reporting of MDI to Health Canada under Vanessa's Law.
PSLS Event	Any unexpected or undesired event directly associated with care or services resulting in harm/injury (or the potential for harm/injury) to a patient. Each PSLS Event is assigned a unique identification number (PSLS ID).
Vanessa's Law	*Protecting Canadians from Unsafe Drugs Act*, Health Canada legislation requiring mandatory reporting from hospitals on adverse drug reactions and medical device incidents within 30 days of event documentation.
WO	Work Order: used to document work in the CMMS

3. Scope

3.1 Included:

3.1.1 All PSLS Events with a device category selected as "Biomedical device or equipment."

3.1.2 All PSLS Events involving a medical device that LMBME supports regardless of the selected device category (LMBME devices may be miscategorized in PSLS reports).

3.1.3 LMBME may participate in investigations of PSLS Events involving devices that LMBME does not typically support (i.e., outside LMBME's typical scope of work). LMBME's participation is determined on a case-by-case basis depending on factors such as (not exclusively):

a) The seriousness of the incident (e.g., severe harm or death or the potential for it)

b) An incident reoccurring without previous resolution

c) A trend in incidents involving the same equipment

d) An incident whereby the manufacturer or vendor responsible for the equipment provided an unsatisfactory response to the incident investigation, and the healthcare organization requests LMBME's opinion on the case

e) A part of a medical device system supported by LMBME is suspected to be a contributing factor to the incident, and parts of this system, which are not typically supported by LMBME, require investigation (e.g., the interaction between consumables/products and medical devices)

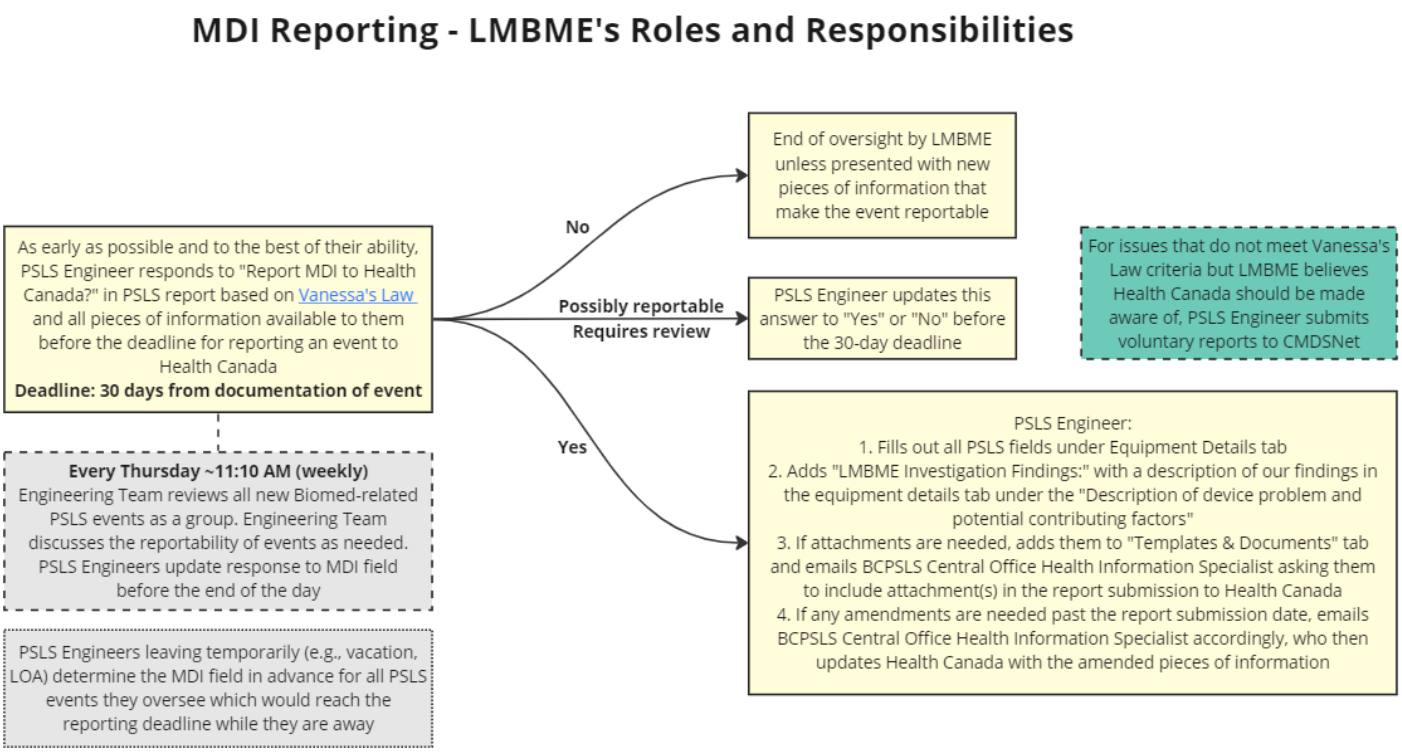
3.2 Excluded:

3.2.1 The majority of PSLS Events involving devices not supported by LMBME (see 3.1.3 for additional details).

4. Procedure

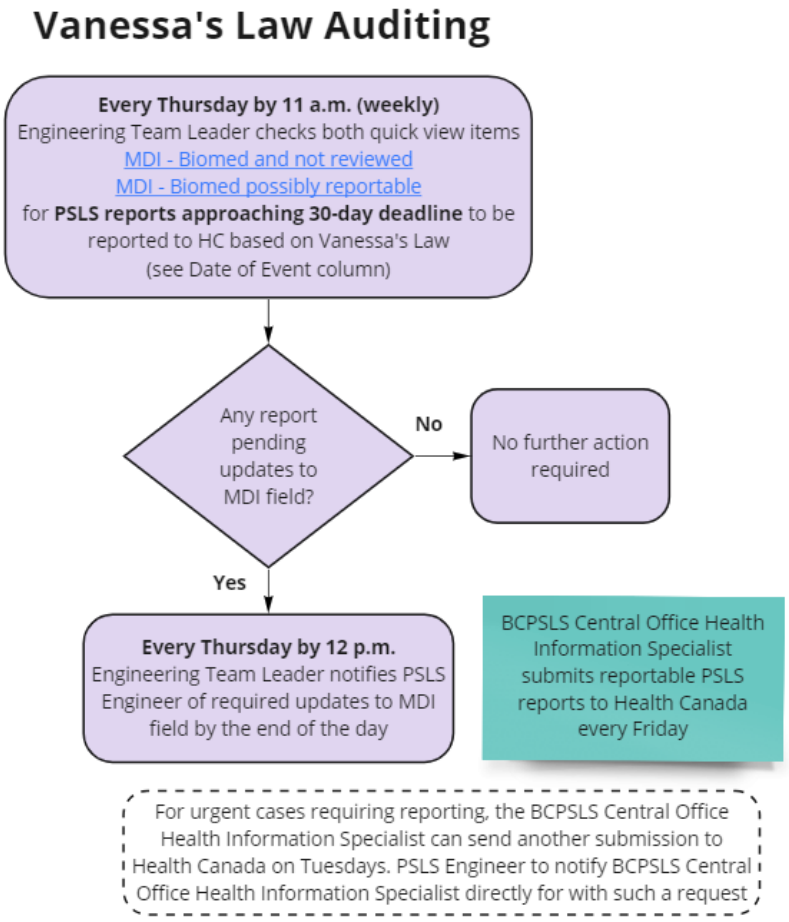
4.1 LMBME's methodology for investigating PSLS Events involving medical devices managed by LMBME is outlined in SOP # ABCD-14-16-40005 Incident Investigations: Biomedical Engineering.

4.2 LMBME's roles and responsibilities in meeting the hospital requirements for mandatory reporting of MDIs to Health Canada under Vanessa's Law regulation are the following:

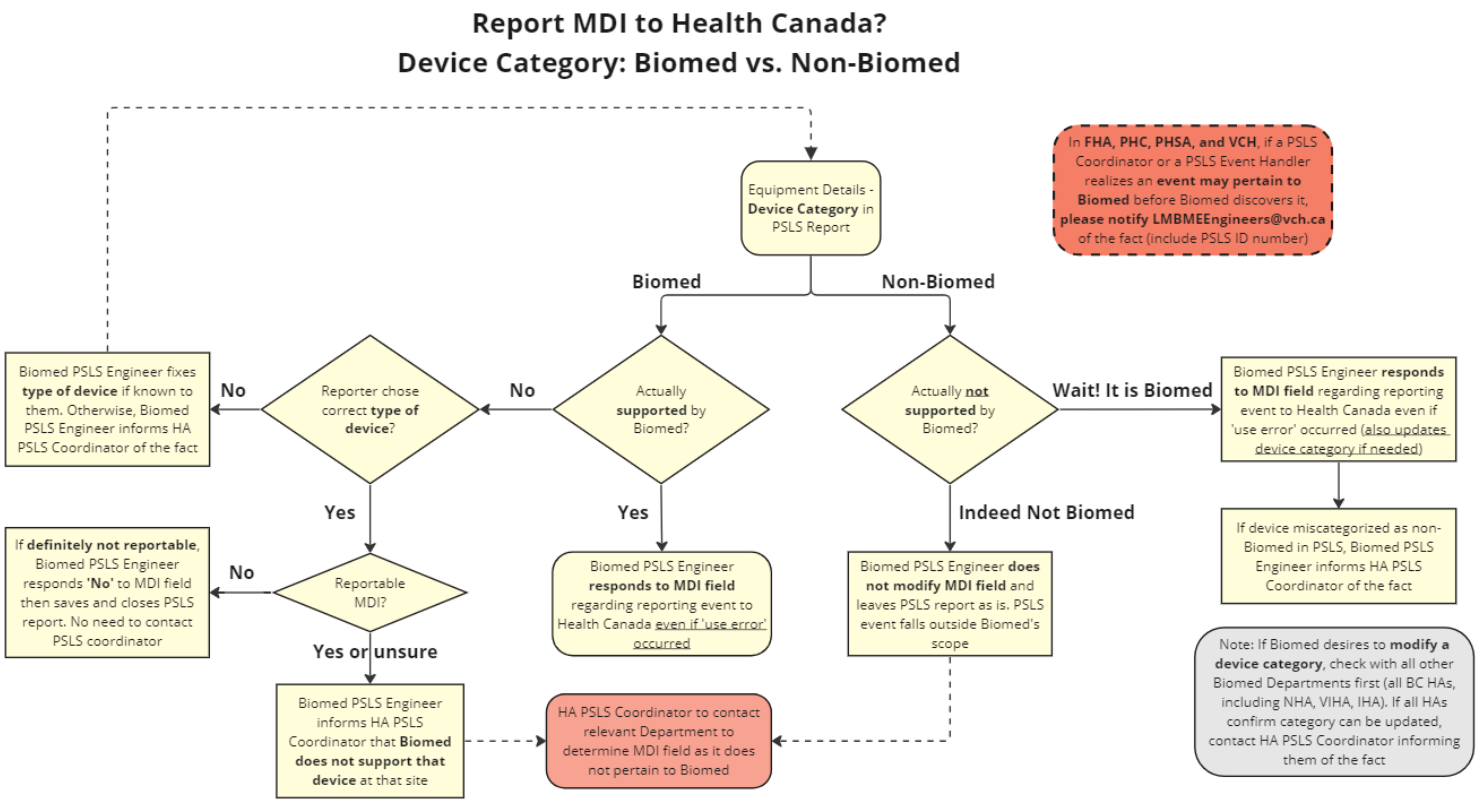


a) Notably, PSLS Engineers report MDIs that meet the mandatory reporting criteria within 30 days of event documentation for devices that LMBME supports.

4.3 LMBME's auditing process for Vanessa's Law compliance is the following:



4.4 LMBME's procedure for handling PSLS events miscategorized in BCPSLS is the following:



a) The roles and responsibilities in this procedure have been agreed upon with BCPSLS Coordinators from all healthcare organizations LMBME supports.

b) All the above processes can be found online in the following shared dashboard. This dashboard is updated as needed based on developments in the regulatory environment or relevant systems affecting the workflow (e.g., updates to BCPSLS).

5. Reference Documents

LMBME SOP # ABCD-14-16-40005 Incident Investigations: Biomedical Engineering (in development)

Health Canada Regulations: Mandatory Reporting Requirements for Hospitals (Vanessa's Law)

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	1.0	08-DEC-2023	Complete re-write of previous PSLS and MDI Reporting SOP	LM Engineering Manager