

## Medical Device Incident Reporting Guideline for Laboratory Medicine

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### Purpose

The purpose of this guideline is to:

- Communicate the Health Canada definition of a Medical Device Incident (MDI)
- Clarify the criteria for reporting to meet the requirements specific to laboratory medicine as set forth in the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law)
- Provide laboratory medicine organizations within British Columbia (BC) with general information and guidance for reporting MDIs related to laboratory medicine

### Background

In November 2014, the Government of Canada ascended the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), as an amendment to the *Food and Drugs Act*, to protect Canadians from the risks related to drugs and medical devices.<sup>1</sup>

On December 16, 2019, regulations came into effect which require **hospitals** to report all serious harm events related to the unexpected malfunction of any medical device, including laboratory equipment, reagents, and supplies, to Health Canada.<sup>2</sup> The laboratory service provider organizations are seeking clear, standardized parameters to enable them to appropriately meet their legal requirement to report.

### Scope

Adverse events related to the transfusion of blood or blood products, including manufactured products such as albumin, purified plasma proteins, or other products are reported through the [Provincial Blood Coordinating Office](#). The [Transfusion Transmitted Injuries Surveillance System](#) describes the reporting responsibilities based on a separate portion of the law. As such, these are not included within the scope of this guideline.

### Definitions

<b>Adverse Event</b>	Any undesirable experience associated with the use of a medical product or device directly involving a patient. <sup>3</sup>
<b>Medical Device</b>	Any manufactured product which is licensed to be used for therapeutic, diagnostic, or patient management purposes including medical laboratory diagnostic instruments and test kits for diagnosis. <sup>2</sup>
<b>Medical Device Incident (MDI)</b>	"...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 recur." <sup>2,4</sup> Specifically, the failure is such that the manufacturer is responsible for providing the corrective remedy. <sup>5</sup>
<b>Non-Conforming Event (NCE)</b>	"An occurrence that does not conform to the laboratory's policies, processes, and/or procedures; does not conform with applicable regulatory or accreditation requirements; or has the potential to affect (or has affected) patient, donor, or employee safety." <sup>6</sup>
<b>Serious Harm</b>	An adverse event in which the patient outcome is death, life-threatening, disability or permanent damage, or initial or prolonged hospitalization. <sup>3</sup>

### Supporting information

The legislation, as written, specifically requires a **hospital** to report an adverse event or MDI regardless of the location of occurrence, if that incident is documented at the hospital.<sup>4</sup> Other facilities or organizations are encouraged to voluntarily report incidents as a means to heighten surveillance of MDIs, enabling Health Canada to link seemingly isolated events across the country to establish patterns of medical device failure. Private laboratory organizations can report an MDI through the [Mandatory Medical Device Problem Reporting Form for Industry](#).

### Guidance

The first criteria for reporting is that the medical device, reagent, or supply used for health care purposes is not operating as expected and the manufacturer is responsible for providing a remedy. The law also includes events which occur due to “deterioration of effectiveness.” Although this language applies most directly to medication, within the context of laboratory testing, this could broadly include an **unexpected** incident that occurs when an analyzer test system is not performing to previously demonstrable specifications despite proper maintenance, calibration, and operation and for which the manufacturer has no known remedy. Initial validation procedures should detect equipment that is not operating to required specifications prior to being put into use. Once implemented, malfunctions may be detected during routine quality control processes which do not resolve an issue.

A malfunction that is known by the manufacturer, for which there is an appropriate remedy, is not necessarily considered a reportable MDI. For example, instruments may have built-in alarm systems or stop mechanisms to prevent an MDI. Only when these systems fail unexpectedly would it fall into the category of a reportable MDI.

In the context of laboratory medicine, inadequacy of labelling would include errors due to incorrect, inappropriate, or misleading Instructions for Use (IFU) from the manufacturer which, when followed as written, caused the error to occur.<sup>4</sup> Although not a frequent occurrence, this should be kept in mind when considering a process or procedural failure. If it is determined that the incident is due to the manufacturer’s error, this should be reported as an MDI.

Equipment, reagent, or supply failure due to improper maintenance or other deviation from proper procedural performance, as defined in the manufacturer’s IFU or other instructional recommendations, is not an MDI. Process or procedural deficiencies that are due to internal practices are the responsibility of the organization to remedy. These scenarios are still reportable as non-conforming events (NCE) for tracking purposes, and for appropriate corrective action and follow-up; however, within the health authorities, these should be reported in the BC Patient Safety Learning System (PSLS) under the Lab category, not MDI.

Second, only those unexpected incidents causing, potentially causing, or possibly linked to or suspected of causing a person’s death or serious deterioration in health which involve laboratory equipment, reagents or supplies are required to be reported as an MDI.<sup>2</sup> In the laboratory, direct serious harm events would be those which occur from interaction with the patient, user, or other person. There are relatively few incidents where an unexpected failure of laboratory equipment or supply is *directly* responsible for causing serious harm or death. Examples would be malfunction of blood collection equipment, such as venipuncture needles, capillary puncture devices or blood gas syringes, or during use of point-of-care devices at the bedside.

It is more likely that an incident could be *indirectly* responsible for serious patient or user harm or death. Indirect incidents can broadly include reporting erroneous or unreliable results while the equipment or reagent was functioning unexpectedly if those results could lead to medical decisions which cause or could cause serious harm. However, the harm outcome due to a laboratory equipment, reagent, or supply failure is often unknown and may be unknowable. When harm cannot be clearly demonstrated or linked to a specific event, laboratories are not required to report. Suspected malfunctions should be reported to the manufacturer. Laboratories can use professional judgment and are encouraged to err on the side of caution when deciding whether the malfunction could cause a harm incident which should be reported to Health Canada.

It is not the laboratory's responsibility to determine the root cause although any and all information regarding how the incident occurred will assist the manufacturer to facilitate resolution of the problem.<sup>2</sup>

### **Recommendations**

Laboratory personnel in the public healthcare system are required to document and report any occurrence of serious harm, or potential harm resulting from the unexpected malfunction of a manufactured equipment, product or supply, or due to incorrect or unclear operating instructions. Report using the MDI icon in the BC PSLs System.

Private laboratory organizations are encouraged to report any occurrence of serious harm, or potential harm resulting from the unexpected malfunction of a manufactured equipment, product or supply, or due to incorrect or unclear operating instructions. Report using the [Mandatory Medical Device Problem Reporting Form for Industry](#).

In instances where there is no requirement by law to report an MDI, laboratories are encouraged to report potential serious harm incidents to the manufacturer so that the manufacturer may act proactively to reduce risk.<sup>2</sup> Laboratories can use professional judgment and are encouraged to also report incidents to Health Canada, even without a clear link to patient harm, in an over-abundance of caution for patient safety.

### **References**

- 1 Government of Canada. Statutes of Canada 2014, Chapter 24 (Bill C-17). Assented 2014Nov6. Retrieved on 2020Apr29 from [https://www.parl.ca/Content/Bills/412/Government/C-17/C-17\\_4/C-17\\_4.PDF](https://www.parl.ca/Content/Bills/412/Government/C-17/C-17_4/C-17_4.PDF)
- 2 Health Canada. Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals – Guidance document. June 2019. Retrieved 2020Apr20 from <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/drugs-devices/guidance/Mandatory-reporting-hospitals-eng.pdf>
- 3 US Food and Drug Administration. What is a Serious Adverse Event? [Webpage]. Current as of Feb 1, 2016. Accessed 2020-07-10 from <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>.
- 4 Government of Canada. Medical Devices Regulations, SOR/98-282. Last updated 2019Dec16. Retrieved on 2020Apr30 from <https://laws-lois.justice.gc.ca/PDF/SOR-98-282.pdf>.
- 5 BC PSLs Central. Everything you need to know about medical device incident reporting for Vanessa's Law. Retrieved 2020Apr20 from <https://bcpslscentral.ca/everything-you-need-to-know-about-medical-device-incident-reporting-for-vanessas-law/>

- 6 Clinical and Laboratory Standards Institute (CLSI). Nonconforming Event Management. 2nd ed. CLSI guideline QMS11 (ISBN 1-56238-910-6 [Electronic]). CLSI, Wayne, Pennsylvania, USA, 2015.
- 7 Government of Canada. Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals – Guidance document [Webpage]. Revision date: 2019Nov04. Retrieved 2020Apr20 from <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html>

### **Appendices**

Appendix A: Requirements for reporting an NCE as an MDI

Appendix B: Process for Reporting MDI to Health Canada

Appendix C: Mandatory Medical Device Problem Reporting Process Flowchart

Appendix D: Frequently asked questions

## **Appendix A: Requirements for reporting an NCE as an MDI:**

### Mandatory Requirements:

The failure of the medical device, reagent, or supply used for health care purposes:

- Must cause serious or the potential for serious harm or death to a patient, user, or other person
- Must be an unexpected incident related to the use of equipment, reagent, or supply
- Must be documented in a hospital or public health care facility
- Must be reported within 30 days of event occurrence

Where there is no mandatory requirement to report, use professional judgment. In general, over-reporting is more helpful for Health Canada to see documented evidence of incidents as it has the ability to track incidents on a national level. If the decision is made to report, health authority laboratories should report in PSLs using the MDI icon. Private laboratories report directly to Health Canada using [Mandatory Medical Device Problem Reporting Form for Industry](#)

### Non-mandatory Adverse Event Reporting:

Report (non-mandatory) an MDI even if:

- Its association with the medical device is only suspected
- Causality is not confirmed
- All the details are not known
- It may or may not be serious<sup>5</sup>

NCE which are not MDI (do not report):

- Deficiencies that would be detected prior to use (e.g. issues addressed during the equipment validation process, issues detected by quality control failure and corrected through laboratory processes, issues discovered during manufacturer-defined maintenance checks)<sup>4</sup>
- Incidents caused by a patient's condition (e.g. a patient with end-stage renal disease dies of renal failure after dialysis treatment)<sup>4</sup>
- Malfunctions where built-in protections operate correctly (e.g. laboratory equipment malfunctions, gives alarm, and stops before harm [i.e. erroneous result is reported] occurs)<sup>4</sup>
- Incidents caused by internal process or procedural error. These events should be reported as Laboratory NCE. Use PSLs – Lab icon within health authorities. Private laboratories use their internal NCE reporting process.

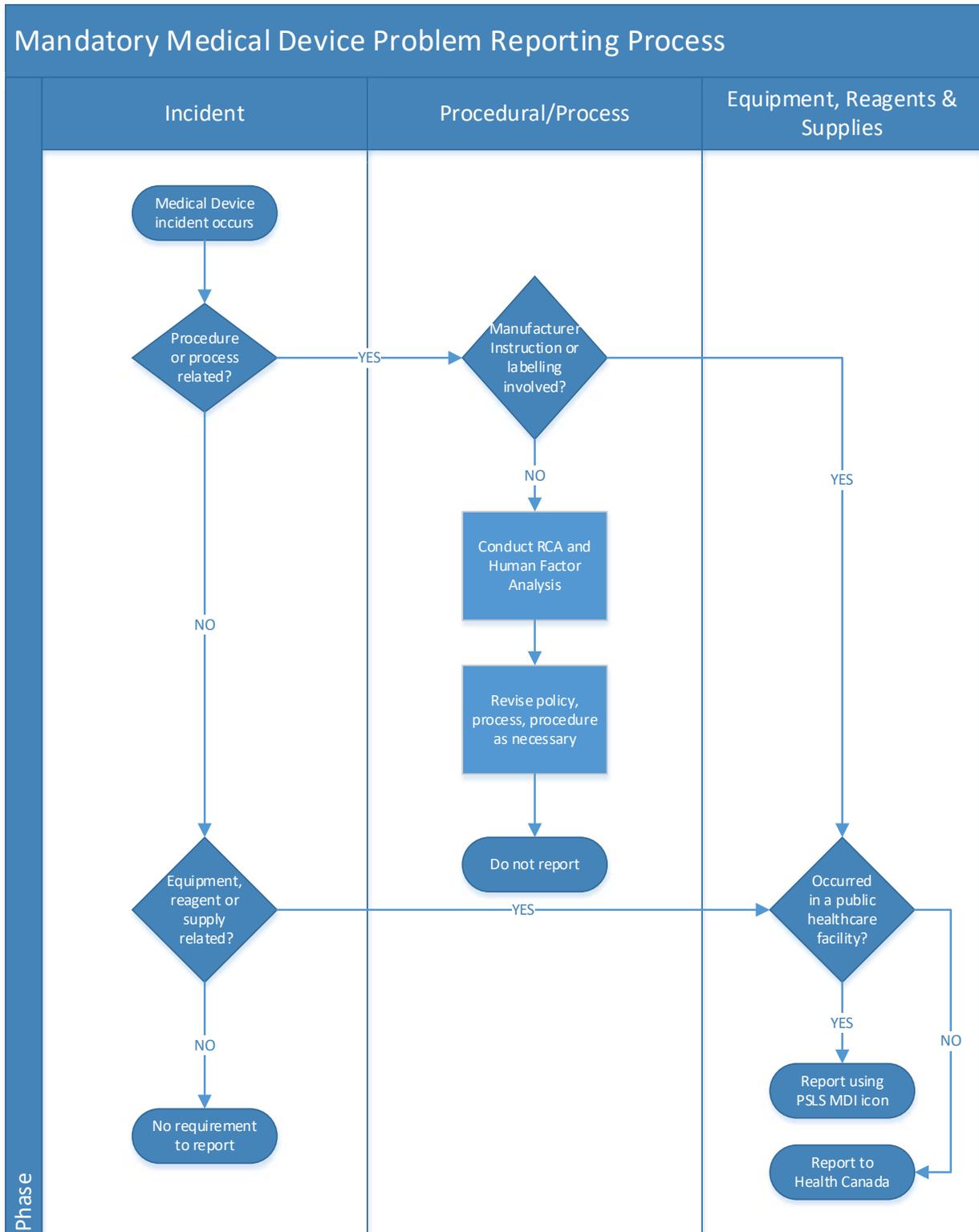
Upon discovering an MDI:<sup>5</sup>

- Identify and isolate the suspected equipment and any related accessories, reagents, or supplies
- Remove from service if possible
- Alert supervisor and BioMed (as appropriate)
- Supervisor or BioMed: Report incident to manufacturer and to supply chain (as appropriate)
- Communicate occurrence to other staff members (use troubleshooting log, staff hand-over communication practices, etc.)
- Capture photo/video documentation of malfunction during operation, if possible
- Document the NCE through the organization's established reporting system
- Report to Health Canada within 30 days: Health authorities use PSLs – MDI icon. Private labs use [Mandatory Medical Device Problem Reporting Form for Industry](#)

## Appendix B: NCE Evaluation Process to determine need to report MDI to Health Canada

1. Did an event occur involving any laboratory equipment, reagent, or supply that caused, or, if the event were to recur, has the potential to cause, serious harm to a patient(s), user, or other person?
  - Yes – See **step 2**
  - No – Do not report as an MDI.
2. Was the incident due to an error in process or procedure?
  - Yes – See **step 3**
  - No – See **step 5**
3. Was the incident due to an issue with the Manufacturer’s Instructions for Use or reagent or supply labelling?
  - Yes – Report using PSLs – MDI icon
  - No – See **step 4**
4. Were institutional policies, processes and procedures followed as written?
  - Yes – Conduct Root Cause Analysis (RCA) and Human Factors Analysis  
Revise policy/process/procedure as necessary  
Report as Laboratory NCE
  - No – Follow-up as appropriate  
Report as Laboratory NCE
5. Was the incident related in any way to the **unexpected** operation of any laboratory equipment, reagent or supply?
  - Yes – See **step 6**
  - No – Use professional judgment to determine whether to report to Health Canada or not. In general, over-reporting is more helpful for Health Canada to see documented evidence of incidents.
6. Did the malfunction occur within a hospital or public healthcare facility?
  - Yes – Report using PSLs – MDI icon  
These reports are reviewed by the PSLs Central Office team. If they determine it necessary to report to Health Canada, they will submit the report within the 30-day deadline.
  - No – Report using [Mandatory Medical Device Problem Reporting Form for Industry](#)

**Appendix C: Mandatory Medical Device Problem Reporting Process Flowchart**



## Appendix D: Frequently asked questions

### **1) *What are the reporting responsibilities related to use of personal use glucose monitoring equipment or supplies?***

Incidents related to personal use of a medical device, including glucose monitors, reagents and supplies, become a responsibility for hospitals or healthcare facilities when the patient presents to the hospital or public medical facility with serious harm or near harm related to the use of the medical device. This responsibility could extend to harm events occurring during care of Emergency Responders even if the individual was not admitted to a hospital.<sup>7</sup> If the meter or the test strip is determined to be at fault, the incident should be reported as a protection for other users who could experience the same failure.

### **2) *What is the reporting responsibility for “off-label use”?***

Incidents of actual or potential serious harm due to off-label use should be reported. Although “off-label use” is defined as “any intentional use of a product that is not covered by the terms of its licensing,”<sup>2</sup> this term is most used in the context of adverse drug reactions. When assessing the connection between a medical device and the incident, professional judgment should be exercised. The degree of risk for significant harm is the primary deciding factor in reporting an MDI due to off-label use.

### **3) *Whose responsibility is it to conduct the root cause analysis?***

The hospital/healthcare worker should report the MDI to the manufacturer as soon as possible after discovery. It is the manufacturer’s responsibility to perform the root cause analysis and undertake the corrective actions.<sup>2</sup> Root cause analysis is not required but is helpful to determine if it was a product or process failure.

### **4) *How should incidents involving multiple people be reported?***

Each individual event of serious harm or possible harm should be reported separately. Health Canada is responsible for connecting individual incidents for tracking and trending.