Mandatory reporting criteria for medical device incidents (MDIs)

1. Does the incident involve a **medical device**?
2. Do you **suspect failure** of device, deterioration in its effectiveness, or any inadequacy in its labelling, packaging, or in its directions for use?
3. Has the incident resulted in the **death or serious deterioration in health** of a patient, user, or other person, or **could it do so were it to recur**?
4. Did the incident take place in **hospital** or was the patient treated in hospital?

If you suspect that the answer to all four questions is YES, it is mandatory to report the incident in PSLS and Central Office will ensure the report is submitted to Health Canada by the 30-day deadline.
If the incident does not meet all four criteria, it can still be reported in PSLS for local learning, tracking, and trending.

Medical device incident scenarios

Scenario	Criteria
The only CT scanner on site would not reboot after a scheduled power bump. No patient was being scanned at the time, but thirteen booked patients were cancelled for the morning while Biomedical Engineering came to work on the scanner. The site was put on diversion.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of potential for serious harm to bumped patients
The only CT scanner on site went down with a hot stroke patient on the table. Biomedical Engineering was paged STAT. Patient scan was delayed as they were too unstable to transfer to another site and therefore unable to get tPA medication in time.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of potential for serious harm to stroke patient
A Nuclear Medicine machine broke down as staff member was handling it. No patients or staff were harmed but there was risk of exposure to unnecessary radiation.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of potential for serious harm

Scenario	Criteria
An MRI tech opened the cupboard to retrieve the coil. The cupboard door fell off and he subsequently dropped and damaged the coil.	☐ Medical device ☐ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital NOT mandatory because cupboard door is not a medical device
A patient in Nuclear Medicine finished using the treadmill for her exercise MIBI exam. She sat down on a chair beside it to rest. Three loud pops were heard, a flash of flames, and smoke were seen coming from the treadmill. No one was injured but the treadmill is now out of service. No other patients were scheduled to use it for the day.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory IF treadmill is licenced as a medical device
A user performed an inflation test prior to inserting a balloon catheter in a patient as required in the instructions for use accompanying the device. A malfunction on inflation was detected and another balloon was used.	☑ Medical device ☐ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital NOT mandatory because defect would ALWAYS be detected prior to use as per device instructions
CT, Nuclear Medicine, or MRI equipment failed during daily quality check and had to be put out of service impacting patient care.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because quality checks depend on hospital policy and are not ALWAYS done prior to use
Nuclear Medicine received a notice from vendor not to use gamma camera as there had been a reported incident somewhere in the U.S.A. Until error has been investigated, the camera must be removed from service.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of potential for serious harm

Scenario	Criteria
An MDI reportable event that happened 42 days ago was just brought to the new x-ray supervisor's attention as the PSLS was assigned to the previous supervisor who recently retired.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory even though 30-day deadline was missed
Sterile, single-use implantable device packaging was labelled with the caution, "Do not use if package is opened or damaged". By incorrect design, the label is placed on the inner packaging. The device was subsequently stored only in the inner packaging, which did not offer a sufficient sterile barrier. The outer package was removed, but the device was not used during the procedure.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of poor design and potential for serious harm
A health care provider incorrectly handled a sterile device, resulting in contamination of the device.	☑ Medical device ☐ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital NOT mandatory because device was not at fault
A patient came into the Emergency Department with severe hypoglycemia and was unconscious. The family believed it was because of incorrect information from the Glucoscan.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of suspected device fault and serious harm
A tray used in neurological cases was found to have hair/blood/tissue on its instruments. The sterilization team was questioned and they indicated that the instructions for cleaning this device did not say to take it apart.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of suspected fault with device instructions and potential for serious harm

Scenario	Criteria
A tray was found to have a black specks on 2x2s in a sterilized basic dressing tray.	☑ Medical device ☑ Suspected failure ☐ Death, serious harm, or potential ☑ Hospital NOT mandatory because no potential for serious harm
A patient was being transferred in a lift when it tipped over and the patient suffered a concussion. The patient was over the weight limit according to the instructions for use.	☑ Medical device ☐ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital NOT mandatory because fault of user, not manufacturer
A patient was found stuck in the bedrails, with bruising to his neck. The instructions did not indicate any particular mattress size or bedrail configuration to decrease the gaps that might allow for entrapment.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of suspected fault with device instructions and potential for serious harm
A patient was admitted for removal of ruptured breast implant. She has had severe chronic immunological response, severe pain, and is at risk for cancer.	☑ Medical device ☑ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital YES, mandatory because of suspected fault with device and serious harm
A patient had emergency surgery due to clotted intravascular catheter. The physician determined that the patient died of existing clotting condition not related to the device.	☑ Medical device ☐ Suspected failure ☑ Death, serious harm, or potential ☑ Hospital NOT mandatory because harm not related to device failure

Please see Health Canada's Guidance Document for additional examples of medical device incidents and non-applicable medical device incidents.