1. **Purpose**

This document defines policies and procedures for evaluating, executing, and documenting medical device reportable events and recalls.

1. **Scope**

This procedure applies to all product related information obtained by employees that is related to adverse events, recalls, and/or MDR’s.

1. **General** 
   1. **Definitions**

* **Adverse Event** – An event that resulted in serious injuries and/or death or a malfunction event that would likely cause or contribute to serious injury if the malfunction were to recur.
* **Become Aware** – The company is determined to be aware once any employee of the company has acquired information that reasonably suggests a reportable adverse event has occurred.
* **Incident** – Any malfunction or deterioration in the characteristics and /or performance of a device, as well as any inadequacy in the labeling or in the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or USER or of other persons or to a serious deterioration in their state of health.
* **Malfunction** – The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.
* **Medical Device Reporting (MDR)** – Reporting of adverse event that reasonably suggest the device may have caused, may cause in the future, or may have contributed to a death or serious injury to regulatory authorities.
* **Recall** – The correction or removal of a device for human use where there is a reasonable probability that the device would cause serious, adverse health consequences or death.
* **Serious Deterioration in the State of Health** - a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage.
* **Serious Injury** – An injury or illness that is life-threatening, results in permanent impairment of the body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
* **Sold in Canada** – Any device for which the company has a valid medical device license
  1. **Responsibilities**

**Quality Management** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

**Director of Quality Assurance** – The Director of Quality Assurance is responsible for management all mandatory device reporting and delegating responsibilities as necessary.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – Quality Assurance personnel shall be trained to the procedures specified in this document.
  4. **Record Management** – MDR and Recall records are managed and maintained by the Quality Department
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**21 CFR 803** – FDAMedical Device Reporting

**21 CFR 806** – FDAMedical Devices; Reports of Corrections and Removals

**ISO 13485** – Medical Device Quality Management Systems

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**MEDDEV 2 12/1**: Guidelines on a Medical Device Vigilance System

**H164-145/2011E**: Guidance Doc for Mandatory Problem Reporting for Medical Devices

**QP-0017** – Risk Management Process

**QP-0012** –Corrective and Preventive Action (CAPA) Process

**QF-0021-1** – Health Hazard Evaluation Form

1. **Criteria for Determining Adverse Events and Incidents**

All events involving distributed medical devices that are associated with death or serious injury or the malfunction that is likely to cause death or serious injury shall be evaluated via this procedure. The information leading to adverse reports may come from customer complaints, distributor feedback, external advisory notices, internal trending, post-market surveillance, and other sources. Events that meet all three of the following criteria shall be deemed reportable to the appropriate regulatory authorities.

* 1. **Criteria 1 – An event has occurred**

Events may result from use by customers, testing performed on the device and/or new scientific information. Events include, but are not limited to:

* A malfunction or deterioration in the characteristics or performance of the device
* For IVD’s, false positive or false negative results that fall outside the declared test performance or where could contribute to serious injury.
* Unanticipated adverse reaction or unanticipated side effect
* Interactions with other substances or products
* Degradation/destruction of the device (e.g. fire)
* Inappropriate therapy
* An inaccuracy in the labeling, instructions for use and/or promotional materials
  1. **Criteria 2 – The device is suspected to be a contributory cause**

In assessing the link between the device and the event, the following information shall be considered:

* The opinion, based on available evidence, of healthcare professionals
* The results of preliminary assessments of the event
* Evidence of previous, similar incidents
* Any other relevant evidence
  1. **Criteria 3 – The event led, or might have led, to death or serious injury**

Serious injury can include, but not limited to:

* Serious deterioration in the state of health
* Life-threatening illness
* Permanent impairment of a body function or permanent damage to a body structure
* A condition necessitating medical or surgical intervention to prevent above items
* Any indirect harm as a consequence of an incorrect diagnostic or IVD test result
* Foetal distress, foetal death or any congenital abnormality or birth defects
  1. **Trend Reports**

Outside of the above criteria, internal trending of data may lead to the discovery of adverse trends involving user safety. Upon identifying significant increase or trend of events or incidents that are usually excluded from the above criteria, a report may be required to be filed with the appropriate regulatory authorities. Such trending information may come from customer complaints, post-market surveillance, medical device reporting, and/or other applicable quality systems. See the FDA, MEDDEV, Health Canada, etc. guidance documents for additional information regarding trending data that is required to be reported.

* 1. **Use Error and Abnormal Use**

For information regarding when it is required to report use error and abnormal use events, see the FDA, MEDDEV, Health Canada, etc. guidance documents.

1. **Medical Device Reporting**

Adverse events and Incidents that meet the criteria listed in the section above shall be reported to the regulatory authorities of the zones of distribution. Medical Device Reporting shall following this procedure.

* 1. **Required Information**

The following information shall be captured upon initiation of the investigation:

* Identity of the medical device and any associate medical devices or accessories
* Name and contact information for company’s official correspondent (e.g. Director of QA)
* Date issue was discovered and surrounding circumstances
* Details known in respect of the incident, date of occurrence, consequences to the patient, user, or other person.
* Name, address, and contact information for party reporting the incident.
* Preliminary Investigation (preliminary findings, risk assessment, previous occurrences, etc.)
* Proposed strategy with timelines for conducting the reporting and corrective actions
  1. **Investigations**

All possible adverse events or incidents shall be investigated upon the date of awareness and documented on QF-0170 – Health Hazard Evaluation Form. Investigation shall include an evaluation of the device in question is possible as well as any feedback from the user of the device. If the event is determined to meet the criteria listed above the incident is reportable and an initial report shall be made to the appropriate regulatory authorities. Otherwise, the investigation is closed and records are filled appropriately.

* 1. **Investigation Outcome and Follow-Up**

All necessary corrective and preventative actions stemming from the investigation of an adverse event shall be documented and managed in the CAPA System. If through the investigation, it is determined that a recall or field safety corrective action is necessary see Recall Section below. Progress or Follow-Up reports shall be submitted if the investigation and corrective actions exceed the timeline provided on the initial report. A Final Report shall be submitted upon the completion of all corrective and preventative actions. The Final Report shall contain the following:

* Description of the incident including number of persons who experienced serious injury or died.
* Detailed description of the root cause of the incident and justification for the actions taken in respect of the incident
* Detailed description of any actions taken as a result of the investigation such as increase post-market surveillance, design/manufacturing corrective actions, or recalling the device.
  1. **Periodic Summary Reporting**

In the certain scenarios it may be acceptable to submit periodic summary reports to regulatory authorizes. See the FDA, MEDDEV, Health Canada, etc. guidance documents for additional information regarding periodic summary reporting.

* 1. **FDA Medical Device Reporting**

For all Reportable Events, a completed Medical Device Report on the *FDA’s form 3500A* shall be submitted it to the FDA, through the Electronic Submissions Gateway, within

* 5 days for events designated by FDA or an event that requires remedial action to prevent unreasonable risk of substantial harm to the public health
* 30 days of becoming aware of an event that may have caused a death or a serious injury or a malfunction that could lead to a death or serious injury if it were to recur.

More information on electronic MDR submissions to the FDA can be found in the FDA Guidance Document for Electronic Medical Device Reporting.

* 1. **EU Medical Device Reporting**

For Reportable Events occurring in the EU or involving medical devices distributed to the EU, a completed Incident Report (see “*Report Form Manufacturer’s Incident Report*” from MEDDEV 2.12/1) shall be submitted to the Authorized Representative, Notified Body, and impacted Competent Authorities. Timeframes for initial report shall be within:

* 2 days if Serious Public Health Threat
* 10 days if death or Serious Injury occurred or
* 30 days if death or Serious Injury might have occurred

EU authorities do not need to be notified if event occurred outside the EU jurisdiction and does not require recall or Field Safety Corrective Actions.

[Company notified body may have specific requirements]

Authorized Representative in Europe

[Enter Name and Address]

* 1. **Health Canada Medical Device Reporting**

For Reportable Event involving medical devices sold in Canada; (refer to CMDR sections 60 and 61 and GUI0059) a completed preliminary report on the Health Canada “*Medical Devices Problem Report Form (HC Pub.: 110180)*” shall be submitted to the address below, within the following timeframe:

* 10 days if death or Serious Deterioration in the State of Health occurred,
* 30 days if death or Serious Injury might occur if the event recurred,
* For incidents that occur outside Canada, as soon as possible after company has indicated the intention to take corrective action (48 hours of decision).

Foreign incidents that do not require any corrective actions are not required to be reported to Health Canada.

Canada Vigilance - Medical Device Problem Reporting Program

Marketed Health Products Directorate

Health Canada

Address Locator 0701E

200 Tunney's Pasture Driveway

Ottawa, Ontario K1A 0K9

Email: [mdpr@hc-sc.gc.ca](mailto:mdpr@hc-sc.gc.ca) (preferred method with “MDPR” in subject line)

1. **Recalls**

Recalls may be voluntarily initiated or mandated by regulatory authorities. In the event of a mandatory regulatory recall, company management shall be advised of the notification and the company shall comply with any instructions or requests made by the regulatory body. Both voluntary and mandatory recalls shall be documented within the Corrective and Preventive Action (CAPA) system. All reasonable efforts shall be made to account for, retrieve, and disposition all products (distributed or inventoried) associated with recalls.

Upon initiation of a recall, a recall letter shall be mailed to all impacted customers with information regarding the recall, actions that should be taken regarding the impacted product, and a Confirmation Notification to be returned with recalled product or notification that they do not have any recalled product.

* 1. **Required Information**

The following information shall be captured upon initiation of any recalls and documented in the associated CAPA file:

* Identity of the medical device and any associate medical devices or accessories
* Reason for the recall and justification for the action (CA or PA)
* Date issue was discovered and surrounding circumstances
* An evaluation of the risk associated with the event
* Name, address, and contact information for party reporting the incident.
* Name, address, and contact information for manufacturer, contract manufacturer, and/or importer.
* Name, address, and contact information for impacted customers and distributors
* Total number of impacted units produced, in stock, and distributed
* Time period of unit production and distribution
* Copies of any recall communications issued
* Preliminary Investigation (preliminary findings, risk assessment, previous occurrences, etc.)
* Proposed strategy with timelines for conducting the reporting and corrective actions
* Name and contact information for company’s official correspondent (e.g. Director of QA)
  1. **US FDA**

The FDA shall be notified of any recalls in accordance with 21 CFR Part 806. An initial notice containing information from the above section shall be sent within 10 business day of initiation. Monthly status reports shall be submitted to the FDA until the recall is complete and a request for closure is sent.

FDA Recall Coordinator

[Address is specific to the region of the company]

* 1. **European Union**

For product distributed in the European Union, the Authorized Representative, Notified Body, and all affected Competent Authorities shall be notified if the impacted product is distributed in their respective jurisdictions. A recall is synonymous to a Field Safety Corrective Action (FSCA). See Section 5.6 for electronic reporting to notified body.

Authorized Representative in Europe

[Enter Name and Address]

* 1. **Health Canada**

Health Canada officials shall be notified of the recall if any of the impacted product is distributed in Canada. The Minister of Health shall be provided with the recall strategy, progress reports, and proposed dates of completion.

Medical Device Unit

Marketed Health Products Directorate

Health Canada

2301 Midland Avenue

Toronto, Ontario M1P 4R7

Tel: 416-973-1596

Email: ONT-MET@hc-sc.gc.ca

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0021 |  |  | Initial release of the Medical Device Reporting and Recall Process |