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Guidance Document for Mandatory Problem Reporting for Medical Devices

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*Canada Vigilance - Medical Device Problem Reporting
Program*



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Foreword

Guidance documents are meant to provide assistance on **how** to comply with governing statutes and regulations. They also serve to provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document **may be** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of marketed health products. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with relevant sections of other applicable guidance documents.

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1 Introduction

1.1 Purpose

The purpose of this guidance document is to assist manufacturers and importers in understanding and complying with the *Medical Devices Regulations* (<http://laws.justice.gc.ca/eng/SOR-98-282/index.html>) concerning mandatory problem reporting (sections 59 through 61.1(2)).

1.2 Background

The mandatory problem reporting provisions in the *Regulations* are intended to improve monitoring and reduce the recurrence of incidents related to medical devices in Canada, and to ensure that the risk to Canadians of problematic devices is managed appropriately. Since Health Canada and its regulatory partners have similar reporting requirements, the *Regulations* enable Health Canada's participation in international alert systems.

Health Canada, along with its international partners in the Global Harmonization Task Force (GHTF), has developed agreements and documents to promote a harmonized approach to medical device regulation around the world. One of the study groups within the GHTF has produced a document entitled "Medical Devices Post Market Surveillance: *Global Guidance for Adverse Event Reporting for Medical Devices*" (N54) (<http://www.ghrf.org/documents/sg2/SG2-N54-R8-2006-Proposed.pdf>) which sets out criteria for adverse event reporting. In discussing the mandatory reporting requirements of the *Regulations*, this document is also intended to illustrate Health Canada's support of the general principles of harmonization and the goals of the GHTF.

1.3 Scope

This guidance document is intended as a supplement to the *Regulations*, to aid in the interpretation of the mandatory problem reporting requirements.

1.4 Definitions

The following definitions are set out for the purposes of interpretation of this document.

Abnormal use

An act, or omission of an act, by the user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted. See Appendix A for examples of potential abnormal uses.

Note: Abnormal use includes intentional use for a non-approved purpose ("off-label" use).

Complainant

The person who made the initial report of the incident to a representative of the manufacturer or the importer. The complainant may be the patient, the user of the device or other person.

Correction

Action to eliminate a detected nonconformity including the repair, modification, adjustment, relabelling, or inspection (including patient monitoring) of a device without its physical removal to some other location. A correction can be made in conjunction with a corrective action. A correction can be, for example, rework or regrade (International Standards Organization, ISO 13485 *Medical Devices quality management systems – System requirements for regulatory purposes*). A correction can also be a recall to address nonconforming devices in distribution.

Note: A nonconformity may include a problem or malfunction with the device

Corrective Action

Action to eliminate the cause of a detected nonconformity or other undesirable situation. There can be more than one cause for a nonconformity. Corrective action is taken to prevent recurrence, whereas preventive action is taken to prevent occurrence. There is a distinction between correction and corrective action (ISO 13485 *Medical Devices quality management systems – System requirements for regulatory purposes*).

Note: A nonconformity may include a problem or malfunction with the device.

If the corrective action meets the definition of a recall, according to the *Regulations*, then recall reporting requirements would apply

Importer

A person, other than the manufacturer of a device, who causes the medical device to be brought into Canada for sale.

Incident

In the context of mandatory problem reporting, information on the incident refers to the circumstances required to be reported under section 59 of the *Medical Device Regulations*.

Malfunction or deterioration

A failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions. Malfunction is synonymous with "fault".

Manufacturer

As is defined in section 1 of the *Regulations*, this term means a person who sells a medical device under their own name, or under a trade mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning it to a purpose, whether those tasks are performed by that person or on their behalf.

Preventive action

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Note: A nonconformity may include a problem or malfunction with the device

Radiation emitting device

As per the Radiation Emitting Devices Act, it refers to:

- (a) any device that is capable of producing and emitting radiation, and
 - (b) any component of or accessory to a device described in paragraph (a);
- where radiation means energy in the form of electromagnetic waves or acoustical waves.

Recall

As is defined in section 1 of the *Regulations*, in respect of a medical device that has been sold, recall means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device (a) may be hazardous to health; (b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or (c) may not meet the requirements of the *Act* or the *Regulations*.

Reporter

The person required to report mandatory problem reports to Health Canada, in accordance with the *Regulations*.

Serious deterioration in the state of health

As is defined in section 1 of the *Regulations*, this term means 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.

Note: Serious deterioration in health also includes a serious public health threat which is any incident type, which results in imminent risk of death, serious deterioration in health, or serious illness that requires prompt remedial action.

Use error

Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the user. Use error includes slips, lapses, mistakes and reasonably foreseeable misuse. See Appendix A for examples of potential use errors.

User

Person responsible for the use of the device. This could be, for example, a health professional, a family member, or even the patient (in the case of a glucose meter, for example).

2 Interpretation

2.1 Interpretation

For the purpose of this document, the manufacturer and the importer (subject to section 61.1 of the *Regulations*) are considered to be reporters of the incident to Health Canada. The complainant is the patient, user, or other person who initially brought the incident to the attention of the reporter.

2.2 What is a mandatory problem report?

A mandatory problem report is required under the *Regulations* for any incident involving a medical device that is sold in Canada when the incident:

- occurs either within or outside Canada;
 - relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use (section 59(1)(a)); and
 - 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 if it were to recur (section 59(1)(b)).
- **Note:** This guidance document interprets “sold” to mean “authorized for sale” (for Class II, III, IV medical devices), regardless of whether any units have yet been distributed.

The manufacturer *and* importer are each required to make both a preliminary and a final mandatory report, unless the manufacturer provides the Minister written authorization to permit the importer to report on its behalf (see section 61.1(1)-61.1(2) of the *Regulations*). Manufacturers remain responsible for ensuring that the information in the incident report is both complete and accurate.

A mandatory problem report is required under section 59(2) of the *Regulations* for any incident occurring outside Canada (foreign incidents), but involving a medical device that is also sold in Canada, only if the manufacturer has informed the regulatory agency in the country where the incident occurred that corrective action is necessary, or when this regulatory agency has requested the manufacturer to take corrective action.

Note: A manufacturer or importer of a radiation emitting device who sends a report to MHPD for the Mandatory Medical Device Problem Reporting Program which concerns a matter within the scope of section 6 of the Radiation Emitting Device Act does not have to re-submit it to the Consumer and Clinical Radiation Protection Bureau (CCRPB) in order to fulfil the notification requirements set out in that section.

2.3 How do I decide if the incident is reportable to Health Canada?

2.3.1 All Incidents

In accordance with section 59 of the *Regulations*, any incident which meets all of the three basic reporting criteria described in sections 2.4.1 through 2.4.3 below, is considered a reportable incident and must be reported to Health Canada.

Note: When a manufacturer, or importer, receives a complaint about a device which meets the three basic criteria described in sections 2.4.1 through 2.4.3, it must be reported even if the device no longer holds a market authorization in Canada.

It is possible that the reporter will not have enough information to decide on the reportability of an incident. In such a case, the reporter should make reasonable efforts to obtain additional information to aid in the decision. Where applicable, the reporter should consult with the medical practitioner or the health professional involved, and make all reasonable efforts to retrieve the device for evaluation.

2.3.2 Foreign Incidents

Foreign incidents must be reported in accordance with section 59(2) of the *Regulations*.

Foreign incidents which occurred prior to the specific incident which resulted in the decision to report a corrective action to a foreign regulatory authority (or to the request by the foreign regulatory authority for a

corrective action to be undertaken) need not be reported to Health Canada. These incidents should, however, be considered in the rationale for undertaking any future corrective action(s).

The specific foreign incident which resulted in the decision to undertake a corrective action should be reported to Health Canada.

Foreign incidents occurring after the decision to undertake a corrective action, and having the same root cause as the incident which precipitated that decision, need not be reported to Health Canada, unless they result in another, separate corrective action.

Note: Guidance on the timing of reporting foreign incidents to Health Canada is found in section 2.9.2.

2.4 What are the criteria to determine reportability?

2.4.1 An incident has occurred – Section 59(1)

The reporter becomes aware of information regarding an incident which has occurred with its device. This may include information from device testing performed by the manufacturer, user or other party.

2.4.2 The device contributed to the incident – Section 59(1)(a)

- In assessing the link between the device and the incident, the reporter should take into account:
- the opinion, based on available information, from a health professional;
- information concerning previous, similar incidents;
- complaint trends; and
- any other information held by the reporter.

This judgment may be difficult when there are multiple devices and drugs involved. If, after becoming aware of a potentially reportable incident, there is uncertainty about whether it is reportable, the reporter should submit a report within the timeframe required for that type of incident.

2.4.3 The incident lead to one of the following outcomes – Section 59(1)(b)

2.4.3.1 Death of a patient, user or other person

When the first two criteria to determine whether an incident is reportable (section 2.4.1 and 2.4.2) are met, **and** when death is the result of an incident, a report to Health Canada must be submitted within 10 calendar days, in accordance with section 60(1)(a)(i) of the *Regulations* (see section 2.9.1, below, for more details).

2.4.3.2 Serious deterioration in health of a patient, user or other person

When the first two criteria to determine whether an incident is reportable (section 2.4.1 and 2.4.2) are met, **and** when serious deterioration in health is the result of an incident, a report to Health Canada must be submitted within 10 calendar days, in accordance with section 60(1)(a)(i) of the *Regulations* (see section 2.9.1, below, for more details).

Under the *Regulations*, a serious deterioration in health means 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.

The interpretation of the term “serious” should be made in consultation with a medical professional, when appropriate. The term “permanent” means irreversible impairment or damage to a body structure or function, and necessarily excludes minor impairment or damage.

Medical intervention is not in itself a serious deterioration in health. The reason that motivated the medical intervention should be used to assess the reportability of an incident.

2.4.3.3 Potential for death or serious deterioration in health of a patient, user or other person

Not all incidents lead to a death or to a serious deterioration in health, either owing to circumstances or to the timely intervention of health care personnel, for example. These situations are known as near incidents. If the incident, in the case of recurrence, could lead to a death or to a serious deterioration in health, a report to Health Canada must be submitted within 30 calendar days, in accordance with section 60(1)(a)(ii) of the *Regulations* (see section 2.9.1 below, for more details).

This requirement also applies if the examination of the device, or a deficiency noted in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an incident involving death or serious deterioration in health.

In the report to Health Canada, it is recommended that **all** relevant information that might impact the understanding or evaluation of the incident be included. For example, “the patient was confused prior to becoming trapped in the bed sides”; “the patient was a very low birth weight premature delivery and had a central line placed three days before onset of cardiac tamponade”; “the X-ray machine was over 20 years old and had been poorly maintained at the time of the incident”, etc. This information should also include an explanation of how this incident could have led to a death or to a serious deterioration in health.

2.5 Examples of reportable incidents

- Loss of sensing after a pacemaker has reached “end of life”. Elective replacement indicator did not show up in due time, although it should have according to device specification.
- During patient examination, the “C” arm on an X-ray vascular system had uncontrolled motion. The patient was hit by the image intensifier. The system was installed, maintained, and used according to manufacturer’s instructions.
- It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. No one was injured in the surgical theatre at that time but a report is necessary (near incident). The system was installed, maintained, and used according to manufacturer’s instructions.
- Sterile, single-use 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. Device was subsequently stored only in the inner packaging, which did not offer a sufficient sterile barrier. Outer package was removed, but device was not used during procedure.
- A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.
- Premature revision of an orthopaedic implant due to loosening. No cause yet determined.
- An infusion pump stopped, due to a malfunction, but failed to give an alarm. Patient received under-infusion of needed fluids and required extra days in hospital to correct.
- Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated side effect of ablation. Manufacturer does not change the label of the ablation device, and fails to warn users of this side effect which may be produced when the device is working within specification.
- Health professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.
- During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient was not revived.

Note: If patient was revived, this would be considered a near incident and would also be reportable.

- Testing of retained samples identified inadequate manufacturing process, which led to detachment of tip electrode of a pacemaker lead, which did, or could, result in the death or serious deterioration in health of an individual.
- A user reported that there were insufficient details in the instructions for use regarding cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of variant Creutzfeld-Jacob Disease (vCJD).

2.6 Multiple incidents with the same device

Reportable incidents involving a medical device that affected one or more patients, users or other persons, on the same, or different, dates are to be reported to Health Canada as separate incidents, because each incident was a separate event. However, in the case of a medical device, such as an automated chemistry analyzer, a reportable incident concerning a particular run or rack of analyses (containing samples from one or more patients) should be reported to Health Canada as a single incident, because the entire rack of analyses represent a single event.

2.7 Use error

As with all reported device complaints, all potential use error incidents must be evaluated by the reporter (see Appendix A for examples). The evaluation should include principles of risk management, usability engineering, design validation, and corrective and preventive action processes. Importers may need to coordinate their evaluation with the manufacturer, in order to ensure that these elements are addressed. Results should be available, upon request, to Health Canada. Please refer to section 2.8.4, below, for guidance on abnormal use (“off-label” use).

2.7.1 Reporting of use error

There is increased international focus on errors in the use of medical devices. Incidents associated with use error must be evaluated by the reporter and the results documented. These types of incidents can be controlled by the manufacturer’s quality systems corrective and preventive action requirements, design validation, usability engineering, and risk management processes. By their nature, incidents involving use error usually involves a degree of uncertainty as to the root cause, but the risks can be managed by the manufacturer through consultation with Health Canada.

2.7.2 Use error resulting in death or serious deterioration in health

Use errors related to medical devices, which **did** result in death or serious deterioration in health, must be reported to Health Canada, providing the criteria specified in sections 2.4.1 and 2.4.2 were also met.

2.7.3 Use error not resulting in death or serious deterioration in health

Use errors related to medical devices, which **did not** result in death or serious deterioration in health, but which have the potential to result in death or serious deterioration in health, also need to be reported to Health Canada, providing the criteria specified in sections 2.4.1 and 2.4.2 were also met.

2.8 What types of common incidents or situations do not meet the reporting criteria?

2.8.1 Deficiency of a device found by the user prior to patient use

Deficiencies of devices that would **always** be detected by the user, **and** where death or serious deterioration in health has not occurred, do not need to be reported, because they do not meet requirements of section 59(1)(b) of the *Regulations*. In these situations, “always” means that even if the incidents were to recur, the user would, again, **always** detect the defect or malfunction prior to use.

Examples of non-reportable incidents:

- User performed an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. A malfunction on inflation was detected. Another balloon was used.

- Packaging of a sterile, single-use device was labelled with the caution, “*Do not use if package is opened or damaged*”, but damage to the packaging was obvious, was discovered, and occurred after manufacture. The device was not used.

2.8.2 Incident caused by a patient’s condition

When the reporter has information that the root cause of the incident is definitely due **solely** to a patient’s condition, the incident does not need to be reported, because it does not meet the requirements of section 59(1)(a) of the *Regulations*. These conditions could be pre-existing or occurring during device use.

To justify not submitting a report, the reporter should have documented information available to conclude that the device performed as intended and did not cause, or contribute to, death or serious deterioration in health. A person qualified to make a medical judgment would accept the same conclusion.

Examples of non-reportable incidents:

- Revision of an orthopaedic implant owing to loosening caused by the patient developing osteoporosis.
- A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.
- The death of a patient that was unrelated to any implanted device or device used to treat the patient.

2.8.3 Malfunction protection operated correctly

Incidents which did **not** lead to a death or to a serious deterioration in health because a design feature protected against a malfunction becoming a hazard, do not need to be reported, because they do not meet the requirements of section 59(1)(a) of the *Regulations*.

Examples of non-reportable incidents:

- After a malfunction of an infusion pump that was not related to a manufacturing defect, the pump gives an appropriate alarm **and** stops. There was no harm to the patient.
- Microprocessor-controlled radiant warmer malfunctions, reverts to an appropriate default condition and provides an audible, appropriate alarm. There was no harm to the patient.
- During radiation treatment, the automatic exposure control is engaged. Treatment stops. In accordance with the relevant standards, the actual dose is displayed. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

2.8.4 Consideration for handling abnormal use

Abnormal use includes intentional use for a non-approved purpose (“off-label” use). It should not be confused with use error (see section 2.7). As with all reported device complaints, all potential abnormal use incidents must be evaluated by the reporter (see Appendix A for examples). Abnormal use need not be reported to Health Canada under mandatory reporting regulations. Abnormal use should be managed by the health care facility and the appropriate provincial or territorial departments of health under specific and appropriate schemes not covered by this document.

2.9 What time frames are specified for reporting an incident to Health Canada?

All reporting time frames refer to when Health Canada must **first** be notified. This notification may be in the form of a preliminary report, or a combination of a preliminary and final report. The choice of report type depends on whether all the required information is available within the appropriate report timeframe. The Mandatory Medical Device Problem Reporting Form for Industry can be used to report preliminary, updates, final, or preliminary and final reports to Canada Vigilance – Medical Device Problem Reporting Program.

Note: The date that a representative of the reporter is notified of the issue (“awareness date”) is considered by Health Canada to be day zero.

2.9.1 Preliminary report for an incident occurring in Canada

Section 60(1)(a) of the *Regulations* requires that if the death or serious deterioration in health of the patient, user or other person has occurred, a report must be submitted to Health Canada within 10 calendar days. If death or serious deterioration in health did not occur as a result of the incident, but might if the incident were to recur, then the report must be submitted to Health Canada within 30 calendar days.

If, after becoming aware of a potentially reportable incident, there is uncertainty about whether it is reportable, the reporter should submit a report within the timeframe required for that type of incident.

2.9.2 Preliminary report for an incident occurring outside Canada

When the decision has been made to report a foreign incident to Health Canada (see section 2.3.2 above, for the criteria), section 60(1)(b) of the *Regulations* requires that a preliminary report be submitted as soon as possible after the manufacturer has informed the foreign regulatory agency of the intention to take corrective action, or, as soon as possible after the foreign regulatory agency has required the manufacturer to take corrective action.

Note: In this case, Health Canada interprets “as soon as possible” to mean within 48 hours after the decision.

A combined preliminary and final report may be submitted to Health Canada if the incident investigation is complete.

2.9.3 Requirement regarding a timetable for submission of the final report for an incident

Section 60(2)(h) of the *Regulations* requires, as part of the preliminary report, that the reporter propose a timetable for carrying out any corrective actions and for submitting the final report. Health Canada will review the proposed timetable to ensure that it does not jeopardize the safety of patients and users. The reporter should provide a final report as soon as the information is available, or as requested by Health Canada.

The timetable should include proposed dates relating to the action plan for resolving the issue, and should not merely include the proposed date for submission of the final report. If the investigation is still in a very preliminary state (e.g.: for a 10-day report), it may be that the timetable only indicates the immediate actions taken (or to be taken) and the proposed date(s) for any updates and for the final report.

Note: A report that contains the information required for a combined preliminary and final report may be submitted to Health Canada, provided that the results of the investigation are available within the 10-calendar-day or 30-calendar-day timeframe for submitting a preliminary report.

2.10 What content is required for a mandatory problem report?

2.10.1 Preliminary report

The purpose of a preliminary report is to inform Health Canada that, 1) a reportable incident has taken place, and 2) the reporter has begun the investigative process required to determine the root cause.

2.10.1.1 What information must be submitted in the preliminary report?

Section 60(2) of the *Regulations* sets out the information requirements for a preliminary report. The required information is listed below by section number, with a brief explanation where necessary. References made to the reporter mean the reporter of the incident to Health Canada, and not the complainant.

Section 60(2)(a) requires the reporter to submit information which will allow for ready identification of the device involved in the incident. This shall include the name of the device (for example: the trade name), the medical device identifier, the device catalogue number, device license number, the model number, serial number, lot number, *etc.*

Sections 60(2)(b)(i) and (ii) require the reporter to specify the manufacturer and the importer (as appropriate) of the device involved in the incident. Information required includes the name and address

of the manufacturer and of the importer of the device (as appropriate). Additional information includes the name, title, telephone and facsimile numbers of the reporter, in order to facilitate contact for any additional information concerning the incident that may be requested by Health Canada.

Section 60(2)(c) requires the submission of the incident awareness date, which is the date the incident came to the attention of the reporter.

Section 60(2)(d) requires the submission of the details known in respect of the incident, including the date the incident occurred and the consequences for the patient, user or other person. The details may include but are not limited to the following:

- What happened (where, when, how, to whom)?
- Is this the first time the device was used by the hospital? the health care worker? the patient? the user?
- If not, how long has the device been in use? When was it used previously?
- Have there been any previous problems with the device? If so, how often have these problems occurred?
- Was the device used according to directions?
- What were the environmental conditions surrounding the incident (if applicable)?
- What were the parameters or control settings at the time of the incident?
- How many other units of the device were involved in the incident?
- Was the device misused in any way (for example: reuse of a single-use device)?
- What method was used to clean, sterilize or re-sterilize the device? Was this consistent with the manufacturer's recommendations?
- How was the product stored or maintained?

Consequences referenced in section 60(2)(d) are the details of any harmful health effect(s) from the incident, the severity of the effect(s) and any treatment required.

Section 60(2)(e) requires the reporter to submit the name, address and telephone number, *etc.*, if known, of the person who reported the incident to the manufacturer or importer.

Section 60(2)(f) requires the reporter to submit the identity of any other medical devices or accessories involved in the incident, if known. This refers to any other equipment that was used with the device or in the vicinity of the device. It is also useful to include information concerning drugs used concomitantly with the device.

Section 60(2)(g) requires the reporter to submit their preliminary comments with respect to the incident. The comments should include a discussion of the preliminary findings of the investigation and an assessment of the risk to patients/users.

Section 60(2)(h) requires the reporter to submit their course of action in respect of the incident, including an investigation, that they propose to follow and a timetable for carrying out any proposed actions and for submitting a final report. This should also include a discussion of whether the device was repaired or replaced following the incident and the details of the repair or replacement, if available when submitting the preliminary report.

Section 60(2)(i) requires the reporter to submit a statement concerning the submission of a previous report for the device and the date of that report. This is interpreted to mean the **last** incident with the **same** root cause for the device. This statement should include both the reporter's and Health Canada's file number for that incident.

The proposed interim correction(s) and corrective action(s) must reduce the risk of the device to patients, users and other people to acceptable levels. Proposed interim actions may include a temporary stop-sale or recall, including communication of information about the risk to all users. The situation should be monitored to confirm that the interim actions have reduced the risk to acceptable levels.

2.10.1.2 What criteria will Health Canada use to assess the adequacy of the proposed course of action and timetable?

In general, Health Canada will use the following criteria:

- Does the proposed course of action determine if the incident is device-related?
- Does the proposed course of action determine if there is a systemic design defect, a quality control defect (lot-related), or a defect specific to that individual device?
- Does the proposed timetable jeopardize the safety of other patients/users?
- Are there any unexplained gaps in the proposed timetable?
- Are there any interim actions (for example: safety alert, temporary stop-sale, interim design change) required to protect the safety of other patients/users while the investigation is under way?
- Does the proposed course of action include an assessment of the risk (severity of hazard and frequency of occurrence)?
- Does the proposed course of action include an analysis of previous similar incidents?
- Does the assessment of the health risk take all known relevant information into account? Is it based on sound methodology and reasonable assumptions?
- Is there a need to test samples of the device? If so, has the manufacturer arranged testing?
- Are the proposed test methods appropriate?

2.10.1.3 What criteria will Health Canada use to assess the adequacy of the interim corrective actions proposed in the preliminary report?

In general, Health Canada will use the following criteria based on all information available:

- Is there a significant risk of death or serious injury without interim corrective action?
- If so, will the proposed interim corrective action reduce the risk to other patients/users to acceptable levels (for example: to a remote chance of device-related death or serious deterioration in health)?
- Is there a need for a temporary stop-sale, or recall, including risk communication to users of the device?
- If so, has the manufacturer proposed this action? Does it appear from the plan of action that it would be timely and effective?
- Will critical information about the risk be communicated to all users via alert letters, supplemental warnings, advisories, public announcements, media releases or other means?
- Have the most timely, efficient and effective methods of communication been selected?
- Is the manufacturer adequately monitoring the situation to confirm that the interim actions have reduced the risk to an acceptable level?
-

2.10.2 Final report

The purpose of a final report is to inform Health Canada of, 1) the results and conclusions of the investigation, and 2) the corrective actions and preventive actions (as appropriate) that have been, or will be, undertaken.

2.10.2.1 What information must be submitted in the final report?

Section 61 of the *Regulations* sets out the information requirements for a final report. The required information is listed below by section number, with a brief explanation where necessary. References made to the reporter, mean the reporter of the incident to Health Canada.

Section 61(2)(a) requires the reporter to submit a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died. All new information obtained since the submission of the preliminary report must be included so that the description of the incident in the final report is unambiguous and complete. This would also include a discussion of whether the device was repaired or replaced following the submission of the preliminary report, and the details of the repair or replacement.

Section 61(2)(b) requires the reporter to submit a detailed explanation of the root cause of the incident and a justification for the actions taken in respect of the incident. The explanation should be clear, scientifically sound, and consistent with the data provided and other relevant available information.

The justification should present evidence that the proposed course of action will resolve the problem and mitigate the risk of its recurrence.

Note: If no corrective actions are to be undertaken, a detailed rationale must be included in the report.

Section 61(2)(c) requires the reporter to submit any actions taken as a result of the investigation, which may include, (i) increased post-market surveillance of the device, (ii) corrective and preventive action respecting the design and manufacture of the device, and (iii) recall of the device.

Note: Section 61(2)(c)(ii) is interpreted to mean the following: corrective action on the device to prevent recurrence of the issue respecting the design and manufacture of the device, and may also include preventive action taken on similar product lines / devices to prevent occurrence of the same issue.

2.10.2.1.1 Increased post-market surveillance

If increased post-market surveillance is required, the final report must present an action plan for increased monitoring and trending of incidents associated with devices already on the market, including the following details:

- Which users will be monitored and by what method(s)?
- How long will the increased post-market surveillance continue?
- The provisions for the timely reporting of the surveillance results to Health Canada.

2.10.2.1.2 Providing information to users of the device

If there is a need to provide information to users of the device, the final report must include details of the risk communication plan. This may be done by referring, in the final report, to the recall notification which was already submitted to Health Canada.

2.10.2.1.3 Preventive action regarding the design and manufacture of the device

Although the *Regulations* refer to preventive actions in section 61(2)(c)(ii), it should be noted that if an incident has occurred, it is not possible to take a preventive action. The manufacturer should always look across its product lines to evaluate whether the issue that resulted in an incident with one product may also occur in another product line, if no action is taken. In this case, since the other product lines have not yet experienced the issue, any action taken is considered to be preventive. This is documented in the manufacturer's quality management system. It is not reported to Health Canada under the mandatory problem reporting provisions of the *Regulations*.

2.10.2.1.4 Corrections and corrective actions

If a correction is required for any units of the device still in use, the final report should include a detailed action plan and timetable for carrying out the correction. If the investigation indicates that there is a design or manufacturing defect, the final report must include a detailed plan of action and timetable to correct this defect and to prevent its recurrence.

Note: Trending is not considered to be a corrective action, but is part of a post-market surveillance program.

Corrections and corrective actions fall under recall activities.

2.10.2.2 What do I do if the device is not returned for evaluation?

It should be noted that in the event a device is not returned for evaluation, an investigation into the root cause of the incident must still be conducted to the extent possible. This investigation may include the evaluation of retained samples from the same lot, and from earlier and later lots of production from the device in question, as well as the evaluation of all related or similar incident records for that lot, for example.

2.10.2.3 What criteria will Health Canada use to determine the adequacy of the final report?

In general, Health Canada will use the following criteria based on all information available:

- Is the description of the incident clear and complete?

- Is the explanation consistent with the data provided and other relevant, available information?
- Does the evidence presented suggest that the proposed course of action will resolve the problem and mitigate its recurrence?
- Do the corrective actions and preventive actions address problems with existing devices (for example: units already on the market) and future devices, respectively?
-

2.10.2.4 What criteria will Health Canada use to assess the adequacy of the actions taken?

In general, Health Canada will use the following criteria based on all information available:

- If there is a design defect, is there reasonable evidence that the manufacturer's actions will correct it? Will the device continue to be safe and effective after these actions?
- If the problem concerns one or more defective lots, have these lots been recalled?
- Have users been adequately notified of the risk associated with the defective device(s)?

2.11 Inadequacies in reporting

It should be noted that absences from a mandatory problem report of any elements outlined in this guidance document may necessitate additional questions, requests for information and compliance verifications by Health Canada. Submission of inadequate mandatory problem reports by reporters, for which Canada Vigilance – Medical Device Problem Reporting Program is consistently required to request additional information, will result in the forwarding of this information to the Health Products and Food Branch Inspectorate, to determine regulatory compliance.

2.12 Follow-up activities

If there are any questions relating to the device or the incident in the report, Health Canada will contact the reporter/manufacturer/importer listed on the mandatory problem report.

2.13 What is the process for submission of a mandatory problem report to Health Canada?

Mandatory problem reports may be submitted to Health Canada using one of the following methods:

E-mail: Although Health Canada accepts reports submitted by mail/courier, facsimile, and email, the preference is that they be submitted by email (mdpr@hc-sc.gc.ca). In order to receive an automated response acknowledging receipt of your report, you must include the acronym “MDPR” in the subject line of the email.

Facsimile: Reports may be submitted by facsimile to 613-954-0941.

Mail: Reports may be submitted by postal mail or courier to the following address:
 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

Once the report has been received and entered into our database, a letter confirming receipt of the report will be sent to the reporter. This letter will contain information concerning the name of the device in the incident, the reporter's file number, Health Canada's file number and the date the report was received by Health Canada. Please ensure that Health Canada's file number and the Reporter file number is included on **all** further correspondence concerning the incident.

Appendix A: Examples of Potential Use Error and Potential Abnormal Use

A.1 Potential use errors

Complaint reports received of incidents occurring despite adequate instructions and design according to manufacturer's analysis. Examples include the following:

- User presses the wrong button.
- User misinterprets the icon and selects the wrong function.
- User enters incorrect sequence and fails to initiate infusion.
- User fails to detect a dangerous increase in heart rate because they have set the alarm limit too high and user is over-reliant on the device's alarm system.
- User cracks catheter connector when tightening.
- A centrifugal pump is made from material that is known to be incompatible with alcohol according to the labelling, marking, and product warnings provided with the pump. Some pumps are found to have cracked owing to inadvertent cleaning with alcohol.
- Unintentional use of pipette out of calibration range.
- Analyzer placed in direct sunlight causing higher reaction temperature than specified.
- MRI system and suite have large orange warning labels concerning bringing metal near the magnet. Technician brings an oxygen tank into presence of magnet and it moves swiftly across the room into the magnet.

A.2 Potential abnormal uses

Potential abnormal uses include complaint reports received of incidents occurring despite proper instructions; proper design; or proper training, and are, according to manufacturer's analysis, determined to be beyond any reasonable means of the manufacturer's risk control. Examples include the following:

- Use of a medical device during installation, prior to completing all initial performance checks as specified by the manufacturer.
- Failure to conduct device checks prior to each use as defined by the manufacturer.
- Continued use of a medical device beyond the manufacturer-defined, planned maintenance interval as a result of user's failure to arrange for maintenance.
- Pacemaker showed no output after use of electrocautery device on the patient, despite appropriate warnings.
- Product analysis showed that the device was working in accordance with specifications; further investigation revealed that the user was inadequately trained due to failure to obtain proper training.
- During the placement of a pacemaker lead, an inexperienced physician or other non-qualified individual perforates the heart.
- The labelling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours duration. After considering the pump options, a clinician decides that the pump will be used in paediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bled to death.
- Safety interlock on a medical laser removed by the user.
- Filter removed, and intentionally not replaced, resulting in particulate contamination and subsequent device failure.
- Tanks delivered to a health care facility are supposed to contain oxygen but have nitrogen in them with nitrogen fittings. The maintenance person at the health care facility is instructed to make them fit the oxygen receptacles. Nitrogen is delivered by mistake resulting in several serious injuries.
- Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
- Pacemaker-dependant patient placed in a MRI system with the knowledge of the physician.
- Ventilator alarm is disabled, preventing detection of risk condition.