Health Canada Santé Canada

OUR MANDATE:

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

Health Products and Food Branch Inspectorate

DRAFT
Guidance Document

Mandatory and Voluntary
Problem Reporting for Medical Devices

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*Revisions were made to this document on 2002-02-01 to reflect changes to the Health Products and Food Branch organizational structure. There were no other changes made to the content of the document.

Ce document est aussi disponible en français.

Canada

Table of Contents

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* for mandatory problem reporting (**sections 59 to 62**). The reporting regulations are intended to reduce the recurrence of adverse incidents related to defective medical devices and to provide the Health Product and Food Branch Inspectorate with information to effectively investigate such incidents and manage the risk posed by problematic devices.

This guidance document will also be of use to those who wish to voluntarily report an incident involving a medical device to the Health Product and Food Branch Inspectorate.

Use of this guidance document will help to assure that all adverse incident reports are comprehensive and accurate. Please note that the guidance document is a supplement to the *Regulations* and not a replacement. If there are any conflicts between the *Regulations* and this guidance document, the *Regulations* take precedence.

1.2 Background

The new mandatory reporting regulations provide a mechanism for the Inspectorate to identify and monitor serious incidents involving medical devices so that problems may be corrected in a timely manner. The previous *Medical Devices Regulations* did not require adverse incidents or problems experienced with medical devices to be reported. Reports were submitted on a voluntary basis predominately from device user facilities and private individuals. These voluntary reports were not based on risk, and there was no mechanism to provide early warning to the Inspectorate of problems with devices having the most serious consequences.

By requiring manufacturers and importers to notify the Inspectorate of serious incidents that come to their attention, the Inspectorate will be better able to manage the risk associated with problematic devices. Canada's major trading partners have similar reporting requirements, and this will enable Canadian participation in international alert systems developed under Mutual Recognition Agreements.

1.3 Scope

This guidance document can be used for both mandatory and voluntary problem reporting. For guidance on mandatory reporting please refer to Sections 2.1 to 2.17 and 2.19. For guidance on voluntary reporting, please refer to Sections 2.18 and 2.19. The report form in Appendix A can be used for either the preliminary mandatory report or a voluntary report. Guidance on completing the form is provided in Section 3.

A standardized report form is not provided for the final mandatory report, but the final report must make reference to the preliminary report.

1.4 Steps for Submitting a Problem Report

The steps to follow when submitting mandatory and voluntary problem reports to the Inspectorate are listed below. Please read the entire guidance document before submitting a problem report for the first time.

1.4.1 Steps for Submitting a Mandatory Report

- Obtain a copy of the report form as per Section 3.1.
- Complete a preliminary form according to the guidance in Section 3.2 to 3.5.
- Send the completed form to the address listed in Section 3.7.
- The Inspectorate will acknowledge receipt of the preliminary report and request further information if necessary.
- Complete a final report according to Section 3.6.
- Send the final report to the address listed in Section 3.7 within the time frame specified in the preliminary report.
- The Inspectorate will acknowledge receipt of the final report and request further information if necessary.

1.4.2 Steps for Submitting a Voluntary Report

- Obtain a copy of the reporting form as per Section 3.1.
- Complete a voluntary form according to the guidance in Section 3.2 to 3.5.
- Send the completed form to the address listed in Section 3.8.
- The Inspectorate will acknowledge receipt of your report and request further information if necessary.
- The Inspectorate will keep you informed of the progress of the investigation.
- The Inspectorate will contact you with the results of the investigation.

2 Interpretation

2.1 What is a mandatory problem report?

A mandatory PROBLEM REPORT is required under **section 59(1)** of the *Medical Devices 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 labeling 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)**).

The manufacturer *and* importer are each required to make both a preliminary and a final mandatory report.

Section 59(2) states:

> *The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action or unless the regulatory agency has required the manufacturer to take corrective action.*

This means that a manufacturer must report any INCIDENT that involves a medical device sold in Canada, meets the criteria of **sections 59(1)(a) and (b)**, and occurs outside 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.

CORRECTIVE ACTION refers to any action taken to prevent a recurrence of the problem and may apply to a device that is not yet sold or to a device that is already in the hands of the user. In the latter case, the action would be considered a RECALL according to the definition in the *Medical Devices Regulations*, and recall reporting requirements would apply. For further information see the guidance document on recall reporting.

2.2 Reporting of Incidents Involving Class I Devices

Under the *Medical Devices Regulations*, **section 26**, manufacturers are not required to obtain licences for Class I devices. However, manufacturers and importers of Class I devices are still required to have procedures in place

- to investigate incidents;
- to maintain records of these incidents;
- to report incidents that meet the criteria for mandatory reports (see Section 2.1); and
- to report recalls.

2.3 Reporting Time Frames

According to **sections 60 and 61** of the *Regulations*, the manufacturer and importer are required to submit two reports for each incident, a preliminary report and a final report (see Section 2.2). If all the information is known and the investigation is complete, the final report may be submitted with the preliminary report.

2.3.1 Preliminary Report for Incidents Occurring in Canada

Section 60(1)(a) of the *Regulations* states that the preliminary report must be submitted

> *(i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or*
>
> *(ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person but could do so were it to recur.*

If a death or serious injury has occurred, the report must be submitted to the Inspectorate within 10 calendar days.

If death or serious injury did not occur as a result of the initial incident but might occur if the incident were to be repeated, then the report must be submitted to the Inspectorate within 30 calendar days.

2.3.2 Final Report for Incidents Occurring in Canada

Section 60(2)(h) of the *Regulations* requires the manufacturer and importer to propose a timetable for submitting the final report. The Inspectorate will review the proposed timetable to ensure that it does not jeopardize the safety of patients and users.

Section 61 requires the manufacturer and importer to submit a final report after completion of the investigation *within the time established pursuant to paragraph 60(2)(h)*. This means that the final report must be submitted within the time specified in the preliminary report.

2.3.3 Reports for Incidents Occurring Outside Canada

Section 60(1)(b) states that a preliminary report must be submitted

> *in respect of an incident that occurs outside of Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.*

This means that when an incident occurs outside Canada, the manufacturer of the device must submit a report as soon as possible after deciding to take corrective action or as soon as possible after being informed by the regulatory agency of the country where the incident took place that corrective action is necessary.

The report may combine the preliminary and final reports as described in **sections 60 and 61**.

2.4 Summary Reports

Section 62 of the *Regulations* states:

> *In addition to making preliminary and final reports concerning an incident, the manufacturer and the importer of a medical device shall, at the Minister's request and within 30 days of the request, make a summary report to the Minister concerning any incident that was the subject of such reports and that occurred during the 12 months preceding the request or during a period specified by the Minister.*

This means that within 30 days of a request by the Minister, manufacturers and importers are required to provide summary reports to the Inspectorate of any incident occurring either inside or outside Canada within the last 12 months or some other specified time period. The format for these reports will be decided upon at the time of their request. At a minimum, the reports will require the name of the device, the date of occurrence, the nature of the problem and the consequences of the incident.

2.5 Serious Deterioration in the State of Health

SERIOUS DETERIORATION IN THE STATE OF HEALTH as defined in the *Regulations* involves a life-threatening illness or injury, permanent impairment of a body function or permanent damage to a body structure, or a condition necessitating medical or surgical intervention to prevent such permanent harm. The application of the term "serious" should be made in consultation with a medical practitioner whenever possible.

In cases of doubt on this issue, there should be a predisposition to report rather than to not report.

2.6 What information do I have to submit with 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.

Section 60(2)(a):

> *the name of the device, the medical device identifier, and the device catalogue number or bar code and the control number, where the device has a control number.*

A control number is a unique combination of letters, numbers or symbols assigned to a medical device by the manufacturer in order to identify the device and trace the history of its manufacture, packaging and distribution. It is sometimes referred to as a lot number, serial number, sterilization lot number or manufacturing date.

Section 60(2)(b)(i):

> *where the report is made by the manufacturer, the name and address of that manufacturer and of any known importer and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident*.

Section 60(2)(b)(ii):

where the report is made by the importer, the name and address of that importer and of the manufacturer and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident.

Section 60(2)(c):

the date the incident came to the attention of the manufacturer or importer.

Section 60(2)(d):

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" required in **section 60(2)(d)** 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? by the health-care worker? by the patient? by 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 are being used or were used?
- Was the device misused in any way (e.g. reuse of a disposable 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?

The "consequences" requested in **section 60(2)(d)** refer to details of any harmful health effect(s) from the incident, the severity of the effect(s) and any treatment required.

Section 60(2)(e):

the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer.

Section 60(2)(f):

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.

Section 60(2)(g):

the manufacturer's or importer's 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):

the course of action in respect of the incident, including an investigation, that the manufacturer or importer proposes to follow and a timetable for carrying out any proposed actions and for submitting a final report.

The proposed interim CORRECTIVE ACTION(s) must be designed to reduce the risk to other users of the device to acceptable levels. Proposed interim corrective actions may include the following:

- A temporary stop-sale or RECALL, including communication of information about the risk to all users; and,
- Monitoring the situation to confirm the interim actions have reduced the risk to acceptable levels.

This section requires the manufacturer and importer to specify the time that will be required to complete the investigation and the proposed CORRECTIVE ACTION(s), and to submit a final report.

2.7 What criteria will the Inspectorate use to assess the adequacy of the manufacturer's proposed course of action and timetable?

In general, the Inspectorate 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 design defect, a quality control defect (lot-related) or a defect in 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 (e.g. manufacturer's 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 manufacturer's assessment of the health hazard 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 there is, has the manufacturer arranged testing?
- Are the proposed test methods appropriate?

2.8 What criteria will the Inspectorate use to assess the adequacy of the interim corrective actions proposed in the preliminary report?

In general, the Inspectorate 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 (i.e. remote chance of device-related death or serious injury)?
- 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 successful (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?

2.9 What information must be submitted with the final report?

Section 61 of the *Regulations* states:

> *After making a preliminary report in accordance with section 60, the manufacturer or importer of a medical device involved in an incident shall each, within the time established pursuant to paragraph 60(2)(h), submit to the Minister a final report containing the following information:*
>
> *(a) 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;*

The final report does not need to include this description if it has already been submitted in the preliminary report to meet the information requirements of **section 60(d)**. However, any new information obtained since the preliminary report must be included so that the description in the final report is unambiguous and complete.

> *(b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and*

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 eliminate its recurrence.

> *(c) any actions taken as a result of the investigation, which may include the following:*
> *(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.*

2.10 Increased Post-Market Surveillance

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

- Which customers will be monitored and by what methods?
- How long will the increased post-market surveillance continue?

The plan should include provisions for the timely reporting of post-market surveillance results to the Inspectorate.

2.11 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 a risk communication plan. The plan should ensure that users are provided with all the information they need to eliminate or minimize the risk. There should also be provision in the plan for monitoring the effectiveness of risk communication.

2.12 Corrective and Preventive Action Respecting the Design and Manufacture of the Device

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 prevent its recurrence. The plan should also answer the following questions:

- Will the company apply for a new device licence?
- Have the design and manufacturing changes been validated?
- Has the quality system been updated?

2.13 Corrective Action on Any Units of the Device Still in Use

If corrective action on any units of the device still in use is required, the final report should include a detailed action plan and timetable for carrying out this corrective action.

2.14 What criteria will the Inspectorate use to determine the adequacy of the manufacturer's final report?

In general, the Inspectorate will use the following criteria:

- 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 eliminate its recurrence?
- Does the corrective action address problems with existing devices (i.e. units already on the market) and future devices?

2.15 What criteria will the Inspectorate use to assess the adequacy of the manufacturer's solution?

In general, the Inspectorate will use the following criteria:

- If there is a serious design defect, is there reasonable evidence that the manufacturer's actions will correct it? Will the device be safe after these actions?
- If the problem concerns a defective lot(s), has the lot(s) been recalled?
- Have users been adequately warned of the risk associated with the defective device(s)?

2.16 Enforcement

The Inspectorate may initiate one or more of the following actions to ensure compliance with the *Medical Devices Regulations*:

- negotiated compliance
- warnings
- import refusal
- stop sale
- public alerts
- seizure
- withdrawal of marketing approval
- injunction

- prosecution

Further information may be obtained by referring to the Health Product and Food Branch Inspectorate *Compliance and Enforcement Policy (POL-0001)*, December 2002.

2.17 What is a voluntary problem report?

A voluntary report is any account of an incident or complaint involving a medical device forwarded to the Inspectorate at the discretion of the reporter. These accounts would pertain to the following:

- actual incidents involving the device;
- concerns about the safety of a device or about its ability to perform as claimed; or
- a contravention of regulatory requirements such as a labelling deficiency or sale of a device without a licence.

If you are unsure that the product concerned is a medical device, contact the Inspectorate's nearest regional office to determine the status of the product. The addresses and phone numbers of regional offices are listed in Section 3.8 of this document.

Health care professionals and the general public are urged to continue voluntary reporting of all types of device problems to the manufacturer or distributor, and to the Inspectorate. An INCIDENT that is the subject of a voluntary report does not have to meet the criteria for a mandatory report in terms of seriousness (death or serious deterioration in the state of someone's health or the potential for either). However, the investigation of voluntary reports will be performed on a risk management basis, higher risk issues being given higher priority.

If the report involves a contravention of the *Regulations* pertaining to the sale or importation for use of a medical device, please ensure that you include sufficient evidence to support the charge. In the case of a trade complaint, the investigation will not proceed unless you include such evidence.

If you wish to make a voluntary report, use the problem report form in Appendix A and the guidance in Section 3, which provides a step-by-step description of the information required in each field of the form. Please note that because the same form is to be used for mandatory reporting, not all of the information requested may apply to a voluntary report.

2.18 Disclosure of Information

Information supplied to the Inspectorate is subject to the *Access to Information Act* and the *Privacy Act.*

3 Completing the Problem Report Form

3.1 Where do I obtain the report form?

The medical devices problem report form is located in Appendix A of this document, at the addresses listed in Sections 3.7 and 3.8, and at the Inspectorate's web site: (http://www.hc-sc.gc.ca/hpb-dgps/Inspectorate/md_pro_rep_form_entire_e.html).

3.2 General Information

Field 1 identifies whether this is a 10-day or 30-day mandatory incident report or if this is a voluntary report. If the reporter (the company or person who is reporting the incident to the Inspectorate) is a manufacturer or an importer meeting the obligations of **sections 59 to 62** of the *Regulations*, check either the 10-day or 30-day box as appropriate according to the following criteria.

If a death or serious injury has occurred or if the incident poses an imminent threat to public health, check the 10-day box. In this case, you have 10 calendar days from the time you became aware of the incident to submit the preliminary report. If an incident has occurred and death or serious injury did not result, but the potential for death or serious injury exists should the incident recur, check the 30-day box. In this case, you have 30 calendar days from the time you became aware of the incident to submit the preliminary report.

If this is not a mandatory report, check the voluntary box.

Field 2 identifies the name of the person submitting the report to the Inspectorate.

Field 3 identifies the reporter as manufacturer, importer, distributor or user (e.g. a health care professional, a home user or a patient).

Field 4 identifies the name of the company or the institution of the reporter for both mandatory and voluntary reports. A home user making a voluntary report may leave this field blank.

Fields 5 to 8 identify the address, postal code, telephone and fax numbers of the person named in Field 2.

Field 9 identifies the name of a contact person for the institution or company named in Field 4 if different from the name of the reporter in Field 2.

Field 10 indicates to whom the incident was reported (the manufacturer, the importer or the distributor) in the case of a voluntary report. If you are submitting the report only to the Inspectorate, then you do not need to complete this field.

Fields 11 and 12 apply only to a voluntary incident report. If you know the name and address of the company or person who sold the device, then complete these fields.

Field 13 applies to either a mandatory or a voluntary incident report. If the device that was involved in the incident is available and you are willing to release it to the Inspectorate for evaluation, mark the check box "yes." If the device is not available, or if you do not wish to make it available, mark

the check box "no."

Field 14 indicates the date the incident occurred for both mandatory and voluntary reports.

Field 15 applies only to a mandatory report. It indicates the date that either the manufacturer or the importer first became aware of the incident, regardless of the actual date of the incident.

3.3 Medical Device Information

Field 16 indicates the full name of the device as it appears on the label or labelling. Please complete this information as accurately as possible. The correct name of the device is extremely important for the timely investigation of the incident. Include the model number of the device if known.

Field 17 indicates the identifier for the medical device in question as set by the manufacturer. It may be a catalogue number, a bar code or any other number chosen by the manufacturer.

Field 18 may be a lot number, serial number or batch number. It may also be a manufacturing date or a sterilization date. This identifier may depend on the method used by the manufacturer to track the device through its manufacture and distribution.

Field 19 is the device licence number given to the manufacturer for the device when it is registered with the Inspectorate. It is important to fill out this field because the licence number will identify the device in the Inspectorate's database.

Field 20 indicates how long the device was in use.

Field 21 identifies the software version associated with the device.

Field 22 indicates whether the device was labelled sterile.

Fields 23 to 28 identify the manufacturer of the medical device. If this is a mandatory report from the importer, fields 23 to 28 must all be completed. If this is a mandatory report from the manufacturer, only Field 28 must be filled out, as the information required for fields 23 to 27 will appear in fields 4 to 8. If this is a voluntary report, please fill in these fields as completely as possible.

Field 28 indicates the licence number that has been assigned to the manufacturer if that company is required to be registered with the Inspectorate.

Fields 29 to 34 identify the importer of the medical device. If this is a mandatory report from the manufacturer, then fields 29 to 34 must be completed. If this is a mandatory report from the importer, then only Field 34 must be filled out as the information required for fields 29 to 33 will appear in fields 4 to 8. If this is a voluntary report please fill in these fields as completely as possible.

Field 34 indicates the establishment licence number that is given to the importer when that organization registers with the Inspectorate.

Fields 35 to 39 apply only to a mandatory report. They indicate the name, address and other pertinent identification of the individual or the institution who reported the incident to the manufacturer or the importer.

3.4 Signature

Field 40 is for your signature and the date the report is completed.

3.5 Problem Description

Field 41 is intended for both mandatory and voluntary reports. When completing this field, please include as much detail as is known about the incident (what happened, when it happened, to whom it happened), as well as any known consequences to the patient, user or other person. Identify any other devices or accessories involved.

Field 42 is intended primarily for mandatory reporting. The manufacturer or importer should assess the incident in terms of involvement of the device as they see it initially. If this is a voluntary report and the incident has been reported to the manufacturer or the importer, please include any comments made by either party respecting the incident, or indicate that no response has been received to date.

Field 43 is for a mandatory report only. The manufacturer or importer should describe the actions taken or to be taken in investigating the incident, the timetable for the investigation, and a date for the submission of the final report.

3.6 Final Report

The final report is required only for mandatory incidents. No standardized form is provided, but all necessary information is outlined in Sections 2.10 to 2.14 of this document. Upon receipt of the preliminary report, the Inspectorate will send you a letter of acknowledgment with an incident ID number. Please quote this ID number on all further correspondence involving this incident, including the final report.

3.7 Where do I send the completed mandatory report?

Please mail or fax mandatory reports to the following location:

Inspectorate Ottawa
Graham Spry Building, 2nd Floor
Address Locator: 2003C
Ottawa, Ontario, K1A 0K9
Telephone: 1-800-267-9675
Facsimile: (613) 954-0941

3.8 Where do I send the completed voluntary report?

A voluntary report of an incident can be mailed or faxed to the Inspectorate Ottawa at the address in Section 3.7 or to the Operational Centre of the Health Product and Food Branch Inspectorate in your area as listed below:

Atlantic Operational Centre
Suite 1625, 1505 Barrington Street
Halifax, Nova Scotia, B3J 3Y6
Telephone: (902) 426-2160 or 1-800-267-9675
Facsimile: (902) 426-6676

Quebec Operational Centre
1001 St-Laurent Street West
Longueuil, Québec, J4K 1C7
Telephone: (450) 646-1353 or 1-800-561-3350
Facsimile: (450) 928-4455

Ontario & Nunavut Operational Centre
2301 Midland Avenue
Scarborough, Ontario, M1P 4R7
Telephone: (416) 973-1600 or 1-800-267-9675
Facsimile: (416) 954-4583

Manitoba & Saskatchewan Operational Centre
510 Lagimodiere Blvd.
Winnipeg, Manitoba R2J 3Y1
Telephone: (204) 983-5490 or 1-800-267-9675
Facsimile: (204) 983-2155

British Columbia, Alberta, Northwest Territories, Yukon Operational Centre
4595 Canada Way, 4th Floor
Burnaby, British Columbia, V5G 1J9
Telephone: (604) 666-3350 or 1-800-267-9675
Facsimile: (604) 666-3149

Health Canada Santé Canada

Health Products and Food Branch Inspectorate

Medical Devices Problem Report Form

For office use only | Incident ID

General Information

1. Mandatory 10-Day Report ☐ Mandatory 30-Day Report ☐ Voluntary Report ☐

2. Name of Reporter:

3. Manufacturer ☐ Importer ☐ Distributor ☐ User ☐

4. Institution/Company:

5. Address:

6. Postal Code:

7. Telephone: 8. Fax:

9. Contact Person (if different from reporter):

10. Incident reported to: Manufacturer ☐ Importer ☐ Distributor ☐

11. Where was the device purchased?

12. Address:

13. Is the device available for evaluation? Yes ☐ No ☐

14. Date of Incident: 15. Manufacturer/Importer Awareness Date:

Medical Device Information

16. Trade Name:

17. Manufacturer Medical Device Identifier: 18. Control #:

19. Licence Number: 20. Age of Device:

21. Software Version: 22. Was the device labeled sterile? Yes ☐ No ☐

23. Manufacturer:

24. Address:

25. Postal Code:

26. Telephone: 27. Fax:

28. Establishment Licence Number (if applicable):

29. Importer:

30. Address:

31. Postal Code:

32. Telephone: 33. Fax:

34. Establishment Licence Number:

35. Reporter to Manufacturer/Importer:

36. Address:

37. Postal Code:

38. Telephone: 39. Fax:

Signature

This problem report has been submitted by:

Date Y M D

40.

Problem Description (attach additional paper if needed)

41. Details of Incident Including Consequences to Patient, User or Other Person, and Description of Other Devices or Accessories Involved in the Incident

42. Manufacturer's Preliminary Comments

43. Course of Action Proposed Including Timetable for Investigation and Submission of Final Report

Appendix B - References

B.1 *Medical Devices Regulations*

B.2 *The Food and Drugs Act*

B.3 Health Product and Food Branch Inspectorate *Compliance and Enforcement Policy*, POL - 0001, December 2001

Appendix C - Definitions

CONSEQUENCES are the effects produced on the patient, user or other person as a result of an INCIDENT. (*répercussions*)

CORRECTIVE ACTION is an action taken to prevent to prevent a recurrence of a DEVICE PROBLEM. Any action which extends to the device in distribution would be considered a RECALL according to the definition of RECALL in the *Medical Devices Regulations*. (*mesure corrective*)

DEVICE PROBLEM is an all inclusive term used by the Inspectorate which encompasses actual or potential occurrences of device failure and other violations of the *Food and Drugs Act* and the *Medical Devices Regulations*. DEVICE PROBLEM includes INCIDENTS and TRADE COMPLAINTS. (*problème d'instrument*)

INCIDENT means any occurrence involving a medical device which encompasses actual or potential occurrences of device failure. (*incident*)

PROBLEM REPORT means the report of information to the Inspectorate which suggests that there is a reasonable probability that the use of, or exposure to, a medical device has lead to the death, or serious deterioration in the state of health, of a patient, user or other person or it is reasonable to believe that if it were to recur, could lead to the death, or serious deterioration of the state of health, of a patient, user or other person. A PROBLEM REPORT also means the report of information to the Inspectorate concerning the use of, or exposure to, a medical device which may have caused temporary deterioration in the state of health, of a patient, user or other person. A PROBLEM REPORT may also include trade complaints. (*rapport d'incident*)

RECALL, in respect to a medical device that has been sold, means any action taken by the manufacturer, importer or distributer 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 *Food and Drugs Act* or the *Medical Devices Regulations*. (*rappel*)

SERIOUS DETERIORATION IN THE STATE OF 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. (*détérioration grave de l'état de santé*)

TRADE COMPLAINT is a report to the Inspectorate from a member of the device industry concerning a possible violation of the *Food and Drugs Act* and *Medical Devices Regulations* by another member of the device industry. Examples are: sale of a device without a license or advertising a device for prevention of a Schedule A disease.
Health care facilities may also be considered to be a part of the device industry inasmuch as they are subject to some or all of the *Regulations* depending on their activities. (*plainte de l'industrie*).