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# Medical devices recall guide



GUI-0054

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Canada

## Medical devices recall guide (GUI-0054)

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### Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

Ce document est aussi disponible en français.

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# About this document

## 1. Purpose

This guide will help anyone who works with medical devices understand and comply with sections of the [Medical Devices Regulations \(MDR\)](#) that relate to medical device recalls.



Recalling a product generally means removing it from sale. In Canada, actions such as notifying users of a potential problem or supplying different labelling for a medical device are also considered recalls. For a more details, see the [Definition of a recall](#) section.

Specifically, this guide will help you learn how to:

- keep medical device distribution records
- recall medical devices
- report medical device recalls to Health Canada
- write procedures for distribution record keeping and recall



If Health Canada believes you are selling a medical device that may seriously or imminently harm someone's health, we may order you to:

- recall the product
- send the remaining product to a specific place

If your company refuses to recall a product or if your recall is not adequate, we may use section 21.3 of the [Food and Drugs Act](#) to enforce the regulatory requirements.

## 2. Scope

This guide is for anyone working with medical devices as a:

- manufacturer

- importer
- distributor

It applies to the following sections of the MDR that are concerned with recalls:

- [Distribution records](#) (sections 52–56 of the MDR)
- [Recall process](#) (section 58(b) of the MDR)
- [Recall reporting process](#) (sections 63–65 of the MDR)

Not all medical devices recall requirements apply to all companies working with medical devices. The requirements to maintain distribution records under 52–56 and to have a recall procedure under 58(b) of the MDR (Part 1) apply to manufacturers, importers and distributors. Recall reporting requirements under sections 64 and 65 apply only to manufacturers and importers. The requirement for a recall procedure also applies to manufacturers, importers and distributors of devices for investigational testing, as specified under section 88(d) of the MDR (Part 3).

Medical device establishment license (MDEL) holders are also required to attest under section 45(g) of the MDR that they have a documented procedure(s) in place for meeting distribution record requirements and for conducting recalls.

## 3. Introduction



This section provides an overview of information found in this guide. Use it to quickly locate the appropriate information and remind yourself of your key regulatory requirements.

### Key requirements

Under the MDR, if you manufacture, import or distribute medical devices, you are required to:

- [keep distribution records](#)
- [establish and use written procedures for how to do recalls](#)

Manufacturers and importers are required to [report recalls to Health Canada](#).

Establishments with a medical device establishment licence (MDEL) must also keep written procedures with step-by-step instructions for how to maintain distribution records and conduct recalls.



Evaluate your establishment's procedures using the self-assessment checklists found in [Appendix D](#) and [Appendix E](#).

## Recall process overview

The [recall process](#) is divided into two parts with five stages:

1. [Initiating a recall](#)
  - [Stage one: Identify the need to initiate a recall](#)
  - [Stage two: Develop recall strategy and scope](#)
2. [Conducting a recall](#)
  - [Stage three: Notify and correct](#)
  - [Stage four: Follow up](#)
  - [Stage five: Review and close recall](#)

## Tips for using this guide

For an overview of the recall process, see the flowchart in [Appendix B](#). To learn about the collaborative relationship between importers, distributors and manufacturers, see the illustration in [Appendix C](#).

For information on how to properly document your establishment's recall process, read [Establishing and using documented processes](#).



If you have questions for Health Canada after reading this guide, consult [Appendix I](#) to find your closest regional office. If you are in Canada, you may also call 1-800-267-9675 to find a regional office.



# Guidance

## 4. Definition of recall

“Recall” is defined in the MDR as follows:



A “recall” in respect of a medical device that has been sold, 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:

- (1) may be hazardous to health
- (2) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety
- (3) may not meet the requirements of the [\*Food and Drugs Act\*](#) or these regulations

A recall may include:

- removing a medical device from the market
- instructing customers to stop using a medical device and destroying remaining units in stock
- doing an on-site correction of a medical device
- advising users of a device about a problem or potential problem
- supplying different labelling (which may include updates to instructions or manuals)



Canadian regulations often define “recall” more broadly than other countries. If you manufacture medical devices outside Canada, be aware that some actions required in your jurisdiction (e.g. field corrections) may be considered recalls in Canada. Ensure your procedures state that reporting requirements under sections 64 and 65 of the MDR apply to you.

## 5. Responsibilities

Recall actions are a collaborative process between all parties involved in the distribution chain, including:

- manufacturers
- importers
- distributors
- retailers
- health care facilities
- users
- consumers

The effectiveness of the collaboration between a manufacturer and its importers and distributors depends, in part, on the extent to which each establishment:

- understands its own roles and responsibilities
- defines and documents its expectations with other establishments in the distribution chain
- communicates and shares recall information

Manufacturers sometimes have special agreements with their importers or distributors that are in place to facilitate recalls. This could include having access to distributors' distribution records or having a contract with distributors that guarantees their cooperation during a recall.



For a flowchart showing the relationship between the recalling establishment and its importers and distributors, see [Appendix C](#).

## 6. Establishing and using documented processes

Your processes for maintaining distribution records and doing recalls (including recall reporting) must be documented in written form - either electronically or on paper. You may document each activity in a single procedure or use a number of procedures, depending on the structure of your quality system. Establishments that use multiple procedures must be able to show that all

parts of the distribution record and recall process are represented. You must also be able to show that your procedures are being followed.

## Documenting the recall and distribution record keeping process

Your establishment's written procedures must:

- define key activities
- assign responsibilities
- provide a detailed description of steps taken from beginning to end of the process
- set out timelines
- use a common format



All manufacturers must comply with the distribution record requirements set out in sections 52 to 56 of the MDR. However, only manufacturers who hold an MDEL must attest that they have documented procedures in place for keeping distribution records.

If your establishment does **not** hold an MDEL—and is therefore not required to attest—you still need a controlled process for meeting distribution record requirements.

Ensure activities described in your recall procedures have a time frame, where appropriate. Base time frames on the level of risk: the higher the risk, the shorter the time frame for completing an action. In particular, specify timing for:

- notifying affected clients
- notifying Health Canada
- following up with anyone who does not respond to your recall notification

You may either set unique time frames for each risk level or set a single time frame for all recalls based on the timing required for a high-risk recall.



You can find more information about how to write procedures in [Appendix F](#).

## Using written procedures

When your establishment initiates a recall or receives notification of a recall, use your step-by-step written procedures as follows:

1. Perform all steps in the procedure.
2. Ensure that each employee responsible for any step in the procedure:
  - has access to the procedure
  - understands their responsibility
  - is appropriately trained and qualified
  - receives support from management to ensure they follow procedure
3. Keep records as required.

To show that a third party will complete agreed-upon parts of the recall procedure, you might also:

- have a documented quality agreement that specifies roles/responsibilities and assures compliance with the MDR (e.g. contacting affected customers and following up with non-responders)
- have the third party sign your written procedures

## 7. Keeping distribution records

The process a manufacturer, importer or distributor follows to create and keep distribution records will vary depending on their sales, accounting and shipping procedures. Keeping records may involve a number of procedures and personnel. Your establishment must define which records to use in identifying the location of affected products during a recall.

Records can be paper-based or electronic. Store them in a way that protects their integrity. For example, back up electronic records on a regular basis and store copies in a different location.



If you have a Medical Device Establishment Licence (MDEL) then you must make an attestation on your application, under section 45(g) of the MDR, stating that you have documented procedures in place to meet the requirements of sections 52–56 of the MDR.

The following pages discuss each of the five distribution record requirements in the MDR. When you are finished reading this section of the guide, use the self-assessment checklist found in [Appendix D](#) to check whether your company is meeting distribution record requirements.

## Section 52

Section 52 of the MDR states:



- (1) The manufacturer, importer and distributor of a medical device shall each maintain a distribution record in respect of each device.
- (2) Subsection (1) does not apply to
  - a retailer; or
  - a health care facility in respect of a medical device that is distributed for use within that facility.

**Manufacturers, importers and distributors** must create and keep a distribution record for each medical device they distribute, including:

- rental units
- samples
- “loaner” units
- donations
- gifts
- devices used for demonstration

Depending on your company’s activities, you may require different procedures for tracking various distribution activities (e.g. sales versus rentals).

**Retailers**—including drug stores and department stores—are not required to keep distribution records of devices they sell.

**Health care facilities** are not required to keep distribution records if distribution is solely within their regional health authority. Health care facilities include:

- hospitals
- clinics
- groups of facilities forming one corporate entity



If you distribute devices outside your regional health authority or corporate entity, then record-keeping requirements apply. However, if you distribute medical devices to patients, this is considered a retail activity and you are not required to keep records.

## Section 53

Section 53 of the MDR states:



The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market.

Your procedures for distribution records should specify:

- how to record customer and device details for each sale
- what format the records should be in (e.g. paper, electronic), including any software programs to be used to keep the records
- where information is stored and how it is accessed

When you receive a product, create a record that includes:

- enough detail to identify the device, including:
  - name
  - device identifier
  - model number
  - catalogue number (if different from the identifier)
  - control number or lot number
- date received
- number of units received
- name of the person or company who supplied the device

When you distribute or ship a product, your record should include:

- enough detail to identify the device, including:
  - name
  - device identifier
  - model number
  - catalogue number if different from the identifier
  - control number or lot number
- date shipped to consignee
- number of units shipped
- name and address of the consignee



Keep client contact information in your records system consistent with how you will notify the client of a recall (e.g. contact name, phone number, fax number, email address).

## Section 54

Section 54 of the MDR states:



- (1) The distribution record maintained by a manufacturer of an implant shall also contain a record of the information received on the implant registration cards forwarded to the manufacturer from a health care facility pursuant to section 67.
- (2) The manufacturer of an implant shall update the information referred to in subsection (1) in accordance with any information received from the health care facility or the patient.

If you manufacture an implant listed in [Schedule 2 of the MDR](#), you are required to:

- include in its distribution record the information forwarded to you from a health care facility when they complete an implantation (per section 67 of the MDR)
- update the record with any further information you receive from the health care facility or the patient



These requirements apply to a select group of implantable devices defined as implants in [Schedule 2 of the MDR](#):

- heart valves
- annuloplasty rings
- active implantable device systems, including:
  - pacemakers
  - defibrillators
  - artificial hearts
  - ventricular support systems
  - drug infusion systems
- devices of human origin, including:
  - human dura mater
  - wound coverings containing human cells

## Section 55

Section 55 of the MDR states:



The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of:

- (1) the projected useful life of the device, and
- (2) two years after the date the device is shipped

Ensure your written procedures show the specific length of time you will keep records (e.g. in years). The manufacturer typically determines the projected useful life of a device.

It is not enough to repeat the text of section 55 in your written procedure. You must specify an amount of time based on the nature of devices you distribute. You may also specify different times for keeping paper and electronic records, or indicate that you will keep all records indefinitely.



## Section 56

Section 56 of the MDR states:



Distribution records shall be maintained in a manner that will allow their timely retrieval.

Ensure distribution records are kept so they can be easily retrieved (regardless of where they are physically located). In most cases, you should be able to retrieve records within one to two business days.

You may need time to access records from archived databases. Identify this as part of your recall strategy. If you change the software program you use to keep records, ensure you can still access records generated by your previous program or have alternate means of accessing those records (e.g. through paper copies).

## 8. Recall process

Section 58(b) of the MDR states:



The manufacturer, importer and distributor of a medical device shall each establish and implement documented procedures that will enable them to carry out an effective and timely recall of the device.

In addition, section 45(g) of the MDR requires a manufacturer, importer or distributor who holds an MDEL to make an attestation on the application stating they have these documented procedures in place.

### Overview of recall stages

This guide divides the recall process into two main parts:

1. [Initiating a recall](#)
2. [Conducting a recall](#)

The recalling company initiates a recall and conducts the recall for their consignees. Other companies further down the distribution chain (e.g. importers, distributors) also participate in the recall and notify their consignees.

Manufacturers, who are ultimately responsible for the device's safety and effectiveness, initiate the majority of recalls. However, importers and distributors must be able to initiate recalls if the cause of the defect or problem is related to their activities (e.g. a temperature-sensitive product freezing during shipping) or if the manufacturer is not willing or able to carry out a recall.

The recall process can be further divided into the following five steps.

## Initiating a recall

1. [Identify the need to initiate a recall](#)
2. [Develop recall strategy and scope](#)

## Conducting a recall

3. [Notify and correct](#)
4. [Follow up](#)
5. [Review and close recall](#)

Companies initiating a recall are involved in all five stages. Companies conducting a recall initiated by another company are involved in stages three, four and five.



For a visual representation of the recall stages described in this guide, see [Appendix B](#). After reading this section, you should use the self-assessment checklist in [Appendix E](#) to evaluate the completeness of your company's recall process.

## Stage one: Identify the need to initiate a recall

Manufacturers should initiate a recall action if they become aware the device (including its labelling) is defective or potentially defective and may:

- be hazardous to health

- fail to meet any claim made by the manufacturer or importer about its effectiveness, benefits or safety
- not meet the requirements of the Act or MDR

You might become aware of a defect or deficiency with a device through complaint investigations, inspections, or internal quality control testing or audits (e.g. for a non-conforming product). Defectiveness may be related to:

- design deficiencies
- component defects or failures
- labelling problems
- manufacturing problems
- software errors
- compliance issues (e.g. related to device licensing)
- improper shipping, installation or servicing

If you manufacture medical devices, you must have a means for determining when to:

- remove a medical device from the market
- correct a device
- notify owners and users that using a device carries risk

Your quality system should include ways to identify defects or deficiencies. It is your responsibility to determine the level of risk and the actions required to correct problems (e.g. investigating a complaint or non-conforming product, taking corrective or preventive actions).

Taking action to fix problems with a device that has been distributed is considered a “correction” and in most cases will meet Health Canada’s definition of a recall. In addition to a correction, you should likely take preventive action to prevent the problem from happening again.

## Stage two: Develop recall strategy and scope

A manufacturer’s documented recall procedures should require the development of a recall strategy that addresses:

- evaluation of risk
- evaluation of significant change to the medical device

- depth of the recall within the distribution chain
- timeliness
- recall communications
- how to notify users who are not readily identifiable
- evaluation of the effectiveness of the actions taken
- initiation date, progress reports to Health Canada and anticipated closure date

Once you have determined that a recall is needed, define the scope of products affected and develop a strategy for implementing the recall. Identify customers who may be affected early.

Your strategy should take into account:

- results of your risk evaluation
- the risk type you assign to the recall
- how easy it is to identify the recalled device
- the degree to which the device's defectiveness is obvious to the consumer or user
- the degree to which the device remains unused in the marketplace
- the continued availability of comparable alternative products with which to replace affected devices

Your strategy should also identify which companies are responsible for notifying clients. If you manufacture medical devices, you may get distribution lists from importers and distributors and conduct the recall notification for end users on their behalf.

## Notifying Health Canada about the recall

Both the importer and manufacturer are required to report the recall to Health Canada as required under S.64 of the MDR. This step must be clearly indicated in your recall procedure.



To read about specific requirements for reporting a recall to Health Canada, see the [Recall reporting process](#) section.

## Evaluation of risk

Recall procedures require companies to evaluate the risk associated with a defective device during the development of the recall strategy. The extent and type of the recall action depend on the hazards associated with using the defective device. When you evaluate risk, take into account:

- the nature and degree of the hazard
- the nature of the particular population at risk
- the size of the population at risk
- the degree of the customer's competence in using the device
- customer awareness of the problem
- whether any disease, injury or death have already occurred from using the device
- the probability that the issue will happen again
- the user's ability to detect the problem

Perform a risk/benefit comparison using the results of your risk evaluation. Use the results of your risk evaluation to assign a health hazard classification (Type I, II or III) for the recall:

- **Type I:** Assign this type to a situation in which there is a reasonable probability that the use of (or exposure to) a recalled device will cause serious adverse health consequences or death.
- **Type II:** Assign this type to a situation where the use of (or exposure to) a recalled device may cause temporary adverse health consequences, or where there is not a significant probability of serious adverse health consequences.



Types I and II include situations where a device that does not have recognized or scientifically supported therapeutic value is promoted such that recognized therapy is avoided, and that avoidance could lead to injury or death.

- **Type III**—Assign this type to a situation where the use of (or exposure to) a recalled device is not likely to cause any adverse health consequences.

You must include your risk evaluation in your initial recall report to Health Canada (see [Recall reporting process](#)). We will assess the information you provide, including the type you assigned to the recall. If our assessment determines the type to be a higher level, we may contact your company to discuss a revised strategy.

## Evaluation of significant change

Manufacturers are required to evaluate corrections that involve Class III and IV medical devices to find out if these corrections meet the definition of “significant change.”



“Significant change” means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. As outlined in section 1 of the MDR, it includes a change to:

- manufacturing processes, facilities or equipment
- manufacturing quality control procedures (including methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture)
- design of the device
- intended use of the device, including any new or extended use

When a Class III or IV device is recalled, you must evaluate whether any intended recall action fits the definition of significant change.

If you are planning a corrective action that fits this definition, then under section 34(a) of the MDR, you must submit an application for an amended medical device licence. Submit this application to Health Canada’s Medical Devices Bureau and describe the significant change. You must receive your amended MDEL before you can sell the modified device.

The results of your significant change review should be included in your final report to Health Canada, required by Section 65 of the MDR (see [Recall reporting process](#) in this guide).



You can find more information about significant change in Health Canada’s [\*Guidance for the Interpretation of Significant Change of a Medical Device\*](#).

## Depth of recall within the distribution chain

A recall strategy must define the “depth” of the recall—that is, how far in the distribution chain the recall will extend. Base the recall’s depth on the type of device (including where and how it is used) and the risk it poses to the public.

A recall may extend to the:

- user level (health care facilities, health care professionals)
- distributor level (including to importers)
- retail level
- general public (consumers and patients)

## Timelines

Your recall strategy must define time frames for key activities.

When initial communication is not the sole recall action, you must have a detailed plan that shows estimated time frames for accomplishing the remaining actions. Base this plan on the:

- complexity of corrective actions
- number and geographic location of customers
- risk associated with the affected device
- validation requirements
- continuing availability of essential products

## Recall communications

Your recall strategy must define the method and content for all communications associated with the recall. In general, recall communications include:

- a description of the device, including:
  - model number
  - lot number(s)
  - serial number(s)
  - other information to help identify the device (e.g. the software version)
- the reason for the recall (i.e. the risks associated with its use)
- when appropriate, that further distribution or use of the remaining product must stop immediately
- when appropriate, an indication for your customers who may have further distributed the device to forward the recall communication to their customers
- when appropriate, instructions for disposition of the product, with specific steps for return, disposal or correction

- request for a prompt response to confirm receipt of the recall communication



To encourage a quick response from customers or other companies, your recall communications might include:

- pre-addressed cards
- telephone replies using a toll-free number
- a form to complete and return by fax or email

Clearly mark your written recall communications (including notifications, cover sheets and envelopes), by displaying “**Medical device recall**” in bold, red font. Label Type I and II recalls “**Urgent**”.

The recalling company is responsible for sending out recall communications. Other companies may develop communications to be sent out along with those of the recalling company if they are carrying the recall forward to their customers.

## Notification of users who are not readily identifiable

Recall strategies must also consider how to contact medical device users who are not easy to identify. In these cases, you may consider other means of communication (e.g. a public notification). This is usually reserved for situations where the risk is classified as Type I or Type II.

Public notification may take different forms, depending on the nature of the population at risk. You could make announcements to the public through the media or posting on websites. Focus your communication by targeting specialized media (e.g. professional or trade presses) or specific segments of the population (e.g. doctors, hospitals or clinics).



The recalling company has primary responsibility for notifying the public. However, some situations could result in Health Canada issuing a public notification. The [Department of Health Act](#) authorizes Health Canada to inform Canadians about serious health risks.



## Stage three: Notify and correct

This stage begins when the recalling company notifies affected consignees (anyone who received or bought the affected device) of the recall. It also applies to consignees who have further distributed the product (e.g. importers, distributors).



The importer and distributor's recall procedures must clearly show the steps to follow when their company receives a recall. In the procedure, name the person or staff position responsible for each step.

This stage may involve several sub-stages. It includes the initial notification, and can be followed by corrections or device replacement.

### Quarantining the affected product

Review current stock to identify and quarantine any affected product still under your control. Quarantine measures can include physical quarantine as well as electronic quarantine methods to prevent products from being distributed.

### Identifying affected clients

Your recall procedures should describe how to generate a distribution list of affected customers. You will also need a method for locating customer contact information. Distribution lists must account for devices distributed by any means, including through:

- sales
- rentals
- provision of loaners, demonstration devices and samples

The degree to which you are able to trace distribution records determines how many clients you will need to contact. For example, during a recall for a specific lot or serial number, you would only need to notify the customers who received the affected lots.



Once you have identified affected clients and are ready to begin the notification process, you are required to submit your initial recall report to Health Canada under section 64 of the MDR (see [Recall reporting process](#)).

## Method of notification

Describe in your recall procedures how you will communicate with affected clients. You can identify both primary and secondary methods of communication.

Make every effort to ensure you contact the most appropriate individual. Include contact information in the distribution records. For large health care facilities, you may keep more than one contact (e.g. a contact for purchasing and a contact for recalls, such as a risk manager).

You can accomplish recall communications using several means, including:

- telephone calls
- personal visits
- fax
- email
- special delivery letters (i.e. registered mail, courier)

When using telephone calls or other personal contact, you may need to follow up in writing to communicate detailed information.

## Notification timelines

Your recall procedures must specify prescribed time frames to initiate contact with affected clients.

If your company was involved in distributing the affected product, you are responsible for promptly notifying each of your consignees about the recall. Use these guidelines:

- For **Type I** recalls, make initial contact within 1–2 business days of starting the recall.
- For **Type II** recalls, make initial contact within 3–5 business days.
- For **Type III** recalls, make initial contact within 5–7 business days.



It is very important that you follow these guidelines. If you cannot contact consignees within the above time frames, you must provide a rationale in your recall strategy.

Also estimate a reasonable response time for consignees in your recall strategy.

## Tracking responses to recalls

Your recall procedures should require that responses be tracked and describe how you will track them. We expect any company involved in a recall to maintain records showing that they made appropriate efforts to contact all consignees. These records could include:

- dates of attempted contact
- name and title of person you contacted
- means of contact (e.g. telephone or fax number, email address, mailing address)
- details of communications once contact is successful
- whether recall instructions were understood and carried out
- response received at each attempt
- copies of completed response forms
- copies of related correspondence

Evidence of contact could include a fax-back form, email response or telephone log. Document details of all contact you make with a client. Ensure you follow up with anyone who does not respond (see [Evaluation of recall effectiveness](#)).

## Completing and tracking recall actions

The recalling company must also complete and track other required actions related to the affected product (e.g. product removal or correction). Once you receive confirmation that your initial notification of the recall was received, complete other actions related to the recall, which could include:

- returning the device for destruction or rework
- having the client destroy the device on site
- having the client inspect or test the device on site
- providing parts to the client so they can correct or retrofit the device
- providing new labelling
- patching or upgrading software
- inspecting, testing, correcting or retrofitting the device at a client's location
- returning the device for inspection, testing, correction or retrofitting

Track each action you complete. Because some recalls involve multiple actions, you may want to use spreadsheets or databases to track completion of recall actions.

## Collecting the affected product

Your recall procedures must identify how the recalled device should be handled until it is disposed. Due to potential risks, any returned product must be controlled to prevent it from being further used or distributed.

## Stage four: Follow up

Specify the steps required to follow up on the corrective actions described in your recall procedures. Follow-up could include:

- evaluating the recall's effectiveness
- remedial actions
- disposition of the affected product

## Evaluating recall effectiveness

When the recall is complete, evaluate its effectiveness. How many responses did you receive following your notification process? How successfully did your company complete corrective actions?

Your recall strategy should specify how to evaluate the recall effectiveness. In most cases, you can monitor the effectiveness of the initial notification through the level of customer response (e.g. how many fax-back forms you received). Responses may involve written acknowledgement that the customer received, read and understood the recall. You may also require customers to provide information about the status of affected devices. Evaluate the effectiveness of each action required under the recall (e.g. responses to the initial notice, corrections or returns).

## Following up with non-responders

If customers do not respond to the initial notification, you must follow up. "Non-responders" are people from whom you do not receive a return fax, email, courier or phone message. Health Canada expects your recall procedures to define how you will follow up with non-responders.

Use the following guidelines:

- **Type I:** No non-responders may remain. Due to the high level of risk, all customers must be aware of the recall as soon as possible. If needed, make a personal visit to inform customers of the recall. If any non-responders do remain, you must provide a justification that includes records of each follow-up attempt.
- **Type II:** Follow up with non-responders two additional times using different contact methods. Keep records of each follow-up attempt.
- **Type III:** Make one additional follow-up effort, preferably using another means of contact.

In addition to monitoring responses, consider information provided by users—especially if it indicates the recall was not effective. For example, there may be cases where the problem affects other products or lots not specified in your original recall notice, or where a correction creates a new problem.

If you cannot easily identify customers who own or have used the affected product, provide a mechanism for them to respond (e.g. public notices with toll-free numbers). In these cases, you may not be able to follow up with all non-responders.

## Checking completion of recall actions

Review your tracking mechanism for corrective actions to ensure you have dealt with all affected product. You are responsible to ensure that all recall actions are complete.



Health Canada recognizes that corrective actions may depend on the consent and cooperation of the user or owner of the device. If the owner does not permit or conduct the actions required by the recall despite repeated attempts to communicate their importance, include this information in your recall records.

Review all information you collect during this evaluation step to determine if you must take additional action to address risk. This may include revising or adding to your recall strategy.

## Health Canada effectiveness checks

After you complete your communication with consignees and follow up with non-responders, we may review your records of customer contact and check the effectiveness of your company's recall strategy.

## Product disposition

When product has been returned, dispose of it as outlined in your recall strategy. Keep appropriate records to show that you have disposed of all affected product.

## Stage five: Review and close recall

Steps required to review and close completed recalls include:

- [doing a final review](#)
- [submitting a final recall report to Health Canada](#)
- [closing the recall](#)
- [completing final documentation](#)

## Final review

The recall procedure requires a final review to determine if the recall is ready to be closed. You may only close a recall once all notifications, corrections and follow-up actions have been completed and have addressed the problem. A qualified person or group must do a final review to ensure the recall file contains or references records for all recall actions.

You must review the following information, as applicable, before determining that a recall is complete:

- number of units recovered
- number of units consignees used
- number of units consignees destroyed (as requested in the recall notice)
- number of units corrected (i.e. modified, repaired or retrofitted), either on site or off site, and returned to consignees
- number of units you could not locate
- statement of the method or intended method used to dispose any recovered units or stock units (evidence of disposition should be available to Health Canada on request)
- final completion date for the recall
- assurance that all consignees received the recall information (evidence should be available to Health Canada on request)

- detailed plan to prevent the problem from happening again and to resolve the problem using measures, including:
  - design change
  - process validation
  - increased quality control
- evaluation of significant change (for **Class III** and **Class IV** medical devices only)

Your review of the completed recall can also provide valuable information about recall strategies and procedures. Companies may use their experiences during a recall to refine their approach for future recalls.

## Notifying Health Canada that the recall is closed

When a company believes a recall can be closed based on their final review, importers and manufacturers must submit a final recall report to Health Canada as required under section 65 of the MDR. This step must be clearly indicated in your recall procedure.



To read about specific requirements for reporting a recall to Health Canada, see the [Recall reporting process](#) section.

## Closing the recall

You must document the closure of your recall. The person you choose to close the recall should be familiar with all aspects of the recall process, and must sign and date the documentation.

When Health Canada receives your final recall report, we will send you a letter to confirm that the recall is closed.

## Completing final documentation

### Records maintained by the manufacturer, importer and distributor

Your company must keep sufficient documentation to show that you completed the necessary recall actions in a timely and effective manner and complied with the MDR.

**Importers** and **distributors** must maintain a recall file showing their involvement in the recall. This file should contain distribution lists, as well as records of notifications, corrections and recall effectiveness checks.

## Retention time

Your recall procedures should define how long to keep recall records. There are no specific regulatory requirements for how long to keep your records. However, Health Canada recommends the following:

- Manufacturers should keep their records as long as the devices involved are being sold.
- Importers and distributors should keep their records for the projected useful life or expected shelf-life of the device.

# 9. Reporting process

## Guidance for recall reports

### Section 63

Section 63 of the MDR states:



Sections 64 and 65 do not apply to:

- (1) a retailer
- (2) a health care facility in respect of a medical device that is distributed for use within that facility

The recall reporting requirements described in sections 64 and 65 of the MDR do **not** apply to retailers or health care facilities (e.g. hospital corporations who distribute devices among organizations they control).



If you manufacture or import medical devices sold in Canada, the recall reporting requirements outlined on the following pages apply to you.



## Sections 64 and 65

Manufacturers' and importers' recall procedures should include information to help write initial and final recall reports for submission to Health Canada. Specify in your procedures:

- specific content required in initial and final recall reports (per sections 64 and 65 of the MDR—see [Appendix G](#) for more information)
- time frame for submitting initial and final recall reports to Health Canada
- need for progress reports, if requested by Health Canada
- contact details for your nearest Health Canada regional office



For a detailed list of information to include in your initial and final recall reports, see [Appendix G](#).

## Submitting your reports

To submit a recall report, follow these guidelines:

1. Submit a section 64 initial report to your nearest Health Canada regional office within three business days of starting the recall. The start date of the recall is when you begin sending out recall notifications (i.e. the date on the recall notification letter). Use the Medical Device Recall Reporting Form - Initial (FRM-0360) to complete your initial recall report.
2. Submit a section 65 final report to your nearest Health Canada regional office as soon as possible after completing the recall. Use the Medical Device Recall Reporting Form - Final (FRM-0360) to complete your final recall report.

Health Canada's [Recall Policy \(POL-0016\)](#) further specifies that you must provide verbal or written notification to Health Canada within 24 hours of deciding to proceed with a recall. If you are not able to notify us within this time frame, you must provide a rationale in your initial recall report.

## Section 65.1

Section 65.1 of the MDR states:



- (1) Despite sections 64 and 65, the manufacturer of a medical device may permit the importer of the device to prepare and submit, on the manufacturer's behalf, the information and documents with respect to the recall if the information and documents that the manufacturer and importer must submit are identical.
- (2) The manufacturer shall advise Health Canada in writing if the manufacturer has permitted the importer to prepare and submit the information and documents with respect to the recall on the manufacturer's behalf.

We require both the manufacturer and the importer to submit recall reports unless the manufacturer designates an importer to report on their behalf. The manufacturer may only designate the sole importer of the device in Canada, and the information the importer submits must be identical to that of the manufacturer. If you are a manufacturer and you want to designate an importer to submit a recall report on your behalf, ensure the importer understands the recall reporting requirements. Once designated, the importer will provide all recall information required by sections 64 and 65 of the MDR.



Manufacturers must submit a written notification to Health Canada confirming that the importer accepts the recall report designation. Send this notification to your regional office. (See [Appendix I](#) to find the Health Canada office nearest you.)

## Interim or progress reports

After we review your initial recall report, we may request that you submit interim or progress reports at agreed-upon intervals. We normally request interim reports for:

- recalls with long projected completion dates
- recalls with multiple stages
- recalls not completed by the projected date

Recall progress reports contain the:

- number of consignees notified of the recall
- date and method of notification
- number of respondents and quantity of affected devices in their possession
- number of non-respondents (we may request their identity)
- number of devices returned or corrected
- number and results of recall effectiveness checks
- estimated time frame for completion (if revised)

# Appendix A – Glossary



These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or associated regulations, including the [Medical Devices Regulations \(MDR\)](#), the definition in the Act or regulations prevails.

**Consignee** – Anyone who received purchased or used a product being recalled.

**Control number** – A unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labelling and distribution of a lot or batch of the device can be determined.

**Correction** – Action to eliminate a detected non-conformity. This can include a recall to address non-conforming devices in distribution. Includes the repair, modification, adjustment, re-labelling 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. It could be, for example, a rework or regrade. ([ISO 13485–Medical Devices Quality Management Systems: System Requirements for Regulatory Purposes](#)).

**Device ID** – The number given to a specific device by Health Canada in order to enter the information about the device into the medical devices database. The device ID was formerly referred to as the “device accession number.” It is not the same as the device “identifier” assigned by the manufacturer.

**Distributor** – A person other than a manufacturer, importer or retailer who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.

**Effectiveness check** – Includes a survey of those affected by the recall (consignees) to verify they have received the recall notification and are aware of any appropriate action to be taken. May include verification of the action taken. The recalling firm is responsible for conducting effectiveness checks, which may also be undertaken or verified by Health Canada.

**Establishment** – A person required to have an establishment licence per section 44 of the MDR. To learn more about licensing requirements, read Health Canada’s [Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licensing Fees \(GUI-0016\)](#).

**Harm** – Physical injury or damage to the health of people, or damage to property or the environment. ([ISO 14971—Medical Devices: Application of Risk Management to Medical Devices](#)).

**Hazard** – Potential source of harm. ([ISO 14971—Medical Devices: Application of Risk Management to Medical Devices](#)).

**Health hazard classification** – The numerical designation (i.e. Type I, II, or III) assigned to a particular device recall to indicate the relative degree of risk presented by the device being recalled, with Type I being of the highest concern.

**Health risk assessment** – The scientific characterization of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to hazards. The process includes these steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

**Device identifier** – A unique series of letters/numbers or a bar code that is assigned to a medical device by the manufacturer to identify and distinguish it from similar devices.

**Implant** – A medical device listed in [Schedule 2 of the MDR](#).

**Importer** – A person in Canada, other than the manufacturer of a device, who is responsible for the medical device coming into Canada for sale.

**Label** – Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. Labels are not only information affixed to a device or the packaging but also manuals, package inserts, brochures and leaflets. (Section 2 of the *Food and Drugs Act*)

**Manufacturer** – A person who sells a medical device under their own name, or under a trademark, 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 to it a purpose, whether those tasks are performed by that person or on their behalf.

**Medical device** – A device within the meaning of the Act except any device that is intended for use in relation to animals. The definition in the Act includes used devices, parts and accessories.

**Person** – Includes a partnership and an association.

**Quarantine** – Effective restriction of the availability of material or device for use or distribution by the company, until released by a designated authority.

**Recall** – In respect of a medical device that has been sold, 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:

- may be hazardous to health
- may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety
- may not meet the requirements of the Act or the MDR

**Recall depth** – The level of distribution from which a device is recalled (i.e. wholesale, retail, user or consumer).

**Recall strategy** – A planned course of action taken by a recalling company in conducting a specific recall, including but not limited to the depth of recall, the need for public warnings and the extent of effectiveness checks for the recall.

**Risk** – Combination of the probability of occurrence of harm and the severity of that harm. ([ISO 14971—Medical Devices: Application of Risk Management to Medical Devices](#)).

**Risk analysis** – Systematic use of available information to identify hazards and to estimate the risk. ([ISO 14971—Medical Devices: Application of Risk Management to Medical Devices](#))

**Risk assessment** – Overall process comprising of risk analysis and a risk evaluation. (([ISO 14971—Medical Devices: Application of Risk Management to Medical Devices](#))).

**Risk evaluation** – Judgment, on the basis of risk analysis, of whether a risk that is acceptable has been achieved in a given context based on the current values of society. ([ISO 14971—Medical Devices: Application of Risk Management to Medical Devices](#)).

**Significant change** – A change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to the:

- manufacturing process, facility or equipment
- manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture
- design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories

- intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device, and any change to the period used to establish its expiry date

**Stock recovery** – A manufacturer, importer or distributor’s removal or correction of a device that has not been distributed or that has not left the direct control of the company. A stock recovery is not considered to be a recall. However, if product leaves the control of a manufacturer but has not left the control of subsequent importers or distributors, the action is considered a recall at the manufacturer’s level and a stock recovery at the importer/distributor’s level. If permitted by the manufacturer (per section 65.1 of the MDR), the importer may prepare and submit recall information and documents on the manufacturer’s behalf.

## Appendix B – Recall stages



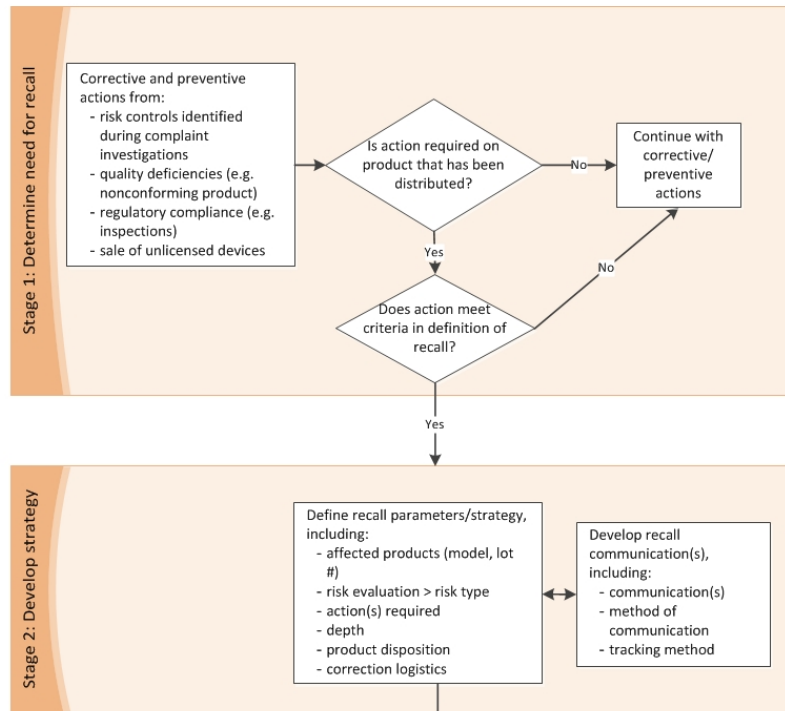
The following flowcharts illustrate stages of the recall process discussed in this guide. The first flowchart covers all stages of the process and is applicable to manufacturers or other companies who initiate a recall.



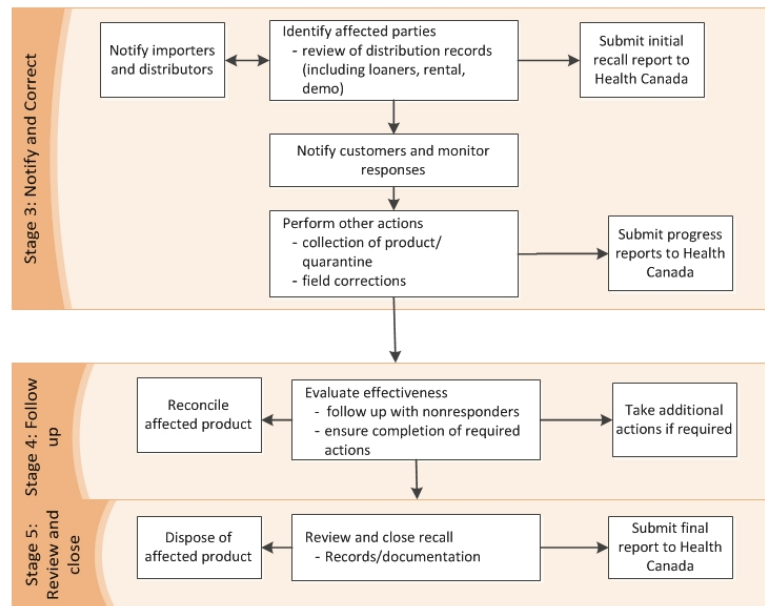
## Medical device recall process for company initiating the recall

Overview – Stages 1-5

Initiating recall



Conducting recall



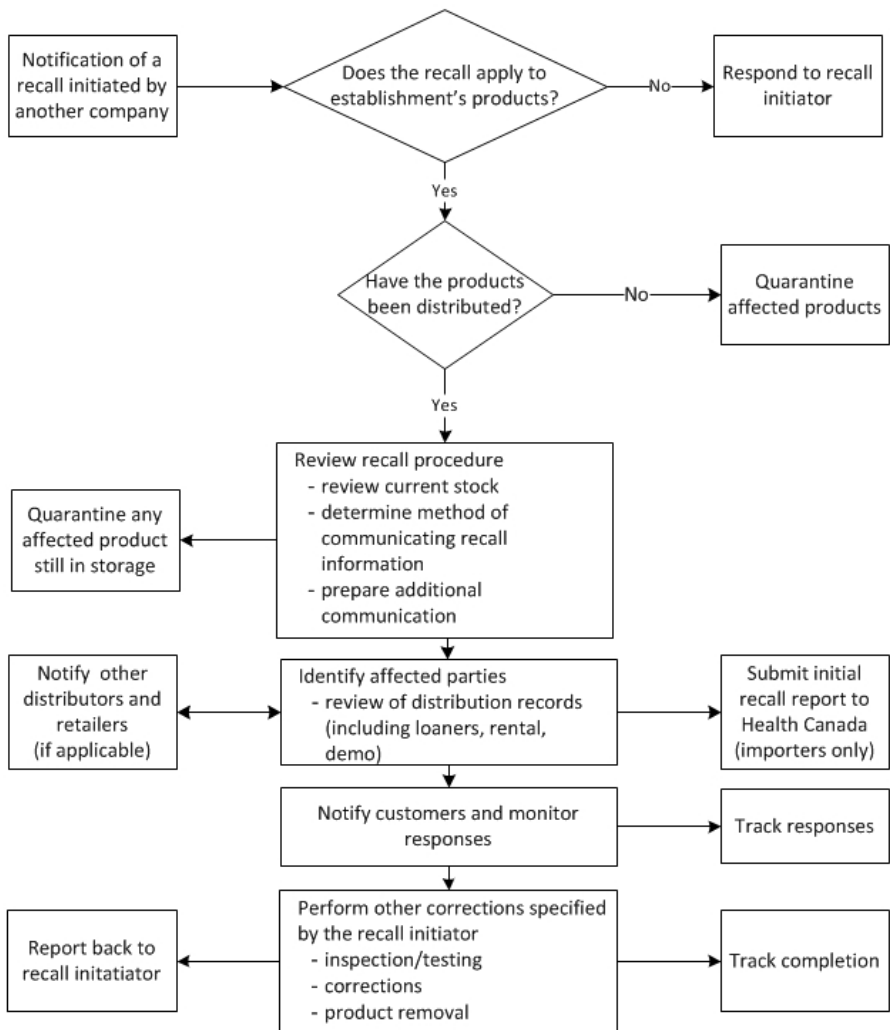


The following flowchart is for importers and distributors who are conducting a recall initiated by a manufacturer.

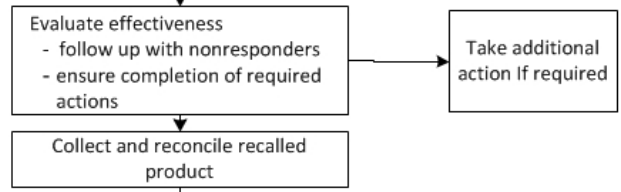
Medical device recall process for conducting a recall initiated by another company

Overview – Stages 3-5

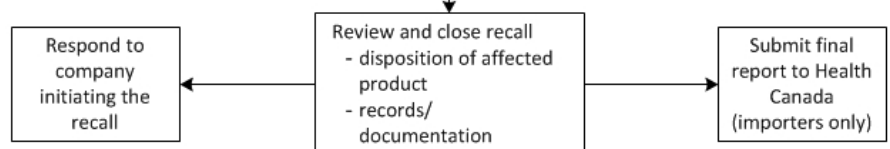
Stage 3:  
Notify and  
Correct



Stage 4:  
Follow up



Stage 5:  
Review and  
Close

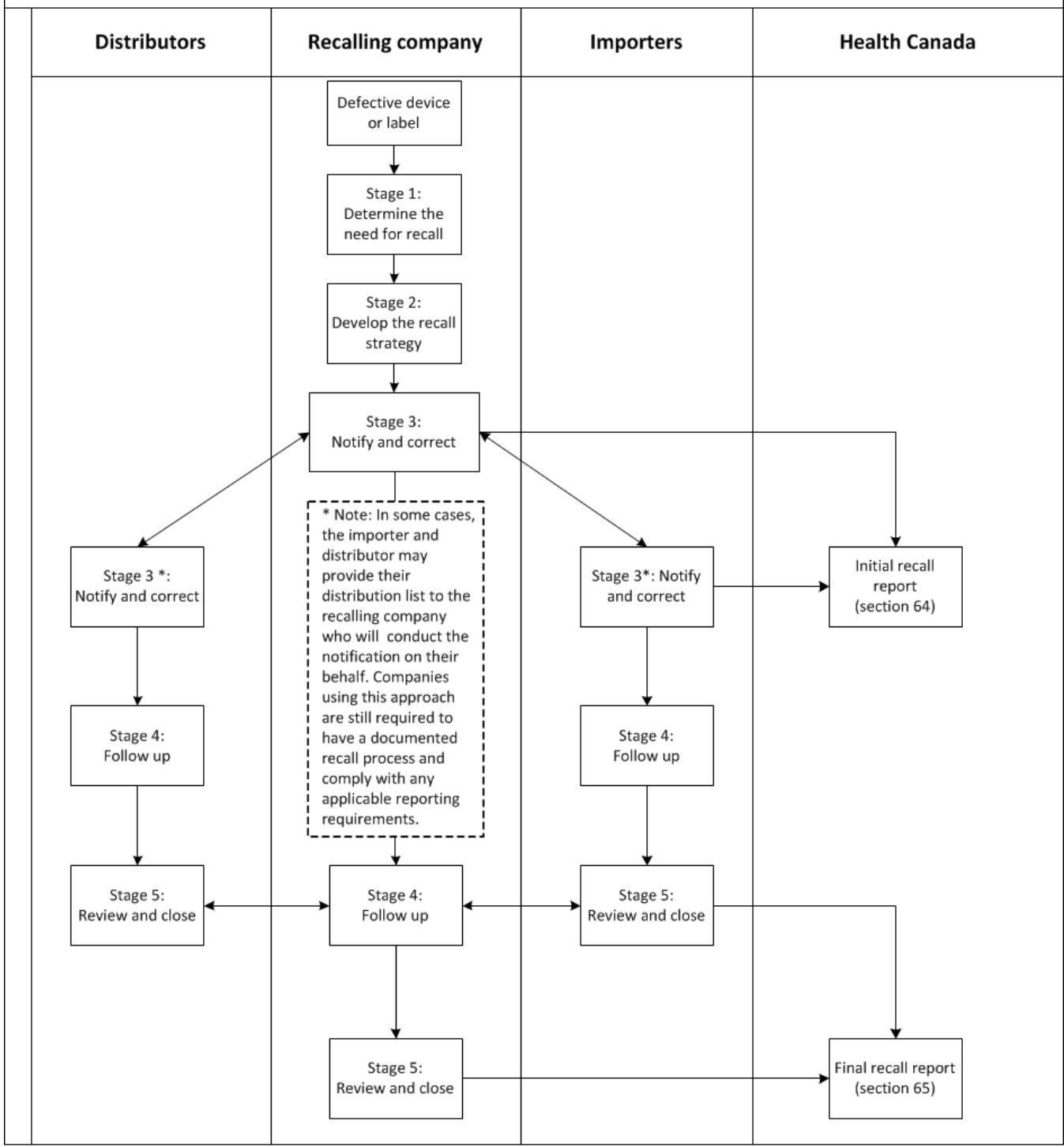


# Appendix C – Roles and responsibilities



This flowchart illustrates the relationship between a recalling companies (normally a manufacturer) and importers and distributors who are conducting the recall further down the chain of distribution.

**Responsibilities and relationships of regulated parties**



# Appendix D – Checklist for distribution records



The following checklist will help you assess your procedures for creating and maintaining distribution records. Use it to check whether you are fulfilling the distribution record-keeping requirements in sections 52 to 56 of the [Medical Devices Regulations \(MDR\)](#).

## Creating a distribution record

- Our company has identified triggers for distributing products. They may include:
  - receipt of purchase orders from clients
  - rental or lease agreements
  - requests for demonstration units, loaner units and samples
- We have described any forms or logs used to collect this information in our written procedures, and copies or templates are attached as applicable.
- We identify which staff members are responsible for recording distribution records.
- If we collect information electronically, we have described the electronic system and how to back up data in our procedures.

## What to include in a distribution record



These requirements come from section 53 of the MDR.

- Our distribution records include customer information.
- Our distribution records include device information.

## Maintaining distribution records



These requirements come from section 55 of the MDR.

- We have specified in our procedures how long our company will keep distribution records for medical devices. This time period is adequate to cover the device's longest projected lifespan.
- We have expressed this time period (e.g. in years), or have indicated that the records will be kept indefinitely.
- We understand that keeping records in archived format is acceptable if we are able to retrieve the records quickly.

## Retrieving distribution records



This requirement comes from section 56 of the MDR.

- We have specified in detail how to retrieve distribution records during a recall in our written procedures.

# Appendix E – Checklist for recalls



The following checklist will help you understand the specific steps to follow during a recall process. It is a valuable tool for evaluating the adequacy of your company's recall procedures. However, it is not intended to provide an exhaustive description of the recall process.

Our company's recall procedures include:

- definitions of key terms, including "recall"
- the person(s) responsible for managing recalls

## Part one: Initiating a recall



Manufacturers initiate most medical device recalls. However, importers and distributors who might also initiate a recall should address the initial recall phase in their written procedures.

### Stage one: Determine the need for a recall

- Our company's procedures address recalls that we initiate within our company versus recalls that are received from a supplier or manufacturer.
- We have linked any procedures that may be sources of recalls (e.g. complaint handling, corrective and preventive actions or handling non-conforming products) to our recall procedures.

### Stage two: Develop a strategy

- Our procedures describe the steps for developing a recall strategy, including factors to consider when researching and writing the strategy.



## Part two: Conducting a recall

### Stage three: Notify and correct

- Our procedures describe the recall notification process.
- Our procedures have set timelines to ensure that recalls are initiated in a timely fashion, according to the level of risk.
- Our procedures require importers and manufacturers of the medical device to provide Health Canada with an initial recall report.
- Our procedures outline how we will communicate a recall to affected clients (e.g. by fax, email or phone). They include any requirements for affected clients to provide an acknowledgement or response when we issue a recall notification.
- Our procedures specify how we will track acknowledgements and responses from affected customers.
- Our procedures specify how a returned product is to be quarantined until it can be corrected or disposed of.

### Stage four: Follow up

- To allow us to evaluate the effectiveness of a recall, our procedures describe how we will track responses from notified customers as well as the completion of our recall actions.

### Stage five: Review and close recall

- Our procedures specify criteria for closing a recall.
- Our procedures require that senior management reviews and signs off on a recall closure.
- Our procedures specify how we will create records showing that each step of the recall was completed. They also specify where, how and how long this documentation will be stored.
- Our procedures require importers and manufacturers to provide final recall reports to Health Canada.

# Appendix F – Guidelines for writing procedures



Use the following general guidelines when writing procedures (e.g. distribution record keeping or recall procedures).

## Definitions

Your written procedures should include definitions for key terms used to describe the activities (e.g. “recall”).

## Responsibilities

Assign overall responsibility for each procedure to a qualified individual with enough knowledge and authority to ensure it is effectively implemented.

## Activities

Include detailed instructions about the steps involved in completing each activity.

## Format

Your written procedures should follow a consistent format. Here is a sample format:

1. **Purpose:** Include a briefly stated reason for the procedure.
2. **Scope:** Define the situations, people or laws to which the procedure applies.
3. **Responsibility:** Define the units or people responsible for carrying out the procedure.
4. **References:** Include any useful references to:
  - corresponding chapters in your quality manual
  - applicable quality system standards
  - related procedures
  - federal regulations

5. **Definitions:** Include any relevant definitions (e.g. for “recall”).
6. **Procedure:** Describe the step-by-step actions that need to be taken. (This section may also be labelled “Instructions,” “Actions” or “Methods.”)
7. **Documentation:** List the kinds of records associated with the procedure, as well as where these records are filed and how long you will keep them. (Alternatively, you may state how long you will keep records in your procedures for data and documentation control.)
8. **Distribution:** Identify staff or departments within your company who will receive the procedure.
9. **Revision sheet or table:** Include:
  - revision level (i.e. letter, number or combination)
  - date of the revision
  - effective date of the revision
  - a brief description of the change(s)

You may also track revisions as part of your general documentation control procedures.

10. **Attachments:** Include all forms you will use to carry out the procedure (e.g. a recall reporting form).

# Appendix G – How to write recall reports



Sections 64 and 65 of the (MDR) require manufacturers and importers to submit reports to Health Canada outlining details about a medical device recall process. This Appendix outlines the information you must provide to Health Canada in your initial and final recall reports.

## Section 64: Initial recall report

This section of the MDR outlines specific requirements for what to include in an initial recall report to Health Canada. It states:



The manufacturer and the importer must, on or before undertaking the recall, provide Health Canada with an initial recall report containing the following information:

- (1) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family
- (2) the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer
- (3) the reason for the recall, the nature of the defectiveness or the possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered
- (4) an evaluation of the risk associated with the defectiveness or possible defectiveness
- (5) the number of affected units of the device that the manufacturer or importer:
  - a. manufactured in Canada
  - b. imported into Canada
  - c. sold in Canada
- (6) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer
- (7) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units sold to each person

- (8) a copy of any communication issued with respect to the recall
- (9) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion
- (10) the proposed action to prevent a recurrence of the problem
- (11) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall

To fulfill section 64 requirements, follow these guidelines when writing your initial report:

1. Describe the device being recalled as completely as possible in your initial notice. Include the device's:
  - licensed name
  - identifier (e.g. catalogue number, product code, bar code)
  - lot number, batch number or serial number
  - licence number
  - medical device identification number, if known
2. Identify the device's manufacturer and importer. Report the full name and address of the manufacturer (found on the device's label) and of the importer (if applicable). Include the street address and postal/ZIP code. If the device was fabricated at a site different from that of the manufacturer, also provide the full name and address of the contract manufacturer.
3. Describe the problem or potential problem with the device. Keep the description to 50 words or less in both official languages (French and English). Additional information required to be provided as per section 64 (such as the date you discovered the problem and how you found out about it, any death or injury resulting from the problem or defect) is to be attached separately.
4. State the level of risk associated with using the device in its defective state and the likelihood that it could injure users.



You should assign a level of risk to each recall. For information about types of risk and how to assess a recall's risk level, read [Risk evaluation](#) in this guide.

5. Account for all affected units of product. State the number of units that remain in the manufacturer or importer's stock. If more than one medical device is involved in the recall, provide numbers of affected units for each.
6. State the distribution period for the device. At minimum, report the dates of the first and last sale of the device in its defective state. If more than one medical device is involved, include each distribution period separately.
7. Report each person to whom the device was sold. Include the:
  - name and contact information for each person or company
  - number of units distributed to that person or company
  - name of each individual to whom you provided the recall information

For example, if the device was sold to a hospital, provide the name and contact information for each individual in the hospital who received the recall notice.

8. Attach copies of all documented communications about the recall in both official languages, including:
  - letters or written notices to consignees
  - acknowledgment forms
  - public notices or press releases
  - notices to professional associations
9. Include specific information about how you plan to conduct the recall, including the dates it will begin and close. You must provide a rationale if you expect the recall to be completed more than three months after your initial notice to Health Canada.



For more guidance on how to develop a recall strategy, read [Stages of the recall process](#) in this guide.

10. Describe how you plan to prevent the problem or potential problem from happening again. Include an analysis of the issue's root cause (if known) and the scope of affected production. If you do not yet have a detailed plan, indicate where you will focus efforts in understanding and resolving the problem.

11. Provide contact information for your company. Specify a representative who is easy to reach and knowledgeable about the recall process. If possible, provide a fax number or email address in addition to the contact's name, title and telephone number. If the recall has been assigned a Type I risk rating, this person should be available on a 24-hour basis.

## Section 65: Final recall report

Section 65 of the MDR states:



The manufacturer and importer of a medical device shall, as soon as possible after the completion of a recall, each report to Health Canada:

- (1) the results of the recall
- (2) the action taken to prevent a recurrence of the problem

Manufacturers and importers must submit a written report upon completion of the recall. Your report should include:

- the number of recovered units
- the number of units used by consignees
- the number of units destroyed by consignees (as requested in the recall notice)
- the number of units corrected (modified, repaired or retrofitted), either on site or off site, and returned to consignees
- the number of units that were not located
- how you intend to dispose of any recovered units or stock units (you must provide evidence of disposition to Health Canada upon request)
- the recall's final date of completion
- assurance that all consignees received the recall information (we may request evidence)
- a detailed plan showing how you have corrected the problem and how you will prevent it from happening again (e.g. design change, process validation or increased quality control)
- evaluation of significant change, if applicable

# Appendix H – References

## Legislation

### *Food and Drugs Act*

[laws-lois.justice.gc.ca/eng/acts/F-27/index.html](http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html)

### Medical Devices Regulations

[laws.justice.gc.ca/eng/sor-98-282/page-1.html](http://laws.justice.gc.ca/eng/sor-98-282/page-1.html)

## Health Canada guidance

### *Guidance Document for Mandatory Problem Reporting for Medical Devices*

[hc-sc.gc.ca/dhp-mps/pubs/medeff/\\_guide/2011-devices-materiaux/index-eng.php](http://hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php)

### *Guidance for the Interpretation of Significant Change of a Medical Device*

[hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchng\\_modimportante-eng.php](http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchng_modimportante-eng.php)

### *Recall Policy (POL-0016)*

[hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-droques/pol\\_0016\\_tc-tm-eng.php](http://hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-droques/pol_0016_tc-tm-eng.php)

## Other guidance

### *ISO 14971—Medical Devices: Application of Risk Management to Medical Devices*

[www.iso.org/iso/catalogue\\_detail?csnumber=38193](http://www.iso.org/iso/catalogue_detail?csnumber=38193)

### *ISO 13485—Medical Devices Quality Management Systems: System Requirements for Regulatory Purposes*

[www.iso.org/iso/catalogue\\_detail?csnumber=36786](http://www.iso.org/iso/catalogue_detail?csnumber=36786)



# Appendix I – Contacts



Submit notification of a recall to the Health Canada regional office nearest you. If you are unsure who to contact, call 1-800-267-9675 to find a regional office.

REGIONAL OFFICE CONTACT INFORMATION	
Location of recalling company	Contact for recall reporting (by region)
<p><b>Canada</b> – New Brunswick, Newfoundland and Labrador, Nova Scotia, Prince Edward Island</p> <p><b>United States</b> – Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, Rhode Island, Vermont</p> <p><b>World</b> – Middle East (Bahrain, Cyprus, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, West Bank and Gaza Strip, Yemen)</p>	<p><b>Atlantic region</b>            Medical Devices Compliance Program            Suite 1625, 16<sup>th</sup> Floor            1505 Barrington Street            Halifax, NS B3J 3Y6            Phone: 902-426-2160            Fax: 902-426-6676            Email: ATL-MED@HC-SC.GC.CA</p>
<p><b>Canada</b> – Quebec</p> <p><b>United States</b> – District of Columbia, Florida, Georgia, New York, North Carolina, Pennsylvania, South Carolina, Virginia, West Virginia</p> <p><b>World</b> – All islands in the Caribbean; Central America (Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama); Scandinavia and Baltic States (Denmark, Estonia, Finland, Latvia, Lithuania, Norway, Sweden); Central Europe (Austria, Belgium, France, Germany, Liechtenstein, Luxembourg, Netherlands, Switzerland)</p>	<p><b>Quebec region</b>            Medical Devices Compliance Program            1001 Rue St-Laurent Ouest            Longueuil, QC J4K 1C7            Phone: 450-646-1353            Fax: 450-928-4313            Email: QUE-MED@HC-SC.GC.CA</p>

Location of recalling company	Contact for recall reporting (by region)
<p><b>Canada</b> – Ontario</p> <p><b>United States</b> – Alabama, Illinois, Indiana, Kentucky, Michigan, Mississippi, Ohio, Tennessee, Wisconsin</p> <p><b>World</b> – Northern Europe (Iceland, Ireland, England, Scotland, Wales, Northern Ireland), Eastern Europe (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovak Republic, Slovenia), Southern Europe (Greece, Holy See, Italy, Malta, Monaco, Portugal, San Marino, Spain); all countries in South America</p>	<p><b>Ontario region</b></p> <p>Medical Devices Compliance Program 2301 Midland Ave. Toronto, ON M1P 4R7 Phone: 416-973-1600 Fax: 416-954-4581 Email: <a href="mailto:ONT-MED@HC-SC.GC.CA">ONT-MED@HC-SC.GC.CA</a></p>
<p><b>Canada</b> – Manitoba, Saskatchewan</p> <p><b>United States</b> – Arkansas, Iowa, Kansas, Louisiana, Minnesota, Missouri, Nebraska, North Dakota, Oklahoma, South Dakota, Texas</p> <p><b>World</b> – All countries in Africa; Mexico</p>	<p><b>Manitoba-Saskatchewan region</b></p> <p>Medical Devices Compliance Program 100 – 391 York Avenue Winnipeg, Manitoba R3C 4W1 Phone: 204-983-5490 Fax: 204-984-2155 Email: <a href="mailto:MS-MED@HC-SC.GC.CA">MS-MED@HC-SC.GC.CA</a></p>
<p><b>Canada</b> – Alberta, Northwest Territories, Nunavut</p> <p><b>United States</b> – Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming</p> <p><b>World</b> – Australia, New Zealand; all islands in the South Pacific</p>	<p><b>Alberta region</b></p> <p>Medical Device Compliance Program Suite 730, 9700 Jasper Avenue Edmonton, AB T5J 4C3 Phone: 780-495-6815 Fax: 780-495-2624 Email: <a href="mailto:AB-MED@HC-SC.GC.CA">AB-MED@HC-SC.GC.CA</a></p>
<p><b>Canada</b> – British Columbia, Yukon</p> <p><b>United States</b> – Alaska, California, Hawaii, Oregon, Washington</p> <p><b>World</b> – All countries in Asia</p>	<p><b>British Columbia region</b></p> <p>Medical Devices Compliance Program 400 – 4595 Canada Way Burnaby, BC V5G 1J9 Phone: 604-666-3350 Fax: 604-666-3149 Email: <a href="mailto:WOC-MED@HC-SC.GC.CA">WOC-MED@HC-SC.GC.CA</a></p>