Guide for recalling medical devices (GUI-0054)

Health Canada Santé Canada

Canada

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Overview

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Disclaimer: This guide is an administrative document and does not constitute legislation. If there's any inconsistency or conflict between the legislation and this guidance document, the legislation takes precedence. This guide is intended to help regulated parties comply with the legislation and the applicable administrative policies.

Purpose

Recalling a product generally means removing it from sale or correcting a device. In Canada, actions such as notifying users of a potential problem or supplying different labelling for a medical device are also considered recalls.

This guide is for manufacturers, importers and distributors who work with medical devices.

It will help you:

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

Scope

This guide applies to the following sections of the Medical Devices Regulations (regulations) that are concerned with recalls:

- Distribution records (sections 52 to 56)
- Recall process (section 58(b))
- Recall reporting process (sections 63 to 65)
- Ordered recall process (sections 65.2(1) and 65.5)
- Recall record (sections 65.3 and 65.4(1))

To determine which sections of the regulations apply to you when you're involved in a recall, refer to the following table. The requirements will vary depending on whether you're a manufacturer, importer or distributor.

Table 1: Sections of the regulations that apply, by activity

Requirement	Section	Manufacturer	Importer	Distributor
Part I – General				
Distribution records	S.52	Yes	Yes	Yes
	S.53	Yes	Yes	Yes
	S.54	Yes	No	No
	S.55	Yes	Yes	Yes
	S.56	Yes	Yes	Yes
Recall procedure	S.58b	Yes	Yes	Yes
Recall reporting	S.63.1	Yes	Yes	No
	S.63.2	Yes	Yes	No
	S.64	Yes	Yes	No
	S.65	Yes	Yes	No

Requirement	Section	Manufacturer	Importer	Distributor
Recall records	S.65.3	Yes	Yes	No
	S.65.4(1) to (2)	No	No	Yes
	S. 65.6(1)	Yes	No	No
	S.65.6(2)	No	Yes	Yes
Part 3 – Medical devices for investigational testing involving human subjects				
Distribution record	S.88(a)	Yes	Yes	Yes
Recall	S.88(d)	Yes	Yes	No

Responsibilities

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

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

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

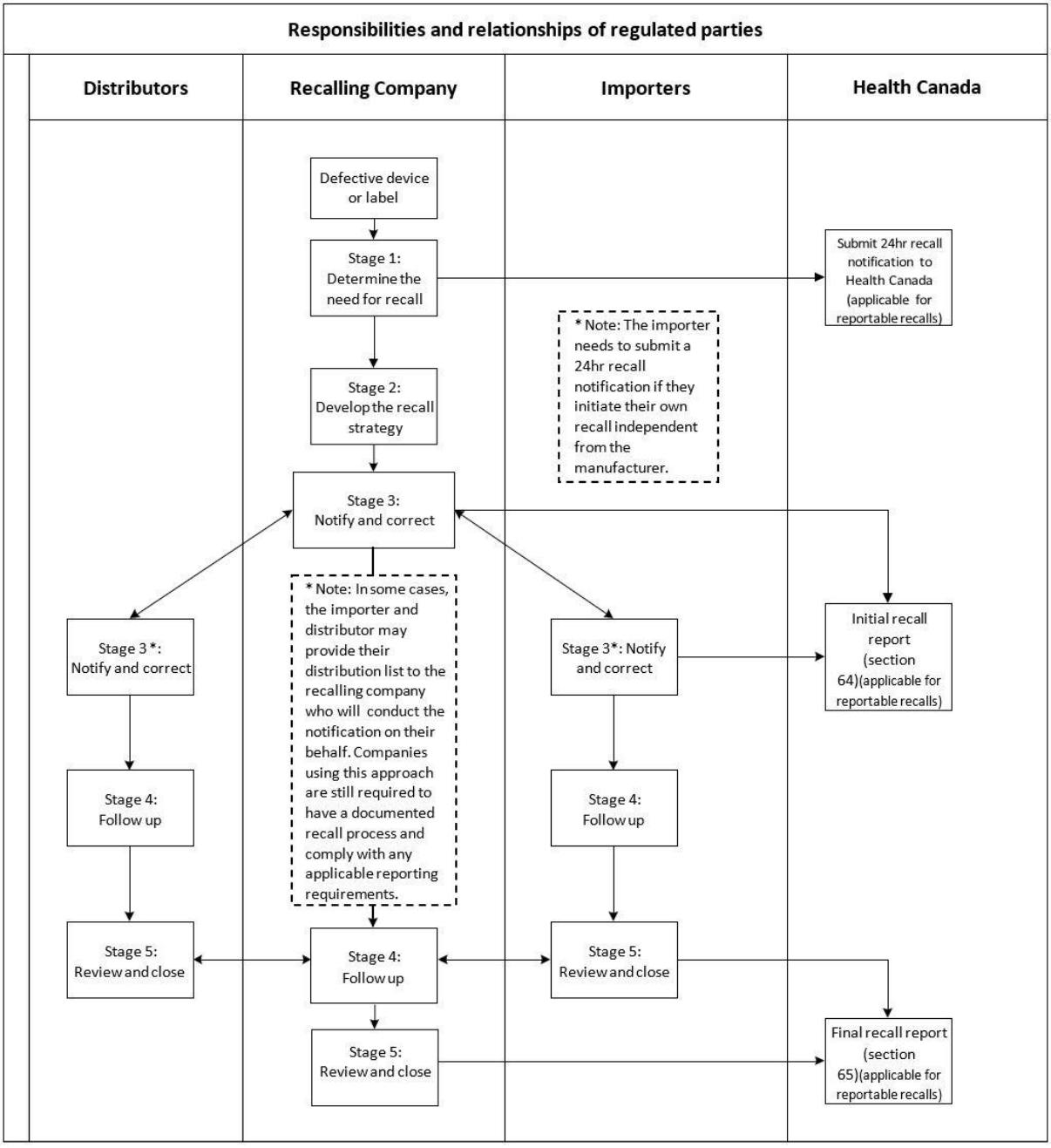
- understands its own roles and responsibilities
- defines and documents its expectations with other establishments in the distribution chain

- communicates and shares recall information

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

Chart 1 shows the responsibilities of and relationship between all regulated parties (manufacturers, importers and distributors) involved in the distribution chain. For more information on the recall process, refer to the section on recall process.

Chart 1: Responsibilities and relationships of regulated parties



Long description

This flow chart is divided into 4 columns or streams labelled "distributors", "recalling company", "importers" and "Health Canada".

The 3 stages that apply to distributors (first column) are to notify and correct, follow up, and review and close.

In the "recalling company" stream (second column), the recalling company is directed through all 5 stages and the steps that must be taken at each stage. If there's a defective device or label, the company is directed to determine the need for recall (stage 1), which prompts the need to submit a 24-hour recall notification for reportable recalls (Health Canada stream). The recalling company is directed to develop the recall strategy (stage 2), then to notify and correct (stage 3). A note at this stage indicates the following: "In some cases, the importer and distributor may provide their distribution list to the recalling company who will conduct the notification on their behalf. Companies using this approach are still required to have a documented recall process and comply with any applicable reporting requirements". The recalling company is directed to submit an initial recall report (section 64) (applicable for reportable recalls) to Health Canada. The recalling company is then directed to follow up (stage 4) and review and close (stage 5).

Column 3 sets out the responsibilities of the importer, who is directed to submit a 24-hour recall notification if they initiate their own recall independent from the manufacturer. At stage 3, to notify and correct, the importer is directed to submit an initial recall report to Health Canada. The next 2 stages are to follow up, review and close, which involves submitting a final recall report to Health Canada (section 65, applicable for reportable recalls).

Introduction

This section gives 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 regulations, if you manufacture, import or distribute medical devices, you must:

- keep distribution and recall records
- establish and use written procedures for how to do recalls

Manufacturers and importers must also report recalls to Health Canada.

Note: Depending on whether you are a manufacturer, importer or distributor, compliance requirements will differ.

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

Learn more about the MDEL requirements:

- Guidance on medical device establishment licensing (GUI-0016)

Recall process overview

The recall process is divided into 2 parts with 5 stages:

1. Initiating a recall
    - Stage 1: Identify the need to initiate a recall
    - Stage 2: Develop recall strategy and scope
2. Conducting a recall
    - Stage 3: Notify and correct
    - Stage 4: Follow up
    - Stage 5: Review and close recall

Learn more on how to properly document your establishment's recall process:

- Establishing and using documented processes

Contact Us

Contact us if you have questions about medical device recalls after reading this guide.

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Related Links

Legislation

- Food and Drugs Act
- Medical Devices Regulations

Health Canada guidance and policy documents

- Recall policy (POL-0016)
- Guidance for the interpretation of significant change of a medical device
- Guidance document for mandatory problem reporting for medical devices

ISO guidance documents

- ISO 13485 - Medical devices quality management systems: System requirements for regulatory purposes
- ISO 14971 - Medical devices: Application of risk management to medical devices

Defining a recall documented processes

Defining a recall

The Medical Devices Regulations (regulations) define "recall" as follows:

a. a recall ordered by the Minister under section 21.3 of the act or
b. any action taken by the manufacturer, importer or distributor of a medical device, after the device has been sold, 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
    i. may present a risk of injury to health
    ii. may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety or
    iii. may not meet the requirements of the 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
    - may include updates to instructions or manuals

Canadian regulations often define "recall" more broadly than other countries. If you manufacture medical devices outside Canada, you should be aware that some actions required in your jurisdiction (for example, field corrections) may be considered recalls in Canada. Make sure your procedures state that reporting requirements under sections 63.2, 64 and 65 of the regulations apply to you.

Establishing and using documented processes

You must document (electronically or on paper) your processes for maintaining distribution records and doing recalls (including recall reporting).

You may document each activity in a single procedure or use a number of procedures, depending on your quality system. If you use multiple procedures, you must be able to show that:

- all parts of the distribution record and recall process are represented
- your procedures are being followed

Documenting the recall and distribution record-keeping process

Your establishment's written procedures must:

- define key activities
- assign responsibilities
- describe steps taken from the start to the end of the process
- set out timeframes
- use a common format

There should be a timeframe for all activities described in your recall procedures, where appropriate. The timeframes should be based on the level of risk: the higher the risk, the shorter the timeframe for completing an action.

Be sure to 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 timeframes for each risk level or a single timeframe for all recalls based on the timing required for a high-risk recall.

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 and responsibilities and assures compliance with the regulations
    - for example, contacting affected customers and following up with non-responders
- have the third party sign and follow your written procedures

Guidelines for writing procedures

Follow these guidelines when writing procedures (for example, keeping distribution records or recall procedures).

Definitions: Your written procedures should include definitions for key terms used to describe the activities (for example, "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 (for example, 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, where these records are filed and how long you will keep them. (Or, 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 (for example, letter, number or combination)
    - date of the revision
    - effective date of the revision
    - a brief description of the change

    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 (for example, a recall reporting form).

Distribution records

Keeping distribution records

The process that 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 indicate the records you will use to identify the location of affected products during a recall.

Records can be paper-based or electronic. They should be stored in a way that will protect their integrity. For example, you could consider backing up your electronic records regularly and storing paper copies in a different location.

If you have a medical device establishment licence (MDEL), you must attest in your application (section 45(g) of the Medical Devices Regulations) that you have documented procedures in place to meet the requirements of sections 52 to 56.

Distribution record requirements

There are 5 distribution record requirements in the regulations.

Section 52 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. a retailer or
b. 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 those that are given out as:

- gifts
- samples
- donations
- rental units
- "loaner" units
- demonstration units

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

Retailers, including drug stores and department stores, do not have to keep distribution records of devices they sell.

Health care facilities do not have to keep distribution records if they distribute solely within their regional health authority. Health care facilities include:

- hospitals
- clinics
- groups of facilities forming 1 corporate entity

You have to keep records if you distribute medical devices outside your regional health authority or corporate entity.

You do not have to keep records if you distribute medical devices to patients, as this is considered a retail activity.

Section 53 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 (for example, 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

Note: The client contact information (contact name, phone and fax numbers, email address) in your records system should be accurate and maintained for when notifying the client of a recall.

Section 54 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 regulations, you must:

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

These requirements apply to the following select group of implantable devices defined as implants in Schedule 2:

- heart valves
- annuloplasty rings
- active implantable device systems, including:
    - all models of implantable pacemakers and leads
    - all models of implantable defibrillators and leads

    - artificial hearts
    - implantable ventricular support systems
    - implantable drug infusion systems
- devices of human origin, including:
    - human dura mater
    - wound coverings containing human cells

Section 55 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. 2 years after the date the device is shipped

Make sure your written procedures show the specific length of time you will keep records (for example, in years). The manufacturer usually 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 states:

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

Keep distribution records so they can be easily retrieved (regardless of where they are physically located). In most cases, you should be able to retrieve records within 1 to 2 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, make sure you:

- can still access records generated by your previous program or
- have alternate means of accessing those records (for example, through paper copies)

Checklist for distribution records

Use this checklist to help you:

- assess your procedures for creating and maintaining distribution records
- check that you are meeting the distribution record-keeping requirements in sections 52 to 56 of the regulations

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 regulations.

- Our distribution records include customer information.

Our distribution records include device information

Maintaining distribution records

These requirements come from section 55 of the regulations.

- 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 (for example, 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 regulations.

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

Recall Process

Overview of recall stages

Section 58(b) of the Medical Devices Regulations (regulations) 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.

Also, under section 45(g), a manufacturer, importer or distributor who holds a medical device establishment licence (MDEL) must attest in the application that they have these documented procedures in place.

This guide divides the recall process into 2 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 such as importers and distributors further down the distribution chain also participate in the recall and notify their consignees.

Manufacturers are ultimately responsible for the device's safety and effectiveness and therefore initiate most of the recalls.

However, importers and distributors must be able to initiate recalls if the:

- cause of the defect or problem is related to their activities (for example, storage or handling issues) **or**
- manufacturer is not willing or able to carry out a recall

Health Canada may use section 21.3 of the Food and Drugs Act if your company refuses to voluntarily recall a product that represents an imminent or serious risk of injury or if your recall is not adequate. Under this section, we may order the recall of a product that was sold on the Canadian market. If this happens, your company will be required to submit recall report as per section 65.1 of the regulations.

The recall process can be further divided into the following 5 stages.

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 that initiate a recall are involved in all 5 stages. Companies that conduct a recall initiated by another company are involved in stages 3, 4 and 5.

Stage 1: 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:

- may present a risk of injury 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 regulations

You might become aware of a defect or deficiency with a device through complaint investigations, inspections, or internal quality control testing or audits (for example, for a non-conforming product).

A defect may be related to:

- software errors
- design deficiencies
- labelling problems
- compliance issues
- for example, related to device licensing
- manufacturing problems
- component defects or failures
- improper shipping, installation or servicing

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

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

Your quality system should include ways to identify defects or deficiencies and determine if a recall is needed. It's your responsibility to determine the:

- level of risk associated with the defects or deficiencies and
- the actions that are required to correct them (such as 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.

Submit a 24-hour recall notification to Health Canada

Under section 63.2 of the regulations, the manufacturer or importer must notify Health Canada if the defect or deficiency is likely to cause injury or serious injury to the health of patient, user or other person. Notification must be made within 24 hours after the decision is made to conduct a recall in Canada.

Importers must submit their own 24-hour recall notification if they initiate a recall independent from the manufacturer. They do not have to do so if the manufacturer initiates a recall and the manufacturer has asked them to conduct a sub-recall.

Stage 2: Develop recall strategy and scope

Manufacturers should also have a recall strategy in place that enables you to:

- evaluate the risk in detail
- determine depth of the recall within the distribution chain
- identify customers who may be affected
- develop recall communications
- ensure timeframes
- identify companies that are responsible for notifying clients
    - you may get distribution lists from importers and distributors and conduct the recall notification for end users on their behalf
- indicate how to notify users who are not readily identifiable
- evaluate if any licence amendment(s) including significant change are required to the medical device
- evaluate the effectiveness of the actions taken
- determine initiation date, progress reports to Health Canada and anticipated closure date

In developing the strategy, you should consider the following:

- results of your risk evaluation
- risk type assigned to the recall
- ability to easily identify the recalled device
- degree to which the device's defectiveness is obvious to consumers or users
- degree to which the device remains unused in the marketplace
- availability of comparable products that could be used instead of the affected device

Reporting recalls to Health Canada

Under section 64 of the regulations, both manufacturers and importers must report recalls to Health Canada. This step must be clearly indicated in your recall procedure.

Note: If a recall initiated by a manufacturer involves an importer, both have to report the recall to Health Canada. However, the use of the word "or" in the regulations allows for situations where an importer may initiate a recall (for example, due to a storage or handling issue) and the manufacturer is not involved. In this case, only the importer must report.

Evaluating risk

Recall procedures require companies to evaluate the risk associated with a device when they are developing their recall strategy. The extent and type of the recall action depend on the hazards and harm associated with using the defective device.

When you evaluate risk, consider the following:

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

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

- Type I: A situation in which there is a reasonable probability that the use of (or exposure to) a device being recalled will cause serious adverse health consequences or death.
- Type II: A situation where the use of (or exposure to) a device being recalled may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
- Type III: A situation where the use of (or exposure to) a device being recalled is not likely to cause any adverse health consequences.

Note: Types I and II include situations where a device that does not have recognized or scientifically supported therapeutic value is promoted over the recognized therapy. The consequence is that injury or death could occur.

You must include your completed risk evaluation in your initial recall report. We will assess the information you provide, including the type you assigned to the recall. If we determine the type to be a higher level, we may contact your company to discuss a revised strategy.

Evaluating licence amendment including significant change

Manufacturers are required to evaluate corrective actions that involve Class II, III and IV medical devices to determine whether these actions require a licence amendment, as per section 34 of the MDR. A medical device licence amendment is required for any intended recall action that includes a:

- change that would affect the class of the device
- change in the name of the manufacturer or name of the device
- change in the device identifier
- change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented in the case of a Class II medical device other than a decorative contact lens
- a significant change in the case of a Class III or IV medical device

"Significant change" is a change that could reasonably be expected to affect the safety or effectiveness of a medical device. Section 1 of the regulations defines this as 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 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 **and**
- intended use of the device, including any new or extended use, such as adding or deleting a contraindication for the device, and any change to the expiry date

Submit this application to Health Canada's Medical Devices Directorate, describe the change and clearly indicate it's related to a recall, when applicable. Obtaining the amended licence before you implement the corrections may mitigate the potential for ineffective corrections in the field. This should not delay notifying customers of the recall and providing temporary measures to mitigate the risk associated with the recall.

The results of your licence amendment review should be included in your final report to us, as stated in section 65.

Learn more about significant change:

- 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 (how far in the distribution chain the recall will extend). Depth should be based on the type of device (including where and how it's used) and the risk the device poses to the public.

A recall may extend to the:

- user level
    - health care facilities, health care providers
- distributor level
    - including to importers
- retail level
- general public
    - consumers, patients

Timeframes

Your recall strategy must define timeframes for key activities.

When initial communication is not the sole recall action, you must have a detailed plan that shows estimated timeframes for accomplishing the remaining actions. The plan should reflect 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 outline 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
    - serial number
    - other information to help identify the device (such as software version)
- the reason for the recall (such as the risks associated with its use)
- when appropriate, that further distribution or use of the remaining product must stop immediately
- when appropriate, instructions to your customers who may have further distributed the device to forward the recall communication to their own customers

- when appropriate, instructions for disposing 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, you could consider providing:

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

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

The recalling company is responsible for sending out recall communications. When carrying the recall forward, other companies may send out their own communications to their customers as well, along with those of the recalling company.

Notifying users who are not easy to identify

Recall strategies must also consider how to contact medical device users who are not easy to identify. In these cases, you may consider communicating in other ways, such as through 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 by posting on websites. You could target specialized media (such as professional or trade presses) or certain segments of the population (such as doctors, hospitals or clinics).

Note: While the recalling company has the main responsibility for notifying the public, in certain cases Health Canada may issue a public notification to inform people in Canada of a serious health risk. This authorization is set out in the Department of Health Act.

Stage 3: 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 may involve several sub-stages and includes the initial notification. It may also include actions taken to mitigate the risk or resolve the issue (for example, corrections or device replacement).

This stage also applies to consignees such as importers or distributors who have further distributed the product. Their recall procedures must clearly show the steps to follow when their company receives a recall, and name the person or staff position responsible for each step.

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
- loaners
- samples
- demonstration devices

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 must submit your initial recall report to Health Canada, as stated in section 64 of the regulations.

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. Large health care facilities may keep more than 1 contact (for example, a contact for purchasing and a contact for recalls, such as a risk manager).

You can use several means to contact affected clients, including, for example:

- fax
- email
- personal visits
- telephone calls
- special delivery letters
    - for example, registered mail, courier

Regardless of the method, you must document in writing all forms of contact, especially when using telephone calls or other personal means.

Notification timeframes

Your recall procedures must specify prescribed timeframes 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.

Follow these guidelines for making initial contact after starting a recall:

- For **Type I** recalls: 1 to 2 business days.
- For **Type II** recalls: 3 to 5 business days.
- For **Type III** recalls: 5 to 7 business days.

If you cannot contact consignees in these timeframes, you must provide a rationale in your recall strategy.

Your recall strategy should also indicate a reasonable response time for hearing from consignees.

Tracking responses to recalls

Your recall procedures should require that responses be tracked and describe how you will track them.

Companies involved in a recall are expected 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
    - for example, telephone, fax, email, mail details
- 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 and follow up with anyone who does not respond.

Completing and tracking recall actions

The recalling company must also complete and track other required actions related to the affected product (for example, product removal or correction).

Once you receive confirmation that your initial notification of the recall was received, you should complete other actions related to the recall. Actions could include:

- returning the device to destroy or rework
- having the client destroy the device onsite
- having the client inspect or test the device onsite
- 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 completed actions.

Collecting the affected product

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

Stage 4: 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
- taking remedial actions
- disposing of the affected product

Evaluating recall effectiveness

When the recall is complete, evaluate its effectiveness by tracking the number of responses you received following your notification process. You could also track how successfully your company completed corrective actions.

Your recall strategy should specify how to evaluate the effectiveness of a recall (for example, responses to the initial notice, corrections or returns). In most cases, you can monitor the effectiveness of the initial notification by the level of customer response (for example, number of fax-back forms 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.

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.

Your recall procedures should outline 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. You must justify and have records of each follow-up attempt for any non-responders that remain.
- **Type II:** Follow up with non-responders 2 more times using different contact methods. Keep records of each follow-up attempt.
- **Type III:** Make 1 more follow-up attempt, 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 way for them to respond (such as through public notices with toll-free numbers). In this case, you may not be able to follow up with everyone.

Checking completion of recall actions

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

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

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.

Health Canada effectiveness checks

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

Product disposition

When a product is returned, you should dispose of it as outlined in your recall strategy. Keep appropriate records to show that this has been done.

Stage 5: Review and close recall

Steps required to review and close completed recalls include:

- doing a final review
- submitting a final recall report to us
- closing the recall
- completing final documentation

Final review

A final review is done to determine if the recall can be closed. You should only close a recall once all notifications, corrections and follow-up actions have been completed and the problem has been addressed.

A qualified person or group must conduct the final review to make sure the recall file contains or references records for all recall actions. The following information, as applicable, must be reviewed:

- number of units recovered
- number of units consignees used
- number of units consignees destroyed (as requested in the recall notice)
- number of units corrected (modified, repaired or retrofitted), either on- or offsite, and returned to consignees
- number of units that could not be located
- method or intended method used to dispose of any recovered units or stock units
    - evidence of disposition should be available to us on request
- final completion date for the recall
- assurance that all consignees received the recall information
    - evidence should be available to us on request

- detailed plan to prevent the problem from happening again and to resolve the problem using measures such as:
    - design change
    - process validation
    - increased quality control
- verification of the device licence amendment review, including an evaluation of significant change for **Class III** and **Class IV** medical devices

Reviewing the completed recall can:

- give you valuable information about recall strategies and procedures
- help you refine your approach to prepare for future recalls

Notifying Health Canada that the recall is closed

After the final review is done and it's been determined that a recall can be closed, importers and manufactures must submit a final recall report to Health Canada within 30 calendar days after completing the recall. This is required under section 65 of the regulations.

This step must be clearly indicated in your recall procedure.

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 we receive your final recall report, we will send you a letter to confirm that the recall is closed.

Completing final documentation

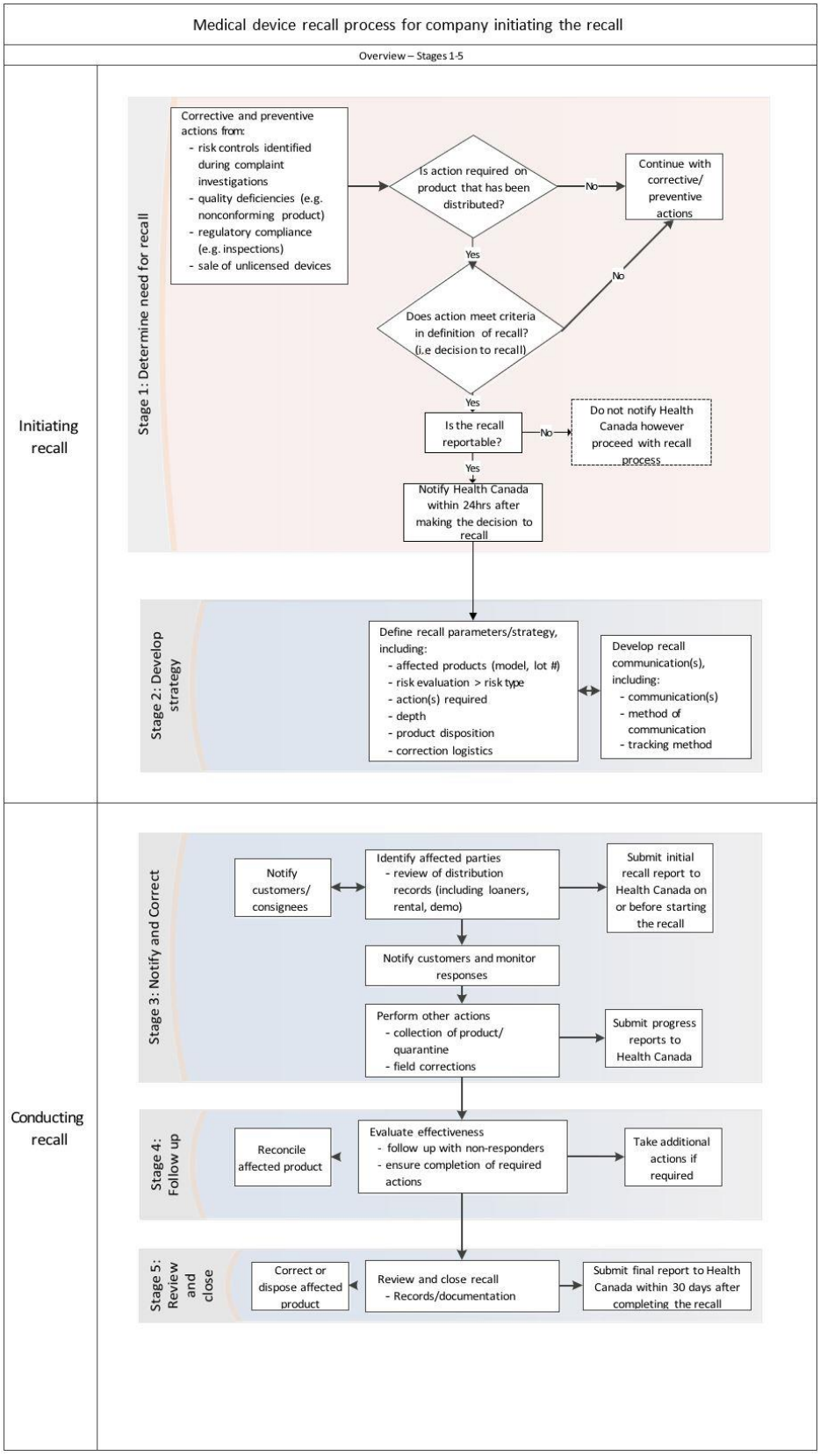
Manufacturers, importers and distributors must keep sufficient documentation to show that the necessary recall actions were completed in a timely and effective manner and complied with the regulations.

Charts showing recall stages

The following charts show the stages of the recall process.

Chart 2 covers all stages of the process and applies to manufacturers or other companies who initiate a recall.

Chart 2: Recall process for company initiating the recall



Long description

This flowchart is divided into 2 sections called "initiating recall" and "conducting recall". These sections are further subdivided into a total of 5 stages.

There are 2 stages in the "initiating recall" section. Stage 1, "determine need for recall", begins with a box that lists the types of corrective and preventive actions that may trigger a recall. Actions include:

- risk controls identified during complaint investigations
- quality deficiencies, such as a non-conforming product
- regulatory compliance following inspections
- sale of unlicensed devices

If a company has taken these or similar actions, they are directed by an arrow in the flowchart to ask 2 questions to help them determine whether a recall is triggered.

First question, "Is action required on product that has been distributed?" If the answer is no, the company is directed to "continue with corrective or preventive actions". No recall is triggered. If the answer is yes, the company is led to the second question, "Does action meet the criteria in definition of recall (decision to recall)?". If the answer is no, the company is directed to continue with corrective or preventive actions. No recall is triggered. If the answer is yes, the company is led to the third question, "Is the recall reportable?" If the answer is no, the company is directed to "not notify Health Canada, however proceed with recall process." If the answer is yes, the company is directed to notify Health Canada within 24 hours after making the decision to recall.

The company continues to stage 2, which is to develop a strategy. Here, the company is directed to define the recall parameters or strategy. The box in the chart lists the following parameters:

- affected products, as identified by their model and lot number
- risk evaluation and risk type
- actions required
- depth
- disposal of the product
- correction logistics

The company is also directed to develop recall communications, which lists the following elements:

- develop communications
- method of communication
- tracking method

This brings the recalling company to the second section, "conducting recall". This section is divided into stages 3, 4 and 5. Stage 3, "notify and correct", directs the recalling company to identify affected parties, which lists:

- review of distribution
- records, including loaners, rentals and demo

One arrow from this box points to a box that indicates to notify customers or consignees. Another arrow points to a box that indicates to submit initial recall report to Health Canada on or before staring the recall. Then, the recalling company is directed to a box that indicates to notify customers and monitor responses, then to:

- collect the product or place in quarantine and
- make field corrections

The recalling company is then directed to submit progress reports to Health Canada. The next stage (stage 4) is to follow up. In this stage, the recalling company is directed to evaluate effectiveness, which involves:

- following up with non-responders and
- ensuring required actions are completed

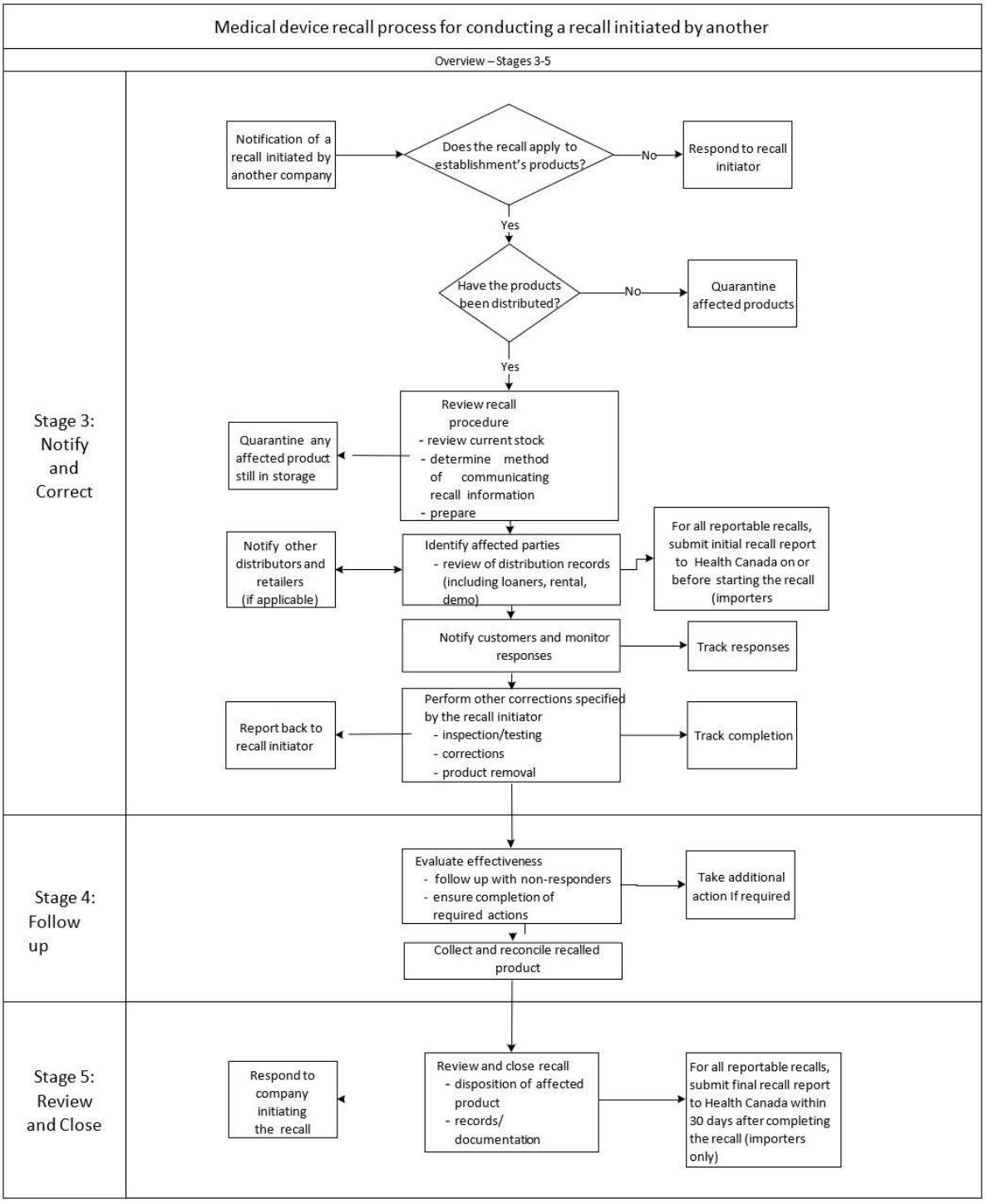
The recalling company is next directed to either reconcile the affected product or take additional actions if required.

The final stage (stage 5) is to review and close, which involves records and documentation. The recalling company is directed to either:

- correct or dispose of affected product or
- submit final report to Health Canada within 30 days after completing the recall

Chart 3 is for importers and distributors who are conducting a recall initiated by a manufacturer.

Chart 3: Recall process for conducting a recall initiated by another company



Long description

The flowchart is divided into 3 stages: "notify and correct" (stage 3), "follow up" (stage 4) and "review and close" (stage 5).

Stage 3 (notify and correct): The company receives a notification of a recall initiated by another company. Two questions are posed to help the company through next steps. If the answer is no to question 1, "Does the recall apply to establishment's products?", the company responds to the recall initiator. If the answer is yes, the company determines if the products have been distributed. Those that haven't are quarantined. If the products have been distributed, the company is directed to take 1 of the following actions:

- review recall procedure
- review current stock
- determine method of communicating recall information
- prepare additional communication

For each of these actions, the company is directed to quarantine any affected products still in storage and to:

- identify affected parties, such as other distributors and retailers (if applicable) and submit an initial recall report to Health Canada if an importer
- notify customers and monitor and track responses
- perform other corrections specified by the company that initiated the recall, such as inspecting, testing or removing products and reporting these back to the company that initiated the recall

Stage 4 (follow up): This stage involves 2 actions:

- evaluate effectiveness, which involves following up with non-responders, ensuring required actions are completed and taking additional action if required
- collect and reconcile recalled products

Stage 5 (review and close): This is the final stage. Companies are directed to dispose of affected products and maintain records and documentation. Then they are to:

- respond to the company that initiated the recall
- submit a final report to Health Canada within 30 days after completing the recall (importers only)

Recall process checklist

The following checklist is a valuable tool you can use to evaluate the adequacy of your company's recall procedure and understand the specific steps to follow during a recall process. 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 1: Initiating a recall

If they wish to designate the importer to submit recall reports on their behalf, manufacturers must submit a written notification to Health Canada confirming that the importer accepts the recall report designation.

Email: meddev-matmed@hc-sc.gc.ca

Stage 1: 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 (for example, complaint handling, corrective and preventive actions or handling non-conforming products) to our recall procedures.
- Our procedures state the need to submit a 24 hour recall notification to Health Canada once a decision has been made to recall medical devices in Canada (also applies to importers if they initiate recalls).

Stage 2: Develop a strategy

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

Part 2: Conducting a recall

Stage 3: Notify and correct

- Our procedures describe the recall notification process.
- Our procedures have set timeframes 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 (for example, 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 4: 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 5: 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 within 30 calendar days after completing the recall.

Recall reporting and process

Reportability of recalls

Section 63.1 of the Medical Devices Regulations (regulations) states:

Sections 63.2, 64 and 65 apply to a manufacturer or importer of a medical device if the device is likely to cause injury to the health of a patient, user or other person, or could cause serious injury to the health of a patient, user or other person.

Note: If a recall is not reportable, none of the notification (section 63.2) and recall reports (sections 64 to 65) have to be submitted to Health Canada. However, the steps outlined in the recall process page still apply to non-reportable recalls. Non-reportable recalls should be conducted as if they were reportable.

Type I and II recalls as defined in this guidance document are reportable. The reportability of a recall depends on the severity and probability of harm. It's the responsibility of the regulated party to determine the recall type based on device and its risk profile. If the device affected by a recall is not likely to cause injury to health, that recall does not need to be reported. Recalls involving unlicensed devices are expected to be reported to Health Canada as these devices have not been reviewed for their safety and efficacy and they could cause serious injury to patient, users or other person.

If your risk evaluation matrix deems a recall to be a type III, it may still be reportable to us as per section 63.1. If the device affected by the recall could cause serious injury to the health, the recall must be reported regardless of probability of occurrence.

If the company conducting the recall is unsure about the reportability of a recall, it can be reported as a precautionary measure. Reportable recalls are listed on Health Canada's recall and safety alerts.

Find recalls, advisories and safety alerts

Guidance for recall reports

If you manufacture or import medical devices sold in Canada, the recall reporting requirements apply to you. These requirements are set out in this section.

Section 63

Sections 63.2, 64 and 65 do not apply to a:

- retailer
- health care facility where a medical device is distributed for use within the facility

Section 63.2 regarding 24-hour notification to Health Canada applies to manufacturers and importers. If you're a manufacturer or an importer, your recall procedures should include information on how to write the initial notification to Health Canada. Your procedures should specify the:

- specific content required for the initial notification
- timeframe for submitting the initial recall notification

The preliminary risk assessment should contain as much information as possible on the risk associated with the device's defectiveness (or possible defectiveness) at the time the decision is made to initiate a recall. The complete risk assessment can be provided when you submit the information required under section 64 of the regulations.

Section 64 and 65

Your recall procedures should include information to help write the initial and final recall reports that are submitted to Health Canada. Your procedures should specify the:

- specific content required in these initial and final recall reports (sections 64 and 65)
- timeframe and contact details for submitting these reports
- need for progress reports, if requested by Health Canada

Submitting your reports

Submit the 24-hour notification of a recall and recall reports.

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Notification

As per section 63.2 of the regulations, an initial notification must be submitted within 24 hours of deciding to conduct a recall in Canada.

To submit a recall report, follow these guidelines:

1. Submit the initial recall report on or before starting the recall. The start date of the recall is when you begin sending out recall notifications (for example, the date on the recall notification letter). The report is to include all the information requested in section 64 of the regulations. You can also use the initial recall reporting form (FRM-0360A) to complete your initial recall report.
2. Submit the final recall report within 30 calendar days after completing the recall. The report is to include all the information requested in section 65 of the regulations. You can also use the final recall reporting form (FRM-0360B) to complete your final recall report.

Medical Device Recall Reporting Form – Initial (FRM-0360A)
Medical Device Recall Reporting Form – Final (FRM-0360B)

Section 65.1

Section 65.1 states:

a. 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.
b. 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.

Both the manufacturer and the importer are required 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're a manufacturer and you want to designate an importer to submit a recall report on your behalf, you must 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 regulations.

Manufacturers must submit a written notification to Health Canada confirming that the importer accepts the recall report designation.

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Interim or progress reports

After reviewing your initial recall report, we may ask you to submit interim or progress reports at agreed-upon intervals. Interim reports are normally requested for recalls that:

- have multiple stages
- have long projected completion dates
- are not completed by the projected date

Recall progress reports contain the following:

- 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 timeframe for completion (if revised)

How to write recall reports

Under sections 63.2, 64, 65 and 65.2 (1) of the regulations, manufacturers and importers must submit reports to Health Canada giving details about their medical device recall process. Your reports must contain the following information:

Section 63.2: Recall notification

This section states:

A manufacturer or importer of a medical device that decides to recall the device without being ordered to do so by the Minister, shall provide the Minister with the following information, in writing, within 24 hours after making the decision:

a. 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
b. in the case of a licensed device, the medical device licence number
c. in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number
d. the name and address of:
    i. the manufacturer
    ii. the establishment where the device was manufactured, if different from that of the manufacturer, and
    iii. the importer
e. the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered
f. a preliminary evaluation of the risk associated with the defectiveness or possible defectiveness

To fulfill section 63.2 requirements, follow these guidelines when writing your recall notification:

- Describe the device being recalled as completely as possible in your notification. Include the medical device's:
    - licensed name
    - identifier (for example, catalogue number, product code, bar code)
    - licence number, if applicable
    - authorization number (under section 68.12), if applicable
- 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 or 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.
- Describe the problem or potential problem with the device at that time. Additional information about the problem that has led to a recall action can be provided with the initial recall report (section 64) or upon Health Canada request.
- Describe the preliminary risk associated with using the device in its defective state and the likelihood that it could injure users. Include as much information available at that time.

Section 64: Initial recall report

This section states:

A manufacturer or importer of a medical device that recalls the device without being ordered to do so by the Minister, shall provide the Minister with the following information and documents, in writing, on or before undertaking a recall of the device:

a. the name of the device

b. the identifier of the device, 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
c. in the case of a licensed device, the medical device licence number
d. in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number
e. the name and address of:
    i. the manufacturer
    ii. the establishment where the device was manufactured, if different from that of the manufacturer, and
    iii. the importer
f. 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
g. an evaluation of the risk associated with the defectiveness or possible defectiveness
h. the number of affected units of the device that the manufacturer or importer:
    i. manufactured in Canada
    ii. imported into Canada
    iii. sold in Canada
i. the period during which the affected units of the device were distributed in Canada by the manufacturer or importer
j. 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
k. a copy of any communication issued with respect to the recall
l. the proposed strategy for conduction the recall, including
    i. the date for beginning the recall
    ii. information as to how and when the Minister will be informed of the progress of the recall and
    iii. the proposed date for its completion
m. the proposed action to prevent a recurrence of the problem and
n. the name, title and contact information 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:

- Describe the device being recalled as completely as possible in your initial report. Include the medical device's:
    - licensed name
    - identifier (for example, catalogue number, product code, bar code)
    - lot number, batch number or serial number
    - licence number
- 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 or 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.

- Describe the problem or potential problem with the device. Keep the description to 50 words or less in both official languages (French and English). Attach additional information that must 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) separately.
- Describe the risk associated with using the device in its defective state and the likelihood that it could injure users.

Remember to assign a level of risk to each recall.

Your initial report should also:

- account for all affected units of product
    - State the number of units that remain in the manufacturer or importer's stock. If more than 1 medical device is involved in the recall, provide numbers of affected units for each.
- indicate the distribution period for the device
    - At a minimum, report the dates of the first and last sale of the device in its defective state. If more than 1 medical device is involved, include each distribution period separately.
- indicate 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.

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

Include specific information about how you plan to conduct the recall, such as the dates it will begin and close. You must provide a rationale if you expect the recall to be completed more than 3 months after your initial notice to Health Canada.

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.

Provide contact information for your company. Specify a representative who is easy to reach and knows the recall process. If possible, provide a fax number or email address with 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 states:

The manufacturer and importer of a medical device shall, within 30 calendar days after the completion of a recall, each report to Health Canada:

a. the results of the recall
b. 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 following details:

- number of recovered units
- number of units used by consignees
- number of units destroyed by consignees (as requested in the recall notice)
- number of units corrected (modified, repaired or retrofitted), either on site or off site, and returned to consignees
- number of units that were not located
- how you intend to dispose of any recovered units or stock units
    - evidence of disposition must be available upon request
- final date the recall was completed
- assurance that all consignees received the recall information
    - evidence must be available upon request
- detailed plan of how you corrected the problem and how you will prevent it from happening again
    - for example, design change, process validation or increased quality control
- results of your licence amendment review and, if applicable, confirmation of the licence amendment application

Recall records

Guidance for keeping recall records

This section outlines the Medical Devices Regulations (regulations) that relate to keeping records for recalls.

Record keeping for manufacturers and importers

Section 65.3 of the regulations states:

A manufacturer or importer of a medical device that recalls the device without being ordered to do so by the Minister, shall keep a record of the following information and documents:

a. the decision to conduct the recall, including:
    i. the name and title of any individual who made the decision and
    ii. the date the decision was made
b. the date the recall was completed
c. the information and documents referred to in sections 63.2, 64 and 65 and
d. the fact that the importer has prepared and submitted the information and documents to the Minister on behalf of the manufacturer in accordance with subsection 65.1(2), as the case may be

All pertinent information related to the recall should be maintained with the recall record. Information may include the following information:

- decision to initiate as well as closure of a recall, including the identification of whom made the decisions
- health risk evaluation
- 24-hour recall notification (section 63.2)
- records of communication with customers and/or relevant stakeholders, including attempts made to contact such people.
    - would also include records of customer responses, such as customer responses forms and reconciliation logs
- information required under sections 64 and 65

Note: The recall record requirements also apply to non-reportable recalls.

Record keeping for distribution

Section 65.4(1) states:

Subject to subsection (2), if a distributor of a medical device conducts a recall of the device that was not ordered by the Minister, the distributor shall keep a record of the following information and documents:

a. the name of the device
b. the identifier of the device, 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
c. in the case of a licensed device, the medical device licence number
d. in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number

e. the name and address of:
    i. the manufacturer
    ii. the establishment where the device was manufactured, if different from that of the manufacturer
    iii. the importer and
    iv. the person who sold them the device
f. the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered
g. the number of affected units of the device that the distributor sold in Canada
h. the period during which the affected units of the device were distributed in Canada by the distributor
i. the name of each person to whom the affected device was sold by the distributor and the number of units of the device sold to each person
j. a copy of any communication issued with respect to the recall
k. the results of the recall and
l. the date the recall was completed

Distributors do not have to report recalls as per section 64, but do have to keep recall records as per section 65.4(1). This applies regardless of who initiated the recall.

Distributors who initiate a recall must also keep records of the following:

- evaluation of the risk associated with the defectiveness or possible defectiveness
- actions that were proposed and taken to prevent the problem from occurring again

Retention time

Section 65.6 states:

1. The manufacturer who is required to keep a record under sections 65.3 or 65.5 shall keep it for at least the longer of the following periods:
    a. the period that is equivalent to the projected useful life of the medical device to which the recall related plus 2 years and
    b. the period during which the device is being sold Canada
2. Any other person who is required to keep a record under section 65.3, 65.4 or 65.5 shall keep it for at least a period equivalent to the projected useful life of the device to which the recall relates plus 2 years
3. For the purpose of paragraph (1)(a) and subsection (2), the retention period begins on the day the recall is completed.

The manufacturer should determine the projected useful life of the device.

The purpose of the manufacturer maintaining recall records is to maintain historical data of safety and compliance of the device. Recall records make it possible for us to verify a company's recall

process. We may use recall records to confirm if recalls are properly classified, as some are not reportable.

Your recall procedures should define how long to keep recall records.

Ordered recall reporting

Guidance for ordered recalls

This section outlines the Medical Devices Regulations (regulations) that relates to Health Canada ordering a company or a person to report a recall.

Section 65.2(1)

Section 65.2(1) of the regulations states:

Sections 65.2 (1) applies to any person who is ordered by the minister to recall a medical device.

If information indicates that a medical device presents a serious and imminent risk of injury to health, Health Canada may issue an order to recall to mitigate the risk to public health. An example would be when a person or a company refuses to conduct a voluntary recall.

The person or company ordered to recall a medical device will submit information required under 65.2(1) in the time and manner specified by the Minister.

Before you begin the recall, you must submit a:

- written notification in the manner specified by the Minister within 24 hours of starting the recall
    - include any additional information as described in the recall order
- copy of the recall communication you intend to send to consignees at the beginning of the recall

During the recall, you must provide any:

- additional communications sent out after the recall began
- progress reports (as applicable) as requested in the recall order
- changes to the contact person responsible for managing the recall order
- written notification within 24 hours in the manner specified by the recall order before completing a recall

As per section 65.2(5), you must submit a final recall report within 30 calendar days of completing the recall.

How to write ordered recall reports

Initial recall order information

Section 65.2(1) states:

A person who is ordered by the Minister to recall a medical device shall provide the Minister with the following information in the time and manner specified by the Minister:

a. the name and address of:
    i. the manufacturer of the device
    ii. the establishment where the device was manufactured, if different from that of the manufacturer
    iii. importer of the device and
    iv. the person who sold them the device, if the person who is conducting the recall is not a manufacturer
b. the nature of the defectiveness or possible defectiveness of the device and the date on which and the circumstances under which the defectiveness or possible defectiveness was discovered
c. the number of affected units of the device that the person:
    i. manufactured in Canada
    ii. imported into Canada and
    iii. sold in Canada
d. the number of affected units of the device in Canada that are in the possession or control of the person
e. the period during which the affected units of the device were distributed in Canada by the person
f. the number of affected units of the device that have been sold by the person at the retail level to consumers in Canada
g. if the person has sold the affected device to persons in Canada other than consumers referred to in subparagraph (f), the names of those persons and the number of units of the sold to each of them
h. the proposed strategy for conducting the recall, including:
    i. the date for beginning the recall
    ii. the time and manner in which the Minister will be informed of the progress of the recall and
    iii. the proposed date for its completion
i. the proposed action to prevent a recurrence of the problem
j. the name, title and contact information of the representative of the person to contact for information concerning the recall and
k. any other information that the Minister has reasonable grounds to believe is necessary to reduce the risk of injury to health

Final recall order notification

Section 65.2(5) states:

The person shall, within 30 days after completing the recall, provide the Minister with the following information, in writing:

a. the results of the recall
b. the action taken to prevent a recurrence of the problem

Note: The recall order may contain additional instructions or requests not outlined in this guide on how to fulfill the requirements of the order.

Glossary

The following definitions explain how terms are used in this guidance document. If there's a conflict with a definition in the *Food and Drugs Act* or associated regulations, including the Medical Devices Regulations (regulations), the definition in the act or regulations prevails.

Where applicable, we have provided the source of the definition, including from the following International Organization for Standardization (ISO) standards:

- ISO 13485 - Medical devices quality management systems: System requirements for regulatory purposes
- ISO 14971 - Medical devices: Application of risk management to medical devices

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's 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 (for example, a rework or regrade). (ISO 13485)

Device identifier:

A unique series of letters or numbers or a bar code that the manufacturer assigns to a medical device to identify and distinguish it from similar devices.

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 as per section 44 of the regulations. Learn more about licensing requirements:

- Guidance on medical device establishment licensing and medical device establishment licensing fees (GUI-0016)

Harm:

Injury or damage to the health of people, or damage to property or the environment. (ISO 14971)

Hazard:

Potential source of harm. (ISO 14971)

Health hazard classification:

The numerical designation (for example, Type I, II or III) assigned to a recall of a device to indicate the degree of risk presented by the recall, 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 hazard identification, hazard characterization, exposure assessment and risk characterization.

Implant:

A medical device listed in Schedule 2 of the regulations.

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 information affixed to a device or the packaging as well as to manuals, package inserts, brochures and leaflets. (Section 2, 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
- 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's intended for use in relation to animals. Includes used devices, parts and accessories.

Medical device identification number (device ID):

The number that Health Canada gives to a device in order to enter the information about the device into the medical devices database. The device ID was formerly known as the "device accession number". It is not the same as the device "identifier" that's assigned by the manufacturer.

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 depth:

The level of distribution from which a device is recalled (for example, wholesale, retail, user or consumer).

Recall strategy:

A planned course of action taken by a recalling company in conducting a specific recall. Examples include the depth of recall, the need for public warnings and the extent of effectiveness checks for the recall.

Risk:

The probability that harm will occur combined with the severity of that harm. (ISO 14971)

Risk analysis:

Systematic use of available information to identify hazards and estimate the risk. (ISO 14971)

Risk assessment:

Overall process comprising a risk analysis and a risk evaluation. (ISO 14971)

Risk evaluation:

Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk.. (ISO 14971)

Significant change:

A change that could reasonably be expected to affect a medical device's safety or effectiveness. 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 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 has not left the direct control of the company.
A stock recovery is not considered 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 (as per section 65.1 of the regulations), the importer may prepare and submit recall information and documents on the manufacturer's behalf.