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

Health Products and Food Branch Inspectorate

Guide to Recall of Medical Devices

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Disclaimer

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1.0 Purpose

This guidance document is intended to provide an interpretation of the recall requirements of the *Medical Devices Regulations (MDR)* in order to assist the medical device industry in conducting effective recalls in compliance with these requirements.

It is also intended to promote transparency and consistency respecting Health Canada's role in assessing compliance with these requirements.

2.0 Scope

This guidance document applies to those Sections of the *MDR* which are concerned with medical device recalls, namely Sections 58 (b), 63, 64 and 65, the definition of "recall" in the *Interpretation* Section of the *MDR* and Sections 52 to 56, *Distribution Records*.

3.0 Glossary of Terms

3.1 Definitions

Consignee: anyone who received, purchased or used the device 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 **nonconformity** including the repair, modification, adjustment, relabelling, or inspection (including patient monitoring) of a device without its physical removal to some other location.

Note 1: A correction can be made in conjunction with a corrective action

Note 2: A correction can be, for example, **rework** or **regrade**

(*ISO 13485 Medical devices quality management systems - System requirements for regulatory purposes*)

Note 3: A correction, for the purposes of this guidance document, can also be a recall to address nonconforming devices in distribution.

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. This "device ID" is not the same entity as the device "identifier" which is assigned by the device manufacturer. See definition of "identifier" below and in the *MDR*.

Note: The "Device ID" was formerly referred to as the "device accession number".

Distributor: a person other than a manufacturer, an importer or a 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 information and are aware of any appropriate action to be taken and may include verification of the action taken. The recalling firm is responsible for conducting effectiveness checks, which may also be undertaken, or verified, by the Inspectorate.

Establishment (for the purpose of guidance on recall of medical devices): a person required to have an establishment license as per Section 44 of the *MDR*. For guidance please refer to: “Guidance on Medical Device Establishment Licensing” (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui_mdel-doc_aeim_20051117_tc-tm-eng.php)

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, Type II, or Type 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.

Type I: 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: a situation in which the use of, or exposure to, a recalled device may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote; or

Type III: a situation in which the use of, or exposure to, a recalled device is not likely to cause any adverse health consequences.

Note: Type I and II include situations where a device (which does not have generally recognized or scientifically supported therapeutic value) is promoted in such a way that avoidance of recognized therapy occurs and where such avoidance could lead to injury or death. The recall Type reflects the priority which will be assigned to the recall by Health Canada.

Health Risk Assessment (HRA): the scientific characterization of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to hazards. The process consists of the following steps: (i) hazard identification (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Identifier (for a medical device): means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. (*MDR*)

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

Label: label includes any legend, word, or mark attached to, included in, belonging to, or accompanying, any food, drug, cosmetic, device, or package. (Section 2 of the *Food and Drugs Act (FDA)*)
Note: This includes not only information that is affixed to a device or the packaging but also information such as manuals, package inserts, brochures and leaflets.

Manufacturer: a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning 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, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device a) may be hazardous to health; b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or c) may not meet the requirements of the *Act* or these *Regulations*.

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.

Regional Inspectorate Program: the regional or local office of the Health Products and Food Branch Inspectorate (addresses and contacts provided in Appendix 1 of this Guidance Document).

Risk: combination of the probability of occurrence of harm and the severity of that harm.(ISO 14971-2000 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 14971-2000 Medical Devices - Application of Risk Management to Medical Devices)

Risk Assessment: overall process comprising of risk analysis and a risk evaluation. (ISO 14971-2000 Medical Devices - Application of Risk Management to Medical Devices)

Risk Evaluation: judgment, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society. (ISO 14971-2000 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 any of the following:

- (a) the manufacturing process, facility or equipment;
- (b) the 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;
- (c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories;
- (d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication 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. It is not considered to be a recall.

3.2 Abbreviations

FDA: *Food and Drugs Act*

FDR: *Food and Drug Regulations*

HPFB: Health Products and Food Branch

HPFBI: Health Products and Food Branch Inspectorate

GHTF: Global Harmonization Task Force

MDR: Medical Devices Regulations

MDCU: Medical Device Compliance Unit (Ottawa)

4.0 Requirements of the Medical Devices Regulations

4.1 Interpretation of the term "Recall"

As defined in Section 1, Interpretation of the MDR, 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

- (a) may be hazardous to health*
- (b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or*
- (c) may not meet the requirements of the Act or these Regulations.*

A recall may include:

1. The removal of the medical device from the market and its consignees;
2. an on-site correction of the medical device;
3. an advisory concerning a problem or potential problem with instructions to work around the problem until an on-site correction can be implemented;
4. the supply of revised labelling related to corrective action;
5. the supply of instructions to stop using the medical device and destroy remaining units in stock.

Note : Recall does not include a stock recovery as defined in Section 3, Glossary of Terms in this document.

Recall requirements, including the requirement for having and implementing written procedures and reporting are described in Sections 52 - 56, 58(b), and 63 - 65 of the Regulations.

4.2 Interpretation of Sections 52 - 56 Distribution Records

The intent of these requirements is to ensure that manufacturers, importers and distributors maintain records that will permit effective and timely post-market surveillance activities, including recall.

4.2.1 Section 52

This section 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 are each required to create and maintain a distribution record for each device distributed including records of devices distributed as samples, for demonstration purposes and loaners.

Retailers (including drug stores and department stores) are not required to keep distribution records of devices distributed at the retail level.

Health care facilities (including hospitals, clinics or groups of these forming one corporate entity) are not required to keep distribution records provided distribution of the device is solely within their own corporate entity.

4.2.2 Section 53

This section states:

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

Upon receipt of product, it is recommended that the record include:

1. Detail sufficient to identify the device being received including the name of the device, the device identifier, the model number, the catalogue number if different from the identifier, and the control number/lot number, as applicable.

2. Date received, the number of units received and the name of the person or company who supplied the device.

For product shipped, it is recommended that the record include:

1. Detail sufficient to identify the device being shipped including the name of the device, the device identifier, the model number, the catalogue number if different from the identifier, and the control number/lot number, as applicable.
2. Date shipped to consignee, the number of units shipped and the name and address of the consignee.

4.2.3 Section 54

This section 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.

An implant, as defined in the *MDR*, means a medical device that is listed in Schedule 2 of the Regulations. Each manufacturer is required to include in its distribution record for the implant, the information received from the health care facility forwarded upon completion of the implantation as stipulated in Section 67 of the Regulations, and to update or amend the record with subsequent information received from the health care facility or the patient.

4.2.4 Section 55

This section states:

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

(a) the projected useful life of the device, and

(b) two years after the device is shipped.

Distribution records are to be maintained by the manufacturer, the importer and the distributor for a period of time at least equivalent to the lifetime of the device as defined by the manufacturer but in no case less than two years from the date of shipping to a consignee.

4.2.5 Section 56

This section states:

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

Each manufacturer, importer and distributor is required to ensure that its distribution records are maintained so as to enable their timely retrieval upon request by Health Canada and to accommodate the company's own post-market activities regardless of where the records are physically located. It is recommended that in most circumstances distribution records be retrievable within 1-2 business days. There may be situations where a company needs more time to access records that are in archived databases. If this is the case this should be identified in and part of the recall strategy.

Paper records should be stored in circumstances which will maintain their integrity.

4.3 Interpretation of Section 58 (b)

This section states:

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

The manufacturer, importer and distributor of a medical device should be able to carry out an effective and timely recall to the end of the distribution chain in order to mitigate the risk to the end user to the extent possible, where the situation demands. Evidence of this capability should be captured in the procedures and documented. Alternative mechanisms to achieve this purpose could include an agreement for timely access to subsequent distributors' distribution records, or a contractual agreement with subsequent distributors establishing their cooperation in the event of a recall. Other equivalent means could be considered.

Note - Although the format for a standard operating procedure is not mandated in Regulations, inclusion of the elements listed in Appendix 2 is recommended for consistency with accepted quality system practices.

4.4 Interpretation of Section 63 and 65.1 Application of Reporting Requirements

4.4.1 Section 63

This section states:

Sections 64 and 65 do 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.

The recall reporting requirements described in Section 64 and 65 of the *MDR* do not apply to retailers or health care facilities, such as hospital corporations who distribute devices among organizations that they control.

The recall reporting requirements apply to manufacturers and importers of devices which they have sold in Canada. Sale includes supplying devices on consignment or lease, devices distributed as samples, for demonstration purposes and loaners.

4.4.2 Section 65.1

This section 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 the Minister 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.

A recall report is required from both the manufacturer and the importer unless the manufacturer takes advantage of Section 65.1 which allows the designation of an importer to submit recall reports on behalf of the manufacturer. The importer so designated has the responsibility of providing all the recall information required by Sections 64 and 65 of the *MDR*.

In preparation for designation of a relevant importer for reporting purposes pursuant to 65.1(2), a manufacturer should first collaborate with the importer to establish a common understanding of the recall reporting requirements and to strengthen mutual communications. The written notification to Health Canada should include evidence of the importer's acceptance of the designation and should be sent to the contacts in Appendix 1.

4.5 Interpretation of Section 64 and 65

Sections 64 and 65 describe the information to be reported to Health Canada by the manufacturer and importer of a device after having made the decision to recall and includes an initial and final notice.

Note - While a distributor is not required to report recalls to Health Canada, the information in these sections should be appropriately referenced in a recall procedure to ensure the distributor meets the regulatory requirements of Section 58(b) referenced previously.

4.5.1 Section 64 The Initial Notice

The manufacturer and importer of a medical device shall on, or before undertaking a recall of the device, each provide the Minister with the following:

4.5.1.1 Section 64 (a)

This section states:

(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;

The requirement to report to the Minister is satisfied by providing the information to the contacts described in Appendix 1. The requirement for reporting described as “on or before” is satisfied by submitting a notice of recall within 3 business days of initiating a recall strategy. The initial notification may be made verbally followed by a written report containing information as required by Section 64.

Note: If notification is not possible according to this guideline, an appropriate rationale regarding the delay should be included in the initial submission of information.

The device subject to recall should be described as completely as possible to enable accurate and rapid identification and to distinguish it from other similar devices. Information should include:

- its full name as it appears on its label;
- its identifier which may be, for example, its catalogue number, product code, or bar code;
- its lot number, batch number or serial number as applicable;
- its licence number, if applicable; and
- its medical device ID number, if known.

4.5.1.2 Section 64 (b)

This section states:

(b) 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;

This section requires the reporting of the full name and address of the manufacturer on the label and the importer as applicable and should include the street address and postal or zip code. If the device is fabricated at a site different from the manufacturer as defined in the *Regulations*, then the full name and address of the contract manufacturer is also required.

4.5.1.3 Section 64 (c)

This section states:

c) the reason for the recall, the nature of the defectiveness or the possible defectiveness and the date and circumstances under which the defectiveness or possible defectiveness was discovered;

The report should fully describe the problem or potential problem with the device which led to the decision to recall and should include the date and details surrounding the discovery of the problem including any death or injury resulting from the problem or defect.

4.5.1.4 Section 64 (d)

This section states:

(d) an evaluation of the risk associated with the defectiveness or possible defectiveness;

The report should include a statement of the hazard associated with use of the device in its defective state and the likelihood that injury will occur. The evaluation of the risk should take into account:

- nature and degree of seriousness of the hazard;
- nature of the particular segments of the population at risk;
- size of the population at risk;
- degree of competence regarding the use of the device;
- user awareness of the problem;
- whether any disease or injuries or death have already occurred from the use of the device.

A risk/benefit comparison of the device should also be performed using the results of the above described risk evaluation. This information should be used to assist in developing the recall strategy.

The results of the risk evaluation should be used to assign a Type (see Definition Section) to the recall.

Health Canada will assess the information provided and assess the Type assigned to the recall or assign one where necessary. Should Health Canada's assessment determine a Type at a higher level than that assigned by the recalling company, the company will be contacted to discuss and if appropriate to revise their strategy.

4.5.1.5 Section 64 (e)

This section states:

- (e) the number of affected units of the device that the manufacturer or importer***
 - (i) manufactured in Canada,***
 - (ii) imported into Canada, and***
 - (iii) sold in Canada;***

All units affected by the recall should be accounted for by the manufacturer and importer as applicable and the report should include a statement of the number of units remaining in stock under the control of the manufacturer or importer as applicable to the specific recall. If many different medical devices are involved, the numbers of affected units should be provided separately for each.

4.5.1.6 Section 64 (f)

This section states:

- (f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;***

As a minimum, the dates of the first and last sale of the device in its defective state should be reported.

4.5.1.7 Section 64 (g)

This section states:

- (g) 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;***

The report should include the name and contact information of each person or company to whom the device was sold as well as the number of units distributed to that person or company and the name of each individual who is provided with the recall information. For example, if the device was sold to an institution such as a hospital or clinic, the recalling company should provide the name and contact information of each individual who was provided with the recall notice.

4.5.1.8 Section 64 (h)

This section states:

- (h) a copy of any communication issued with respect to the recall;***

This includes copies of all documented communications concerning the recall in both official languages, as applicable, such as letters or written notices to consignees, acknowledgment forms, public notices or press releases and notices to professional associations.

4.5.1.9 Section 64 (i)

This section states:

- (i) 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;***

Following the decision to conduct a recall, the recalling company should develop a strategy which suits the

individual circumstances of the situation, taking into account the following aspects:

- the results of the risk evaluation;
- the Type assigned to the recall;
- the ease in identifying the recalled device;
- the degree to which the device defectiveness is obvious to the consumer or user;
- the degree to which the device remains unused in the marketplace and
- the continued availability of comparable alternative products.

A recall strategy should address the following elements regarding the conduct of the recall:

- (i) the depth of the recall;
- (ii) timeliness;
- (iii) the recall communications;
- (iv) notification of users not readily identifiable;
- (v) the effectiveness of the action;
- (vi) initiation date, progress reports to Health Canada and anticipated closure date.

4.5.1.9 (i) Depth of Recall

The level in the distribution chain to which the recall is to extend should be consistent with the risk posed by the affected device. For example the recall may extend to the:

- general public (consumers and patients);
- retail level;
- user level (health care facilities, health care professionals);
- distributor level (including importers). Note that pharmacies and healthcare facilities are considered to be distributors where product is sold to other healthcare facilities or other pharmacies.

4.5.1.9 (ii) Timeliness of Initiation and Completion

The speed with which the various elements of the recall are to be accomplished should be clearly addressed in the recall strategy. Where the initial communication is not the corrective action, a detailed plan, including estimated time frames for accomplishing the corrective action should be included in the recall strategy. This should be based on a satisfactory rationale which takes account of factors such as complexity of the fix, number and geographic location of customers, the risk associated with the affected device, validation requirements, and continuing availability of essential products.

4.5.1.9 (iii) Recall Communications

4.5.1.9 (iii) (a) Timeliness In Communicating With Consignees

The recalling company is responsible for promptly notifying each of its consignees (anyone who received or purchased the affected device) about the recall. The following are included as guidelines:

For Type I recalls, the initial contact with consignees should be made within 1-2 working days of initiation of the recall strategy.

For Type II recalls, the initial contact with consignees should be made within 3-5 working days.

For Type III recalls, the initial contact should be made within 5-7 working days.

Note : If contact is not possible according to this guideline, an appropriate rationale regarding the delay should be included in the recall strategy.

The recalling company should also include an estimate of a reasonable response time expected from its consignees as part of the recall strategy. The response time should reflect the expected time frames for initial contact.

4.5.1.9 (iii) (b) Methods of Communication

Every effort should be made to ensure contact is made with the most appropriate individual relative to the recall issue.

Recall communications can be accomplished by several means, including telephone calls, personal visits, fax, email and special delivery letters (registered mail, courier, etc.).

Where telephone calls or other personal contacts are used, these should ordinarily be confirmed by one of the written communications listed above and documented in an appropriate manner.

Written communications, including cover sheets and envelopes, should be conspicuously marked by displaying, for example, the statement “**Medical Device Recall**” in bold, red type. Type I and II recalls should be labelled “**Urgent**”.

4.5.1.9 (iii) (c) Contents of Communications

The format, content and degree of detail of a recall communication should be commensurate with the risk associated with the device being recalled.

Recall communications should be brief and to the point and should not contain irrelevant qualifications, promotional material, or any element that may detract from the message.

In general, recall communications should include the following:

- that the device in question is subject to a recall;
- a description of the device including model number, lot number(s), serial number(s) or other relevant descriptive information to enable the immediate and accurate identification of the device;
- the reason for the recall - the risk associated with use of the device should be clearly explained;
- where appropriate, that further distribution or use of any of the remaining product should cease immediately;
- where appropriate, that the direct accounts should in turn notify customers who received the product about the recall;
- instructions regarding disposition of the product, with specific steps given for return, disposal or correction;
- request for a prompt response to confirm receipt and understanding of the action to be taken and to

provide any recall information where required. Response mechanisms may include, for example, pre-addressed cards, telephone replies using a toll free number, or a form to complete and return by fax or email.

4.5.1.9 (iv) Notification of Users Not Readily Identifiable

4.5.1.9 (iv) (a) Purpose

The primary purpose for public notification is to reach users or patients not readily identifiable from distribution records. This mechanism is usually reserved for situations where the risk is classified as Type I or Type II.

4.5.1.9 (iv) (b) Responsible Source

The primary responsibility for utilizing public notification, where deemed appropriate in the recall strategy, lies with the recalling company. Nevertheless, circumstances in some situations may result in a public notification issued jointly by the company and Health Canada.

It should be noted that Health Canada is authorized by the *Department of Health Act* to inform the Canadian public of serious health risks.

4.5.1.9 (iv) (c) Format

Public notification may take different forms depending on the nature of the population at risk to be reached. For example, announcements to the general public may be made through the media and/or posting on appropriate web sites. Alternatively, communication may be more focused by, for example, targeting specialized news media, such as, professional, trade or ethnic press, or specific segments of the population, such as, physicians, hospitals or clinics.

4.5.1.9 (v) Effectiveness of the Recall Action

4.5.1.9 (v) (a) Effectiveness Checks by the Recalling Company

The purpose of effectiveness checks is to verify that all consignees specified in the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. The recalling firm is responsible for conducting effectiveness checks.

For each Type of recall, Health Canada expects the recalling company to maintain records that appropriate efforts were made to ensure that all consignees were suitably contacted. Records should include as appropriate:

- dates of attempted contact;
- response received at each attempt;
- name and title of person contacted;
- means of contact including telephone or facsimile number, email or mailing address;
- details of communications once contact is successful;
- conclusion as to whether recall instructions were understood and carried out;

- copies of completed response forms;
- copies of related correspondence.

Satisfactory evidence of contact may include a fax back form, an email response, a telephone log or a courier receipt. Details of all contacts and attempts to contact should be appropriately documented.

The firm's recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted by the recalling firm as follows:

- Level A - 100 percent of the total number of consignees to be contacted,
- Level B - Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees
- Level C - 10 percent or less of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, or
- Level D - No effectiveness checks.

4.5.1.9 (v) (b) Reasonable Follow-up Efforts By the Recalling Company

Non responders are those from whom no return fax, email, courier or phone message was received. Health Canada expects recalling companies to follow-up with non responders using these guidelines:

Type I - there should be no non-responders remaining. If indicated, a personal visit by a company representative could be made to non-responders. If non-responders remain, justification should be provided. Records should be carefully maintained.

Type II - two follow-up efforts are expected using different contact methods as appropriate. Records should be carefully maintained.

Type III - one additional follow-up effort is recommended, preferably by some other means of contact than first used

4.5.1.9 (v) (c) Health Canada Effectiveness Checks

Following a pre-determined time frame, within which the recalling company is to complete its initial communication with consignees and receive responses, Health Canada may review the company's records of customer contact and conduct checks to verify the effectiveness of a company's recall strategy.

4.5.1.9 (vi) Progress Reports to Health Canada and Anticipated Closure Date

Recall progress reports should normally contain the following:

1. number of consignees notified of the recall and date and method of notification;
2. number of respondents and quantity of affected device(s) in possession of each;
3. number of non-respondents (identity of these may be requested by Health Canada);
4. number of devices returned or corrected and the quantity of devices accounted for;
5. number and results of effectiveness checks;
6. estimated time frame for completion if revised from the original.

The anticipated closure date should be provided in the initial report. A rationale should also be provided if the completion is expected to take longer than 3 months.

The reporting interval should be agreed upon with Health Canada.

4.5.1.10 Section 64 (j)

This section states:

(j) the proposed action to prevent a recurrence of the problem;

This section requires a description of the measures the company will take to prevent the problem or potential problem from recurring and should include an analysis of the root cause (if known at this time) and scope of affected production. If a detailed plan is not yet available, the initial report should indicate where the manufacturer will focus its efforts in resolving the problem.

4.5.1.11 Section 64 (k)

This section states:

(k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall;

The representative should be easy to reach and aware of all developments concerning the recall. For Type I recalls or as deemed necessary, the representative should be accessible on a 24 hour basis. A fax number or email address should also be provided if available.

4.5.2 Section 65 The Final Notice

4.5.2.1 Section 65

This section states:

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

(a) the results of the recall; and

(b) the action taken to prevent a recurrence of the problem.

A written report is required on completion of the action by the company with the results of the action, including as applicable:

- the number of units recovered;
- the number of units used by consignees;
- the number of units destroyed by consignees as requested by 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 not located;
- a statement of the method or intended method of disposition of any recovered units or stock units (evidence of disposition should be available on request);
- the final completion date;
- assurance that all consignees received the recall information (the evidence should be available if requested);

- a detailed plan to prevent a recurrence and resolve the problem by such measures as design change, process validation, increased quality control, etc.;
- evaluation of significant change as applicable. (See paragraph below.)

4.5.2.2 Significant Change

In the case of a Class III or IV device that has been subject to recall, an evaluation should be made to determine whether the intended corrective action fits the definition of “significant change” (reference document written by MDB (Medical Device Bureau)-Guidance for Industry - Guidance for the Interpretation of Significant Change of a Medical Device)

(http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchng_modimportante_v3-eng.php). A statement of the results and rationale should be included in the written report of the recall required under Section 65.

If the corrective action fits the definition of “significant change” an application pursuant to an amended medical device licence (Section 34(a) of the Regulations) must be submitted to the Medical Devices Bureau describing the “significant change”. The amended license must be received before further sale of the device occurs.

5.0 Appendices

Contacts for Reporting Medical Device Recalls
Element included in a Standard Operating Procedure

6.0 References

Food and Drugs Act: (<http://laws.justice.gc.ca/eng/F-27/index.html>)

Medical Devices Regulations: (<http://laws.justice.gc.ca/eng/sor-98-282/page-1.html>)

POL-0016 HPFBI Recall Policy:

(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php)

Appendix 1

Contacts for reporting Medical Devices Recalls

Notification of recall should be submitted to the appropriate Region.

Note-Companies that do not know under which Region of responsibility they fall, should contact the Medical Devices Compliance Unit of the Inspectorate at: 613-957-3836

British Columbia (Northwest Territories, Yukon)	Medical Devices Unit Health Products and Food Inspectorate 400 - 4595 Canada Way Burnaby, British Columbia V5G 1J9 Phone 604-666-3350 Fax 604-666-3149 Email- WOC-MED@HC-SC.GC.CA
Manitoba, Saskatchewan	Medical Devices Unit Health Products and Food Inspectorate 510 Lagimodiere Blvd Winnipeg, Manitoba R2J 3Y1 Phone 204-983-5490 Fax 204-984-2155 Email- MS-MED@HC-SC.GC.CA
Ontario, Nunavut	Medical Devices Unit Health Products and Food Inspectorate 2301 Midland Ave. Toronto, Ontario M1P 4R7 Phone 416-973-1596 Fax 416-954-4581 Email- ONT-MED@HC-SC.GC.CA
Quebec	Medical Devices Unit Health Products and Food Inspectorate 1001 Rue St-Laurent Ouest Longueuil, Quebec J4K 1C7 Phone 450-646-1353 Fax 450-928-4105 Email- QUE-MED@HC-SC.GC.CA

Atlantic

(Nova Scotia, New Brunswick,
Prince Edward Island and
Newfoundland)

Medical Devices Unit
Health Products and Food Inspectorate
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6
Phone 902-426-2160
Fax 902-426-6676
Email-ATL-MED@HC-SC.GC.CA

Alberta

(Alberta and Northwest Territories)

Medical Device Unit
Health Products and Food Inspectorate
Suite 730, 9700 Jasper Avenue
Edmonton, Alberta
T5J 4C3
Phone 780-495-6815
Fax 780-495-2624
Email-INSP_ABOC-COA@HC-SC.GC.CA

Appendix 2

Elements included in a standard operating procedure

- Purpose-includes a briefly stated reason for the procedure.
- Scope-defines the area covered and any relevant exclusions.
- Responsibility-defines, as an overview, the functional unit(s) or individuals responsible for carrying out the procedure.
- References-includes, as appropriate, reference to the corresponding chapter in a quality manual, applicable quality system standard, regulation or other related procedure.
- Procedure (or Instructions, Actions or Methods)-describes the step-by-step actions that need to be taken.
- Documentation-includes the kinds of records associated with the procedure; indicates where these records are filed; indicates the length of time they are retained; record retention time periods may alternatively be stated in general procedures for control of documentation and data and simply referred to in individual procedures.
- Distribution-identifies functions receiving the procedure.
- Revision Sheet or Table-includes the revision level (letter, number or combination), the date of the revision, the effective date of the revision, and a brief description of the change(s); tracking of revisions may alternatively be maintained as part of general documentation control procedures.
- Attachments include forms to be used in carrying out the procedure; the procedure should refer to the specific attachment that includes the relevant form; for this procedure a recall reporting form is recommended.

Other recommended good documentation practices include the following:

- involving users in writing, reviewing and modifying procedures;
- printing the names of individuals who prepare and approve procedures;
- signatures and written dates of those approving the procedure;
- numbering of sections, paragraphs and pages to facilitate reading and discussion;
- text that is clear, simple and concise.