Drugs and Health Products

Recall Policy (POL-0016)

Our Mandate:
The Inspectorate's mandate is to manage and deliver a national compliance and enforcement program for drugs (human and veterinary), medical devices, natural health products, blood, cells, tissues and organs, and donor semen, collaborating with and across all regions.

Supersedes: April 18, 2006
Date issued: March 5, 2015
Date of implementation: March 5, 2015

Disclaimer

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

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1.0 Purpose

This policy states what should be achieved by all parties planning for and carrying out recalls in accordance with the requirements of the Food and Drugs Act (the Act), Food and Drug Regulations, Medical Devices Regulations, Natural Health Products Regulations, Blood Regulations, Safety of Human Cells, Tissues and Organs for Transplantation Regulations and Processing and Distribution of Semen for Assisted Conception Regulations (the Regulations) regarding the recall of health products in Canada.

2.0 Background

A recall is the removal or correction of a distributed health product (including its packaging or labelling) that violates the Act or the Regulations or that may present a risk to the health of the consumer. Recalls of health products may be undertaken anytime, in response to a formal request or order to recall by
Health Canada through the Health Products and Food Branch Inspectorate and/or the Inspectorate Program (Regions and Programs Bureau) (collectively the Inspectorate), or on the initiative of responsible parties. This serves to carry out our combined responsibility to ensure compliance with the legislation, and to protect the health of consumers. A responsible party's recall does not preclude other actions which could be taken by the Inspectorate or the responsible party.

Information on certain recalls is shared with other countries in line with agreements negotiated with those countries (see Mutual Recognition Agreements (MRAs) and Pharmaceutical Inspection Cooperation Scheme (PIC/S) in the section titled 4.0 Definitions).

This document replaces the Recall Policy (POL-0016) issued April 18, 2006 and implemented May 18, 2006. The Act and the Regulations are the final authority in all matters of recall.

3.0 Scope

This policy is applicable to all recalls as defined in this policy. Recalls do not include stock recovery of products which have not left the direct control of a responsible party, product withdrawals which are conducted when there is no health and safety risk or no contravention of the applicable legislation, or the issuing of product communications that reinforce labelling information. This policy also applies to the information dissemination stipulated in international agreements (e.g., Rapid Alert notifications). This policy does not apply to biological products for veterinary use licensed with the Canadian Food Inspection Agency or to devices for veterinary use. This policy does not address investigation, reporting or other obligations outside of the recall context, including any obligations in respect of adverse reactions.

4.0 Definitions

Many of the terms used throughout this document are defined in the Act or the Regulations, in the Criminal Code or in other Inspectorate compliance and enforcement policies. The following terms are consistent with definitions in other Inspectorate documents.

Blood Establishment: A person that conducts importation, processing, distribution, transformation or transfusion in respect of blood. (See section 1 of the Blood Regulations.)

Consignee (for medical devices): Anyone who has received, purchased, or used the product being recalled.

Correction (for medical devices): Repair, modification, adjustment, relabelling, or inspection (including patient monitoring) of a product without its physical removal to some other location.

Distributor (for drugs): A person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word, or mark controlled by them, sells a drug. (See A.01.010 of the Food and Drug Regulations)

Note that Divisions 1A and 2 to 4 of the Food and Drug Regulations apply to the following distributors:

- a distributor of an active ingredient or a drug in dosage form that is listed in Schedule C to the Act; and
- a distributor of a drug for which the distributor holds the drug identification number. (C.01A.003 of the Food and Drug Regulations)

Distributor (for natural health products): A person who sells a natural health product to another person for the purpose of further sale by that other person. (Section 1 of the Natural Health Products Regulations)

Distributor/Distribute (for health products other than drugs and natural health products) each has its common meaning, except:

- In the case of blood, distribute does not include to transfuse. (Section 1 of the Blood Regulations)
- In the case of cells, tissues and organs, distribute does not include to transplant. (Section 1 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations)
Effectiveness Check: Includes a survey of those affected by the recall (including consignees, in the case of medical devices) 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.

Health Product: Includes any product under the mandate of the Inspectorate, such as: pharmaceutical, biological and radiopharmaceutical drugs for human use; veterinary drugs; medical devices; natural health products; blood; cells, tissues and organs for transplantation; and semen for assisted conception.

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 consists of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Health Risk Classification: A numerical designation that may be assigned by Health Canada to a particular product to indicate the relative degree of risk to human health presented by the product, as follows:

- **Type I**: a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death
- **Type II**: a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote
- **Type III**: a situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences

Types I and II include situations where a product 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.

International Medical Device Regulators Forum (IMDRF): A voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.

Legal Agent (for drugs): For a drug imported into Canada for the purpose of sale, whether an active ingredient or a drug in dosage form, the person in Canada responsible for the sale of the drug. (See C.01.004.1(1) and C.02.003.2(1) of the Food and Drug Regulations)

Manufacturer (for drugs): A person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a drug. (A.01.010 of the Food and Drug Regulations)

Manufacturer (for medical devices): 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. (Section 1 of the Medical Devices Regulations)

Manufacturer (for natural health products): A person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient. (Section 1 of the Natural Health Products Regulations)

Mutual Recognition Agreement (MRA): An international agreement that provides for the mutual recognition of compliance certification for Good Manufacturing Practices for drugs. (C.01A.001 of the Food and Drug Regulations)

Pharmaceutical Inspection Cooperation Scheme (PIC/S): The purpose of PIC/S is to pursue and strengthen the cooperation established between the participating authorities in the field of inspection and...
related areas with a view to maintaining the mutual confidence and promoting quality assurance of inspections, to provide the framework for all necessary exchange of information and experience, to coordinate mutual training for inspectors and for other technical experts in related fields, to continue common efforts towards the improvement and harmonization of technical standards and procedures regarding the inspection of the manufacture of medicinal products and the testing of medicinal products by official control laboratories, to continue common efforts for the development, harmonization and maintenance of Good Manufacturing Practices (GMP), and to extend the cooperation to other competent authorities having the national arrangements necessary to apply equivalent standards and procedures with a view to contributing to global harmonization.

**Processor:** A person or establishment that collects, tests, prepares, preserves, labels, and stores semen for use in assisted conception. (See section 1 of the *Processing and Distribution of Semen for Assisted Conception Regulations*).

**Product Withdrawal:** The removal from further sale or use or correction of a distributed product where there is no health and safety risk and no contravention of the legislation or regulations. It is not considered to be a recall.

**Recall (for health products other than medical devices):** A responsible party’s removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates the Act or the Regulations.

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

**Responsible Party:** The person responsible for initiating and conducting the recall. Without limiting the generality of the foregoing, responsible parties may include manufacturers, distributors, importers, legal agents and wholesalers for drugs; sponsors of clinical trials; manufacturers, importers and distributors for medical devices; manufacturers, importers, distributors, and product licence holders for natural health products; blood establishments for blood; source establishments for cells, tissues and organs; and processors for semen.

**Sell:** Includes offer to sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration. (Section 2 of the *Food and Drugs Act*).

**Source Establishment (for cells, tissues and organs)** is as defined in section 1 of the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*.

**Sponsor:** An individual, corporate body, institution or organization that conducts a drug clinical trial. (C.05.001 of the *Food and Drug Regulations*).

**Stock Recovery:** The removal or correction of a product that has not been distributed or that has not left the direct control of the party ordering the removal or correction. It is not considered to be a recall.

**Two-Way Alert (or Rapid Alert):** A system implemented amongst MRA partners to rapidly notify each other of any situations that is known or may be expected to negatively affect the quality of a medicinal product/drug covered under the scope of the MRA. It may include but is not limited to:

- confirmed problem reports, corrective actions, or recalls
- the cancellation or suspension of a manufacturing authorization or an establishment licence related to quality deficiencies, in whole or in part, by a regulatory authority listed in the agreement
- counterfeiting and tampering

**Wholesaler (for drugs):** A person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at retail sale:
a. a drug in dosage form that is listed in Schedule C or D to the Act, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001(1);

b. an active ingredient; or
c. a narcotic as defined in the Narcotic Control Regulations. (C.01A.001 of the Food and Drug Regulations)

5.0 Policy Statement

It is the policy of the Inspectorate to verify that recalls of health products in Canada are conducted and reported in accordance with the Act and the Regulations. The Inspectorate expects responsible parties to take full responsibility for product recalls, whether they are undertaken at the initiative of a responsible party or in response to an order to recall under the Act. Mandatory actions relating to recalls under the Act and the Regulations are as outlined in Appendix 1. Further compliance actions in accordance with the Inspectorate's Compliance and Enforcement Policy (POL-0001) may be taken if a responsible party fails to recall a health product.

The objectives of the Inspectorate as they relate to recall are to verify that:

a. Non-compliant or potentially harmful health products are removed from distribution in accordance with the principles of risk management, and measures are taken to correct the deficiencies in an effective and timely manner;

b. Health Canada's voluntary and mandatory commitments to international partners are fulfilled, including the distribution of Rapid Alert notifications on recalled drug products;

c. the Inspectorate is informed when investigations and recalls are initiated, per the Act and the Regulations, and is provided with information about the results of recalls and the actions taken to prevent recurrence of problems;

d. responsible parties have documented procedures that enable them to carry out effective and timely investigation of reported problems and recalls; and

e. Responsible parties maintain records as required of:

   ▪ incidents
   ▪ errors and accidents
   ▪ complaints
   ▪ actions taken in response to incidents, errors and accidents, and complaints

6.0 Responsibilities

6.1 Responsible Parties

Responsible parties are expected, in accordance with the Act, the Regulations, and this policy, to notify Health Canada when a risk to health which may lead to the recall of a distributed health product is identified and when a recall is initiated, to undertake recalls when requested to do so by Health Canada, and to make progress reports when requested by Health Canada. The Inspectorate expects responsible parties to take full responsibility for product recalls and to conduct effectiveness checks. Effectiveness checks may also be undertaken or verified by the Inspectorate. Parties subject to an order to recall under the Act must comply with all terms and conditions set out in the order.

Reporting to Health Canada:

Further to the above paragraph, the Regulations and this policy require a documented recall system which can be implemented to ensure that Health Canada is notified of recalls as follows:

- For drugs, the responsible party should notify Health Canada if there is a potential need for recall at
the time a risk to health from a distributed product is identified. C.01.051 of the Food and Drug Regulations requires a manufacturer or importer who commences a recall to submit information to Health Canada concerning the recall "forthwith". This is interpreted to mean that the manufacturer or importer who is recalling a drug must submit to Health Canada the information specified in section C.01.051 within 24 hours of having made the decision to recall. This initial notification may be made verbally or in writing. This notification should be followed within 72 hours by a written report containing sufficient information to enable Health Canada to assess the risk to health of the implicated drug.

- For medical devices, section 64 of the Medical Devices Regulations requires the manufacturer and importer of a medical device to provide Health Canada with information concerning a recall "on or before undertaking a recall". This is interpreted to mean that the manufacturer and importer must submit to Health Canada as much recall information as is known within 24 hours of having made the decision to recall. This initial notification may be made verbally or in writing. This must be followed within three business days by a written report containing full information as required by section 64. Per section 65 of the Medical Devices Regulations, a report on the results of the recall and the action taken to prevent a recurrence of the problem must be submitted as soon as possible after the completion of a recall.

- For natural health products, the responsible party should notify Health Canada if there is a potential need for recall at the time a risk to health from a distributed product is identified. Sections 25 and 62 of the Natural Health Products Regulations require every product licence holder, manufacturer, importer or distributor who commences a recall of a natural health product to provide to Health Canada the information referred to in section 62 within three days after the day on which the recall is commenced.

- For blood, section 107 of the Blood Regulations requires that a blood establishment conducting an investigation into a suspected error or accident that is thought to have occurred during an activity that it conducted, that is identified after the blood is distributed or transfused, where there is a reasonable probability that the error or accident could lead to a serious adverse reaction, must provide to Health Canada a preliminary report within 24 hours after the start of the investigation that includes all relevant information that is available. The blood establishment must provide a written update within 15 days after the start of the investigation on any new information about the suspected error or accident, on the progress of the investigation, and on the steps taken to mitigate further risks. The blood establishment must provide further written updates on Health Canada’s request at any time after the preliminary report. The blood establishment must also file a final report containing (a) the results of the investigation; (b) the final disposition of the blood that was the subject of the investigation and the reasons for that disposition; and (c) any corrective actions taken and any other changes that are recommended to be made to relevant processes, on completion of the investigation.

- For cells, tissues and organs, section 51 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations requires that a source establishment conducting an investigation of a suspected error or accident, that is identified after distribution, that could lead to a serious adverse reaction involving the transmission of an infectious disease or disease agent, must provide to Health Canada a preliminary report within 24 hours after the start of the investigation that includes all relevant information that is available at that time. The source establishment must provide an update every 15 days on the progress of the investigation and on the steps taken to mitigate further risks until the final report is provided. Per section 54 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations, the source establishment must submit a detailed final report containing (a) the results of the investigation; (b) the final disposition of the cells, tissues and organs that were the subject of the investigation and the reasons for that disposition; and (c) any corrective actions taken, on completion of the investigation.

- For semen, subsection 15(3) of the Processing and Distribution of Semen for Assisted Conception Regulations requires that every processor conducting an investigation to determine if semen is contaminated by an infectious agent must provide to Health Canada the information specified in
that section **within three days after the start of an investigation**, and must provide an update **every 30 days after the start of the investigation** on the progress of the investigation, until the final report is provided. Per section 18 of the *Processing and Distribution of Semen for Assisted Conception Regulations*, the processor must submit a detailed final report setting out the results of the investigation, including, where the semen is required to be collected, destroyed or reserved for special access distribution, the disposition of all containers of that semen, on completion of the investigation.

Notifications and other communications to Health Canada should be made by contacting the Inspectorate as outlined in Appendix 2, or via the Inspectorate’s toll free number at 1-800-267-9675.

**Record keeping and standard operating procedures:**

The Regulations generally require regulated parties to maintain necessary records and to develop a system of control for product recalls that can be put into effect when needed:

- For clinical trial drugs, the sponsor has a system for retrieving clinical trial drugs and documenting this retrieval of deficient product.

- Action taken to recall a product that is suspected or known to be defective is prompt and in accordance with a predetermined plan. The procedures to be followed are in writing and known to all responsible staff.

- The persons responsible for initiating and coordinating all recall activities are identified.

- The procedure can be put into operation at any time, during and outside normal working hours.

- Recall procedures put into place by the responsible party outline the means by which the responsible party notifies Health Canada, product distributors and users, conducts a recall and carries out any follow-up activities.

- Distribution records enable tracing of products and accounting for all products including those in transit, on loan, samples removed by the quality control department and any professional samples distributed.

- Recalled products are identified and placed in quarantine until disposition is determined.

- Progress and efficacy of the recall are assessed and recorded at intervals and a final report issued including a final reconciliation of implicated products.

- Foreign manufacturers or commercial customers in countries outside of Canada that have imported the product are notified.

### 6.2 Inspectorate

The Inspectorate’s responsibility under this policy is to enforce the Act and Regulations, to monitor company recalls and to assess the effectiveness of a responsible party’s actions. The Inspectorate assesses the causes of the problem and reviews the product disposition. The Inspectorate ensures that an appropriate health risk assessment (e.g., Type I, II, III) is assigned to the risk posed by the product. This may involve a request for a formal health risk assessment report. Although the responsible party recalling the product may issue a press release, Health Canada may issue its own communiqué about a recall when it believes the public needs to be alerted to a serious risk to health. The responsible party may be advised of this communiqué and when possible a draft may be shared.

The Inspectorate’s responsibilities under the drug MRAs are stipulated in those agreements, and include an alert notification of recalls as appropriate to the level of risk of the product recalled.

There also exist several voluntary agreements for international exchange of information on recalls. These include:
For medical devices, information on high risk recalls disclosed under the IMDRF (formerly GHTF) National Competent Authority Report (NCAR) exchange program. Courtesy copies to individual countries as appropriate for Type I and II health risk classifications (e.g. PIC/S).

Where no such agreements are in place, the Inspectorate will make efforts to inform the foreign authority of the status of any exported products posing a serious health risk.

Appendix 1 Mandatory Actions

**Drugs**

<table>
<thead>
<tr>
<th>Person</th>
<th>Applicable Legislative and Regulatory Sections</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sellers (incl. persons distributing not for consideration)</td>
<td>Section 21.3 and 31.2 of the <em>Food and Drugs Act</em></td>
<td>(legal obligation to comply with) Order to recall, to send to a specified place, or to take corrective action, where Health Canada believes that a drug or device other than a natural health product presents a serious or imminent risk of injury to health.</td>
</tr>
<tr>
<td>Manufacturers, Importers</td>
<td>C.01.051 of the <em>Food and Drug Regulations</em></td>
<td>Notification of recall to Health Canada.</td>
</tr>
<tr>
<td>Fabricators, Packagers/Labellers, Distributors (referred to in section C.01A.003), Importers, Wholesalers</td>
<td>C.02.012(1)(a) of the <em>Food and Drug Regulations</em></td>
<td>Maintenance of a product control system to enable the recall of a drug.</td>
</tr>
<tr>
<td>Wholesalers, Distributors (referred to in section C.01A.003), Importers</td>
<td>C.02.022 of the <em>Food and Drug Regulations</em></td>
<td>Records of all sales are retained or kept readily accessible, for a period of at least one year after the expiration date of that lot or batch (or in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed), in a manner that will permit a complete and rapid recall of any lot or batch of a drug. This requirement need not necessarily involve tracking by lot number.</td>
</tr>
<tr>
<td>Packagers/Labellers</td>
<td>C.04.075 of the <em>Food and Drug Regulations</em></td>
<td>Recall of Bacille Calmette-Guerin (BCG) vaccine by packagers/labellers under certain circumstances.</td>
</tr>
<tr>
<td>Sponsors</td>
<td>C.05.010(j) of the <em>Food and Drug Regulations</em></td>
<td>C.02.012 and C.02.022 of the <em>Food and Drug Regulations</em> apply. Per GUI-0036, procedures for retrieving clinical trial drugs, including comparators, and documenting this retrieval should be established by the sponsor, in collaboration with the manufacturer or importer where different. The qualified investigators need to understand their obligations under the retrieval procedure.</td>
</tr>
</tbody>
</table>

**Medical Devices**

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<tr>
<td>Sellers (incl. persons)</td>
<td>Section 21.3 and 31.2 of the <em>Food and Drug Regulations</em></td>
<td>(legal obligation to comply with) Order to recall, to</td>
</tr>
<tr>
<td>Person</td>
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<td>Requirements</td>
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<tr>
<td>distributing not for consideration)</td>
<td>Food and Drugs Act</td>
<td>send to a specified place, or to take corrective action, where Health Canada believes that a drug or device other than a natural health product presents a serious or imminent risk of injury to health.</td>
</tr>
</tbody>
</table>
| Manufacturers, Importers | (Part 1 General) Sections 52, 53, 57, 58, and 63 to 65 of the Medical Devices Regulations  
(Part 3 Medical Devices for Investigational Testing Involving Human Subjects) Section 88 of the Medical Devices Regulations | Complaint handling, implementation of investigation and recall procedures, notification of a recall to Health Canada, and report of completion of a recall and corrective action taken. |
| Distributors | (Part 1 General) Sections 52, 57, 58, of the Medical Devices Regulations | Complaint handling, implementation of investigation and recall procedures. |

**Natural Health Products**

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<tr>
<th>Person</th>
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</thead>
<tbody>
<tr>
<td>Product Licence Holder</td>
<td>Sections 25 and 62 of the Natural Health Products Regulations</td>
<td>Notification of a recall to Health Canada.</td>
</tr>
<tr>
<td>Manufacturers, Importers and Distributors</td>
<td>Sections 25, 50, 53, 56, 57 and 62 of the Natural Health Products Regulations.</td>
<td>Investigation of complaints, corrective actions, system of control and record-keeping to enable a recall, and notification of a recall to Health Canada.</td>
</tr>
<tr>
<td>Packagers/Labellers</td>
<td>Sections 50, 51, 54 and 55 of the Natural Health Products Regulations</td>
<td>Investigation of complaints, corrective actions, system of control and record-keeping to enable a recall.</td>
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**Blood**

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<tr>
<td>Sellers (incl. persons distributing not for consideration)</td>
<td>Section 21.3 and 31.2 of the Food and Drugs Act</td>
<td>(legal obligation to comply with) Order to recall, to send to a specified place, or to take corrective action, where Health Canada believes that a drug or device other than a natural health product presents a serious or imminent risk of injury to health.</td>
</tr>
<tr>
<td>All blood establishments required to be licensed or registered</td>
<td>Sections 93 to 94 of the Blood Regulations</td>
<td>Quality management system including a system for identification and investigation of post-donation information, errors, accidents and adverse reactions, and the conduct of recalls.</td>
</tr>
<tr>
<td>All blood establishments</td>
<td>Section 95 of the Blood Regulations</td>
<td>Operating procedures for activities with respect to human safety and the safety of blood.</td>
</tr>
<tr>
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</tr>
<tr>
<td>All blood establishments</td>
<td>Sections 103 to 108 of the Blood Regulations</td>
<td>Quarantine; notification of suspected compromise of blood to other establishments; investigation if error or accident during activity conducted by establishment may have compromised safety of blood; notification of investigation to other establishments; information-sharing with other establishments; provision of preliminary, progress and final reports on investigation (including corrective actions) to Health Canada.</td>
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### Human Cells, Tissues and Organs for Transplantation

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<td>Sellers (incl. persons distributing not for consideration)</td>
<td>Section 21.3 and 31.2 of the Food and Drugs Act</td>
<td>(legal obligation to comply with) Order to recall, to send to a specified place, or to take corrective action, where Health Canada believes that a drug or device other than a natural health product presents a serious or imminent risk of injury to health.</td>
</tr>
<tr>
<td>All establishments</td>
<td>Sections 55 to 63, 71 to 76 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations</td>
<td>Record-keeping, quality assurance system and standard operating procedures to enable compliance with regulations.</td>
</tr>
<tr>
<td>Source establishments</td>
<td>Sections 44, 51, 53 and 54 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations</td>
<td>Quarantine; investigation; notification of investigation to Health Canada and others; provision of preliminary, progress and final reports (including corrective actions) to Health Canada; and summary of final report to others.</td>
</tr>
<tr>
<td>Establishments other than source establishments</td>
<td>Sections 43, 46 and 50 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations</td>
<td>Quarantine; notification to other establishments; information-sharing with other establishments.</td>
</tr>
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</table>

### Semen for Assisted Conception

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<td>Section 21.3 and 31.2 of the Food and Drugs Act</td>
<td>(legal obligation to comply with) Order to recall, to send to a specified place, or to take corrective action, where Health Canada believes that a drug or device other than a natural health product presents a serious or imminent risk of injury to health.</td>
</tr>
<tr>
<td>Processors</td>
<td>Sections 12, 15, 16 and 18 of the Processing and Distribution of Semen for Assisted Conception Regulations</td>
<td>Procedures and record-keeping to trace semen; quarantine; investigation; notification of investigation to Health Canada and others; collection and destruction of contaminated semen; provision of reports to Health Canada; summary of investigation results to others.</td>
</tr>
<tr>
<td>Distributors</td>
<td>Sections 13, 14 and 17 of the Processing and Distribution of Semen for Assisted Conception</td>
<td>Record-keeping to trace semen; stop-distribution and notification to processor of suspected transmission of infectious agent; quarantine or destruction of contaminated semen; report on actions.</td>
</tr>
</tbody>
</table>
### Person | Applicable Legislative and Regulatory Sections | Requirements
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 | Regulations |  

**Appendix 2 - Inspectorate Contact Information**

**For drugs, natural health products and medical devices:**

- Inspectorate offices

**For blood:**

- Regulations - Error or Accident Investigation Preliminary Report Form (FRM-0337)

**For human cells, tissues and organs:**

- Human Cells, Tissues and Organs for Transplantation - Error or Accident Investigation Preliminary (FRM-0172)

**For semen:**

- Guidance on the Processing and Distribution of Semen for Assisted Conception Regulations (GUIDE-0041)

Date Modified: 2015-03-06