



**HEALTH PRODUCTS
STEWARDSHIP
ASSOCIATION**

**SHARPS COLLECTION PROGRAM PLAN FOR
THE PRINCE EDWARD ISLAND MEDICAL
SHARP STEWARDSHIP PROGRAM**

DECEMBER 2014

EXECUTIVE SUMMARY

On June 10, 2014 Prince Edward Island approved the *Environmental Protection Act Materials Stewardship and Recycling Regulations* (Regulation), pursuant to Section 25 of the Environmental Protection Act (EPA). Under the Regulation, Division 7 “Medical Sharps” designates medical sharps as a regulated material and defines medical sharps and Brand Owners (Producers). Division 7 also makes Producers of medical sharps responsible for establishing a Medical Sharp Stewardship Program and states the program requirements that Producers must meet. The Regulation allows the Health Products Stewardship Association (HPSA) to act as an agent on behalf of Producers to operate a medical sharp stewardship program and fulfill compliance obligations under the Regulation.

For the purposes of this program plan document and program operation, the Medical Sharp Stewardship Program (MSSP) required under the Regulation is referred to as the Island Sharps Collection Program (ISCP). The ISCP addresses EPR for all types of medical sharps sold for use in the province of Prince Edward Island but is limited to the “Consumer” waste stream. The program is designed to ensure that collection service is available to all regions of the province and all returned medical sharps are collected, handled, stored, packaged, transported and disposed of in a safe, compliant and environmentally responsible manner.

The ISCP is administered by the Health Products Stewardship Association (HPSA), a not-for-profit industry stewardship organization (ISO), established in 1999. HPSA was formed to provide the health product industries with a collective means for managing their extended producer responsibilities including the associated product liability and regulatory compliance requirements that vary from province to province.

The ISCP covers a five year period as stated in the Regulation beginning June 1, 2015 through to May 31, 2020 after which the program plan will undergo a review.

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1. GLOSSARY OF KEY DEFINITIONS AND ACRONYMS

1.1 Acronyms

CAP:	Canada-Wide Action Plan for EPR
CAPDM:	Canadian Association for Pharmacy Distribution Management
CCME:	Canadian Council for Ministers of the Environment
EPA:	Prince Edward Island Environmental Protection Act
EPR:	Extended Producer Responsibility
HPSA:	Health Products Stewardship Association
ISCP:	Island Sharps Collection Program
ISO:	Industry Stewardship Organization
IWMC:	Island Waste Management Corporation
MOELJ:	Prince Edward Island Department of Environment, Labour and Justice
MSSP:	Medical Sharp Stewardship Program
NPAC:	Neighbourhood Pharmacies Association of Canada
OECD:	Organization for Economic Co-operation and Development
PEICP:	Prince Edward Island College of Pharmacists
PEIPA:	Prince Edward Island Pharmacists Association
RCC:	Retail Council of Canada

1.2 Terms and Definitions

a) Agent

The Health Products Stewardship Association acts as an agent of Brand Owners (Producers) designated under section 104 of the *Environmental Protection Act* Materials Stewardship and Recycling Regulations.

b) Brand Owner (Producer):

For the purposes of the industry stewardship plan, the Brand Owner for a pharmaceutical product sold, offered for sale, or otherwise distributed in or into the province of Prince Edward Island is:

- i) a person who manufactures a pharmaceutical product and sells, offers for sale or distributes a pharmaceutical product in Prince Edward Island under its own brand, or;
- ii) a person who is not the manufacturer of a pharmaceutical product but is the owner or licensee of a trademark under which the pharmaceutical product is sold or distributed in Prince Edward Island, whether or not they own the Drug Identification Number.
- iii) if subparagraphs (i) and (ii) do not apply, a person who imports the product in the province for sale or distribution

c) Collection Location(s):

A location, typically a retail pharmacy with a public facing dispensary, at which the collection of medical sharps is provided for.

d) Consumer:

Means an individual acting for personal, family or household purposes.

e) Cytotoxic Waste:

Means a cytotoxic drug, a medicinal chemical or a waste containing a cytotoxic drug or medicinal chemical, including waste needles.

f) Medical Sharp (Designated Material):

Under the *Environmental Protection Act* Materials Stewardship and Recycling Regulations, a medical sharp is defined as a needle, safety engineered needle, lancet or other similar instrument that is designed to puncture the skin for medical purposes and that is sold or otherwise distributed, and includes anything affixed to the sharp, including a syringe.

For the purposes of the ISCP, a medical sharp is further defined into the following categories including components of, or attached to, a medical sharp that are typically disposed of in a sharps container by Consumers:

- a. Infusion sets, infusion pods.
- b. Lancets,
- c. Pen tips
- d. Needles
- e. Syringes
- f. Prefilled

g) Over Packing:

Biomedical waste packaging used for the containment of filled sharps containers from the ISCP during handling, storage or transportation. Over packing for sharps containers should, at a minimum, meet the standards stated in the "Guidelines for the Management of Biomedical Waste in Canada" published by the Canadian Council of Ministers of the Environment.

h) Program Plan:

A document that provides producers with a strategy for individually or collectively managing the extended producer responsibility of their products including any safety, environmental and regulatory requirements.

i) Retailer:

Under the *Environmental Protection Act Materials Stewardship and Recycling Regulations*, a retailer means a person who sells or offers for sale medical sharps directly to Consumers.

j) Sharps Container:

A colored coded, puncture, break and leak resistant container designed for containing used medical sharps that is labeled with a fill line, a universal biohazard symbol and/or cytotoxic symbol.

k) Waste Watch Drop-Off Centres:

Permanent locations (six) operated by Island Waste Management Corporation in Prince Edward Island where Consumers can drop off used sharps and other hazardous waste from households for transfer and end-of life processing.

2. INTRODUCTION

The Organization for Economic Co-operation and Development (OECD) has defined EPR as "a policy approach in which a producer's responsibility, physical or financial, for a product is extended to the post-consumer stage of a product's lifecycle".

The purpose of this document is to provide a plan for the management of EPR for post-consumer medical sharps in Prince Edward Island. The primary objective of this document is to ensure, through a detailed program plan, that HPSA member Producers with medical sharps devices are in compliance with the Prince Edward Island *Environmental Protection Act* Materials Stewardship and Recycling Regulations.

2.1 Regulatory Review

The ISCP is a regulatory driven EPR initiative. The following regulatory review examines the acts, regulations, guidelines and standards that are relevant to the ISCP.

2.1.1 *Environmental Protection Act* Materials Stewardship and Recycling Regulations

The compliance requirements of the ISCP are dictated primarily by the *Environmental Protection Act* Materials Stewardship and Recycling Regulations. This regulation requires Brand Owners of medical sharps to provide for the collection and safe environmental management of their leftover products from Consumers. Brand Owners must also provide Consumers with access to free and convenient collection locations, such as retail pharmacies, to return their medical sharps.

The Regulation defines "Medical Sharps" as:

A needle, safety engineered needle, lancet, or other similar instrument that is designed to puncture the skin for medical purposes and that is sold or otherwise distributed, and includes anything affixed to the sharp, including a syringe.

The Regulation defines "Brand Owners" as:

In respect of medical sharps sold, offered for sale or otherwise distributed in or into the province:

- a) a manufacturer of the medical sharp;
- b) a distributor of the medical sharp in or into the province; or
- c) where the medical sharp is imported into the province, the first person to sell the medical sharp in or into the province.

HPSA is the industry designated ISO that has developed compliance protocols to ensure a level playing field among Brand Owners selling medical sharps in Prince Edward Island. Brand Owners not compliant with the *Environmental Protection Act* Materials Stewardship and Recycling Regulations are subject to enforcement under the EPA which is the responsibility of the government of Prince Edward Island.

2.1.2 Other Applicable Acts, Regulations, Guidelines and Standards

The list of additional acts, regulations, guidelines and standards that have been considered in the creation of the Medical Sharp Stewardship Program plan is as follows:

- a) Canadian Council for Ministers of the Environment (CCME) Canada-Wide Action Plan on EPR (CAP)

The CCME CAP for EPR is a guideline for regulatory and EPR program clarity for government, producers and ISOs like HPSA. It is used as the guideline on key elements common to all EPR programs in Canada.

- b) Canadian Council for Ministers of the Environment (CCME) Guideline for the Management of Biomedical Waste in Canada

This CCME guideline sets uniform practices and minimum national standards for the handling, packaging, transportation and disposal of biomedical waste, including sharps.

- c) Waste Resource Management Regulations

The Waste Resource Management Regulations set forth the requirements for waste carriers, generators and receivers in the Province of Prince Edward Island. The regulation defines special waste and requires generators/transporters of special waste to obtain a Special Waste Permit. Transporters of Hazardous Waste must be registered and issued a provincial registration number.

Under the Waste Resource Management Regulations the definition of Special Waste includes sharps such as needles, broken glass and other sharp objects capable of causing cuts or punctures.

- d) Pharmacy Act

The Pharmacy Act of Prince Edward Island defines what a pharmacy is and how it is accredited. Retail pharmacies with a public facing dispensary act as the primary collection locations for the ISCP.

- e) Prince Edward Island Environmental Protection Act

The Act is Prince Edward Island's key legislation for Environmental Protection. The act grants the Department of Environment, Labour and Justice (DELJ) and specifically the Minister broad powers to deal with the discharge of contaminants which cause negative environment effects.

- f) Interprovincial Movement of Hazardous Waste Regulations (SOR/2002-301)

The goal of the Interprovincial Movement of Hazardous Waste Regulations (hereinafter referred to as the Interprovincial Regulations) is to ensure that the Canadian manifest tracking and hazards classification conditions for waste, formerly set out in the Transportation of Dangerous Goods Regulations, are maintained for the interprovincial movements of hazardous wastes.

Under section 191 of the Canadian Environmental Protection Act, 1999 (CEPA 1999), the Governor in Council has the authority to make regulations respecting conditions governing the movement within

Canada of hazardous wastes and hazardous recyclable materials. The Interprovincial Regulations were required as a consequence of the new Transportation of Dangerous Goods Regulations (TDG Regulations), made pursuant to the Transportation of Dangerous Goods Act, 1992. These new TDG Regulations, which came into force on August 15, 2002, no longer included provisions for manifest tracking of hazardous waste.

3. THE HEALTH PRODUCTS STEWARDSHIP ASSOCIATION

The HPSA is the ISO created to manage safe disposal of unused or expired health products returned from the public in regulated provincial programs. HPSA's predecessor, the Post-Consumer Pharmaceutical Stewardship Association began in 1999 by managing the British Columbia Medications Return Program on behalf of Producers as required under British Columbia Recycling Regulation 449/2004. HPSA's member Producers represent the majority of Brand Owners selling health products in Canada. The list of medical sharps Brand Owners that are members of the HPSA and are participating in the ISCP is attached in Appendix A.

The HPSA successfully introduced and has operated a medical sharps collection program in the province of Ontario since October 1st, 2012. The Ontario Sharps Collection Program maintains producer compliance under the Ontario Regulation 298/12.

3.1 Vision

The vision of the HPSA is to be the recognized ISO for environmental waste management programs of health products.

3.2 Mandate

The mandate of the HPSA is to collect and dispose of medical sharps and medications returned by the public in a cost-efficient and environmentally acceptable manner that meets government policy and/or regulatory requirements for its producer members.

3.3 Guiding Principles

1. **Level Playing Field:** Provide a level playing field (fair competition), achieve a high level of compliance, and reduce the potential for having Brand Owners fail to meet their financial obligations.
2. **Environmental Standards:** Ensure materials are disposed of in a responsible manner that safeguards the environment and worker health and safety in accordance with regulatory requirements.
3. **No Cross-Subsidization:** Ensure the collection of revenue from the program is in balance with the expenses for the program with fees closely reflecting the costs of managing each obligated product.
4. **Operational Efficiencies:** Ensure the program is delivered effectively and efficiently at the lowest possible cost.
5. **Business Sustainability:** Ensure sustainable management of the association by maintaining an appropriate operating contingency reserve, but not accumulating a surplus.
6. **Continuous Improvement:** Adhere to provisions for best practices to strive for continuous improvement in environmental and economic performance.
7. **Harmonization:** To the greatest extent possible, harmonize with other programs to achieve economies of scale.

4. DESIGNATED MATERIAL (MEDICAL SHARPS)

A fundamental component of the ISCP plan is the definition of medical sharps that Consumers can return.

For the purposes of the ISCP, medical sharps as a designated material, are defined into categories as:

- a. Infusion sets, infusion pods.
- b. Lancets, including safety cap.
- c. Pen tips.
- d. Needles
- e. Syringes
- f. Prefilled

4.1 Medical Sharps Product Category and the Prince Edward Island Marketplace:

The definition of a Brand Owner under the *Environmental Protection Act* Materials Stewardship and Recycling Regulations is referenced in section 1.2 (b) of the program plan. In the province of Prince Edward Island the following medical sharp Brand Owner distribution scenarios exist:

- Manufacturers selling their brand to wholesalers and retail pharmacies;
- Retail pharmacies selling their private label branded sharps to Consumers;
- First importers selling sharps to wholesalers and retail pharmacies.

4.2 Categories of Medical Sharps Waste

Post-consumer medical sharps waste collected in the ISCP fall into two categories; biomedical sharps and cytotoxic sharps.

Biomedical sharps are medical sharps products used by Consumers that are designed to puncture the skin for medical purposes. Used biomedical sharps should be properly placed in an approved sharps container with a universal biohazard symbol on the outside, for primary containment purposes in order to be accepted at collection locations.

Cytotoxic sharps are medical sharps products used by Consumers for a chemotherapeutic application. Used cytotoxic sharps should be placed in an approved sharps container, and should have a cytotoxic label placed on the outside, for primary containment purposes in order to be accepted at collection locations.

4.3 Collectors of Medical Sharps Waste

Under the ISCP, medical sharp waste is brought to collection locations in approved sharps containers by Consumers. Collection locations will consist of retail pharmacies with a public facing dispensary located across Prince Edward Island.

4.4 Retailers of Medical Sharps

The *Environmental Protection Act* Materials Stewardship and Recycling Regulations define a retailer as a person who sells or offers for sale medical sharps directly to Consumers. Under the Regulation, retailers must display education and awareness program information that is supplied to it by the Brand Owner's agent. HPSA acting as the collective agent for member Brand Owners participating in the ISCP will make available education and awareness program information to medical sharp retailers in Prince Edward Island.

5. PROGRAM DESIGN

The ISCP provides all Consumers with reasonable access to collection locations on a province-wide basis. HPSA is responsible for strategic planning, overseeing the program and financial operations.

The goals of the program are to:

- Establish a province-wide industry run Medical Sharp Stewardship Program (ISCP) in compliance with the *Environmental Protection Act* Materials Stewardship and Recycling Regulations.
- Provide a plan for collecting post-consumer medical sharps.
- Ensure that the Brand Owners who sell, offer for sale or distribute medical sharps in Prince Edward Island are members of HPSA and fund a Medical Sharp Stewardship Program.
- Ensure environmentally responsible disposal of medical sharps.
- Ensure that the public is able to return medical sharps for disposal throughout the province.
- Provide the public and medical sharp retailers with information about:
 - The ISCP and the products accepted for collection and disposal;
 - How and when medical sharps can be returned; and
 - The environmental benefits of using the ISCP.
- Harmonize the plan with other provincial programs.

According to the *Environmental Protection Act* Materials Stewardship and Recycling Regulations the program plan must provide for the following:

1. The management structure of the program (Section 3);
2. How discarded medical sharps will be collected (Section 5.1);
3. The plans for the receipt of discarded medical sharps at the medical sharp return facilities that participate in the program and the policies and procedures to be followed by the medical sharp return facilities (Section 5.1);
4. The quality control and assurance aspects of the program, including tracking and auditing mechanisms (Section 5.6); and
5. An education and awareness program for Consumers of medical sharps (Section 5.4) that includes information about
 - i. The ISCP, specifying products accepted by the program,
 - ii. How and when Consumers can access medical sharps return facilities, and
 - iii. The environmental benefits of participating in the ISCP.

5.1 Program Requirements for Collection, Transportation and Processing of Medical Sharps

5.1.1 Collection Location Requirements:

Retail pharmacies participating in the ISCP as collection locations must have a registered pharmacist or registered pharmacy technician that is trained on how to receive, handle and package medical sharps returned to the pharmacy by Consumers.

Biomedical sharps are medical sharps products used by Consumers that are designed to puncture the skin for medical purposes and must be properly placed in an approved sharps container, colour-coded with a universal biohazard symbol on the outside and a lid that is sealed shut in order to be accepted at collection locations. At the pharmacy, the sharps containers must then be placed into approved biomedical waste over packing for transportation and disposal.

When a prescription is filled for a cytotoxic medication that has a medical sharp, the lead practice is to provide a new sharps container with a cytotoxic label to the customer at the same time. Cytotoxic sharps are medical sharps products used by Consumers for a chemotherapeutic application and should be placed in an approved sharps container, colour-coded with the cytotoxic symbol on the outside and a lid that is sealed shut in order to be accepted at collection locations. These containers should then be placed into approved secondary containment packaging with a cytotoxic label prominently displayed on the outside of the packaging for transportation and disposal.

Since the voluntary participation of a pharmacist or pharmacy technician is central to the success of the program, HPSA works closely with these stakeholders to ensure full participation and awareness of the ISCP. Pharmacy managers interested in offering the program in their store must complete a registration form. Specific information is provided to ensure that pharmacy managers and staff are knowledgeable on the program objective and the way the program operates. All participating collection locations receive a kit containing instructions on the program, a service request form, and sample of education material developed for this program along with approved sharps containers for the public and over packing supplies for sharps containers returned by the public. Once the registration form is completed and submitted to HPSA, the pharmacist is contacted directly by HPSA to review the following information:

- Medical sharps from hospitals, institutions, doctor's offices or internal pharmacy operations are not acceptable.
- Key employees working at the collection location must be knowledgeable about the program offered to Consumers.
- The pharmacy shall only receive medical sharps in a hard-shell container (approved sharps container) which is labelled with the universal biohazard symbol.
- Sharps containers must be segregated from waste pharmaceuticals.
- Approved sharps containers returned by Consumers are placed in over packing.
- Medical sharps used to administer cytotoxic drugs shall be deposited into a sharps container and labelled with a cytotoxic label.
- The pharmacist or pharmacy technician will inform medical sharps users on the proper disposal of needles.
- Upon receiving sharps containers, pharmacists should ensure that the tops of the containers are securely closed and placed securely inside the over packing.

Once the over packing is full, the pharmacist must complete the service request form and contact the waste management service provider contracted by HPSA to schedule service.

Collection locations must also meet the following requirements:

- Collection locations must provide the service of collecting medical sharps from Consumers at no charge.
- The collection location must provide the Consumer the ability to drop off medical sharps in approved containers during regular business hours.
- Collection locations must have promotion and educational materials for Consumers.
- A registered pharmacist or pharmacy technician must be present when a Consumer drops off used medical sharps.
- There must be an agreement in place between the collection location and HPSA that addresses the types of containers that are to be used for the collection, handling, storage and labeling of medical sharps. The agreement must also stipulate how sharps containers are to be collected, handled and stored at the collection location.
- If the location is offering collection of sharps under the ISCP and it is not a retail pharmacy then the location has to be approved by the HPSA and has to meet the full requirements of the Waste Management Resource Regulations of the PEI EPA before participation in the program can begin.

5.1.2 Transportation Requirements:

- All conditions of the Waste Resource Management Regulations must be adhered to by the waste management service provider(s) when transporting sharps waste.

5.1.3 Processing Requirements:

- Biomedical sharps must be treated using a high pressure steam sterilization process (typically a commercial autoclave) or high temperature incineration.
- Cytotoxic medical sharps must be treated by high temperature incineration.
- A waste-to-energy facility permitted to handle municipal solid waste is the preferred post-processing treatment method for medical sharps waste that has been rendered non-infectious through steam sterilization (classified as treated medical waste).

5.2 Program Efficiencies

HPSA will be working directly with industry associations, waste management service provider(s) and retail pharmacy collection sites to ensure adherence to program standards. Consumer facing collection locations can accept sharps waste from the public under the structure of the ISCP. For example, hospital pharmacies and commercial pharmacies serving only institutions are not eligible to participate in the ISCP. HPSA will be monitoring program usage through collection location data analysis, vendor support and random inspections at collection site locations.

5.3 Accessibility

As of November 14, 2014 a total of 49 pharmacies were registered by the Prince Edward Island College of Pharmacists (PEICP). HPSA will work to register public facing retail pharmacies in the ISCP.

5.4 Promotion and Education

Island Waste Management Corporation's (IWMC) collection notices, including calendars and participant guides, instruct the public to return used sharps to pharmacies across the Island. Residents are reminded that they can receive sharps containers at any pharmacy in the province.

HPSA will be launching a promotion and education strategy to Consumers and collection locations about the ISCP. The strategy will have the following components:

5.4.1 Consumer Outreach Strategy

- A new brochure will announce that HPSA is administering the ISCP on behalf of Brand Owners and explain to Consumers how the program works and the environmental benefits. It will include a description of how Consumers can get sharps containers at no charge under the program and how they should safely handle and store used medical sharps before bringing them to participating collection locations. A print version of the brochure will be available to Consumers at all participating collection locations and will also be available in electronic format on the HPSA website.
- Consumers can find other ISCP details on the website as well as the location of the nearest ISCP collection location.

5.4.2 Collection Location Outreach Strategy

- Outreach/education packages for collection locations will clearly explain the HPSA industry-run program, timelines, the inclusion of medical sharps as a designated material and expectations for participating collection locations.
- ISCP brochures and the collection location education packages will be sent to each collection location and can be ordered by collection locations by calling HPSA or going through the HPSA website.
- HPSA will engage the Retail Council of Canada (RCC), the Prince Edward Island Pharmacists Association (PEIPA), the Prince Edward Island College of Pharmacists (PEICP), the Canadian Association for Pharmacy Distribution Management (CAPDM), and the Neighbourhood Pharmacy Association of Canada (NPAC) to promote the ISCP through their networks and outreach channels (i.e., industry newsletters, events and websites).

5.4.3 Retailer Outreach Strategy

HPSA will provide promotional and educational materials for Consumers to be displayed by retailers free

of charge. Materials can be ordered by retailers directly or by Brand Owners for distribution to their clients through an HPSA supplied order form available on its website.

5.5 Financial Resources Summary

HPSA is the ISO responsible for the ISCP. HPSA staff administers the program and its various components including contracts with waste management service providers and material vendors for the provision of sharps containers, over packaging, transportation and disposal.

Funding from the industry covers expenses incurred in the collection, transportation, storage, disposal, promotion activities and education in connection with the ISCP. The cost of program administration, promotion and educational activities and the logistics of managing medical sharps waste are paid for entirely by industry (HPSA medical sharps Producer members are listed in Appendix A).

There is no visible user fee (eco fee) directed to the Consumer at the point of purchase of sharps products or at the point of collection under the ISCP.

5.6 Quality Control and Assurance

5.6.1 Collection Location

A Collection Standards Agreement will be developed for pharmacies to register as collection locations in the ISCP. This Agreement will apply to each participating pharmacies for the collection, handling, storage, transportation and disposal of used medical sharps generated by residents a resident of Prince Edward Island.

5.6.2 Service Providers

Approved service providers under an HPSA stewardship programs will have to sign a Transportation Standards Agreement and/or Disposal Standards Agreement. The Agreements are specific to the on-going collection of used sharps at pharmacies registered under the ISCP for the sole purpose of secure and compliant transportation and disposal. The Agreements are intended to prevent any potential for inappropriate possession at the point of collection and during transportation and transfer to approved end disposal facilities.

5.7 Auditing and Reporting

5.7.1 Auditing

Due to the infectious and/or chemotherapeutic nature of post-consumer medical sharps waste collected in the Medical Sharp Stewardship Program, the potential health and safety hazard prohibits the ability of

HPSA to physically audit the medical sharps waste stream to gather specific data on the different types of medical sharps products or to monitor levels of contamination of other types of waste.

5.7.2 Annual Report

The reporting requirements that HPSA will provide on behalf of its member medical sharps Brand Owners are clearly defined in the *Environmental Protection Act* Materials Stewardship and Recycling Regulations. HPSA will submit an annual report on the Medical Sharp Stewardship Program on or before June 30th of each year to the Minister of the Department of Environment, Labour and Justice.

The annual report has to meet the following minimum requirements:

- The name of all medical sharp Brand Owners on whose behalf the HPSA prepared the report must be listed;
- The total weight of all medical sharps received at collection locations for the previous year;
- A description of how medical sharps generated by collection locations were handled and disposed of during the previous calendar year;
- A description of the actions taken by HPSA to ensure compliance with the requirements for collection and disposal of medical sharps and sharps containers returned by Consumers to collection locations; and
- The annual report must be ready for release on or before June 30th each year.

APPENDIX A: *Environmental Protection Act* Materials Stewardship and Recycling Regulations – Division 7

Updated 2014

Environmental Protection Act
Materials Stewardship and Recycling Regulations

Cap. E-9

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DIVISION 7

Medical Sharps

98. In this Division,

Definitions

- (a) “administrator” means an administrator appointed under section 104; administrator
- (b) “agent” means an agent of a brand owner designated under section 101; agent
- (c) “brand owner” means, in respect of medical sharps sold, offered for sale or otherwise distributed in or into the province, brand owner
 - (i) a manufacturer of the medical sharp,
 - (ii) a distributor of the medical sharp in or into the province, or
 - (iii) where the medical sharp is imported into the province, the first person to sell the medical sharp in or into the province;
- (d) “medical sharp” means a needle, safety engineered needle, lancet, or other similar instrument that is designed to puncture the medical sharp

	skin for medical purposes and that is sold or otherwise distributed, and includes anything affixed to the medical sharp, including a syringe;
medical sharp stewardship program	(e) “medical sharp stewardship program” means a program approved by the Minister under section 102 that establishes a process for the collection, transportation and disposal of medical sharps;
retailer	(f) “retailer” means a person who sells or offers for sale medical sharps directly to consumers. (EC349/14)
Designation	99. (1) For the purposes of the Act and these regulations, medical sharps are a designated material.
Discarding medical sharps	(2) No person shall discard medical sharps except (a) at a facility approved to accept medical sharps pursuant to these regulations; or (b) in accordance with an approved medical sharp stewardship program. (EC349/14)

Medical Sharp Stewardship Program

Prohibition	100. (1) No brand owner of a medical sharp shall sell, offer for sale or otherwise distribute medical sharps in or into the province unless the brand owner, or an agent of the brand owner of the medical sharp, operates a medical sharp stewardship program in respect of the medical sharp.
<i>Idem</i>	(2) No retailer shall sell, offer for sale or otherwise distribute medical sharps in or into the province unless the brand owner of the medical sharp, or an agent of the brand owner of the medical sharp, operates a medical sharp stewardship program in respect of the medical sharp. (EC349/14)
Designation of agent	101. A brand owner may, by written agreement with any person, designate that person as the agent of the brand owner to operate a medical sharp stewardship program on the brand owner’s behalf. (EC349/14)

Proposal

Proposal for approval of medical sharp stewardship program	102. (1) A brand owner who wishes to apply for approval of a medical sharp stewardship program shall file with the Minister a completed proposal in a format approved by the Minister.
<i>Idem</i>	(2) An agent of a brand owner who wishes to operate a medical sharp stewardship program on the brand owner’s behalf and who wishes to

apply for approval of the program shall file with the Minister a completed proposal in a format approved by the Minister.

- (3) An applicant shall submit with a proposal made under subsection (1) or (2) detailed information respecting **Material to be submitted**
- (a) the management structure of the program;
 - (b) how discarded medical sharps will be collected;
 - (c) the plans for the receipt of discarded medical sharps at the medical sharp return facilities that participate in the program and the policies and procedures to be followed by the medical sharp return facilities;
 - (d) the quality control and assurance aspects of the program, including tracking and auditing mechanisms; and
 - (e) an education and awareness program for consumers of medical sharps that includes information about
 - (i) the medical sharp stewardship program, specifying products accepted by the program,
 - (ii) how and when consumers can access medical sharp return facilities, and
 - (iii) the environmental benefits of participating in the medical sharp stewardship program.
- (4) The Minister may require an applicant to provide any additional information that the Minister requires to consider the application. **Additional information**
- (5) The Minister shall approve a medical sharp stewardship program if the Minister is satisfied that **Requirements for approval of medical sharp stewardship program**
- (a) the proposal has been made in accordance with the requirements of these regulations;
 - (b) the proposal
 - (i) includes the information referred to in clauses (3)(a) to (e) and is otherwise acceptable to the Minister, and
 - (ii) adequately provides for the operation of the medical sharp stewardship program in compliance with the Act and these regulations; and
 - (c) approval of the program is in the public interest having regard to the matters referred to in clauses (3)(a) to (e).
- (6) Where the Minister refuses to approve a medical sharp stewardship program, the Minister shall provide written reasons for the refusal to the applicant. **Reasons for refusal**
- (7) Where the Minister approves a medical sharp stewardship program, the applicant shall, not later than the commencement date of the program, pay the fee prescribed by subsection (8). **Approval of medical sharp stewardship program**

Approval fee (8) The fee for an approval of a medical sharp stewardship program is \$5,000, payable to the Minister of Finance, Energy and Municipal Affairs. (EC349/14)

Payment of annual fee **103.** (1) A brand owner or an agent who operates a medical sharp stewardship program shall, on or before June 30 of each year, pay the annual fee prescribed by subsection (2).

Annual fee (2) The annual fee for a medical sharp stewardship program is \$5,000, payable to the Minister of Finance, Energy and Municipal Affairs. (EC349/14)

Appointment of administrator **104.** The Minister may
 (a) appoint any person as the administrator of a medical sharp stewardship program; and
 (b) specify the duties and responsibilities of an administrator appointed under clause (a). (EC349/14)

Information

Request for information by Minister **105.** A brand owner or an agent who operates a medical sharp stewardship program shall, upon request in writing from the Minister, provide the Minister with any information about the medical sharp stewardship program, including any of the following:
 (a) the types of processes used to dispose of discarded medical sharps;
 (b) the location of the medical sharp return facilities for discarded medical sharps;
 (c) the location of any long-term destruction or final treatment and processing facilities for discarded medical sharps;
 (d) records showing that the program adheres to established industry vendor qualification standards, or information demonstrating that the medical sharps collected are managed in a manner that employs environmental and human health and safety standards meeting or exceeding applicable federal, provincial and local regulations. (EC349/14)

Internalization of fees **106.** No retailer shall charge a consumer any separate fee with respect to the costs associated with implementing or operating a medical sharp stewardship plan. (EC349/14)

Display of education and awareness program information **107.** A retailer shall prominently display, at the point of display or the point of sale of a medical sharp, the education and awareness program information referred to in clause 102(3)(e) that is supplied to it by the brand owner or the brand owner's agent. (EC349/14)

108. A brand owner or an agent who operates a medical sharp stewardship program shall review the medical sharp stewardship program and

Review of medical sharp stewardship program

(a) submit to the Minister all proposed amendments to the medical sharp stewardship program; or

(b) advise the Minister in writing that in its opinion no amendments to the medical sharp stewardship program are necessary,

not later than the date that is 5 years after the date the medical sharp stewardship program was first approved under subsection 102(5) and every 5 years thereafter. (EC349/14)

109. A brand owner or an agent who operates a medical sharp stewardship program shall, on or before June 30 of each year, or on or before the date set by the Minister, inform the Minister in writing of the total quantity of discarded medical sharps collected during the previous calendar year. (EC349/14)

Reporting quantity of medical sharps collected

110. (1) No brand owner who operates a medical sharp stewardship program shall fail to operate the medical sharp stewardship program in accordance with the program as approved under subsection 102(5).

Operation of medical sharp stewardship program

(2) No agent who has been designated to operate a medical sharp stewardship program on a brand owner's behalf shall fail to operate the medical sharp stewardship program in accordance with the program as approved under subsection 102(5). (EC349/14)

Idem