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Electronic Medical Devices and Equipment Stewardship Plan for British Columbia

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1.0 Executive Summary

This stewardship plan has been developed in response to Part 2 of the British Columbia Recycling Regulation Reg. 449/2004 for the electronic and electrical medical devices and equipment product category. Schedule 3, Section 2.3 of the Recycling Regulation defines electronic and electrical medical devices and equipment as followed:

electronic and electrical medical devices or equipment used for detecting, preventing, monitoring, treating or alleviating illness, injury or disability, other than a medical device that has been implanted in a person or that has been exposed to infectious matter.

Abbott is committed to take on producer responsibility in developing a stewardship plan and will work in collaboration with appointed and qualified suppliers and/or service providers to perform the duties in compliance with Part 2 of the Recycling Regulation.

This plan anticipates a launch of July 1, 2012 and proposes actions and targets for five consecutive years through to June 30, 2016.

All stakeholders are encouraged to review the present document and provide feedback.

The program plan will be submitted to the BC Ministry of Environment for approval on October 1, 2011.

Following the approval of the program plan by the BC Ministry of Environment, next steps will involve program implementation, which will include the following:

- identification of collection sites, transporters and processors;
- implementation of communication and public awareness strategy
- establishing a monitoring and reporting system

2.0 Program Principles

The stewardship program will be based on the following guiding principles:

- **Producer/User Responsibility:** The lifecycle management of products covered by this stewardship plan is the responsibility of Abbott and appointed service providers and/or suppliers by Abbott. The responsibility will not be shifted to other levels of government without consent.

- **Compliance:** The stewardship program will be in compliance with the British Columbia Recycling Regulation and the Ministry of Environment Stewardship Business Plan Principles.

- **Level playing field:** All products in the electronic and electrical medical devices and equipment product category are subject to the same stewardship program. This entails products of the following Abbott divisions: Abbott Diagnostics, Abbott Molecular, Abbott Diabetes Care and Abbott Point of Care.

- **Results-based:** The stewardship program allows for flexibility in determining the most cost effective means to achieve high product recovery results and in turn maximizing environmental efficiency. Government involvement will be minimized.

- **Transparency and Accountability:** The stewardship program will ensure the opportunity for continuous input of all stakeholders throughout its development and implementation. Stakeholders will be informed of ongoing progress and activities in relation to the stewardship program. Furthermore, the stewardship program will encourage a shared responsibility model with appropriate roles from the government, consumers and other stakeholders.

In addition, the stewardship program will strive for continuous improvement and program performance throughout its implementation.

3.0 Program Products

This stewardship program plan is designed to cover all products marketed by the respective Abbott divisions: Abbott Diagnostics, Abbott Molecular, Abbott Diabetes Care and Abbott Point of Care products.

4.0 Program Performance Measures and Targets [Section 5 (1) (a)]

The program's goal is to develop, monitor and report performance measures as outlined in the present stewardship plan. Program performance will be presented in annual reports available to the public on the Abbott Canada website www.abbott.ca and will be reported to the BC Ministry of Environment.

Section 5 (1)(a)(i) of the Regulation specifies a 75% recovery rate of all end of life products as a minimum performance target or other rate that may be set by the Director.

Abbott will evaluate appropriate measurements of program performance specific to the type of product and method of sale of product:

- Abbott's electronic medical devices and equipment vary in distribution, user patterns and the average lifespan of the product. The metric to be used will consider the quantity collected compared to quantity available for collection in the present year. A second metric will compare the amount of product recovered in one year to the average amount sold for previous years.

- Products are sold through a broad distribution channel. Direct sales to consumers are easily tracked by Abbott's internal systems. Retail sales pose a difficulty in ensuring complete reporting and return of products.

Should the proposed targets not be met, Abbott will perform an investigation to identify limitations and design a corrective action plan to address them.

With the next five years of program implementation and prior to resubmission of the stewardship plan, sufficient data should be gathered to allow for the establishment of valid performance measures and targets for future success in collecting and appropriately managing the product at its end of life.

5.0 Program Funding Structure [Section 5 (1) (c) (i)]

Abbott's commitment to take extended producer responsibility for the life cycle management of our products ensures the costs of collection and recycling of products are shifted from general taxpayers and the government to the producer. Abbott will oversee the costs for the collection, transportation and management for all products.

6.0 Collection, Transportation and Processing [Section 5 (1) (c) (iii)]

The program will establish a system for the collection, transportation and processing of end-of-life electronic medical devices and equipment. The program intends to contract with an existing service provider (s) and/or supplier (s) for the services of transportation from collection sites to

the processor(s). Abbott is currently evaluating potential service providers and/or suppliers who may carry out the collection, transportation and processing of our products.

Standards for collection, transportation and processing services will be developed in compliance with local, provincial and national regulations as well as the British Columbia Hazardous Waste Regulation. Adherence to these standards will be required of all service providers which will be verified through audits.

Abbott will notify the BC Ministry of Environment in writing of the appointed service provider and/or supplier before the service provider and/or supplier begins to carry out the duties on behalf of Abbott.

A tracking system will be developed to track all Abbott products from the point of collection to final disposition stage. Information on the final disposition of products will be reported in annual reports shared with the public on the Abbott Canada website and provided to the BC Ministry of Environment.

7.0 Public Education and Consumer Awareness [Section 5 (1) (c) (iv)]

The Regulation requires that the plan makes adequate provision for informing consumers of the product stewardship program and its benefits, the location of collection facilities and safe product handling. Abbott intends to develop a comprehensive consumer awareness program to educate its consumers about the program. The program intends to use a number of communication methods which will include the following:

Company website: The Abbott Canada website www.abbott.ca will be used to deliver up to date stewardship program information and will include Abbott's Stewardship Plan for electronic medical devices and equipment as well as progress reports.

Annual reports: Abbott will annually test the level of consumer awareness about the stewardship program through surveys and review the effectiveness strategies accordingly. The reports will be posted on the Abbott Canada website.

Organizations: An information package will be sent to the Recycling Council of British Columbia, the British Columbia Stewardship Council and MEDEC organization.

Local government: An information package will be sent to local governments to inform them of the new stewardship program.

The above communication methods may be refined and other communication methods may be added throughout the communication plan development to further enhance consumer awareness.

8.0 Management of Program Costs [Section 5 (1) (c) (iv)]

Abbott will oversee the costs for the collection, transportation and management for all products. The program costs will be established through a contractual agreement between Abbott and the service provider and/or supplier. Abbott will work in collaboration with the supplier and/or service provider to ensure costs of the program lead to an environmental benefit and are appropriate for the service provided.

9.0 Dispute Resolution Procedure [Section 5 (1) (c) (vi)]

Abbott will have contracts with all service providers and/or suppliers to the program by the use of commercial agreements. Should any disputes arise from the collection, transportation or processing contracts, Abbott commits to working with service provider and/or supplier in question to develop reasonable and cost effective procedures to address the issues of mutual concern. Should a mutual agreement not be met between Abbott and the service provider and/or supplier the dispute will be resolved using normal legal procedures.

10.0 Product Life Cycle Management and Pollution Prevention Hierarchy [Section 5 (1) (c) (vii -viii)]

The stewardship program adequately provides for options of reuse and recycling of products to reduce and/or eliminate the environmental impact of a product throughout the product's life cycle.

Design for the Environment

Future incentives in the design process of electronic and electrical medical devices and equipment will be considered to improve reusability or recyclability of products and to reduce their impact on the environment.

Reuse

All products that reach end-of-life will be carefully evaluated by a qualified Abbott representative who will determine whether a product and/or its parts may be refurbished and reused prior to entering the recycling stream.

Recycle

Electronic medical devices and equipment entering the processing stream will be disassembled into their component parts. The resulting material will be recovered as well as energy from the product will be recovered where appropriate. Landfill disposal will be the ultimate recycling option and the waste from the product will be disposed in compliance with the Environmental Management Act B.C. Reg. 63/88.

All processing of products will be completed by an appointed Abbott contractor who has been qualified to carry out recycling duties and adheres to government standards as well as the British Columbia Hazardous Waste Regulation.

11.0 Annual Reporting [Section 8]

In compliance with Section 8 of the Regulation, Abbott will provide an annual report to the BC Ministry of Environment by July 1st each year. The annual report will be issued on the Abbott Canada website www.abbott.ca. The report will include, but is not limited to the following:

- (a) a description of the educational materials and educational strategies used
- (b) the location of its collection facilities, and any changes in the number and location of collection facilities from the previous report;
- (c) efforts taken by or on behalf of the producer to reduce environmental impacts throughout the product life cycle and to increase reusability or recyclability at the end of the life cycle;

- (d) a description of how the recovered product was managed in accordance with the pollution prevention hierarchy;
- (e) the total amount of the producer's product sold, collected and recovered
- (f) independently audited financial statements (if applicable)
- (g) a comparison of the approved plan's performance for the year with the performance requirements and targets in this regulation and the approved plan;
- (h) any other information specified by the director

12.0 Stewardship Plan Review [Section 6]

Every five years Abbott will review the approved plan and resubmit the plan including any amendments, if applicable, to the director as per section 6 of the Regulation. If there are no amendments, Abbott will advise a director in writing that no amendments to the approved plan are necessary.

13.0 Stakeholder Consultation [Section 5 (1) (b)]

This draft stewardship plan will be used during consultation with stakeholders. Stakeholders are encouraged to review the document and send their comments and questions by e-mail to ADD_CAN_RAQA@abbott.com.

The results of the consultation will be reviewed and the Stewardship Plan will be modified where appropriate. The final copy of the stewardship plan will be submitted to the BC Ministry of Environment on October 1, 2011 for approval.

The approved stewardship plan will be posted on the Abbott Canada website www.abbott.ca.

Appendix A BC Recycling Regulation Requirements Checklist

Recycling Regulation Requirement	Stewardship Plan Sections
1(a) the plan will achieve, or is capable of achieving within a reasonable time,	
(i) a 75% recovery rate or a higher recovery rate established by the director,	Section 4.0
(A) for each subcategory listed in section 4 of Schedule 1 for the beverage container product category, and	N/A
(B) for each product category covered by the plan, other than the beverage container product category, if required by the director,	Section 4.0
(ii) any performance requirements or targets established by the director, and	N/A
(iii) any performance requirements or targets in the plan,	Section 4.0
(b) the producer has undertaken satisfactory consultation with stakeholders prior to submitting the plan for approval and will provide opportunity for stakeholder input in the implementation and operation of the product stewardship program, and	Section 13.0
(c) the plan adequately provides for	
(i) the producer collecting and paying the costs of collecting and managing products within the product category covered by the plan, whether the products are currently or previously sold, offered for sale or distributed in British Columbia,	Section 5.0
(ii) with respect to the solvent and flammable liquids, pesticide, gasoline and pharmaceutical product categories,	N/A
(A) The collection of residuals and containers that are or were in direct contact with a residual, and	N/A
(B) the management of residuals and containers collected,	N/A
(iii) reasonable and free consumer access to collection facilities,	Section 6.0
(iv) making consumers aware of	
(A) the producer's product stewardship program,	Section 7.0
(B) the location of collection facilities, and	Section 7.0
(C) how to manage products in a safe manner,	Section 7.0
(v) assessing the performance of the producer's product stewardship program, the management of costs incurred by the program and the management of environmental impacts of the program,	Section 8.0
(vi) a dispute resolution procedure for disputes that arise between a producer and person providing services related to the collection and management of the product during implementation of the plan or operation of the product stewardship program,	Section 9.0
(vii) eliminating or reducing the environmental impacts of a product throughout the product's life cycle, and	Section 10.0
(viii) the management of the product in adherence to the order of preference in the pollution prevention hierarchy.	Section 10.0
(2) In deciding whether to approve the plan, the director may consider any of the following:	N/A
(a) the advice of a committee of up to 12 persons the director appoints for the purpose of giving advice on the plan;	N/A
(b) the timelines and effectiveness of the plan respecting the matters referred to in subsection (1);	N/A
(c) the population and geographical area of the markets in which the producer sells, offers for sale or distributes the product;	N/A
(d) the manner in which the product is marketed and retailed by the	N/A

producer;	
(e) the nature of the product;	N/A
(f) the amount of product the producer expects to sell or distribute each year;	N/A
(g) the amount of product the producer expects to collect each year;	N/A
(h) the size of the population intended to be served by each collection facility;	N/A
(i) the provision of convenient options for the collection of products in urban centres and small, isolated communities, and for persons with disabilities or who have no access to transportation;	N/A
(j) the manner, kind and amount of advertising and consumer education planned by the producer to inform consumers of the location and operation of collection facilities and the environmental and economic benefits of participating in the product stewardship program;	N/A
(k) the methods of product collection, storage, transportation and management;	N/A
(l) the product stewardship programs of other producers for products in the same product category;	N/A
(m) the structure of financial and operational co-operation with other producers.	N/A
(3) For the purposes of subsection (1) (c) (viii), the pollution prevention hierarchy is as follows in descending order of preference, such that pollution prevention is not undertaken at one level unless or until all feasible opportunities for pollution prevention at a higher level have been taken:	
(a) reduce the environmental impact of producing the product by eliminating toxic components and increasing energy and resource efficiency;	Section 10.0
(b) redesign the product to improve reusability or recyclability;	Section 10.0
(c) eliminate or reduce the generation of unused portions of a product that is consumable;	Section 10.0
(d) reuse the product;	Section 10.0
(e) recycle the product;	Section 10.0
(f) recover material or energy from the product;	Section 10.0
(g) otherwise dispose of the waste from the product in compliance with the Act.	Section 10.0
(6) A producer must review its approved plan and	
(a) submit to a director proposed amendments to the approved plans, or	Section 12.0
(b) advise a director in writing that no amendments to the approved plan are necessary	Section 12.0
no later than the date that is 5 years after the date the approved plan was originally approved under this section and every 5 years thereafter.	
(7) The director must provide the producer with written reasons whenever	N/A
(a) a product stewardship plan submitted under section 4[<i>submission of product stewardship plan</i>] is not approved under section 5 [<i>approval of product stewardship plan</i>],	N/A
(a.1) the director amends an approved plan,	N/A
(b) an amendment to an approved plan is not approved, or	N/A
(c) the approval of a plan is rescinded	N/A
(8) (1) On or before July 1 in each year, a producer must	
(a) provide to a director a report respecting the one-year period ending not later than March 31 of that year or December 31 of the previous year, and	Section 11.0
(b) post and report on the Internet	Section 11.0
(8)(2) Subject to subsection (4), the report referred to in subsection (1) must include the following:	

(a) a description of educational materials and educational strategies the producer has used	Section 11.0
(b) the location of its collection facilities, and any changes in the number and location of collection facilities from the previous report;	Section 11.0
(c) efforts taken by or on behalf of the producer to reduce environmental impacts throughout the product life cycle and to increase reusability or recyclability at the end of the life cycle;	Section 11.0
(d) a description of how the recovered product was managed in accordance with the pollution prevention hierarchy;	Section 11.0
(e) the total amount of the producer's product sold and collected and, if applicable, the producer's recovery rate;	Section 11.0
(e.1) effective for a report required on or before July 1, 2013 and for every report required under subsection (1) after that date, the total amount of the producer's product recovered in each regional district;	Section 11.0
(f) independently audited financial statements detailing	Section 11.0
(i) all deposits received and refunds paid by the producers covered by the approved plan, and	Section 11.0
(ii) revenues and expenditures for any fees associated with the approved plan that are charged separately and identified on the consumer receipt of sale;	Section 11.0
(g) a comparison of the approved plan's performance for the year with the performance requirements and targets in this regulation and the approved plan;	Section 11.0
(h) any other information specified by the director.	Section 11.0
8 (3) If the report referred to in subsection (1) is in respect of the beverage container product category, the information required under subsection (2) (c) to (g) must be provided for each subcategory listed in section 4 of Schedule 1.	N/A
(3.1) If an agency is appointed by more than one producer to carry out the duties of the producer under this section, the agency may provide and post one report referred to in subsection (1) on behalf of all of those producers.	N/A
8 (4) The director may specify classes of information the producer is not required to include in the report posted on the Internet under subsection (1) (b).	N/A