Guideline C-4:
The Management of Biomedical Waste in Ontario

November 2009

PIBS 7397

Disclaimer: This guideline is not and should not be construed as legal advice. Please review the Environmental Protection Act (www.e-laws.gov.on.ca) and the Ministry of Environment website (www.ene.gov.on.ca) for more information on the laws that apply to the handling of waste. Should you have any questions about the application or interpretation of the laws of Ontario or have other legal questions, you should consult a lawyer.

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1.0 Introduction

Biomedical waste is one of the many types of wastes regulated by the Ministry of the Environment through the Environmental Protection Act. This guideline details the Ministry of the Environment's ("Ministry") expectations for the management of that waste.

Although biomedical waste is estimated to represent less than ten percent of the waste generated by the health care field, it poses risks to public health and the environment and therefore, must be segregated and managed accordingly.

The guideline is primarily directed at two main audiences: (1) generators of biomedical waste; and (2) carriers and receivers who are responsible for treatment, transportation and disposal of biomedical waste.

For generators, this guideline describes best management practices to be followed to minimize the impact of biomedical waste on the environment through appropriate packaging, segregation, treatment, storage and disposal methods.

For carriers and receivers of biomedical waste, in addition to describing best management practices, the guideline will in part inform the Ministry's review of applications for certificates of approval for waste management systems and waste disposal sites under Part V of the Environmental Protection Act and the setting of conditions of approval.

The underlying purpose of this guideline is preserving the integrity of the environment and reducing potential public health risk through proper management of biomedical waste. Everyone involved in the generation and management of this waste has a role to play, and can reduce its impact on the environment through the adoption of these best management practices.

2.0 Scope

This guideline is intended for use by generators (sections 4 through 7), carriers (section 7) and receivers (section 8) of biomedical waste and by the Ministry's Environmental Assessment and Approvals Branch. This document will assist the reader in determining the best practices for the management biomedical waste.

The recommendations set out in this guideline are in addition to any requirements under Part V of the EPA, Regulation 347 (General - Waste Management), and any other statutory or legal requirements. Generators, carriers and receivers of biomedical waste must comply with this legislation and all other applicable legislation and subordinate instruments. Although the recommendations in the guideline are likely to apply in most circumstances, it is the responsibility of those handling biomedical waste to assess and take any additional precautions that are appropriate in the specific circumstances.

Although not specifically listed below, other generators and handlers of biomedical

waste, such as police, fire, and ambulance services, and pharmacies are encouraged to use these guidelines when formulating their best management practices.

3.0 Definitions

For the purpose of the guideline, the following definitions apply:

"animal blood waste" means waste related to an animal treated for an infectious substance (animal) and that is,

(a) liquid or semi-liquid animal blood or blood products,
(b) items saturated with liquid or semi-liquid animal blood products,

(c) body fluids visibly containing animal blood, or

(d) body fluids removed in the course of surgery, treatment or necropsy of an animal, other than urine, feces or milk unless visibly containing animal blood.

"animal anatomical waste" means waste related to an animal that is infected or suspected of being infected with any infectious substance (animal) and the waste is animal bedding, animal carcass, tissues, organs, or other body parts, other than teeth, nails, hair, feathers, hooves or horns.

"biomedical waste" means:

(a) human anatomical waste,

(b) human blood waste,

(c) animal anatomical waste,

(d) animal blood waste,

(e) microbiology laboratory waste,

(f) sharps waste,

(g) cytotoxic waste,

(h) waste that has come into contact with human blood waste that is infected or suspected of being infected with any infectious substance (human), or

(i) a waste containing or derived from one or more wastes described in clauses (a) through (h),

but does not include,

(j) domestic waste,

(k) animal anatomical waste or animal blood waste disposed of in accordance with,

(i) the Meat Inspection Act (Canada),

(ii) the Health of Animals Act (Canada),

(iii)the Health Protection and Promotion Act,

(iv)the Food Safety and Quality Act, 2001, or

(v) the Nutrient Management Act, 2002.

(m) treated biomedical waste, or

(n) dialysis waste not saturated with blood or blood products that is tubing, filters, towels or disposable sheets.

"biomedical waste generating facility" means any facility where biomedical waste is likely to be generated, including,

(a) a human health care and residential facility,

(b) a laboratory or specimen collection centre within the meaning of the Laboratory and Specimen Collection Centre Licensing Act,

(c) the office of a health professional or of a member of the staff of a board of health within the meaning of the Health Protection and Promotion Act,

(d) the office of a health professional within the meaning of the Regulated Health Professions Act, 1991,

(e) a funeral establishment or transfer service as licensed by the Board of Funeral Services within the meaning of the Funeral Directors and Establishments Act,

(f) a private morgue or public morgue within the meaning of the Anatomy Act,

(g) a research facility within the meaning of the Animals For Research Act,

(h) a veterinary facility within the meaning of the Veterinarians Act,

(i) the professional office of a member of the College of Veterinarians of Ontario within the meaning of the Veterinarians Act,

(j) a mobile health care facility,

(k) a facility where post mortem exams are performed, and

(l) any facility where one or more of the following activities occur,

(i) research, testing or teaching related to human health care or veterinary services,

(ii) production, research, testing or teaching related to vaccines,

(iii) research, testing or teaching related to microbiology, or

(iv) the provision of needle and syringe exchange programs.

"cytotoxic drug" means a drug that was designed or selected for its capacity to selectively destroy cells of a certain type, including antineoplastic drugs and cancer drugs that selectively kill dividing cells.

"cytotoxic waste" means waste consisting of,

(a) a cytotoxic drug

(b) a medicinal chemical, or

(c) waste containing a waste listed in (a) or (b) including waste that is tubing, tissues, needles, gloves, vials, preparation materials, ampoules, cleaning materials and personal protective equipment.

"disinfection" means a level of destruction or inactivation of pathogen bacteria.

"human anatomical waste" means waste consisting of human tissues, organs or other body parts, other than teeth, hair or nails.

"human blood waste" means waste consisting of,

(a) liquid or semi-liquid human blood or blood products,

(b) items saturated with liquid or semi-liquid human blood or blood products,

(c) body fluids visibly containing human blood, or

(d) body fluids removed in the course of surgery, treatment or necropsy of a human, other than urine and feces unless visibly containing human blood.

"human health care and residential facility" means a facility intended for the care of human beings that is:

(a) a hospital within the meaning of the Public Hospitals Act or the Community Psychiatric Hospitals Act,

(b) a private hospital within the meaning of the Private Hospitals Act,

(c) a psychiatric facility within the meaning of the Mental Health Act,

(d) a nursing home within the meaning of the Nursing Homes Act,

(e) a home within the meaning of the Homes for the Aged and Rest Homes Act,

(f) an approved charitable institution within the meaning of the Charitable Institutions Act that is:

i) a halfway house where rehabilitative residential group care may be provided for adult persons,

ii) a home where residential group care may be provided for handicapped or convalescent adult persons, or

iii) a home for the aged,

(g) a long-term care home within the meaning of the Long-Term Care Homes Act, 2007,

(h) a cancer centre established by the Ontario Cancer Treatment and Research Foundation under the Cancer Act, (HR)

(i) a home for special care within the meaning of the Homes for Special Care Act,

(j) an approved home within the meaning of the Mental Hospitals Act,

(k) a facility designated by the regulations under the Developmental Services Act as a facility to which that Act applies,

(l) a supported group living residence within the meaning of the Services and Supports to Promote the Social Inclusion of Persons with Developmental Disabilities Act, 2008,

(m) a facility where a development service or child treatment service, within the meaning of the Child and Family Services Act, is provided, or

(n) an independent health facility within the meaning of the Independent Health Facilities Act.

"infectious substance (animal)" means, a disease listed in,

(a) Schedule VII of the Health of Animals Regulations made under the Health of Animals Act (Canada) as amended, or

(b) the Reportable Diseases Regulations made under the Health of Animals Act (Canada) as amended.

"infectious substance (human)" means,

(a) a substance known or reasonably believed to contain viable micro-organisms such as bacteria, viruses, rickettsia, parasites, fungi and other agents such as prions that are known or reasonably believed to cause disease in humans and that are listed in Appendix 3 to Part 2 of the Transportation of Dangerous Goods Regulations made under the Transportation of Dangerous Goods Act, 1992 (Canada) as amended, or

(b) a substance that exhibits characteristics similar to a substance described in clause (a).

"microbiology laboratory waste" means waste containing

(a) human or animal cultures,

(b) stocks or specimens of micro-organisms,

(c) human diagnostic specimens, other than urine and feces,

(d) live or attenuated vaccines developed for use in humans, or

(e) disposable laboratory material that has come into contact with one or more of items (a) to (d).

"mobile health care" means human or animal health care that takes place at,

(a) the home of a human being or animal to whom the health care is provided, or

(b) a location at which emergency services or ambulance services are provided to a human being or animal,

but does not include

(c) health care provided at a human health care and residential facility.

"sharps waste" means blades, needles, syringes, including safety engineered needles, laboratory glass, or other materials capable of causing punctures or cuts and which have come into contact with human blood waste, animal blood waste or other animal or human bodily fluids.

“treated biomedical waste” means biomedical waste that has been treated utilizing the non-incineration treatment criteria outlined in Section 5.2.

4.0 On-Site Management of Biomedical Waste by Generators

4.1 On-Site Management of Biomedical Waste by Generators

Specific Requirements

Biomedical waste should be segregated from all other waste and handled in accordance with the containment, labelling and storage requirements in Tables 4A and 4B, and sections 4.2 and 4.3.

Table 4A: Containment and Labelling for Biomedical Waste (excluding Sharps Waste)

	Waste Category	Containment		Container Label		Refrigeration Storage at or below 4°C	
		O Indicates Single-use container acceptable	**O Indicates Reusable container acceptable**	**Label Colour**	**Label (See Appendix 1)**	**O Indicates waste should be refrigerated at all times**	**O Indicates waste should be refrigerated if being stored for a period greater than 4 days**
1.	**human anatomical waste**	O	-	Red	Anatomical symbol	O	-
2.	**animal anatomical waste**	O	-	Red	Anatomical symbol	O	-
3.	**human or animal anatomical waste (fixed in formaldehyde or other preservative)***	O	-	Red	-	-	-
4.	**human blood waste**	O	O	Yellow	Universal Biohazard symbol	-	O
5.	**animal blood waste**	O	O	Yellow	Universal Biohazard symbol	-	O
6.	**microbiology laboratory waste**	O	O	Yellow	Universal Biohazard symbol	-	O
7.	**Cytotoxic waste (not commingled with sharps waste)**	O	-	Red	Cytotoxic symbol	-	-
8.	**waste that has come into contact with human blood waste that is infected or suspected of being infected with any infectious substance (human)**	O	-	Red	Universal Biohazard symbol	O	-

* Note: Waste fixed in formaldehyde or other preservative should be decanted prior to disposal.

Table 4B: Containment and Labelling for Sharps Waste

	Waste Category	Containment		Container Label		Refrigeration Storage at or below 4°C	
		O Indicates Single-use Sharps container acceptable	**O Indicates Reusable Sharps container acceptable**	**Label Colour**	**Label (See Appendix 1)**	**O Indicates waste should be refrigerated at all times**	**O Indicates waste should be refrigerated where it is likely to be stored for a period exceeding 48 hours**
1.	**sharps waste**	O	O	Yellow	Universal Biohazard symbol	-	-
2.	**Cytotoxic sharps waste**	O	O	Red	Cytotoxic symbol	-	-

4.2. Containment and Packaging

In addition to the requirements set out in Tables 4A and 4B, biomedical waste should be segregated from all other wastes and immediately deposited into an appropriate single use or reusable container that conforms to the minimum standards described in this section.

Biomedical Waste Containers (Non Sharps Waste)

The following are the minimum standards for a single use and reusable biomedical waste containers, other than a container for sharps waste.

Single Use Biomedical Waste Containers

The container consists of:

(a) an unlined rigid and leak proof plastic drum or pail, or

(b) an outer cardboard container that can be sealed and is lined with a liner made of a leak proof plastic film that can be securely tied.

The container must also be:

(a) capable of withstanding the weight of the biomedical waste without tearing, cracking, crushing, breaking or otherwise allowing the accidental release or discharge of the waste, and

(b) colour coded and clearly marked as specified in Table 4A.

Reusable Biomedical Waste Containers

A container that is:

(a) fabricated of a puncture resistant and leak proof material that can be cleaned and disinfected prior to reuse,

(b) capable of withstanding the weight of the biomedical waste without tearing, cracking, crushing, breaking or otherwise allowing the accidental release or discharge of the waste, and

(c) is visually inspected for tears, cracks, breaks or leaks every time it is emptied.

A reusable container is not an appropriate container for biomedical wastes destined to be incinerated.

Biomedical Waste Containers (Sharps Waste)

The following are the minimum standards for a single use and reusable biomedical waste containers for sharps waste.

Single-Use Sharps Waste Containers

A single-use sharps container should:

(a) be made of rigid materials that are puncture resistant and leak resistant, and

(b) have a lid which cannot be removed after the container is sealed.

Re-usable Sharps Waste Containers

A reusable sharps container should:

be made of rigid materials that are puncture resistant and leak resistant,

(a) have a lid that is securely attached to the container that can be closed and locked when the container is full, and

(b) designed or intended by the manufacturer to be suitable for reprocessing and reuse.

4.3 Central Storage of Biomedical Waste On Site

Storage

In addition to the storage requirements of Tables 4A and 4B, biomedical waste should be stored in an area that is:

(a) secure, not accessible to the general public, and not adjacent to supply storage areas or areas used for food preparation or consumption,

(b) refrigerated or is itself a refrigeration or freezer unit, where refrigeration of the waste is required in accordance with Table 4A or 4B, and

(c) clearly marked with the Universal biohazard symbol (see Appendix 1).

5.0 Technologies for the Treatment and Disposal of Biomedical Waste On Site

5.1 Incineration

It is recommended that the following biomedical wastes be incinerated if treated at the

site where the waste was generated:

(a) human anatomical waste,

(b) animal anatomical waste,

(c) cytotoxic waste,

(d) waste that has come into contact with human blood waste that is infected or suspected of being infected with an infectious substance (human), and

(e) waste that has come into contact with animal blood waste.

The following Ministry of the Environment guidelines (available at www.ene.gov.on.ca) outline the minimum design and emissions criteria for incineration and should be followed:

(a) Guideline A-1: Combustion, Air Pollution Control and Monitoring Requirements for Biomedical Waste Incinerators in Ontario (October 2002), as amended.

(b) Guideline A-8: Guideline for the Implementation of Canada-wide Standards for Emissions of Mercury and of Dioxins and Furans and Monitoring and Reporting Requirements for Municipal Waste Incinerators, Biomedical Waste Incinerators, Sewage Sludge Incinerators, Hazardous Waste Incinerators, Steel Manufacturing Electric Arc Furnaces, Iron Sintering Plants (August 2004), as amended.

5.2 Non-incineration

Biomedical wastes not listed in section 5.1 may be treated with non-incineration methods provided the technology will reduce bacterial spores of B. stearothermophilus within the waste by a level of 6 Log_{10} (99.9999%).

5.2.1 Testing of Non-Incineration Treatment Equipment

Non-incineration technologies used to treat biomedical waste should be tested at least once in every six operating days to confirm that the equipment is capable of meeting the requirements set out in section 5.2.

A record of each test shall be retained at the treatment facility for a minimum of two years and must be in a format that is available for inspection by Ministry of the Environment staff.

6.0 On Site Biomedical Waste Treatment Facilities

6.1 Treatment On-Site

Processing:

The on site processing of biomedical waste should be undertaken in accordance with section 5.2.

It should be noted that section 17.1 of Regulation 347 (General - Waste Management) may apply to exempt waste processing activities occurring at a waste generation facility from the requirement to hold a certificate of approval under Part V of the EPA. The regulation and Part V of the EPA should be referred to for more information. In all circumstances Regulation 347, Part V of the EPA and any other applicable laws must be complied with.

Treated biomedical waste generated by a facility should be stored separately from untreated biomedical waste and all other wastes.

When compacting treated biomedical waste mechanical compaction that is part of a single, self-contained process, should be used.

Disposal:

At a minimum, the on-site disposal of biomedical waste should follow the standards specified in sections 5.1. Regulation 347 (General - Waste Management) and Part V of the EPA may apply additional requirements to a waste generation facility that uses incineration. In all circumstances Part V of the Act, Regulation 347 and any other applicable laws must be complied with.

7.0 Transportation of Biomedical Waste Off-Site

7.1 General Requirements

Prior to the removal of biomedical waste from a site for off-site disposal, the generator should package the waste in accordance with Section 4.0 of this guideline. The waste may only be transported by a waste management company for which a waste management system certificate of approval has been issued under Part V of the EPA.

7.2 Vehicle Standards

The following standards apply to vehicles used to transport biomedical waste and are in addition to any standards prescribed by Regulation 347(General - Waste Management).

It is recommended that these standards be incorporated into a biomedical waste carrier's waste management system certificate of approval.

(a) Vehicles must be appropriately designed and outfitted to accommodate the biomedical waste to be transported in the vehicle, including a storage compartment that:

i. is enclosed and insulated,

ii. is kept refrigerated at or below 4 degrees Celsius at all times, when the vehicle contains any waste,

iii. has an independent refrigeration system which shall be operable at all times when the vehicle is parked or inoperable,

iv. has walls that are made of a washable material and a floor surfaced with metal for effective cleaning and disinfecting,

v. has a floor that is sealed and leak proof,

vi. has a suitable system capable of containing liquids,

vii. has no windows or ventilation,

viii. only one lockable door and at least one interior light, and

ix. is not capable of mechanical compaction.

(b) The vehicle must be equipped with spill clean-up equipment and disinfectant appropriate for the waste being transported.

(c) The vehicle shall not be used for a purpose other than transporting biomedical waste unless it has been completely disinfected.

(d) The vehicle's storage compartment door must be kept locked at all times when the vehicle is not being actively loaded or unloaded.

(e) At the end of each day of operation, the interior of the storage compartment of the vehicle shall be thoroughly cleaned and disinfected with a disinfecting solution.

8.0 Final Disposal of Treated Biomedical Waste

8.1 Treatment Off-Site

A waste disposal site receiving biomedical waste from another site is required to comply with Regulation 347 (General - Waste Management), Part V of the EPA, including the requirement that the facility hold a valid certificate of approval authorizing the handling of the waste, and all other applicable laws.

8.2 Transportation for Final Disposal

Prior to treated biomedical waste leaving a facility for final disposal at a waste disposal site, the facility operator should do the following:

(a) Provide written notification to the operator of the waste disposal site where the waste is destined detailing both the quantity of the waste and its approximate time of arrival.

(b) Provide written notification to the carrier of the waste confirming that all the waste in the shipment has been treated.

A carrier of treated or untreated biomedical waste should transport the waste as directly as practicable to its final waste disposal site without the use of transfer stations or other intermediary sites. No other waste should be transported in a vehicle containing treated or untreated biomedical waste.

8.3 Land Disposal of Treated Biomedical Waste

Treated biomedical waste should be deposited for final disposal at an Ontario waste disposal site with an appropriate certificate of approval issued under Part V of the EPA.

The disposal of the waste should be supervised by the operator of the site or a person designated by the operator for this purpose.

After the waste is deposited in the site, a sufficient quantity of other waste or cover material should be placed over it to prevent direct contact between site equipment and the waste.

APPENDIX 1

UNIVERSAL BIOHAZARD SYMBOL

ANATOMICAL SYMBOL

CYTOTOXIC SYMBOL