PROPOSED REVISIONS TO GUIDELINE C-4

The Management of Biomedical Waste in Ontario

October 2008

Table of Contents

1.0 Introduction

The Ministry of the Environment ("the ministry") is committed to ensuring that waste is regulated and properly managed to protect human health and the environment. Biomedical waste represents less than ten percent of the waste generated in health care but can still pose potential risks to public health and the environment and therefore, must be segregated and managed accordingly.

The intent of this guideline is to provide clear expectations about the management of biomedical waste to two main audiences: (1) generators of biomedical waste; and (2) carriers and receivers, which are responsible for treatment, transportation and disposal of biomedical waste.

For generators, this guideline describes best management practices. Generators can play an important role in minimizing the impact of biomedical waste to the environment by following this guideline to ensure effective management of these wastes through appropriate packaging, segregation, treatment, storage and disposal methods.

For carriers and receivers of biomedical waste, the regulatory framework is outlined in their individual Certificates of Approval. Compliance with the guideline is required by the appropriate conditions in the Certificates of Approval.

The foundation 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

Guideline C-4: The Management of Biomedical Waste in Ontario is intended for use by generators, carriers and receivers of biomedical waste and by the ministry. This document will aid the reader in best management of biomedical waste to protect human health and the environment.

This guideline is intended to supplement, not replace existing acts and regulations. Generators, carriers and receivers of biomedical waste should comply with all applicable legislation and any existing Certificates of Approval.

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 from or related to an animal that is being treated for, or is suspected of being infected with, one or more of the infectious substances, within the meaning of the Transportation of Dangerous Goods (TDGR) Regulations, as amended, and consisting of,

i) liquid or semi-liquid animal blood or blood products,
ii) items contaminated with animal blood that would release liquid or semi-liquid blood or blood products if compressed, or
iii) animal body fluids visibly contaminated with animal blood and body fluids removed in the course of surgery, treatment or necropsy, excluding urine, faeces and milk, unless visibly contaminated with blood.

“animal anatomical waste” means waste consisting of all carcasses, tissues, organs, body parts or bedding, where the animal is being treated for, or is suspected of being infected with, one or more of the infectious substances, within the meaning of the Transportation of Dangerous Goods (TDGR) Regulations, as amended, **excluding** teeth, nails, hair, feathers, hooves or horns.

“biomedical waste” means waste that is generated by a biomedical waste generating facility, and includes the following:

1) **human anatomical waste**;

2) **human blood waste**;

3) **animal anatomical waste**;

4) **animal blood waste**;

5) **microbiology laboratory waste**;

6) **sharps waste**;

7) **cytotoxic waste**; and

8) **other waste** that is:

    i) waste that has come into contact with a human or animal being treated for, or is suspected of being infected with, one or more of the infectious substances, within the meaning of the Transportation of Dangerous Goods (TDGR) Regulations, as amended,

ii) waste that the generator considers should be handled as biomedical waste,
iii) a mixture of waste referred to in clauses (1) to (8)(ii), and any other waste or material, or
iv) a waste derived from a waste referred to in clauses (1) to (8)(ii) unless the waste that is derived from the waste referred to in clauses (1) to (8)(ii) is produced in accordance with a Certificate of Approval that states that, in the opinion of the Section 39 Director, the waste that is produced in accordance with the Certificate of Approval does not have characteristics similar to the characteristics of biomedical waste referred to in clauses (1) to (8)(ii),

but does not include,

- waste from animal husbandry,
- domestic waste,
- waste that is controlled in accordance with the *Health of Animals Act* (Canada), the *Dead Animal Disposal Act*, *Food Safety and Quality Act, 2001* (Ontario), or the *Meat Inspection Act* (Canada),
- waste that is generated in food production, general building maintenance or office administration,
- treated biomedical waste, or
- dialysis wastes, such as tubing, filters, towels and disposable sheets that are not contaminated with blood or blood products that would release liquid blood if compressed.

"biomedical waste generating facility" means a facility where biomedical waste is generated, and includes the following:

1) a human health care and residential facility,

2) a medical research and medical teaching establishment,

3) a health care teaching establishment for humans,

4) a clinical testing facility,

5) a facility involved in mobile health care for humans,

6) a research, diagnostic or microbiological laboratory,

7) a facility involved in the production and testing of vaccines,

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

9) 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*,

10) the office of a health professional within the meaning of the *Regulated Health Professions Act*, 1991,

11) a funeral establishment or transfer service approved by the Board of Funeral Services for the provision of educational courses within the meaning of the *Funeral Directors and Establishments Act*[†],

12) a private morgue or public morgue within the meaning of the *Anatomy Act*,

13) a place in which post mortem examinations are carried out,

14) a research facility within the meaning of the *Animals For Research Act*,

15) a veterinary facility within the meaning of the *Veterinarians Act*,

16) the professional office of a member of the College of Veterinarians of Ontario within the meaning of the *Veterinarians Act*,

17) a facility involved in mobile health care for animals, or

18) a needle and syringe exchange program operated by or for a municipality.

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

"cytotoxic waste" means waste consisting of,

i) leftover or unused cytotoxic drugs,
ii) contaminated waste materials including tubing, tissues, needles, gloves, vials, preparation materials and ampoules, or
iii) waste materials generated in cleaning up a spill.

"disinfection" means a level of destruction or inactivation of pathogen bacteria. Disinfection levels can range from low level to high level, to sterilization. Sterilization is the highest level of disinfection in biomedical waste treatment.

"human anatomical waste" means waste consisting of tissues, organs or

[†] Reference to the *Funeral Directors and Establishments Act* contained in this Guideline would be updated on proclamation of the *Funeral, Burial and Cremation Services Act, 2002.*

body parts, **not** including teeth, hair or nails.

"human blood waste" means waste consisting of,

i) liquid or semi-liquid human blood or blood products,
ii) items contaminated with human blood or blood products that would release liquid or semi-liquid human blood if compressed, or
iii) human body fluids visibly contaminated with blood, and body fluids removed in the course of surgery, treatment, autopsy, embalming or for diagnosis, excluding urine and faeces, unless visibly contaminated with blood.

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

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

2) a private hospital within the meaning of the *Private Hospitals Act,*

3) a psychiatric facility within the meaning of the *Mental Health Act,*

4) a nursing home within the meaning of the *Nursing Homes Act*,

5) a home within the meaning of the *Homes for the Aged and Rest Homes Act*,

6) 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,

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

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

9) a cancer centre established by the Ontario Cancer Treatment and Research Foundation under the *Cancer Act,*

10) an independent health facility within the meaning of the *Independent*

Health Facilities Act,

11) an approved home within the meaning of the *Mental Hospitals Act,*

12) a home for special care within the meaning of the *Homes for Special Care Act*.

"microbiology laboratory waste" means waste consisting of,

i) human or animal cultures,
ii) stocks or cell lines,
iii) animal specimens, excluding milk, urine and faeces,
iv) human specimens, excluding urine and faeces,
v) live or attenuated vaccines, or
vi) any material that has come into contact with any of the wastes in this sub-clause.

"mobile health care" means human or animal health care provided at a location that is not,

1) a human health care and residential facility,

2) the professional 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*,

3) the professional office of a health professional within the meaning of the *Regulated Health Professions Act, 1991,*

4) the professional office of a member of the College of Veterinarians of Ontario within the meaning of the *Veterinarians Act,* or

5) a veterinary facility within the meaning of the *Veterinarians Act.*

"sharps waste" means waste consisting of,

i) clinical and laboratory materials consisting of blades, needles, or needles attached to syringes; or
ii) laboratory glass or other materials capable of causing punctures or cuts, which have come into contact with human or animal blood and bodily fluids,

but does not include a syringe without a needle attached that shows no indication of blood.

"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

4.1 Segregation and Packaging

Generators should segregate biomedical waste from the general waste stream to ensure the special handling and treatment required for this waste. Generators should ensure that biomedical waste generated at their facilities is placed into a container suitable for the particular waste, immediately after it is generated.

4.1.1 Packaging

Single-Use and Reusable Containers
Both single-use and reusable containers may be used to package biomedical waste, provided that they are suitable for such intended use and should be equivalent to the Canadian General Standards Board standard CAN/CGSB-43.125- 99 (Packaging of Infectious Substances , Diagnostic Specimens, Biological Products and Biomedical Waste for Transport), as amended.

Biomedical waste should be segregated and packaged in accordance with the following criteria:

i) deposited directly into a suitable leak-proof single use plastic drum or plastic pail, without a liner; or
ii) deposited directly into a suitable plastic film liner that is securely tied and is then deposited into (a) a suitable single-use cardboard container or fibre drum, or (b) a suitable reusable container that is designed for repeated use.

A single-use cardboard container should be:

i) capable of withstanding the weight of the biomedical waste without tearing, crushing, breaking or otherwise allowing accidental release or discharge of biomedical waste, and
ii) closable and capable of being sealed,

but should not display any conflicting colours or labelling as specified in Section 4.1.2.

A reusable container should be:

i) fabricated of puncture-resistant leak-proof material (metal, plastic, or other) that can be cleaned and disinfected;

ii) capable of withstanding the weight of the biomedical waste without tearing, cracking, breaking or otherwise allowing accidental release or discharge of biomedical waste;
iii) cleaned with a chemical disinfection, steam sterilization, thermal inactivation, or other suitable processes prior to reuse; and
iv) visually inspected for tears, cracks, breaks or leaks every time it is emptied,

but should not display any conflicting colours or labelling as specified in Section 4.1.2.

Sharps Containers

Waste sharps (needles, scalpels, blades, etc.), broken glass or other materials that are capable of causing punctures or cuts, should be placed into a rigid, puncture-resistant and leak-resistant container designed specifically for that purpose. The container should have a lid which has been designed such that it cannot be removed once it has been closed.

Sharps containers may be reusable or single-use and should be equivalent to the CSA Standard Z316.6-07(*Evaluation of single-use and reusable medical sharps containers for biohazardous and cytotoxic waste*), as amended.

4.1.2 Labelling

Containers and plastic film liners must be clearly marked with the universal biohazard symbol displayed in Appendix 1.

In addition to the biohazard symbol, containers with cytotoxic waste must be clearly marked with the universal cytotoxic hazard symbol as displayed in Appendix 1, and labelled, ”Cytotoxic/Cytotoxique”.

Note: Cytotoxic sharps containers need only display the universal cytotoxic hazard symbol.

Colour Coding

All biomedical waste should be identified using the colour coding outlined below to specify the type of biomedical waste contained within the packaging. The colour coding may be achieved through:

- the use of a coloured inner liner of single-use or reusable containers; or
- the use of coloured outer packaging (e.g. sharps container).

Colour	Type of Biomedical Waste
(i) Red	• human anatomical waste; • animal anatomical waste; • cytotoxic waste; or • waste that has come into contact with a human or animal being treated for, or suspected to be infected with, one or more of the infectious substances within the meaning of the Transportation of Dangerous Goods (TDGR*)* Regulations, as amended.
(ii) Yellow	• Biomedical waste that is not specified in clause (i) above.

4.2 Central Storage of Biomedical Waste

Human anatomical waste and animal anatomical waste should be stored by the generator in an area where the temperature is maintained at or below 4 degrees Celsius.

All other biomedical wastes stored for greater than four days after generation should also be stored in an area where the temperature is maintained at or below 4 degrees Celsius.

Waste sharps, broken glass, cytotoxic waste and human or animal waste fixed in formaldehyde or another preservative do not require refrigerated storage.

Biomedical waste storage areas at a generator's site may include:

i) a permanent area specifically designed and constructed for the refrigerated storage of biomedical waste, inside the building;
ii) a stand-alone refrigeration/freezer unit; or
iii) a segregated waste storage area for the storage of properly packaged biomedical waste that does not require refrigeration e.g. sharps waste and cytotoxic waste.

Biomedical waste storage areas should be kept locked, except when public access is strictly prohibited or where authorized personnel are present. Only biomedical waste and/or biomedical waste packaging components should be stored in the biomedical waste storage area. Biomedical waste storage areas should be physically separate from food preparation or supply areas of the facility.

The storage area should be clearly marked as being a biomedical waste storage area with a sign that has the universal biohazard symbol clearly displayed (see Appendix 1). The biomedical waste storage area should be thoroughly cleaned in accordance with facility requirements.

Biomedical waste should be stored so as to prevent leaks and spills from the waste, or damage to, or deterioration of, the container in which the waste is stored. As a best management practice, biomedical waste should not be stored for a period exceeding 90 days.

5.0 Technologies for the Treatment and Disposal of Biomedical Waste

5.1 Incineration

Incineration shall be used to treat human anatomical waste, animal anatomical waste, cytotoxic waste and waste that is from or has come into contact with a human or an animal being treated for, or suspected of being infected with, one or more of the infectious substances within the meaning of the Transportation of Dangerous Goods (TDGR) Regulations, as amended. The Ministry's *Guideline A1: Combustion, Air Pollution Control and Monitoring Requirements for Biomedical Waste Incinerators in Ontario*, September 2002, as amended, outlines the design criteria for this technology.

5.2 Non-incineration

Non-incineration technologies may be used to treat biomedical wastes that do not require incineration (see Section 5.1). The use of a treatment technology shall reduce bacterial spores of *B. stearothermophilus* by a level of 6 Log_{10} (99.9999%) resulting in treated biomedical waste.

5.2.1 Record Keeping

Generators of biomedical waste conducting biomedical waste treatment should ensure that the equipment used undergoes microbiological testing sufficient to demonstrate compliance with applicable standards for treated biomedical waste, at least every six days. A written record should be made of the results of testing and the record should be retained at the facility for a period of two years after it is made.

Receivers of biomedical waste conducting biomedical waste treatment shall ensure that the equipment used undergoes microbiological testing sufficient to demonstrate compliance with applicable standards for treated biomedical waste, at least every six days. A written record shall be made of the results of testing and the record should be retained at the facility for a period of two years after it is

made.

6.0 Biomedical Waste Treatment Facilities

6.1 On-Site Treatment

Section 17.1 of Regulation 347 identifies the requirements for on-site processing of waste and activities that take place at waste generating facilities without the need for approvals required by sections 27, 40 and 41 of the *Environmental Protection Act* (EPA). An on-site biomedical waste treatment facility's processing should follow the standards specified in Sections 5.1 and 5.2 above. For each day the facility is in operation, a written record of the date, volume and final disposition of biomedical waste treated is recommended. Such written records should be kept by the treatment facility for a minimum of two years.

6.2 Off-Site Treatment

Where a biomedical waste treatment does not meet the requirements of section 17.1 of Regulation 347, sections 27, 40 and 41 of the EPA would apply to that facility.

7.0 Transportation of Biomedical Waste Off-Site

7.1 General Requirements

Prior to biomedical waste being transported off-site for disposal, the generator should ensure that all biomedical waste has been packaged in accordance with Section 4.0 of the guideline. Biomedical waste shall only be transported by a waste management company for which a Waste Management System Certificate of Approval has been issued under the EPA.

7.2 Vehicle Standards

The following biomedical waste transportation vehicle standards will be enforced by including these conditions in Waste Management System Certificate of Approval for carriers of biomedical waste.

When only sharps are transported, these requirements may be waived in the Certificate of Approval permitting transportation.

1) All transportation vehicles shall be specifically designed to accommodate

the special interest to be served in the vehicle. The following features shall be provided in the storage compartment:

a) The storage compartment shall be insulated and must be kept refrigerated at a temperature at or below 4 degrees Celsius or lower, when the vehicle contains any wastes.
b) The independent refrigeration system shall be operable at all times when the vehicle is parked or inoperable.
c) The walls shall be of a washable material, and floors shall be metal surfaced to ensure effective cleaning and disinfecting.
d) The floor of the storage compartment shall be sealed and leak proof.
e) The vehicle shall have a form of collection basin, below the floor level, to contain leakage from the waste.
f) No windows or ventilation openings shall exist in the waste storage compartment.
g) The waste storage compartment shall have only one lockable door. An interior light shall be provided.
h) The vehicle shall have appropriate spill cleanup equipment and disinfectant on the vehicle in the event of a spill.
i) The vehicle shall not be used for any other purpose than transporting biomedical waste.
j) The storage compartment door shall be kept locked at all times during transportation or when the vehicle is parked, except for normal entry.

2) At the end of each day of operation, the interior of the waste storage compartment of the vehicle shall be thoroughly cleaned with a disinfecting solution.

8.0 Final Disposal of Treated Biomedical Waste

8.1 Transportation for Final Disposal

Treated biomedical waste generated by the facility should be stored separately from biomedical waste and other municipal waste.

Prior to the treated biomedical waste leaving the site for final disposal, the operator of the landfill shall be advised in advance as to the quantity of the waste and approximate time of arrival. A Notice/Certificate, which confirms that the waste contained within each bin or self-contained compacter, has been treated and is rendered non-hazardous, should accompany each shipment.

Treated biomedical waste shall be transported, as directly as may be practicable, to the final disposal site. No other waste shall be transported in the vehicle with treated biomedical waste. Treated biomedical waste shall not be transported to a

transfer station or other facility where final disposal will not take place.
The waste storage compartment of the vehicle shall be enclosed and must not be a compaction-type waste haulage vehicle. The vehicle shall have on hand, at all times, suitable emergency spill clean-up equipment.

Compaction of treated biomedical waste may not be conducted unless mechanical compaction is part of a single, self-contained process.

Any treated biomedical waste which becomes loose or is in a container that is punctured, broken or leaking shall be immediately re-packaged.

8.2 Landfilling of Treated Biomedical Waste

Treated biomedical waste shall be deposited at approved Ontario landfill sites where locations in the landfilling site have been adapted for the purpose of receiving treated biomedical waste.

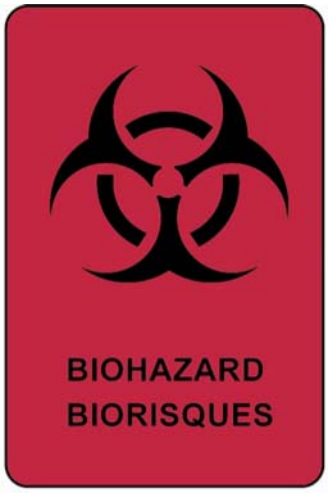
Treated biomedical waste can be deposited at the landfilling site only when the depositing is being supervised by the operator of the landfill site or a person designated by the operator for this purpose.

Once the treated biomedical waste is deposited in the site, a sufficient quantity of garbage or cover material must be placed over the treated biomedical waste. This ensures that direct contact between site equipment and treated biomedical waste is avoided.

APPENDIX 1

UNIVERSAL BIOHAZARD SYMBOL

ANATOMICAL SYMBOL



CYTOTOXIC SYMBOL