Guidance Document

Title: Management of Biomedical and Pharmaceutical Waste (BPW)

Prepared By: Joan Hann, Environmental Scientist

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SUBJECT

Biomedical and pharmaceutical waste (BPW).

OBJECTIVE

To define and outline environmentally acceptable approaches for the management and disposal of Biomedical and Pharmaceutical Waste (BPW) in the province.
This document is not applicable to the final disposal of human or animal remains originating from funeral homes or crematoria.

BACKGROUND

Biomedical and pharmaceutical waste, as defined below and in Appendix A1 and A2 must be appropriately managed, contained and transported by a licensed transporter to a licensed final disposal facility outside the Province. A list of additional references applying to the management of biomedical and pharmaceutical waste is provided in Appendix B of this document. For the purpose of this guideline, BPW waste may be considered Waste Dangerous Goods/Hazardous Waste (WDG/HW) under the Environmental Protection Act by the Department as it may potentially have an adverse impact on human health and the environment if improperly managed. Institutions generating this waste stream are responsible for developing management plans which should include procedures for: waste identification, segregation, packaging, disposal and training requirements for staff. Other types of WDG/HW (characteristic waste under (TDG), mercury amalgams, radioactive waste and lab chemicals) generated at the same facilities are outside the scope of this document. Please note: this document does not include

BPW may be generated by the following establishments:

- human or animal health care facilities/establishments
- teaching or research establishments
- needle and syringe exchange programs
- medical and dental offices and pharmacies

DEFINITIONS

Biohazard
Material that can be contaminated with viable micro-organisms (including prion protein material), or toxins under certain circumstances that can cause disease or illness.

*Biomedical Waste*
Waste originating from medical/health facilities and procedures that requires special handling and disposal because it presents a particular risk of disease transmission. Please refer to Appendix A1 for full definitions and examples.

*Chemical waste*
Waste that contains one or a mixture of chemicals that may be hazardous in nature.

*Controlled drug*
A drug or preparation that contains a substance specified in the Controlled Drugs and Substances Act and Regulations (Canada).

*Halogenated*
A type of plastic that contains halogen atoms such as chlorine, fluorine, etc. Examples of these plastics include polyvinyl chloride and fluorocarbon compounds such as Teflon. Combustion or Thermal degradation of these types of plastics results in the generation of toxic compounds during autoclaving.

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

*Non-pathogenic*
Not known to cause disease.

*Pharmaceutical Waste*
Waste of pharmacological nature/origin that requires special handling and disposal because it presents a particular risk to humans and/or the environment. Please refer to Appendix A2 for full definitions and examples.

Sterilization
A process that kills all microorganisms, including bacteria, viruses and fungi. Autoclaving would be considered a sterilization process.

Waste Dangerous Goods/Hazardous Waste (WDG/HW)
Waste that may have the following characteristics: corrosive, reactive, flammable, ignitable, carcinogenic, teratogenic, mutagenic, infectious, oxidizing, radioactive, explosive, poisonous/toxic (acute and chronic), bioaccumulative, persistent and/or leachable.

LEGISLATION
The activities associated with BPW management may involve, but are not necessarily limited to, the following Acts and Regulations;

Provincial Legislation

*Environmental Protection Act and Regulations*
*Water Resources Act and Regulations*
*Occupation Health and Safety Act and Regulations*

Federal Legislation

*Transportation of Dangerous Goods Act and Regulations (Transport Canada)*
*Canadian Environmental Protection Act and Regulations (Environment and Climate Change Canada)*
*Controlled Drug and Substance Regulations and Act (Health Canada)*

ENVIRONMENTAL ASSESSMENT AND APPROVAL PROCESS
All treatment methods and storage facilities for BPW may require registration under the Environment Assessment regulations (Part X EPA). Once released from the Environmental Assessment process a request must be made to the Waste Management Section of the Pollution Prevention Division for a Certificate of Approval to construct and operate a waste
management facility pursuant to the Environmental Protection Act, Parts XI. Prior to issuing an approval prerequisite information shall be submitted for review (refer to APPENDIX C).

TRANSPORTATION
Transporters of BPW are required to contact the Department for details on prerequisite information to be submitted for review prior to issuance of an approval. Organizations participating in take back pharmaceutical programs are exempt from the requirement to obtain a transporter approval.

Small quantities of BPW generated at remote locations may be transported to larger centres provided waste is packaged according to CCME Guidelines and it may be transported in a trunk luggage area or floor of a vehicle. The waste shall be secured from moving sliding or tipping over and capable of being locked.

A Permit of Equivalent Level of Environmental Safety (PELES) under the Canadian Environmental Protection Act, 1999 may authorize an activity to be conducted in a manner that does not comply with the requirements of Division 8, Part 7 of CEPA 1999 (Control of Movement of Hazardous Waste and Hazardous Recyclable Material and of Prescribed Non-Hazardous Waste for Final Disposal). Environment Canada should be contacted for further details.

BIOMEDICAL WASTE (BW)

Biomedical waste (refer to Appendix A1 for identification and parameters) represents a small proportion of total waste generated at health care and related facilities. But, concerns about the environment and the transmission of infectious diseases have increased the need for proper handling and disposal of waste. The fraction of the BW stream that is likely to cause disease or injury is minimal; risks include exposure to infectious disease organisms and physical injury (such as puncture and cuts) caused by sharps. People working in various establishments may be affected, as well as those who regularly handle or transport BW. The greatest risks are largely eliminated by proper segregation; packaging, labelling and transportation to approved final treatment/disposal site (refer to Table 1 for a general summary). Appendix B provides additional references to publications and guidance documents related to BW.
BIOMEDICAL WASTE TEMPORARY STORAGE REQUIREMENTS

Temporary storage (generator site) of BPW while awaiting shipment requires the following:

- All wastes shall be segregated from other types of waste at the source and stored in appropriate colour-coded labelled containers and as per WHMIS and TDG requirements (see Table 1);
- Storage areas shall be totally enclosed, marked and separate from supply rooms or food preparation areas and kept at a temperature of 4°C or lower for material stored more than four (4) days;
- The storage room/area shall be lockable and access shall be restricted to authorized personnel only;
- All floors, walls and ceilings in a storage area shall be thoroughly cleaned in accordance with the facility’s established procedures;
- The waste shall be stored in reusable plastic containers with lids that can be firmly secured during transport;
- Compacting is prohibited;
- Infectious waste shall be segregated from other types of biomedical wastes and handled using procedures outlined in the written exposure control plan required by Occupational Health and Safety Regulations and/or applicable Health agencies;
- The Department of Health and Community Services and Newfoundland and Labrador Health Care Board Association (NLHBA), and health care board sites are encouraged, where appropriate, to segregate and to treat at source, a portion of the waste stream, to minimize the volume of waste generated and to provide, to an authorized private sector company, collected biomedical for ultimate disposal at approved treatment and disposal facilities/sites located outside the province.

PHARMACEUTICAL WASTE (PW)

Because of potential adverse effects to human health and the environment, PW cannot be disposed of as conventional waste and requires special handling whether it comes from a hospital, clinic, pharmacy or private household (refer to Appendix A2 for identification). There is also a risk that poorly controlled PW could end up in the hands of people who misuse medications. In addition some PW may contain heavy metals, hormones, antibiotics and other compounds that may have adverse impacts on animals and the environment as they accumulate and bioaccumulate. Some pharmaceuticals that are not hazardous waste may be
considered endocrine disruptors, carcinogenic and/or mutagenic. Examples may include: creams, inhalers, patches, powders, capsules, IV bags, vials, syringes and ampules. Releasing PW into the environment also has the potential to disrupt the balance of microorganisms at wastewater and sewage treatment facilities.

To minimize the harmful effects to human health and the environment, the Department recommends that PW be disposed of as WDG/HW and disposed by approved destruction methods (refer to Table 1 for a general summary). Appendix B provides additional references to publications and guidance documents related to PW.

The Department recommends that nonhazardous pharmaceuticals, including most hormones, antibiotics and antidepressants, be disposed as WDG/HW and incinerated due to potential adverse effects to human health and the environment.

PHARMACEUTICAL WASTE TEMPORARY STORAGE REQUIREMENTS

- Generators are responsible for proper identification, labeling and placement of PW into appropriate collection containers. Please note pharmaceutical and hazardous pharmaceutical waste should be placed in separate containers. Provide a list of pharmaceutical waste inside the box. Include drug/chemical name and container size.

- Pharmaceutical waste shall be placed in approved containers securely taped and labelled “PHARMACEUTICAL WASTE - FOR INCINERATION ONLY”.

- Hazardous PHARMACEUTICAL WASTE shall be placed in approved containers and labelled “Hazardous Pharmaceutical waste- FOR HIGH TEMPERATURE INCINERATION ONLY”.

BIOMEDICAL/PHARMACEUTICAL WASTE EXEMPTIONS

The wastes described below falls into the category of general waste (non-hazardous) and requires no safety measures and can be safely dealt with in the same manner as municipal/solid waste. (However, in some cases local waste management authorities might place restrictions on general waste material with visible residual blood).
wastes that are controlled under the *Health of Animals Act (Canadian Food Inspection Agency)*

- wastes that result from the breeding or raising of animals
- urine or feces; teeth, hair or nails
- soiled dressings containing blood; sponges; surgery drapes; disposable gloves; casts; specimen containers
- IV bags; tubing (provided the tubing is thoroughly rinsed with saline or empty and with only residual blood);
- non bloody gloves; catheters; lavage tubes
- lab slides with tissue fixed (treated as glass waste)
- syringes without needles
- waste generated from building maintenance, office administration or food preparation and consumption
- empty capsules, empty bottles (containing no liquid)
- pill cups that have been used to dispense patient medications
- empty medication containers or vials

**TREATMENT**

There are several treatment methods used for the treatment of BPW. These methods may vary depending on the type of waste. For the purpose of this guidance document a brief summary of two acceptable methods are provided below. Refer to Table 1, for a summary of acceptable treatment/disposal methods for each type of BPW.

**Steam Autoclaving**

Steam autoclaving is considered a decontamination process used for microbiology laboratory waste prior to disposal. The effectiveness of the autoclave should be verified regularly, based on its frequency of use. Biological indicators, such as the presence of *Bacillus stearothermophilus*, are typically found to be reliable. Personnel who operate steam autoclaves must be thoroughly trained in the use of the equipment. Laboratory waste must be rendered non-pathogenic on site by this process prior to landfill disposal.

Several factors to be considered for this process:
➢ operating conditions shall have a temperature of at least 121°C at a pressure of 105 kPa (15 psi) for more than 60 minutes;
➢ laboratory wastes, such as Petri dishes and syringes that are liable to melt and trap air or liquids, may require longer times;
➢ all decontaminated wastes shall be stored in clear, unmarked autoclaved bags (with the presence of thermal autoclaved tape) is permitted for regular landfill disposal

**The following items are not permitted for autoclaving:**
➢ cytotoxic agents, such as chemotherapy drugs and other chemical wastes;
➢ organic wastes containing oxidizing agents like sodium hypochlorite or solvents due to the potential for explosion (effectiveness) and integrity throughout the autoclave cycle; and
➢ having chemicals of radioactive material **within the waste**

**Incineration**

High temperature incineration is the preferred method for management of specific types of BPW (including waste contaminated with Ebola and hazardous pharmaceuticals containing heavy metals). High temperature incineration is currently the only option that can be used for the treatment of hazardous pharmaceutical and cytotoxic agents and waste. A high temperature incinerator consists of primary and secondary incineration chambers with a minimum temperature of 1000°C and shall include air pollution control equipment.

It is required that incineration for BPW has approved environmental control equipment such as scrubbers to achieve applicable standards outlined in the **Air Pollution Control Regulations**. Incinerators operating in the province will require registration under the **Environmental Assessment Regulations** prior to operation; and also require applicable approvals to operate.
Table 1 Summary of BPW Management and Disposal Options

<table>
<thead>
<tr>
<th>Type of waste</th>
<th>Examples</th>
<th>Packaging: *</th>
<th>Container colour and label</th>
<th>Type of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal and Human Anatomical Waste</td>
<td>organs, tissues, body parts, carcasses</td>
<td>Rigid containers – refrigeration required</td>
<td>Orange (animal)/Red(human)</td>
<td>Incineration</td>
</tr>
<tr>
<td>Cytotoxic Chemical Waste</td>
<td>IV bags, urine bags, drugs, pads, sponges</td>
<td>Sealed rigid containers</td>
<td>Red/Cytotoxic</td>
<td>High Temperature Incinerion</td>
</tr>
<tr>
<td>Non anatomical Human and Animal waste</td>
<td>Pads, sponges, tubing etc. saturated/dripping with blood and body fluids</td>
<td>Sealed yellow bags/containers – refrigeration required</td>
<td>Yellow</td>
<td>Decontamination/Sterilization and disposal to approved landfill out of province</td>
</tr>
<tr>
<td>Microbiology Laboratory Wastes</td>
<td>Culture dishes</td>
<td>Sealed containers or regular plastic bags if decontaminated</td>
<td>Yellow/biohazard</td>
<td>Decontamination/Sterilization and disposal within approved landfills in the province</td>
</tr>
<tr>
<td>Sharps- needles or other sharp objects</td>
<td>needles or sharp objects glass contaminated with infectious material</td>
<td>Sealed, spill proof and lockable rigid containers – Refrigeration not necessary</td>
<td>Yellow or red if incinerated</td>
<td>Decontamination/Sterilization and disposal to approved landfill out of province</td>
</tr>
<tr>
<td>Pharmaceutical Waste</td>
<td>oral medications, vials and ampoules syringes, IVs</td>
<td>Sealed containers</td>
<td>Rx – Label as pharmaceutical waste Incineration only Rx</td>
<td>Incineration</td>
</tr>
<tr>
<td>Hazardous Pharmaceutical Waste</td>
<td>drugs may contain listed and or characteristic waste</td>
<td>Sealed container*</td>
<td>Rx – Label as hazardous pharmaceutical waste high temperature incineration</td>
<td>High temperature incinerator</td>
</tr>
</tbody>
</table>

*Generators shall use non halogenated materials where incineration and/or autoclaving are required. This is due to the fact that halogenated plastics when combusted release of dioxins and furans into the atmosphere.
APPENDIX A1: Definition and Examples of Biomedical Waste

Export and Import of Hazardous Waste and Hazardous Recyclable Materials Regulations

under the Canadian Environmental Protection Act

SCHEDULE 3 (Paragraphs 1(1)(a) and 2(1)(a), subparagraph 8(j)(v), paragraphs 9(c) and 16(b) and subparagraph 38(1)(a)(iii))

HAZARDOUS WASTES AND HAZARDOUS RECYCLABLE MATERIALS

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of Hazardous Waste and Hazardous Recyclable Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Biomedical waste – the following wastes, other than those generated from building maintenance, office administration or food preparation and consumption, that are generated by human or animal health care establishments, medical, health care or veterinary teaching or research establishments, clinical laboratories or facilities that test or produce vaccines and needle and syringe exchange programs:</td>
</tr>
<tr>
<td></td>
<td>(a) human tissues, organs or body parts, excluding teeth, hair or nails;</td>
</tr>
<tr>
<td></td>
<td>(b) human blood or blood products;</td>
</tr>
<tr>
<td></td>
<td>(c) human bodily fluids that are contaminated with blood;</td>
</tr>
<tr>
<td></td>
<td>(d) human bodily fluids removed in the course of autopsy, treatment, or surgery for diagnosis;</td>
</tr>
<tr>
<td></td>
<td>(e) animal tissues, organs, body parts or carcasses, excluding teeth, nails, hair, bristles, feathers, horns and hooves, resulting from the treatment of an animal for contamination or suspected contamination with one or more of the agents set out in paragraph 2.36(a) or (b) of the Transportation of Dangerous Goods Regulations;</td>
</tr>
<tr>
<td></td>
<td>(f) animal blood or blood products resulting from the treatment of an animal for contamination or suspected contamination with one or more of the agents set out in paragraph 2.36(a) or (b) of the Transportation of Dangerous Goods Regulations;</td>
</tr>
<tr>
<td></td>
<td>(g) animal bodily fluids that are visibly contaminated with animal blood and that result from the treatment of an animal for contamination or suspected contamination with one or more of the agents set out in paragraph 2.36(a) or (b) of the Transportation of Dangerous Goods Regulation;</td>
</tr>
<tr>
<td></td>
<td>(h) animal bodily fluids removed in the course of surgery, treatment or necropsy, and that result from the treatment of an animal for contamination or suspected contamination with one or more of the agents set out in paragraphs 2.36(a) or (b) of the Transportation of Dangerous Goods Regulations;</td>
</tr>
<tr>
<td></td>
<td>(i) live or attenuated vaccines, human or animal cell cultures, microbiology laboratory cultures, stocks or specimens of</td>
</tr>
</tbody>
</table>
microorganisms and any items that have come into contact with them;
(j) any items that are saturated with the blood or bodily fluids
referred to in paragraphs (b) to (d) or (f) to (h), including items that
were saturated but that have dried; and
(k) cytotoxic drugs and any items, including tissues, tubing, needles
or gloves, that have come into contact with a cytotoxic drug.

Biomedical waste does not include
(a) urine or feces;
(b) wastes that are controlled under the Health of Animals Act; or
(c) wastes that result from the breeding or raising of animals.

ADDITIONAL COMMENTS ON BIOMEDICAL WASTE

Human Blood and Body Fluids Wastes

Includes fluid blood, blood products and body fluids used for diagnosis or removed during surgery, treatment or autopsy and any other materials that have contacted this waste and are saturated or dripping with blood, (e.g., surgical drapes, surgical gowns, sponges, closed drainage tubes and dressings, etc.).

Microbiological Laboratory Waste
Microbiology laboratory cultures (whether positive or negative), stocks or specimens of microorganisms, live dead or attenuated vaccines, human or animal cell cultures used in research as well as laboratory material that has come into contact with waste contaminated with microorganisms that may have the potential to transmit diseases.

Sharps
Any object that can penetrate the skin or have had or are likely to have had contact with infectious agents. They consist of: clinical and laboratory materials consisting of needles, syringes, blades or laboratory glass capable of causing puncture cuts.

Special precaution waste
Associated with patients or animals that have been identified to contain a pathogen/toxin that produces very serious diseases and may be readily transmitted from one individual to another or from animal to human directly or indirectly.
APPENDIX A2: DEFINITIONS AND EXAMPLES OF PHARMACEUTICAL WASTE

CATAGORIES OF PHARMACEUTICAL WASTE
Pharmaceutical waste may be a hazardous chemical waste, controlled substance or biomedical waste (refer to cytotoxic waste). Proper classification is required prior to transport. PW consist of unused/used or expired drugs and medicines/vaccines/ that is no longer required and includes the following:

Note: Refer to APPENDIX B item #s 6, 7 and 9 for details on the identification of PW

**Hazardous pharmaceutical waste**

- Includes those wastes exhibiting Transportation of Dangerous Goods characteristic's and/or leachable toxic under CEPA) of hazardous chemicals:
  - Ignitability
  - Corrosively
  - Reactivity
  - Toxicity

**Controlled Drugs Substances**
Contains a substance specified in Part G of the Food and Drug Regulations.

**Other Pharmaceutical waste**
Other waste that that are carcinogenic, mutagenic, endocrine disruptors and/or have an adverse impact on the environment if improperly disposed (examples are steroids, hormones and chemotherapy drugs (refer to cytotoxic drugs below)

**Cytotoxic Chemical Wastes:**

- Pharmaceutical drugs (referred to as antineoplastic/chemotherapy) used in the treatment of cancer and or conditions that has a specific destructive effect on certain cells or that can be genotoxic, oncogenic, mutagenic, teratogenic or hazardous to cells. This type of waste is restricted to drugs and other medicinal chemicals used in patient/animal treatment or diagnosis. Waste in this category shall include intravenous needles, tubing, syringes used to inject cytotoxic drugs and personal protective equipment that is used when handling cytotoxic drugs.
## Appendix B: List of Publications/Guidelines

<table>
<thead>
<tr>
<th>Item #</th>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. BW Packaging</td>
<td>Packaging and Handling of Waste Dangerous Goods</td>
</tr>
<tr>
<td>4. BW General Management</td>
<td>Requirements for packaging collection, storage, handling, treatment and disposal of waste materials within healthcare facilities</td>
</tr>
<tr>
<td>5. BW Sharps</td>
<td>Sharp Container - Related</td>
</tr>
<tr>
<td>7. PW Identification</td>
<td>Identification OF PHARMACEUTICAL DRUGS</td>
</tr>
<tr>
<td>No.</td>
<td>Title</td>
</tr>
<tr>
<td>-----</td>
<td>----------------</td>
</tr>
<tr>
<td>11</td>
<td>BW Pathogens</td>
</tr>
<tr>
<td>14</td>
<td>Dental</td>
</tr>
</tbody>
</table>
APPENDIX C: PREREQUISITE INFORMATION REQUIRED FOR AN APPROVAL

The following is an outline of information required for the submission of an application for a Certificate of Approval for the collection and transportation of hazardous waste. A submission is not limited to the general direction provided in this document.

- Letter requesting a Certificate of approval (Name of the proponent(s) to be included)
- Nature of business, including expected number of shipments, classes/characteristics and description of wastes to be transported.
- Area to be serviced in the Province
- Information on the name and location of the receiver (treatment and/or disposal).
- A description of the equipment (totes/containers etc. - provide photos and/or diagrams) to be used for the transport of hazardous waste, storage facilities to be used in the operation, (vehicle list/equipment used in transportation/related storage).
- The experience and training courses completed by your company and its drivers (health, safety, and environmental emergency response).
  Such as: Workplace Hazards Management Information System (WHMIS);
  - Transportation of Dangerous Goods Regulations (TDG);
  - Emergency spill response and contingency plans procedures;
  - Use of personal protective equipment;
  - Standard First Aid and Cardio-Pulmonary Resuscitation (CPR);
- A $20,000 Surety Bond (original signed), deposit of funds (certified cheque) or irrevocable letter of credit must be supplied to satisfy section 84 of the Environmental Protection Act. The surety bond must be maintained to assure satisfactory maintenance and operation of the waste management system. This bond must be kept in force as long as the system is operated.
- Proof of Automobile liability insurance for all owned and un-owned licensed vehicles used in connection with the operation of the facility and which provides coverage against liability arising from third party bodily injury or property damage for a minimum of $1.0 million per occurrence. If the automobile liability policy excludes coverage for sudden and accidental pollution, this coverage shall be provided under an environmental impairment liability policy.
- Proof of environmental liability impairment insurance in the amount of at least $1.0 million dollars.
- Emergency Response Plan (Contingency Plan) Plan which is specific to the proposed operation and to the location of operation (i.e. Newfoundland and Labrador). The Emergency Response Plan (Contingency Plan) must be submitted to the Department. A copy of the proponent's current contingency plan, shall be kept in each vehicle used in the operation of this waste management system. Personnel shall be briefed on the contents of the plan and any associated emergency response equipment.

Provide a Contingency Plan which is a set of predetermined procedures for the reporting, containment, removal and cleanup of a contaminant(s). A plan should reduce potential health hazards, damage to property and the environment and the cost of clean-up. The plan must be specific to Newfoundland and Labrador. The plan should include such items as:
- the role of the driver in response to an incident
- notification and alerting procedures (internal and external procedures) including provincial contacts
- (telephone numbers)
- responsibilities of the on site commander
- spill control and clean up procedures
- restoration of the spill site
- information on the disposal of contaminants
- resource inventory: equipment, manpower, consultants, treating agents, expertise, contacts, emergency information systems.
- Information on staff training (health, safety and environmental response)

The renewal of this approval is dependent upon the receipt of the information listed above. Additional information may be required throughout the approval process. The Department may be contacted for clarification on any of these issues or with any other inquiry/questions

Inquiries on hazardous wastes permitting, policy and provincial legislation may be directed to me at 709-729-1771 (phone), 709-729-6969 (fax) or by email at joanhann@gov.nf.ca.