U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

1200 New Jersey Ave., SE
Washington, DC 20590

AUG 24 2009

Mr. Rob Ellis
Director of Market Development
Otto Environmental Systems
12700 General Drive
Charlotte, NC 28273

Reference No. 09-0043

Dear Mr. Ellis:

This is in response to your February 22, 2009 letter requesting clarification of the packaging requirements for "UN 3291, Regulated medical waste, n.o.s., 6.2 (infectious), PG II" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). We have paraphrased your questions and answered them in order. We apologize for the delay in responding and any inconvenience this may have caused.

Q1. Based on the regulatory language in § 173.134, are packaging requirements applicable to regulated medical waste (RMW) limited to those prescribed in § 173.197 that were revised on October 1, 2007?

A1. No. Regulated medical waste that contains a Category A infections substance must be described as "UN2814, Infectious substances, affecting humans, 6.2" or "UN2900, Infectious substances, affecting animals, 6.2", as appropriate, and packaged in accordance with the requirements in §173.196. Regulated medical waste that contains a Category B infectious substance may be placed in packagings that meet the requirements in § 173.6 (materials of trade), 173.134 (exceptions), or 173.197 (regulated medical waste), as applicable. Section 173.6(a)(4)(ii) requires RMW to be placed in a combination packaging; § 173.196(a) requires RMW to be placed in a triple packaging; and §§ 173.134(c)(1) and (c)(2), and 173.197 require RMW to be placed in a single or combination packaging depending on the packaging's design type and performance.

Q2. May RMW be transported in a bulk outer packaging (BOP) such as a plastic 32 g, 65 g, 95 g, 660 L or 770 L cart with an appropriate inner container such as a standard "red bag" and with an appropriate exterior label on the plastic cart (examples attached).

A2. Yes. Under the HMR, regulated medical waste may be transported in a BOP provided the packaging conforms to the requirements in § 173.197(a), (d), and (e).

Q3. May chemotherapeutic waste be transported in a BOP such as a plastic 32 g, 65 g, 95 g, 660 L or 770 L cart with an appropriate inner container such as an approved chemotherapeutic yellow container and appropriate labeling (examples attached).

A3. The hazard class assigned to chemotherapeutic waste is based on its chemical composition, concentration of ingredients, and hazard characteristics. Under § 173.22, the shipper is responsible for determining if a material meets the definition of a hazard class, and for assigning the material an appropriate proper shipping name and selecting the appropriate packaging, markings, and labels. Division 6.2 chemotherapeutic waste may be placed in a BOP that conforms to the packaging requirements prescribed in § 173.197 (c), (d), and (e). Section 173.134(d) requires a Division 6.2 material listed in the exceptions under § 173.134(b) and (c) that also meets the definition of another hazard class, or that is a hazardous substance, hazardous waste, or marine pollutant to comply with the applicable requirements of the HMR for each hazard class it contains, which includes, if applicable, placing the Division 6.1 label on the outside of the package. Please note that chemotherapeutic waste that meets more than one hazard class must be classed in accordance with the provisions contained in § 173.2a, and, as stated earlier, must conform to the applicable requirements for each hazard class. Also, § 173.2a(c)(3) requires a Division 6.2 material that also meets the definition of another hazard class, which may include a limited quantity Class 7 material but no other type of Class 7 material, to be classed as Division 6.2.

Q4. May sharps be transported in a BOP such as a plastic 32 g, 65 g, 95 g, 660 L or 770 L cart with an appropriate inner container such as an approved sharps container and appropriate labeling (examples attached).

A4. Yes. Under the HMR, sharps that are regulated medical waste may be transported in a BOP provided the packaging complies with § 173.197(a), (d), (e) introductory paragraph, and (e)(3).

I hope this satisfies your request.

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Edmonson
§173.134
§173.197
Regulated Medical Waste
09-0043

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Reference: Questions regarding clarification on "Regulated Medical Waste Packaging" regulations requirements:

To PHMSA Information Center:

Thank you for the opportunity to utilize your professional expertise regarding CFR49 and regulated medical waste. Numerous hours have been spent researching this document and hence a few questions have developed. With this stated, I would like to ask you (4) questions to clarify my interpretation of these regulations and to either receive confirmation from you that my understanding is correct or guidance from you as to appropriate interpretation of the regulation if I am incorrect.

Understanding, based on review and interpretation of the U.S. Depart of Transportation's Regulations on Medical Waste found in the CFR49 document can it be interpreted that Regulated Medical Waste does not fall under the packaging requirements for infectious substances CFR49 173.196 for the reason of an exception found in CFR49 173.134 sec (c), *"Exceptions for Medical Waste..."*

QUESTION (1): Based on this section of CFR 173.134, does this mean that the pertinent regulations for packaging "Regulated Medical Waste" are limited to CFR49 173.197, revision October 1st, 2007 which have been highlighted below.

CFR49 173.134 sec (c), *"Exceptions for Medical Waste..."*

[Code of Federal Regulations]
[Title 49, Volume 2]
[Revised as of October 1, 2006]
From the U.S. Government Printing Office via GPO Access
[CITE: 49CFR173.134]

http://www.access.gpo.gov/nara/cfr/waisidx_06/49cfr173_06.html

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TITLE 49--TRANSPORTATION

CHAPTER I--PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 173_SHIPPERS_GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS--

Subpart D_Definitions Classification, Packing Group Assignments and Exceptions for Hazardous Materials Other Than Class 1 and Class 7

Sec. 173.134 Class 6, Division 6.2--Definitions and exceptions.

...

(c) Exceptions for regulated medical waste. The following provisions apply to the transportation of regulated medical waste:

(1) A regulated medical waste transported by a private or contract carrier is excepted from--

(i) The requirement for an ``INFECTIOUS SUBSTANCE'' label if the outer packaging is marked with a ``BIOHAZARD'' marking in accordance with 29 CFR 1910.1030; and

(ii) The specific packaging requirements of Sec. 173.197, if packaged in a rigid non-bulk packaging conforming to the general packaging requirements of Sec. Sec. 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030, provided the material does not include a waste concentrated stock culture of an infectious substance.

Exceptions for Regulated Medical Waste transported by Private or Contract Carrier

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Sharps containers must be securely closed to prevent leaks or punctures.

QUESTION (2): If the answer to the first question is yes, then based on these sections of CFR49 173.197, does this mean that "Regulated Medical Waste" can be transported in a (BOP) such as a plastic 32g, 65g, 95g, 660L or 770L cart with an appropriate inner container such as a standard "Red-Bag" and with appropriate exterior labeling on the plastic cart. Example of the 32g, 65g, 95g, 660L and 770L carts are illustrated at the bottom of this email and attached .pdf's.

QUESTION (3): If the answer to the first question is yes, then based on these sections of CFR49 173.197, does this mean that "Chemotherapeutic Waste" can be transported in a (BOP) such as a plastic 32g, 65g, 95g, 660L or 770L cart with an appropriate inner container such as an approved chemotherapeutic yellow container and appropriate labeling. Example of the 32g, 65g, 95g, 660L and 770L carts are illustrated at the bottom of this email and attached .pdf's.

QUESTION (4): If the answer to the first question is yes, then based on these sections of CFR49 173.197, does this mean that "Sharps" can be transported in a (BOP) such as a plastic 32g, 65g, 95g, 660L or 770L cart with an appropriate inner container such as an approved sharps container and appropriate labeling. Example of the 32g, 65g, 95g, 660L and 770L carts are illustrated at the bottom of this email and attached .pdf's.

CFR49 173.197, Regulated Medical Waste

[Code of Federal Regulations]
[Title 49, Volume 2]

[Revised as of October 1, 2007]
From the U.S. Government Printing Office via GPO Access
[CITE: 49CFR173.197]

http://www.access.gpo.gov/nara/cfr/waisidx_06/49cfr173_06.html

[Page 549-552]

TITLE 49--TRANSPORTATION

CHAPTER I--PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 173_SHIPPERS_GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS--Table of Contents

Subpart E_Non-bulk Packaging for Hazardous Materials Other Than Class 1 and Class 7

Sec. 173.197 Regulated medical waste.

...

(d) Non-specification bulk packaging. A wheeled cart (Cart) or bulk outer packaging (BOP) is authorized as an outer packaging for the transportation of regulated medical waste in accordance with the provisions of this paragraph (d).

(1) General requirements. The following requirements apply to the transportation of regulated medical waste in Carts or BOPs:

(i) Regulated medical waste in each Cart or BOP must be contained in non-bulk inner packagings conforming to paragraph (e) of this section.

(ii) Each Cart or BOP must have smooth, non-porous interior surfaces free of cracks, crevices, and other defects that could damage plastic film inner packagings or impede disinfection operations.

(iii) Except as otherwise provided in this paragraph (d), each Cart or BOP must be used exclusively for the transportation of regulated medical waste. Prior to reuse, each Cart or BOP must be disinfected by any means effective for neutralizing the infectious substance the packaging previously contained.

(iv) Untreated concentrated stock cultures of infectious substances containing Category A materials may not be transported in a Cart or BOP.

Regulated Medical Waste

(v) Division 6.1 toxic waste or Class 7 radioactive waste, with the exception of chemotherapeutic waste, may not be transported in a Cart or BOP.

(vi) Division 6.1 or Class 7 chemotherapeutic waste; untreated concentrated stock cultures of infectious substances containing Category B infectious substances; unabsorbed liquids; and sharps containers may be transported in a Cart or BOP only if packaged in rigid non-bulk packagings conforming to paragraph (a) of this section.

(2) Wheeled cart (Cart). A Cart is authorized as an outer packaging for the transportation of regulated medical waste if it conforms to the following requirements:

(i) Each Cart must consist of a solid, one-piece body with a nominal volume not exceeding 1,655 L (437 gallons).

(ii) Each Cart must be constructed of metal, rigid plastic, or

Chemotherapeutic Waste

fiberglass fitted with a lid to prevent leakage during transport.

(iii) Each Cart must be capable of meeting the requirements of Sec. 178.810 (drop test) at the Packing Group II performance level.

(iv) Inner packagings must be placed into a Cart and restrained in such a manner as to minimize the risk of breakage.

...

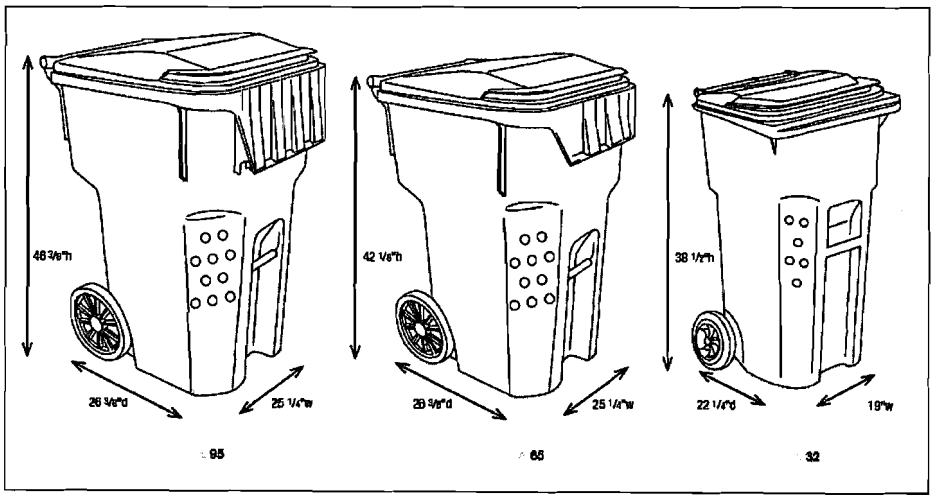
(3) Sharps. Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container must be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer. Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in Part 178, subpart M, of this subchapter at the Packing Group II performance level. A sharps container may be reused only if it conforms to the following criteria:

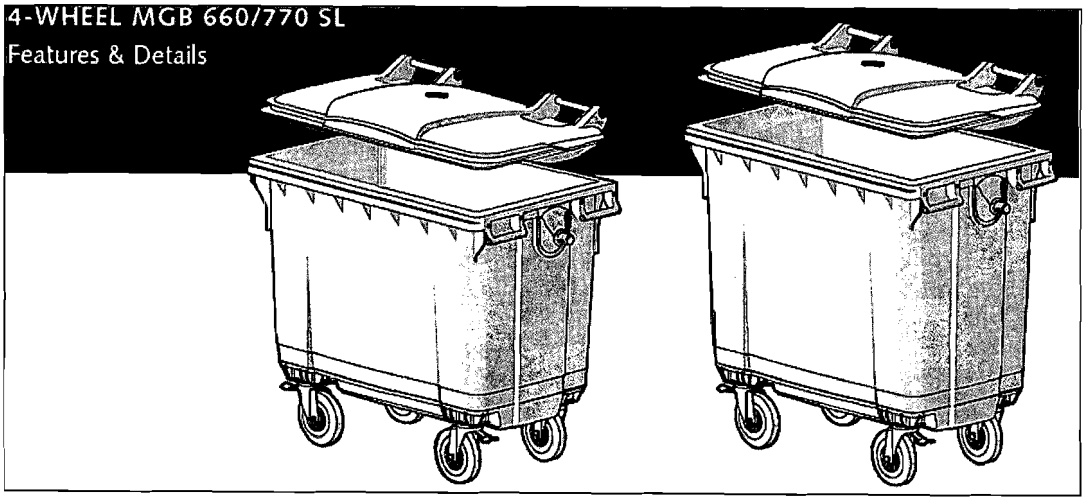
(i) The sharps container is specifically approved and certified by the U.S. Food and Drug Administration as a medical device for reuse.

(ii) The sharps container must be permanently marked for reuse.

(iii) The sharps container must be disinfected prior to reuse by any means effective for the infectious substance the container previously contained.

Sharps





Thank you for your assistance, clarification and answers to these questions,