



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

MAR 24 2008

Mr. Lane Arbittier
Director, Quality Assurance and Regulatory Affairs
BD Medical - Medical Surgical Systems
4665 North Avenue
Oceanside, CA 92056

Reference No. 08-0035

Dear Mr. Arbittier:

This is in response to your January 14, 2008 e-mail asking how hospitals may properly package drugs, chemicals (including those contained in vials, syringes, intravenous tubing, and intravenous bags), and infectious substance wastes in one package and transport them for disposal under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if hospitals may combine these materials in one "super" package at the Packing Group I level without having to comply with the HMR's segregation requirements, what design features this package should have, and what materials may and may not be combined.

Under the HMR, shippers may combine hazardous materials with other hazardous or non-hazardous materials in the same package provided these materials are not capable of reacting dangerously with each other or causing combustion; a dangerous evolution of heat; evolution of flammable, poisonous, or asphyxiant gases or vapors; or forming an unstable or corrosive material. See §§ 173.21(e) and 173.24(e)(4). Additional requirements regarding the interaction of different hazardous materials within one package, with their packaging materials, and within a transport vehicle are prescribed in § 173.24(b), the remaining paragraphs in §§ 173.24(e), and 173.24a(a) and (c), 173.24b, 174.81, 175.78, as well as Subpart D of Part 176, and Subpart C of Part 177.

If the materials and method a hospital wants to use, such as a super "all purpose" package to combine and ship these materials, do not conform with the existing HMR requirements, the hospital may wish to seek authorization to transport these materials under the terms of a special permit. The procedures for submitting an application for a special permit are

prescribed in § 107.105. Please note the application must contain sufficient information to demonstrate that, if a special permit is issued, a level of safety will be achieved that is equal to or greater than that required under the HMR.

I hope this satisfies your request.

Sincerely,

A handwritten signature in black ink, appearing to read 'H. Mitchell', with a long horizontal flourish extending to the right.

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

Edmonson Page 1 of 2
3173.197
Regulated Medical Waste
08-0035

Drakeford, Carolyn <PHMSA>

From: Edmonson, Eileen <PHMSA>
Sent: Wednesday, February 06, 2008 1:00 AM
To: Drakeford, Carolyn <PHMSA>
Subject: FW: Letter Concerning Packaging Requirements for Hospital Waste
Attachments: pic25329.gif

From: Lane_Arbittier@bd.com [mailto:Lane_Arbittier@bd.com]
Sent: Mon 1/14/2008 9:48 PM
To: Edmonson, Eileen <PHMSA>
Subject: Packaging Requirements for Hospital Waste

Eileen,

BD is a manufacturer of sharps containers and we periodically get requests from our customers for hospital generated hazardous waste containers. Hospitals would like to segregate waste at the source in the hospital in the most efficient and cost effective manner possible. At the same time, they want to transport the hazardous waste in containers that meet the hazardous materials transportation regulations. It might be most cost effective to utilize in-hospital containers (lower cost plastic containers) and then put these containers into different containers (metal drums?) designed for transport on the road.

Based on my somewhat limited knowledge of all EPA and DOT regulations related to storage and transport of hospital waste, it seems to me that the hospitals are supposed to be segregating each drug, chemical and infectious waste that they need to dispose. Unfortunately, it is not practical or affordable for a hospital to have a different container for each hazardous waste in every section of the hospital. Recently, hospital waste segregation has grown to be a bigger issue because hospitals have become more aware that it is unacceptable to pour many unused drugs down the drain. I've heard that some hospitals have begun using plastic containers labeled "RCRA Hazardous Waste" with a UN packing Group II code on the label and combining multiple drugs and chemicals (vials, syringes, IV tubing, IV bags) into one container. I wonder if this practice complies with the DOT regulations.

I heard from Jennifer Harris at Lion Technologies (973-383-0800) that the EPA might be thinking of establishing a practical guidance for in-hospital, temporary storage of hazardous materials. It might offer some practical alternatives to segregating each hazardous material.

I wonder if there are "super packages" that we (BD and DOT) could define for our customers. These "super packages" might allow hospitals to combine certain drugs, chemicals and infectious wastes in the same package/container. In other words, if the hospital had a container that met the Packing Group I labeling and functional test requirements, could the hospital combine certain drugs, chemicals or infectious wastes and be acceptable for transport on the road? If so, could you help me understand which drugs, chemicals and infectious wastes could be combined? Could you also help me understand what design features a DOT compliant "super package" should have, such as a water tight primary package and a secondary package?

- In summary, I would appreciate your help in offering recommendations for:
1. Combining hospital wastes into convenient groups of drugs, chemicals and infectious wastes
 2. Defining the DOT package requirements to properly transport them

The ultimate goal is to make it easier for hospital personnel to comply with the hazardous material transportation regulations.

Thanks,
Lane

(Embedded image moved to file: pic25329.gif)
Lane Arbittier
Director / Quality Assurance and Regulatory Affairs

BD Medical - Medical Surgical Systems
4665 North Avenue, Oceanside, CA 92056 USA
tel: 760-631-6520
E-mail: Lane_Arbittier@BD.com Website: www.bd.com

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Corporate Headquarters Mailing Address: BD
(Becton, Dickinson and Company) 1 Becton Drive
Franklin Lakes, NJ 07417 U.S.A.
