U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

JUN 7 2006

Mr. Terry Grimmond
Clinical Director
Daniels Sharpsmart, Inc.
3 Tarbett Road Hillcrest
Hamilton 2001, New Zealand

Reference No. 05-0182

Dear Mr. Grimmond:

This is in response to your e-mails and telephone calls with members of my staff concerning how to transport medical devices and "Regulated medical waste, 6.2 (infectious), UN 3291, PG II" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). We have paraphrased your questions, removed duplicate questions, and answered them in the order provided. For the purposes of this letter, we consider the terms "medical device" and "medical equipment" to be essentially the same. We apologize for the delay in responding and any inconvenience this may have caused.

Q1. May packages complying with the Packing Group II performance criteria under the HMR and containing contaminated medical equipment, including sharps, be imported into the United States from other countries to be cleaned and refurbished by Food and Drug Administration-approved companies? Are such devices regulated medical waste (RMW) regardless of whether or not they meet the definition of a sharp or are decontaminated before shipping? Section § 173.134(b)(7) refers to medical equipment being shipped for "cleaning or refurbishment" as being excepted from regulation and not classified as regulated medical waste. Is this correct?

A1. In accordance with § 173.134(b)(7), medical equipment, excluding that transported for disposal, that is known or suspected of being contaminated with a Division 6.2 material and is intended for use, cleaning, or refurbishment where the components of the equipment essentially function as a packaging, is excepted from the HMR provided the equipment conforms to the Occupational Safety and Health Administration's (OSHA's) bloodborne pathogen requirements prescribed in 29 CFR 1910.1030. Medical equipment known or suspected of containing a Division 6.2 material that does not conform to the requirements in 29 CFR 1910.1030 must be transported in accordance with the HMR requirements applicable to the transportation of RMW. Medical equipment that previously contained an infectious substance that has been decontaminated is not subject to the HMR.

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173.134(b)(7)

Q2. If contaminated medical equipment is not subject to the HMR's Division 6.2. requirements, is it subject to any other requirements under the HMR for packaging, transport, or labeling?

A2. Medical equipment transported in commerce that contains a material meeting the definition of any hazard class under the HMR is subject to the applicable requirements contained within the HMR for that hazard class.

Q3. May any state within the United States impose transportation requirements for medical equipment that are more stringent than those in the HMR?

A3. Generally, the answer is no. In accordance with the Federal hazardous materials transportation law (Federal hazmat law; 49 U.S.C. 5101 *et seq.*), a requirement of a state, local, or tribal government is preempted, unless otherwise authorized by another Federal statute or DOT issues a waiver of preemption, under the conditions specified in § 171.1(f) of the HMR. Note, however, that PHMSA makes preemption determinations applicable to specific non-Federal requirements on a case-by-case basis.

Q4. If blood-stained medical equipment is imported into the United States for cleaning and refurbishment and meets FDA and OSHA requirements, is it excepted from complying with the HMR for Division 6.2 materials?

A4. See A1 above.

Q5. What other United States agencies regulate imported medical waste devices?

A5. Imported medical equipment may be subject to regulations issued by the U.S. Postal Service; the Department of Health and Human Services' Centers for Disease Control and Prevention, and Food and Drug Administration; the Department of Labor's Occupational Safety and Health Administration; the U.S. Department of Homeland Security' Transportation Security Administration and U.S. Coast Guard; or the U.S. Department of Agriculture's Animal Plant and Health Inspection Service. You may wish to contact those agencies directly.

Q6. May a state enact regulations reclassifying non-infectious medical equipment as RMW making these items subject to the HMR?

A6. No. See A3 above.

Q7. Is it correct that medical equipment transported for reprocessing is not subject to the requirements for used health care products in § 173.199 because medical equipment is excepted from regulation under § 173.134(b)(7) of the HMR?

A7. Yes. Note that the requirements for used health care products in § 173.199 apply to products being returned to the manufacturer or the manufacturer's designee.

Q8. Is it correct that medical equipment cleaned prior to shipment for refurbishment may be transported both internationally and domestically as general goods not subject to OSHA requirements, including those for puncture resistance, leakproofness, or BIOHAZARD labeling?

A8. Medical equipment cleaned to the point that it no longer meets the definition of a HMR hazard class not subject to regulation under the HMR. To learn whether or not cleaned medical equipment would be subject to OSHA requirements, you may wish to contact OSHA directly at: U.S. Department of Labor, Occupational Safety & Health Administration, Safety Standards Division, 200 Constitution Avenue, Washington, D.C. 20210, (202) 693-2222.

I hope this information is helpful.

Sincerely,

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

Edmonson
§173.134(b)(7)
Regulated Medical Waste
Exceptions
05-0182

Edmonson, Eileen <PHMSA>

From: Terry Grimmond [TGrimmond@danielsinternational.com]
Sent: Tuesday, August 02, 2005 7:14 AM
To: Edmonson, Eileen <PHMSA>
Subject: RE: Shipping RMW to USA

Hi Eileen,
Thanks for confirmation that RMW coming into US comes under DOT jurisdiction.

My specific Q is: *Can containers (PG2 compliant) of non-decontaminated medical devices, which may include "sharps", be received in US from other countries so as to be cleaned and refurbished by FDA-approved companies?*

In US, expensive, disposable Medical Equipment/Devices are sent back to mfg or third party for reprocessing and resale. This is a rapidly growing industry in US.

Somewhere, I thought I saw such devices were NOT classed as RMW irrespective of whether they were sharp, and irrespective of whether they were decontaminated before shipping. Can you advise DOT's regulations on this?

Para 173.134 (b) (7) refers to medical equipment being shipped for "..cleaning or refurbishment" as being an exception and not classified as RMW - do I read this correctly?

Kind regards,

Terry

From: Edmonson, Eileen <RSPA> [mailto:eileen.edmonson@RSPA.dot.gov]
Sent: Friday, 11 February 2005 9:39 AM
To: Terry Grimmond
Cc: Gorsky, Susan <RSPA>
Subject: RE: Shipping RMW between counties

Hi Terry,

The answer is yes to both questions when RMW is being transported in commerce in, through, or intended for transportation to the United States or one of its territories. See § 171.1(a) of 49 CFR Parts 171-180, and 49 U.S.C. 5101 et seq.

Eileen Edmonson
Transportation Regulations Specialist
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-----Original Message-----
From: Terry Grimmond [mailto:terry.grimmond@sharpsmart.com]
Sent: Monday, February 07, 2005 11:42 PM
To: Edmonson, Eileen <RSPA>
Subject: Shipping RMW between counties

Hi Eileen,

Does DOT have jurisdiction over:

- RMW shipped to USA from other countries - eg Canada, UK, Europe?
- RMW generated in USA but shipped to other countries - eg Canada, UK, Europe?

Kind regards,

Terry