U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

September 18, 2019

Lawrence W. Bierlein
Attorney at Law
1101 30th Street NW
Suite 500
Washington, DC 20007

Reference No. 19-0014

Dear Mr. Bierlein:

This letter is in response to your February 11, 2019, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to medical devices. Specifically, you ask whether an offeror can utilize the exception provided in § 173.134(b)(12)(i) for used medical devices shipped for refurbishment when some of the devices may be "rejected" as determined by the consignee's facility and then disposed of.

The exception provided in § 173.134(b)(12)(i) is for laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030 and includes medical equipment intended for use, design, and refurbishment. This exception does not apply to medical equipment being transported for disposal. Once an offeror determines the laundry or medical equipment is not capable of being cleaned or refurbished and is to be disposed of, the provision in § 173.134(b)(12)(i) cannot be utilized. Therefore, an offeror cannot knowingly ship hazardous material meant for disposal under the provision in § 173.134(b)(12)(i). Please note that no person may offer or accept a hazardous material for transportation in commerce unless the hazardous material is properly classed, described, packaged, marked, labeled, and in condition for shipment.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

T. Glenn Foster

T. Glenn Foster
Chief, Regulatory Review and Reinvention
Standards and Rulemaking Division

Ballengee
§173.134(b)12
19-0054

Dodd, Alice (PHMSA)

From: Kelley, Shane (PHMSA)
Sent: Monday, February 11, 2019 11:45 AM
To: Hazmat Interps; January, Ikeya CTR (PHMSA); Dodd, Alice (PHMSA)
Cc: Foster, Glenn (PHMSA); DerKinderen, Dirk (PHMSA); Nickels, Matthew (PHMSA)
Subject: Fwd: Request for interpretation of Sec 173.134(b)(12)
Attachments: Sterilmed request for interpretation.docx

Please log for response. Thank you

From: larry hazmat-lawyer.com <larry@hazmat-lawyer.com>
Sent: Monday, February 11, 2019 11:26 AM
To: Kelley, Shane (PHMSA)
Subject: Request for interpretation of Sec 173.134(b)(12)

Shane, please see the attached request for an interpretation to enable Sterilmed to continue shipping certain medical devices. Please let me know if you have any questions on this request, or if I should provide more information. Thank you.

Larry Bierlein, (202) 631-3222

LAWRENCE W. BIERLEIN
ATTORNEY AT LAW

February 11, 2019

Mr. Shane Kelley, Director
PHMSA Standards & Rulemaking, PHH-10
U.S. Department of Transportation
Washington, DC 20590

Re: Request for interpretation of 49 CFR 173.134(b)(12)

Dear Mr. Kelley:

My client Sterilmed, Inc., is a subsidiary of Johnson & Johnson engaged in refurbishing single-use medical devices. The company is authorized by the Food & Drug Administration to refurbish used devices and to market those devices back to hospitals. Devices used in surgery are collected in a Sterilmed program conforming to the Occupational Safety & Health Administration bloodborne pathogen standard in 29 CFR 1910.1030. This OSHA standard prescribes requirements for employee training and the packaging, marking, labeling, and handling of articles that may be contaminated.

Used devices collected from hospitals in the U.S. and Canada are sorted, inspected, cleaned and refurbished to the specifications of the original equipment manufacturer. Devices tested and determined by Sterilmed to meet these specifications are returned to hospitals for additional use, resulting in cost savings to the hospitals. These processes result in the rejection of certain devices as no longer being equivalent to new devices. Some rejected devices are those that Sterilmed is not capable of refurbishing, but the significant majority of rejected devices are ones no longer capable of being refurbished to be equivalent to new devices.

At the time of shipment of used devices to the Sterilmed facility, no one knows which of them ultimately may be discarded as medical waste, although it is known that a percentage of the devices will be discarded. The waste determination is made by trained and qualified professionals at the Sterilmed facility after the sorting, inspection, and evaluation of each device.

An exception from certain DOT regulations in 49 CFR 173.134(b)(12)(i) describes "Laundry or medical equipment" conforming to the OSHA bloodborne pathogen standard. This paragraph includes medical devices for use, cleaning, or refurbishment. A sentence in this subparagraph reads: "This exception does not apply to medical equipment being transported for disposal."

Please advise whether this quoted sentence precludes use of this exception for used medical devices being transported for refurbishment, recognizing that the process will result eventually in some of them being discarded. Thank you.

Sincerely,

Lawrence W. Bierlein

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