



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

JAN 02 2020

Kelly V. Camp, CHMM, CPEA
Senior Project Manager
Woodard & Curran, Inc.
33 Broad Street
Floor 7
Providence, RI 02903

Reference No. 19-0106

Dear Ms. Camp:

This letter is in response to your August 16, 2019, letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to hazard communication requirements for regulated medical waste. Specifically, you provide a variety of scenarios regarding shipments of regulated medical waste.


We have paraphrased and answered your questions as follows:

- Q1. You ask whether a package of regulated medical waste marked with a "BIOHAZARD" marking in black ink on the package with no orange or orange-red background complies with § 173.134(c)(1)(i).
- A1. The answer is no, if the "BIOHAZARD" marking does not conform with 29 CFR 1910.1030. In accordance with § 173.134(c)(1)(i), a package of regulated medical waste transported by private or contract carrier is excepted from the "INFECTIOUS SUBSTANCE" label if the outer packaging is marked with a "BIOHAZARD" marking in accordance with 29 CFR 1910.1030. As noted in your request, 29 CFR 1910.1030(g)(1)(i)(C) specifies "[t]hese labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in contrasting color." You may wish to contact the Occupational Safety and Health Standards (OSHA) for clarification on whether your scenario meets the requirements of 29 CFR 1910.1030(g)(1)(i)(C). If the "BIOHAZARD" marking does not conform to 29 CFR 1910.1030, the package must display the § 172.432 infectious substances label.
- Q2. You ask whether regulated medical waste placed in red bags that are further placed inside an outer package meets the exception of 29 CFR 1910.1030(g)(1)(i)(E).
- A2. See A1. You may wish to contact OSHA for clarification on whether your scenario meets the requirements of 29 CFR 1910.1030(g)(1)(i)(E).

- Q3. You ask whether closure instructions are required for a package of regulated medical waste offered in accordance with the exceptions in § 173.134(c).
- A3. The answer is no. In accordance with § 178.2, closure instructions are required for DOT Specification or UN standard packaging. Both §§ 173.134(c)(1) and (2) provide exceptions for regulated medical waste, including packaging regulated medical waste in rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and the packaging requirements specified in 29 CFR 1910.1030. Therefore, when meeting these requirements, as well as the additional requirements in §§ 173.134(c)(1) or (2), the regulated medical waste is not subject to DOT Specification or UN standard packaging requirements, and thus is not required to have closure instructions.
- Q4. You provide photos of packaging for regulated medical waste and ask whether the marking “UN 3291 N.O.S. 6.2, PG II” complies with § 172.301(a).
- A4. The answer is no. As mentioned in your request, § 172.301(a) requires that except as otherwise provided by the subchapter, non-bulk packaging must be marked with the proper shipping name and identification number (preceded by “UN”, “NA”, or “ID”, as appropriate) of the hazardous material(s) being offered for transportation. As listed in the § 172.101 Hazardous Materials Table, the proper shipping name for UN3291 is “Regulated medical waste, n.o.s. *or* Clinical waste, unspecified, n.o.s. *or* (BIO) Medical waste, n.o.s., *or* Biomedical waste, n.o.s. *or* Medical waste, n.o.s”. As defined in § 171.8, “N.O.S.” means “not otherwise specified,” and is not an appropriate proper shipping name for UN3291 or any hazardous material. Therefore, the marking on the packaging pictured in your request does not meet the requirement of § 172.301(a) to mark the non-bulk package with the proper shipping name of the material being offered for transportation.

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

Sincerely,



Dirk Der Kinderen
Chief, Standards Development Branch
Standards and Rulemaking Division

Meller

19-0106

Dodd, Alice (PHMSA)

From: INFOCNTR (PHMSA)
Sent: Friday, August 16, 2019 4:34 PM
To: Hazmat Interps
Subject: FW: Questions on Marking and Labeling for Regulated Medical Waste
Attachments: 2019.08.16 DOT Letter.pdf

Hi Alice and Ikeya,

Please see the letter of interpretation request below.

Thanks,
Kathryn, HMIC

From: Kelly Camp [mailto:kcamp@woodardcurran.com]
Sent: Friday, August 16, 2019 3:58 PM
To: PHMSA HM InfoCenter <PHMSAHMInfoCenter@dot.gov>
Subject: Questions on Marking and Labeling for Regulated Medical Waste

Please see the attached letter for questions on the DOT regulations. We look forward to your reply.

Kelly

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COMMITMENT & INTEGRITY DRIVE RESULTS

Via Electronic Mail

August 16, 2019

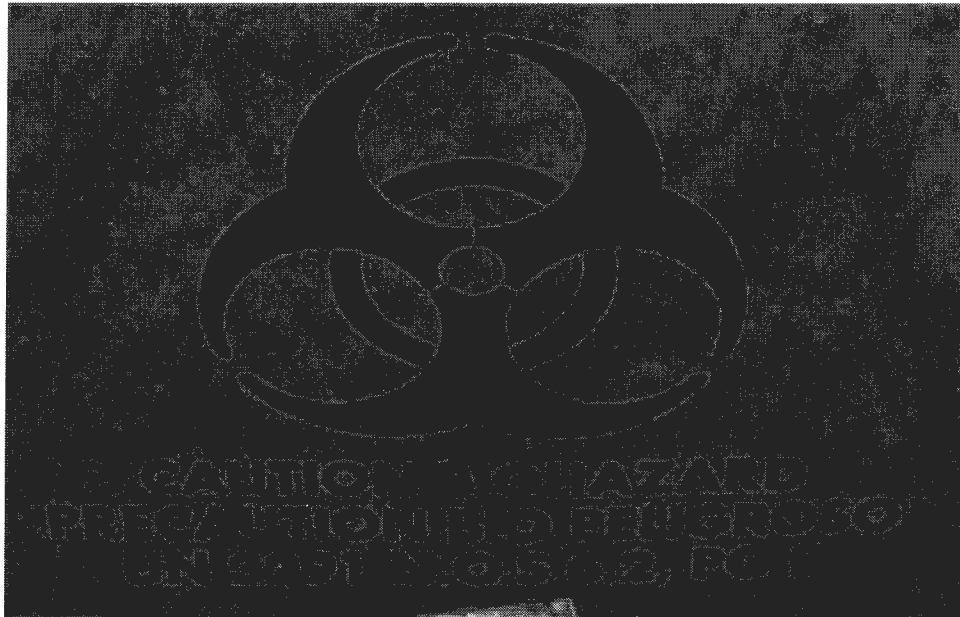


Mr. Shane Kelley
Director, Standards and Rulemaking Division
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

Dear Mr. Kelley:

I work for a consulting company. One of our clients was recently provided with packages for shipping regulated medical waste. These questions apply to these packages and the marking and labels printed on them.

1. 49 C.F.R. §173.134(c)(1)(i) states that a regulated medical waste transported by a private or contract carrier is excepted from the requirement for an "INFECTIOUS SUBSTANCE" label if the outer packaging is marked with a "BIOHAZARD" marking in accordance with 29 C.F.R. §1910.1030. 29 C.F.R. §1910.1030(g)(1)(i)(C) states that these labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color. To comply with 49 C.F.R. §173.134(c)(1)(i), does a box marked with a BIOHAZARD mark in black ink on the box with no orange or orange-red background comply? A picture of the marking is below.



2. Related to the above, 29 C.F.R. §1910.1030(g)(1)(i)(E) states that red bags or red containers may be substituted for labels. Although red bags are used inside the boxes, since they are not visible at the time of shipment, it would seem that the biohazard marking must be present. Please confirm.
3. 49 C.F.R. §173.22(a)(4) requires that for a DOT Specification or UN standard packaging subject to the requirements of 49 C.F.R. part 178, a person must perform all functions necessary to bring the package into compliance with 49 C.F.R. parts 173 and 178, as identified by the packaging



manufacturer or subsequent distributor and that for other than a bulk package or a cylinder, a person must retain a copy of the manufacturer's notification, including closure instructions. If regulated medical waste is shipped under the exceptions in 49 C.F.R. §173.134(c), please confirm that no instructions are required to be provided by the packaging manufacturer or retained by the shipper.

4. 49 C.F.R. 173.301(a) requires that, except as otherwise provided by the DOT regulations, each person who offers a hazardous material for transportation in a non-bulk packaging must mark the package with the proper shipping name and identification number (preceded by "UN", "NA" or "ID," as appropriate). For regulated medical waste, packaging is provided by the regulated medical waste disposal company and it is marked as shown in the pictures below of all four sides. Information identifying the company that supplied the boxes has been blocked. The only other information added is a label that includes the generator name, address, and phone; transporter name, address, and phone; and a bar code for tracking the package. Does this marking comply with DOT's marking requirements?

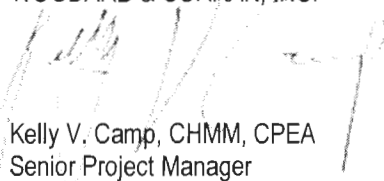




Please contact me at 401.427.1322 or kcamp@woodardcurran.com if you need additional information. We look forward to your prompt reply so that we can ensure compliance with DOT regulations. Thank you.

Sincerely,

WOODARD & CURRAN, INC.



Kelly V. Camp, CHMM, CPEA
Senior Project Manager

KVC/dam

PN: 0225138.03