



U.S. Department of Transportation
**Pipeline and Hazardous Materials
Safety Administration**

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

JAN 30 2011

Kristi Henderson, DVM
Assistant Director, Scientific Activities
American Veterinary Medical Association
1931 North Meacham Road, Suite 100
Schamburg, IL 60173

Reference No. 10-0188

Dear Dr. Henderson:

This is in response to your e-mail requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to training requirements. Specifically, you request guidance on what type of hazardous materials (hazmat) training and documentation is required to ship veterinary medical samples. You also ask if the statements posted on your website pertaining to this subject are correct, or need to be revised or supplemented. We have paraphrased your statements and responded in the order you provided.

Q1: Is specific formal hazmat training and documentation of this training required for all staff, including veterinarians, who package and/or transport Category A, Division 6.2 (infectious) materials?

A1: The staff and veterinarians who package and transport Category A infectious substances are required to have hazmat training. These requirements are prescribed in 49 CFR Part 172, Subparts H (training) and I (security) of the HMR, and apply to all hazmat employers, including those who are self employed, and hazmat employees who transport hazardous materials in commerce. See § 171.1(c) for the "transportation functions" description and § 171.8 for the definitions of "hazmat employer," "hazmat employee," and "hazardous material." A hazmat employer must ensure that each of its hazmat employees has been trained and tested, and create and retain a record of their current training as specified in §§ 172.702 and 172.704(d). Hazmat employees must be retrained at least every three years. The HMR are available at "www.ecfr.gov" under Title 49, Parts 100-180, or through the regulations portion of our web site at "<http://hazmat.dot.gov>."

The standard hazmat training requirements of the HMR consist of five parts: (1) general awareness; (2) function-specific; (3) safety; (4) security awareness training; and, when transporting certain high hazard materials such as select agents, 5) in-depth security training (see § 172.704(a)). Additional training requirements or exceptions to this training are prescribed throughout the HMR based on the risks a hazardous material poses in transportation and other safety factors, such as its packaging, employee knowledge of the

material, or operational effects on a material or packaging that may occur in a specific mode of transportation.

On October 1, 2010, the Pipeline and Hazardous Materials Safety Administration (PHMSA) revised the requirements for in-depth security training (see Docket Nos. PHMSA-06-25885 (HM-232F; 75 FR 10974) and PHMSA-2010-0195 (HM-244C; 75 FR 53593). These changes include requiring that in-depth training contain information on organizational security structure; specific security responsibilities for each employee; specific actions to be taken by each employee if a security breach occurs; and expanded the list of materials that require a security plan. They also include requiring that the plan contains an assessment of the site and location-specific risks at the facilities where these materials are being prepared, stored, or unloaded in transportation. Further, they expand the information that must be included in the plan, require it to be reviewed annually, and require that all employees responsible for implementing the plan be notified when the plan is updated or revised. See §§ 172.704(a)(5), 172.800(b), and 172.802. If this in-depth security plan is revised within the three-year recurrent training period, hazmat employees must receive training on the revised plan within 90 days of its implementation (see § 172.704(c)(2)).

- Q2: Is informal hazmat training and documentation of this training required for all staff, including veterinarians, who package and/or transport Category B, Division 6.2 (infectious) materials?
- A2: A "UN 3373, Biological substance, Category B" infectious substance must be transported in conformance with the requirements prescribed in §§ 173.134 or 173.199 of the HMR. A Category B infectious substance that meets the exceptions prescribed in § 173.134(b), such as patient samples transported for research, or human or animal samples transported for routine testing, is excepted from all other requirements of the HMR, including those for hazmat training, provided the package conforms with the conditions required for the material in § 173.134(b). A hazmat employee that offers or transports a waste culture or stock of a Category B infectious substance as a "UN 3291, Regulated medical waste, n.o.s., 6.2, PG II" in the manner prescribed in § 173.134(c)(2) must be hazmat trained. Category B infectious substances packaged in conformance with § 173.199 need only be trained on, and comply with, the requirements in that section (see § 173.199(e)).
- Q3: Most clinics package and transport Category B infectious substances on a routine basis. If individuals who package these materials have not had the required training, is it imperative that they receive this training immediately and that this training is documented? Will clinics shipping Category A infectious substances need to have responsible staff formally trained on transporting these materials?
- A3: Unless otherwise excepted, individuals who perform pre-transportation and transportation functions for Category A or B infectious substances for transportation in commerce are hazmat employees and must be hazmat trained before performing these tasks. A record must be made of this training, as described in Answers A1 and A2. Hazmat employees performing these tasks without this training may be in violation of the HMR. Enforcement procedures and civil penalty guidelines for violations of the HMR are prescribed in 49 CFR

Part 107, Subpart D. However, the HMR permit a new employee to perform regulated functions and activities prior to the completion of training provided the employee performs the functions under the direct supervision of a properly trained and knowledgeable hazmat employee, and the new employee's training is completed within 90 consecutive days from the first time they perform a regulated function. See § 171.1(b) and (c), and § 172.704(c)(1). "Direct supervision" consists of the supervising employee instructing the new employee how to properly perform the hazmat function, observing the employee's performance of the function, and being able to take corrective action with regard to any function not performed in conformance with the HMR.

Q4: Is each clinic responsible for maintaining the hazmat training record of its employees for at least three years for each employee it has trained to package these materials?

A4: Each hazmat employer must create and retain a record of current hazmat training, inclusive of the preceding three years, for each hazmat employee for as long as that employee works for that employer, and for 90 days after the employee stops working for that employer, as specified in § 172.704(d). However, the HMR do not specify the location of the training documents, provided they are retained by the hazmat employer. Therefore, they may be retained at an individual clinic or at a clinic's parent company headquarters. Wherever they are retained, under 49 U.S.C. § 5121(b)(2), a hazmat employer must make the required training documentation specified in § 172.704(d)(1) through (d)(5) available for inspection to a designated officer, employee, or agent of the Secretary of Transportation when the Secretary or his authorized representative conducts an investigation or makes a request. In addition, a hazmat employer must make the security plan prescribed in 49 CFR Part 172, Subpart I, available upon request to an authorized official of the Department of Transportation or the Department of Homeland Security (see § 172.802(d)).

Q5: Must hazmat training records be made available to the proper regulatory authorities upon request?

A5: See A4.

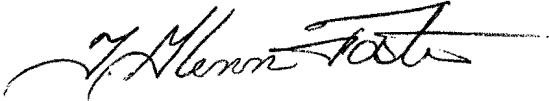
Q6: Does the PHMSA publication "What You Should Know: a Guide to Developing a Hazardous Materials Training Program" provide valuable information and resources, including sample training records?

A6: PHMSA's Hazardous Materials Training Program guidance document explains the training requirements in the HMR, identifies those employees who must be trained, and provides several tools, including a sample employee training record, to help hazmat employers develop and implement an effective training program for their employees. If you have not already done so, you may also want to consult our publications entitled 1) "Transporting Infectious Substances Safely," 2) "Enhanced Security Requirements (however, the list of materials that require this training has changed – see Answer A1)," and 3) "Does Your Hazmat Training Measure Up?" In addition, you may also find our interactive compact disks (CDs), entitled "Hazmat General Awareness/Familiarization Training," and "Hazmat Transportation Security Awareness Training Module Revised," helpful. These publications

may be downloaded from our website or ordered, along with the CDs, at [“https://hazmatonline.phmsa.dot.gov/services/”](https://hazmatonline.phmsa.dot.gov/services/) under the link for “Training Materials and Publications.” However, please note these materials must not be used as a substitute for the requirements prescribed in the HMR.

I hope this satisfies your request.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Glenn Foster". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

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

Drakeford, Carolyn (PHMSA)

From: Betts, Charles (PHMSA)
Sent: Friday, September 03, 2010 1:46 PM
To: Drakeford, Carolyn (PHMSA)
Cc: Simon, Candace (PHMSA); Foster, Glenn (PHMSA)
Subject: FW: Questions about training -- infectious substances Cat. A & B

Edmonson

§ 173.134

§ 173.196

§ 173.199

Infectious Substances

10-0188

From: Dr. Kristi Henderson [mailto:KHenderson@avma.org]
Sent: Tuesday, August 17, 2010 12:34 PM
To: training (PHMSA)
Subject: Questions about training -- infectious substances Cat. A & B

My name is Dr. Kristi Henderson, and I am one of the veterinarians on staff with the American Veterinary Medical Association (AVMA) working with various topics, including those related to packaging and shipping of veterinary medical samples. The AVMA and its membership need guidance on the type of training and documentation of such required for veterinary practices / clinics / hospitals sending samples that fall within Category A or Category B infectious substances because we have had questions from our membership about them.

The following is some of the information that we have recently compiled on our website at http://www.avma.org/issues/pack_ship_lab_specimens.asp pertaining to specimen shipping. Can you tell me if the following bullet points are correct, or if DOT recommends any edits, corrections, or additions? Other thoughts??

- **Category A:** Specific **formal** training and documentation of it is required for all staff (including veterinarians) who package or transport items in this category.
- **Category B:** Training and documentation of it is required for all staff (including veterinarians) who package or transport items in this category; however, the training may be **informal** and in-house.
- Most clinics package and ship Category B items on a routine basis. If the individuals who package these items have not had the required training, it is imperative that they receive it immediately and that the training is documented. Any clinics shipping Category A items will need to have the responsible staff formally trained on the subject.
- Each clinic is responsible for maintaining the training record for at least 3 years for each employee trained to package these substances.
- Training records must be made available to the proper regulatory authorities upon request.
- The DOT / PHMSA website and publication, *What You Should Know: a Guide to Developing a Hazardous Materials Training Program*, provides valuable information and resources including sample training records.

Any guidance you can provide regarding this will be greatly appreciated.

Sincerely,

Kristi Henderson, DVM

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