U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

1200 New Jersey Ave., SE
Washington, DC 20590

JUL 0 8 2009

Mr. David Vulcano
Chair, ACRP Board of Trustees
Association of Clinical Research Professionals
500 Montgomery Street, Suite 800
Alexandria, VA 22314

Reference No. 09-0011

Dear Mr. Vulcano:

This is in response to your January 7, 2009 letter concerning the training requirements for hazmat employees who prepare and package only Category B infectious substances (Division 6.2) in conformance with § 173.199 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You ask if the HMR excepts these employees from all other training requirements under the HMR if they are trained to carry out the provisions of this section.

The answer is yes. Employees trained to know and carry out the requirements prescribed in § 173.199 for Category B infectious substances are excepted from all other training requirements under the HMR when preparing and offering these materials for transportation in commerce. See § 173.199(a) and (e).

You also ask if the learning objectives and methods your association is considering (i.e., a paper-based self-training module, a post test, recurring 3-year training, and a record keeping system) to satisfy the training requirements in § 173.199 are sufficient and/or correct. It is the opinion of this Office that the training scenario you present is sufficient as long as all of the provisions of §173.199 are covered. Section 173.199 stipulates that persons who offer and transport these packages in commerce must be knowledgeable about the requirements of this section. See § 173.199(e).

I hope this information satisfies your request.

Sincerely,

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

ACRP
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS
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Infectious Substances
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January 7, 2009

U.S. Department of Transportation
PHMSA Office of Hazardous Materials Standards
Attn: PHH–10
East Building
1200 New Jersey Avenue, SE
Washington, DC 20590–0001

RE: Request for Guidance or Interpretation on 49CFR173.199 (Category B Infectious Substances)

Dear Reviewer:

The Association of Clinical Research Professionals (ACRP) is a professional association of over 20,000 members, most within the United States. A very large percent of our member's activity involves clinical trials that draw lab specimens for diagnostic purposes that fit in the definition of Category B Infectious Substance. As many of these studies are multi-center studies, it is not uncommon for our members to be asked to ship lab specimens to a "central lab" that is contracted by the sponsor of a particular clinical trial. The usual course of action is to draw the specimen and ship (with or without Dry Ice) via commercial couriers such as FedEx, UPS etc. As regulations for Category B specimens have seen several drastic changes over the past 7 years, there remains a tremendous amount of myth and opinions surrounding the training requirements to perform this task.

Years ago when these was no "Category B" or "Diagnostic Specimen" designation in the HMT, people went through great expense to receive full hazmat training as required by 49CFR172.700 to ship any biological specimen. Through a series of events, pharmaceutical companies and other clinical trial sponsors gained a heightened awareness and required assurance that their research site's staff "certification". Although the laws have changed since then, there are still legacy interpretations and checklists out there as well as sales pressure from for-profit education providers to pursue full hazmat training for hazmat "certification". Many of our members do not believe that this is necessary and I seek your clarifications so that we may foster a more uniform approach to this issue, in full compliance with the law. The prevailing interpretation and proposed training is described in the subsequent paragraphs. I have contacted HazMat helpline several times since 49CFR173.199 was rewritten and

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received agreement with the below interpretation. As our industry always appreciates when the FDA puts their guidance in writing, it was suggested that I send this request to you so that I may have a formal, written interpretation.

49CFR172.700 describes the training that a "HazMat" employee must undergo prior to undertaking their duties. The regulation states that the employee must be "trained" [.702(a)] and "tested" [.702(d)] on the specific requirements (as listed in .704) pertaining to hazardous materials. There are also requirements set forth regarding recordkeeping of such training, specifically .704(d)(5) stating "Certification that the hazmat employee has been trained and tested, as required by this subpart". Finally, the regulations state that the employee should receive training every 3 years [.704(c)(2)].

While such intense training is required for a person handling Category A Infectious Substances, we read in the regulations pertaining to Category B Infections Substances [49CFR173.199(a)] that "Category B infectious substances are excepted from all other requirements of this subchapter when offered for transportation or transported in accordance with this section". We interpret this as meaning that the requirements of 49CFR172.700 do not apply when an individual shipping Category B Infectious Substances is trained under .199(e), which only requires that "Each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section". Given that, we interpret this as an individual who only packages Category B Infectious Substances for shipment does not need the full "certification" that the hazmat employees shipping Category A substances require but, instead, needs to demonstrate awareness of the content of 49CFR173.199. Assuming our prevailing interpretation is correct (that full hazmat training as required by 49CFR172.700 is not required for those only shipping Category B Infectious Substances that meet the training requirement of 49CFR173.199(e)), we request an opinion on if a paper-based self-training module that had the following learning objectives would be sufficient to meet the requirements of 49CFR199(e).

1) The trainee shall be able to differentiate between Category A and Category B Infectious Substances.
2) The trainee will demonstrate knowledge that the subsequent training is only adequate for the packaging and shipping of Category B Infectious Substances and that should they desire to pack or ship Category A Infectious Substances, they require additional training outside the scope of the module.
3) The trainee will recall the requirements of 49CFR199(a)-(d).
4) The trainee will recall the requirements of 49CFR173.217 (for dry ice).

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We also have 3 other considerations we would like comments on, assuming our interpretation is correct.

1) Although not required to be tested (as in 49CFR172.702(d)), we believe that a post-test would be a good suggestion to our members to develop in conjunction with the training module.
2) Although employees are not required to receive recurring training (as in 49CFR172.704(c)(2)), we believe that our members should embrace the need for recurring training in this area at the same three year interval by policy.
3) Although recordkeeping is not required by 49CFR199(e), we believe that a recordkeeping system should be suggested to our members in the form of maintaining the names of the employees trained and their dates of training. This may be accomplished by maintaining for each employee a copy of the training module attached to the dated and signed posttest (if applicable).

On behalf of over 20,000 clinical research professionals in the United States who want to do the right thing, I thank you for your attention to this matter so that we may protect the safety of others through the compliant transport of Category B Infectious Substances while we pursue medical advances.

Looking forward,

David Vulcano
Chair, ACRP Board of Trustees
Daytime Phone Number: (615) 268-2638