

Required Training for Packaging and Shipping Lab Specimens

Since 1969, the AVMA has had the policy titled "Shipment of Diagnostic Specimens" (<http://www.avma.org/KB/Policies/Pages/Shipment-of-Diagnostic-Specimens.aspx>). This policy states that laboratory specimens properly "*packaged to prevent leakage or breaks in the containers*" pose "*no health hazard or sanitation problem.*" This is true because once specimens are packaged correctly neither the package handlers nor the environment will be exposed to the specimen. Additionally, the policy states that veterinarians are "*to review their methods of preparing diagnostic specimens and ensure that they are in compliance with all applicable guidelines and federal and state laws,*" which includes required training.

Incorrect packaging of infectious substances can quickly land a veterinary practice in hot water. Veterinary practices send specimens to diagnostic labs on a daily basis, and it is vital to ensure that the staff (including veterinarians) who package the items have had the required documented training and that each shipment meets current packaging standards. Any items found to fall below these standards may result in the shipper being visited by the Federal Aviation Administration (FAA) or the U. S. Department of Transportation (DOT). Fines associated with noncompliance of packaging or training can be substantial.

According to our resources, requirements associated with packaging infectious substances were last updated in 2006 when the U. S. standards became harmonized with international United Nations (UN) standards. The DOT Pipeline and Hazardous Materials Safety Administration (PHMSA) has published two documents which are designed to help shippers understand their responsibilities which when followed will provide safety for all involved in the transport of these substances. The publication titled [Transporting Infectious Substances Safely](#) is the DOT / PHMSA guide for shippers regarding these [regulatory changes](#), including the establishment of a classification system for infectious substances (categories A and B). In 2009, DOT / PHMSA released [What You Should Know: a Guide to Developing a Hazardous Materials Training Program](#), which explains the training requirements.

Quick Overview of What You Need To Know

1. The classification of the sample being shipped determines the packaging and training requirements which are applicable.

- **Category A:** "*An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.*" [49CFR § 173.134 Class 6, Division 6.2(a)(1)(i)] *
 - **Examples of Category A infectious substances are confirmed cultures of organisms such as Bacillus anthracis, Brucella abortus, Chlamydia psittaci or Eastern equine encephalitis virus.**
- **Category B:** "*An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise*

healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes."
[49CFR § 173.134 Class 6, Division 6.2(a)(1)(ii)] *

- **Examples of Category B infectious substances are samples that are suspicious for organisms such as leptospirosis or suspected but not confirmed cases of Category A infectious substances.**
- **Exempt:** 49CFR § 173.134 Class 6, Division 6.2(b) * provides multiple specific examples of materials and samples that are exemptions to the shipping regulations of Categories A and B. An exempt material is one "*that does not contain an infectious substance or that is unlikely to cause disease in humans or animals.*" This includes:
 - Samples collected for "*routine testing not related to the diagnosis of an infectious disease, such as...*" blood chemistries " ... or ... *for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.*"
 - Samples, other than Category A materials, which are transported by private or contract carrier in a motor vehicle used exclusively for these materials.
- Pages 6 – 17 of the DOT PHMSA guide, [*Transporting Infectious Substances Safely*](#), provides further discussion of the categories and very helpful diagrams of how to decide if what you are shipping is Category A, B, or exempt.

2. General packaging guidelines (not meant to be complete) for each category.

- **Category A:** Watertight primary container for the specimen, absorbent material, watertight secondary container with list of contents on the outside, United Nations (UN) rated rigid outer container with proper UN labeling.
- **Category B:** Leak proof primary container with the specimen, absorbent material and leak proof secondary packaging like a sealed plastic bag, rigid outer package with proper markings. Cushioning material should be added as needed. It is no longer appropriate to use the term "*Diagnostic Specimen*" or "*Clinical Specimen*" to label the package.
- **Exempt:** Leak-proof primary container with the specimen, absorbent material and leak-proof secondary packaging like a sealed plastic bag, rigid outer package marked "*Exempt animal specimen.*" Biohazard symbols or bags should not be used.
- In all cases, fragile primary sample packaging (tubes, slides, vials, etc.) must be wrapped or separated to prevent breakage.
- Always ask the receiving lab how best to package the sample, or if it can provide the proper packaging materials to be used. When in doubt, package it as the more stringent conditions require.
- The DOT/ PHMSA guide, [*Transporting Infectious Substances Safely*](#), provides additional packaging information on pages 27 – 34, with especially helpful diagrams on pages 28 – 31.

3. Training requirements: The law requires all involved in the packaging and shipping of infectious substances to have the proper training on a regular basis.

- **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:** Documented training is required for all staff (including veterinarians) who package or transport items in this category. Veterinarians and staff who ship waste cultures or stock of a Category B infectious substance must be hazmat trained. Otherwise those who ship Category B infectious substances such as samples for routine testing must be trained on the information and compliant packaging techniques presented in 49 CFR 173.199. Even though the training may be **informal** and in-house, it must be documented.
- 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. Remember 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, and for 90 days beyond the duration of employment.
- Training records must be made available to the proper regulatory authorities upon request.
- The DOT / PHMSA provides answers to frequently asked question on the required training on its website, [Hazmat Training](#), and in its publication, "[Does Your HazMat Training Measure Up?](#)".
- 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.

In addition to the above resources, the DOT / PHMSA Office of Hazardous Materials Safety (OHMS) maintains a section on its website dedicated to providing viewers with replies to questions submitted about the Hazardous Materials Regulations. Although the interpretive letters are not legally binding, they do provide valuable guidance. Among other letters which may be available, an [interpretation letter](#) posted by DOT / PHMSA / OHMS in July of 2009, addresses a training question. Please, visit the *Hazmat Interpretations* webpage (<http://www.phmsa.dot.gov/hazmat/regs/interps>) for more details. PHMSA also maintains a [library of free publications](#) which are helpful resources.

Remaining questions regarding these regulations should be directed to the Office of Hazardous Materials Initiatives and Training (address listed below) or to any one of its regional offices, which are listed on the [DOT / PHMSA Training and Outreach website](#).

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* This is a specific citation from the US Code of Federal Regulations