

Transporting Ebola Contaminated Items: Category A Infectious Substance

Scope: The U.S. Department of Transportation (DOT's) Hazardous Materials Regulations (HMR; 49 C.F.R., Parts 171-180) govern the transportation of hazardous materials in all modes of transportation – air, highway, rail and water in interstate, intrastate, and foreign commerce.

An infectious substance is regulated as a hazardous material under the DOTs Hazardous Materials Regulations. The HMR's apply to any material DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. An infectious substance must conform to all applicable HMR requirements when offered for transportation by air, highway, rail, or water in interstate, intrastate, and foreign commerce. Refer to The Centers for Disease Control (CDC) for guidance on handling these agents before transporting them (see <u>http://www.cdc.gov/vhf/ebola/hcp/index.html</u>).

This document provides guidance on DOT regulations regarding the transportation of a Category A infectious substance only and highlights some of the requirements of the HMR, which can affect transportation safety. This document is intended to provide general guidance and does not address many of the specific provisions and exceptions contained in the HMR. It should not be used as a substitute for the HMR to determine compliance.

What is a Category A infectious Substance?

- A Category A infectious substance is a material known or reasonably expected to contain a pathogen, such as Ebola, that is in a form capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals when exposed to it.
- An infectious substance classification is based on the patient or animal's known medical history or symptoms, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

How is waste associated with a Category A infectious substance different from regulated medical waste?

- Regulated medical waste is a waste or reusable material known or suspected of containing a Category B pathogen that is derived from medical treatment or biomedical research. (See §§ 173.134(a)(1)(ii) and (c)(2)).
 - A Category B pathogen is not in a form that is generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals.
 - Waste contaminated by Category A infectious substances, which have been inactivated (autoclaved, incinerated) on-site prior to transport, can be transported as regulated medical waste.
- Because of the hazards posed by Category A infectious substances, these materials have more stringent packaging requirements and are not included in the definition of a "regulated medical waste".

Are used health care products that may be contaminated regulated?

Yes, the transport of medical equipment, sharps, linens, and used health care products (such as soiled absorbent pads or dressings, kidney-shaped emesis pans, portable toilets, used Personal Protection Equipment (gowns, masks, gloves, goggles, face shields, respirators, booties, etc.) or byproducts of cleaning) contaminated or suspected of being contaminated with a Category A infectious substance must comply with the packaging requirements for infectious substances in §173.196.

What is the correct packaging for a Category A infectious substance?

The specific requirements for authorized packaging and materials for transporting a Category A infectious substance are listed in § 173.196. In addition, each packaging must meet specific test standards in accordance with § 178.609.

In general, a Category A infectious substance must be triple packed in a:

- primary watertight receptacle,
- watertight secondary packaging, and
- rigid outer packaging.

Are there any additional HMR packaging requirements for a Category A infectious substance?

Yes, depending on the physical state and other characteristics of the material:

- Category A infectious substances shipped at ambient temperatures or higher must be packaged in accordance with § 173.196(b)(1),
- Category A infectious substances shipped refrigerated or frozen must be packaged in accordance with § 173.196(b)(2), and
- Category A infectious substances shipped in liquid nitrogen must be packaged in accordance with § 173.196(b)(3). (See http://www.ecfr.gov/cgi-bin/text-idx?SID=1baa09de1469d4c6ede30d6f6f303959&node=pt49.2.173&rgn=div5

Must the shipment of a Category A infectious substance be accompanied by a shipping paper?

Yes, the shipping paper requirements identify key hazard communication information. The shipping paper must include the following:

- UN number and proper shipping name for the applicable Category A infectious substance-- For Ebola, the shipping name is: "UN 2814, Infectious substances, affecting humans;"
- Hazard class: Division 6.2 (infectious);
- Packing group: N/A;
- Type and quantity of packaging; and
- Emergency response information (e.g., telephone number).

What information is required on the outside of the outer packaging?

- The outer packaging must be marked with the UN identification number and proper shipping name (see above), and labeled with the black and white "INFECTIOUS SUBSTANCE" label that conforms to § 172.432.
- The manufacturer who represents that the packaging is manufactured to meet a UN standard must mark it with the appropriate packaging standard markings. The markings must be durable, legible, and placed in a location as to be readily visible, in accordance with § 178.503(a).
- Directional arrows to indicate the correct (upright) orientation of the closures of inner packaging that contain liquids must be used in accordance with § 172.312.

Are there additional requirements for specific modes of transportation?

Yes, all hazardous materials packaging intended for transportation by aircraft must comply with the general requirements for transporting hazardous materials by aircraft in § 173.27.

• When unloaded from an aircraft, each package, overpack, pallet, or unit load device containing a Class A infectious substance must be inspected for signs of leakage. If evidence of leakage is found, the cargo compartment hold where the substance was stowed must be disinfected and the incident must be reported by telephone within 12 hours to the National Response Center at 1-800-424-8802. (See §§ 175.630(c) and 171.15(b)(3)).

Shippers and carriers also have the option of using international standards and regulations, instead of the HMR, in accordance with the provisions in §§ 171.22-171.24.

- For air transportation, the carrier may use the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO).
- For maritime transportation, the carrier may use the International Maritime Dangerous Goods Code (IMDG).

Do the HMR require you to report incidents involving a Category A infectious substance?

All incidents during transportation involving fire, breakage, spillage, or suspected contamination involving a Category A infectious must be reported by telephoning the National Response Center at 1-800-424-8802 within 12 hours. See § 171.15(b)(3)).

Who must be trained to prepare and transport a Category A infectious substance?

In general, employees who handle a Category A infectious substance inside a facility or hospital are not regulated by the HMR. Employees who prepare hazardous materials for transportation (i.e., prepare shipping papers, packaging, labeling, and marking of packaging) are hazardous materials employees and must be trained in accordance with 49 C.F.R., Part 172, Subpart I. The training must include:

- general awareness;
- function-specific;
- safety;
- security awareness training; and
- if applicable, modal specific training, such as driver training and the procedures necessary for the safe operation of a motor vehicle.

For detailed training requirements see § 172.704.

What type of security plan is required?

If you are offering for transportation or transporting a Category A infectious substance, you must develop and implement a security plan, and train your hazardous material employees on this plan. (See §§ 172.800-822). The plan must address:

- personnel security,
- unauthorized access, and
- en route security.

Are there any Category A infectious substance exceptions from the HMR?

Yes, the following are excepted from the HMR when contaminated with a Category A infectious substance:

- Corpses, remains, and anatomical parts transported for interment, cremation, or medical research at a college, hospital, or laboratory. (Importation of human remains to the United States for which the cause of death was a quarantinable communicable disease must comply with Centers for Disease Control (CDC) regulations (42 C.F.R. § 71.55)).
- Laundry or medical equipment complying with the Occupational Safety and Health Administration regulations in 29 C.F.R. in § 1910.1030 (bloodborne pathogens standard) intended for use, cleaning or refurbishment. This exception does not apply to medical equipment being transported for disposal.
- Material that has been treated to fully eliminate, neutralize, or inactivate the pathogen (e.g., through autoclave or incineration).

The complete list of additional exceptions is located in § 173.134(b).

References

- Department of Transportation Pipeline and Hazardous Materials Safety Administration <u>http://phmsa.dot.gov/hazmat/phmsa-provides-guidance-for-transporting-ebola-</u> contaminated-items
- "Transporting Infectious Substances Safely" brochure that explains the HMR for transporting infectious substance is available at: <u>http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_54AC1BCBF0DFBE298024C4C70</u> 0569893C2582700/filename/Transporting_Infectious_Substances_brochure.pdf