

APPENDIX F TO SC EBOLA PLAN

U.S. DEPARTMENT OF TRANSPORTATION GUIDANCE FOR TRANSPORTING EBOLA CONTAMINATED ITEMS

The U.S. Department of Transportation issued Guidance for Transporting Ebola Contaminated Items, a Category A Infectious Substance, dated 27 Oct 2014

- I. An infectious substance is regulated as a hazardous material under the U.S. Department of Transportation's (USDOT's) Hazardous Materials Regulations (HMR; 49 C.F.R., Parts 171-180). The HMR apply to any material USDOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce.¹ An infectious substance must conform to all applicable HMR requirements when offered for transportation or transported by air, highway, rail, or water. Refer to the Center for Disease Control (CDC) for guidance on handling these agents before transporting them (see <http://www.cdc.gov/vhf/ebola/hcp/index.html>).
- II. This document provides guidance on USDOT 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.
- III. Category A Infectious Substance Definition
 - A. 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.
 - B. 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.
- IV. Waste Associated With a Category A Infectious Substance Differs From Regulated Medical Waste
 - A. 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)).
 - B. 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.
 - C. 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."
- V. Regulation of Used Health Care Products

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.

VI. Packaging Category A Infectious Substances

- A. 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.
- B. In general, a Category A infectious substance must be triple packed in a:
 - 1. Primary watertight receptacle,
 - 2. Watertight secondary packaging, and
 - 3. Rigid outer packaging.
- C. Depending on the physical state and other characteristics of the material:
 - 1. Category A infectious substances shipped at ambient temperatures or higher must be packaged in accordance with § 173.196(b)(1),
 - 2. Category A infectious substances shipped refrigerated or frozen must be packaged in accordance with § 173.196(b)(2), and
 - 3. 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=d_iv5)

VII. Shipment of Category A Infectious Substance Accompanying Shipping Papers. These identify key hazard communication information. and must include the following:

- A. 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;”
- B. Hazard class: Division 6.2 (infectious);
- C. Packing group: N/A;
- D. Type and quantity of packaging; and
- E. Emergency response information (e.g., telephone number).

VIII. Outside Outer Packaging Requirements

- A. 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.
- B. 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).
- C. Directional arrows to indicate the correct (upright) orientation of the closures of inner packagings that contain liquids must be used in accordance with § 172.312.

IX. Additional Requirements for Air and Maritime Transportation

- A. Hazardous materials packagings intended for transportation by aircraft must comply with the general requirements for transporting hazardous materials by aircraft in § 173.27.
 - 1. 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)).
 - 2. 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.
 - 3. 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).
- B. For maritime transportation, the carrier may use the International Maritime Dangerous Goods Code (IMDG).

X. Reporting Incidents Involving Category A Infectious Substances

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)).

XI. Training to Prepare and Transport a Category A Infectious Substance

- A. 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 packagings) are hazardous materials employees and must be trained in accordance with 49 C.F.R., Part 172, Subpart I. The training must include:
 - 1. General awareness;
 - 2. Function-specific;
 - 3. Safety;
 - 4. Security awareness training; and
 - 5. If applicable, modal specific training, such as driver training and the procedures necessary for the safe operation of a motor vehicle.
- B. For detailed training requirements *see* § 172.704.

XII. Security Plans are 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:

- A. Personnel security,
- B. Unauthorized access, and
- C. Enroute security.

XIII. Category A Infectious Substance Exceptions from the HMR

- A. The following are excepted from the HMR when contaminated with a Category A infectious substance:
 - 1. 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 Center for Disease Control (CDC) regulations (42 C.F.R. § 71.55)).
 - 2. 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.

3. Material that has been treated to fully eliminate, neutralize, or inactivate the pathogen (e.g., through autoclave or incineration).

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

XIV. If Compliance With HMR Requirements is Not Feasible

A. You may apply for a special permit, which sets forth alternative requirements, or variances, to the requirements in the HMR. *See* § 107.105).

B. USDOT may grant a special permit if you can demonstrate that an alternative packaging will achieve a safety level that:

1. Is at least equal to the safety level required under Federal hazmat law or

2. Is consistent with the public interest if a required safety level does not exist.

C. The HMR also provides for emergency processing of a special permit. (*See* § 107.117).

D. Information on applying for a special permit is available at:
<http://phmsa.dot.gov/hazmat/permits-approvals/special-permits>

XV. Additional Information

A. “Transporting Infectious Substances Safely” brochure that explains the HMR for transporting infectious substance is available at:
http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_54AC1BCBF0DFBE298024C4C700569893C2582700/filename/Transporting_Infectious_Substances_brochure.pdf

B. All Center for Disease Control guidance regarding Ebola is available at:
<http://www.cdc.gov/vhf/ebola/hcp/index.html>

C. For questions on the HMR requirements, please contact the Pipeline and Hazardous Materials Safety Administration’s (PHMSA’s) Hazardous Materials Information Center at 1-800-467-4922, 9am-5pm Eastern time.

¹ The HMR applies to interstate, intrastate, and foreign commerce.

URL: <http://phmsa.dot.gov/hazmat/phmsa-provides-guidance-for-transporting-ebola-contaminated-items>