



TEAMSTERS

Safety & Health FACTS

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TRANSPORTATION OF INFECTIOUS SUBSTANCES

49 CFR Parts 171, 172, 173, 177, and 178

The safe transportation of hazardous materials is a matter of concern to the public, Congress, and Federal, state and local officials. To ensure public safety and minimize risks posed by hazardous materials in transportation, Congress requires the Secretary of Transportation to prescribe regulations for safe transportation of hazardous materials.

The Research and Special Programs Administration (RSPA) is the agency within the Department of Transportation responsible for developing and issuing the hazardous materials regulations (HMR; 49 CFR Parts 171-180). The HMR govern the classification, hazard communication, and packaging of hazardous materials for transportation.

Infectious substances, including regulated medical waste, are one class (Division 6.2) of hazardous materials regulated under the HMR. An infectious substance may not be offered for transportation or transported in interstate or foreign commerce by rail, water, air, or highway, unless the requirements of the HMR are met.

Definitions

According to the Department of Transportation, an **infectious substance** is a material known to contain or suspected of containing a pathogen that has the potential to cause disease when exposure to it occurs. Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant micro-organisms (hybrid or mutant) that cause infectious disease in humans or animals. It includes agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services and any other agent that causes or may cause severe, disabling or fatal disease.

The DOT defines ``**regulated medical waste**'' to mean waste or reusable material containing or suspected of containing an infectious substance in Risk Groups 2 or 3. RMW is generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment, or immunization of human beings or animals; or the production or testing of biological products. RMW containing an infectious substance in Risk Group 4 must be classed as Division 6.2 (infectious substances), described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

A **diagnostic specimen** is any human or animal material being shipped for purposes of diagnosis. It includes but is not limited to excreta, secreta, blood, blood components, tissue, and tissue fluids. Diagnostic specimens meeting the definition of a Risk Group 4 material are classed and required to be transported as infectious substances. All other diagnostic specimens should be packaged in non-specification packagings meeting minimum performance criteria.

A **biological product** is a material prepared and manufactured in accordance with certain regulations of the Department of Agriculture or the Department of Health and Human Services. Unlicensed biological products meeting the definition of a Risk Group 2, 3, or 4 infectious substance are classed as infectious substances, Division 6.2, and packaged in specification packagings authorized for the transportation of infectious substances.

Assigning a Risk Group

Infectious substances must be assigned to risk groups based on the degree to which they cause injury through disease, with Risk Group 1 presenting the lowest risk and Risk Group 4 presenting the highest risk. Assignments to risk groups are based on the known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgment concerning the individual circumstances of the patient or animal. Please find a description of Risk Groups in the table below:

Risk Group	Pathogen	Risk to Individuals	Risk to the Community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	HIGH	HIGH
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	HIGH	LOW
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	MODERATE	LOW
1	A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter.	NONE OR VERY LOW	NONE OR VERY LOW

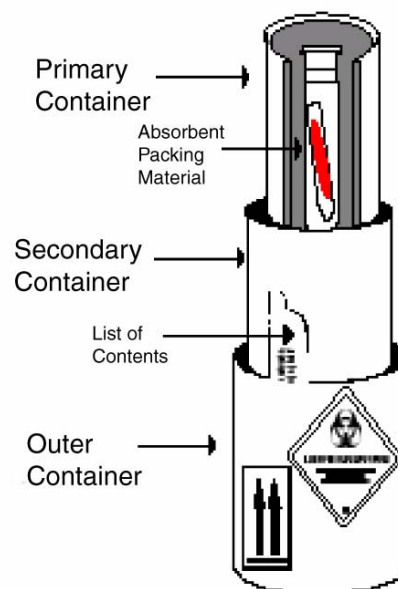
Infectious substances assigned to Risk Group 1 are excepted from all HMR requirements, unless they meet the definition of another hazard class.

Packaging of Infectious Substances for Transport

Infectious substances packaging is a triple packaging consisting of the following components:

- A watertight primary receptacle;
- A watertight secondary packaging;
- An outer packaging of adequate strength for its capacity, mass, and intended use;
- For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles; and,
- An itemized list of contents enclosed between the secondary and outer packaging.

An example of a typical infectious substance packaging configuration:



An example of the Infectious Substances label:



Reporting Spills

All spills of infectious waste occurring during transport must be reported to the Centers for Disease Control and Prevention at 1-800-232-0124.

Exceptions

The following are not subject to the previous requirements as Division 6.2 materials:

- ♦ A biological product known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen.
- ♦ A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen, or a diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs.
- ♦ A biological product, including an experimental product or component of a product, subject to Federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration of the Department of Health and Human Services or the U.S. Department of Agriculture.
- ♦ Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; tissues or organs intended for use in transplant

operations; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act.

- ♦ Blood collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped in accordance with 49 CFR 173.199.
- ♦ A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products.
- ♦ Laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment being transported for disposal.
- ♦ A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.
- ♦ A living person.
- ♦ Any waste or recyclable material, other than regulated medical waste.
- ♦ Corpses, remains, and anatomical parts intended for interment, cremation, or medical research at a college, hospital, or laboratory.
- ♦ Forensic material transported on behalf of a U.S. Government, state, local or Indian tribal government agency.
- ♦ Environmental microbiological samples, such as a sample of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.
- ♦ Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act.

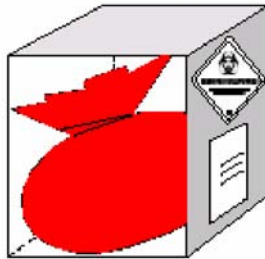
Regulated Medical Waste

Non-bulk and bulk packagings used for the transportation of regulated medical waste must be rigid containers that meet the provisions of the standard. The packaging must be

puncture-resistant for sharps (any object that may be contaminated with a pathogen that is also capable of cutting or penetrating skin or a packaging material) and sharps with residual fluid as demonstrated by conducting certain performance tests specified in the standard.

In addition, each Large Packaging used to transport liquid RMW must contain absorbent material in sufficient quantity and appropriate location to absorb the entire amount of liquid present in the event of an unintentional release of contents.

An example of a typical RMW packaging configuration:



Bulk packages containing RMW must be marked with the appropriate UN identification number and with a BIOHAZARD marking. The effective date for both marking requirements is one year after the effective date of the final rule (February 14, 2004).

RMW transported by a private or contract carrier is excepted from the requirement for an "INFECTIOUS SUBSTANCE" label if the outer packaging is marked with a "BIOHAZARD" marking.

An example of the BIOHAZARD label:



Please see 49 CFR 173.134 and 49 CFR 173.196 -§ 173.199 for a complete description of exceptions and additional packaging requirements.

For more information, please contact the Safety and Health Department at (202) 624-6960.

