Appendix C—Transportation of Infectious Substances

An infectious substance is a material known to contain or reasonably expected to contain a pathogen. A pathogen is a microorganism (i.e., bacteria, viruses, rickettsiae, parasites, fungi) or other agent (e.g., proteinaceous infectious particle [prion]) that can cause disease in humans or animals. Infectious substances may exist as purified and concentrated cultures but may also be present in a variety of materials or physical states, such as body fluids or tissues or lyophilized materials. Infectious substances and materials that are known or suspected to contain them are regulated as hazardous materials by the United States Department of Transportation (DOT), when transported in commerce in, to, or through the United States and by the International Civil Aviation Organization (ICAO) when transported internationally.

International Harmonization of Shipping and Transport Regulations

The United States works to assure the compatibility of its hazardous materials regulations with those of other bodies such as the United Nations, which issues Recommendations on the Transport of Dangerous Goods. Specialized organizations within the United Nations, such as ICAO, issue detailed instructions based on these recommendations that national governments, including the United States, agree to comply with in full or in part. ICAO references, including the International Air Transport Association (IATA) Dangerous Goods Regulations, establish international standards for the air transport of infectious or toxic materials.[1,2] The United States prescribes how to comply with these international instructions in 49 CFR Part 171, Subpart C.

Transportation Regulations

International and domestic transport regulations for infectious substances are designed to prevent the release of these materials in transit and to protect the public, workers, property, and the environment from the harmful effects that may occur from exposure to these materials. Protection is achieved through packaging requirements and multiple types of hazard communication. Packages must be designed to withstand rough handling and other forces experienced in transportation, such as vibration, stacking, moisture, and changes in air pressure and temperature. Hazard communication includes shipping papers, labels, markings on the outside of packages, and other information necessary to enable transport workers and emergency response personnel to correctly identify the material and respond efficiently in an emergency situation. Packaging and hazard communication exceptions exist to avoid duplication with other governmental regulations or to appropriately transport infectious substances with fewer risks. In addition, shippers and carriers must be trained on these regulations so that they can properly prepare shipments and recognize and respond to the risks posed by these materials.

Select Agents

Select Agents and Toxins are a subset of biological agents and toxins that the Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. Persons or organizations who either offer for transportation or transport Select Agents and Toxins in commerce into or throughout the United States must comply with the Select Agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331), including requesting prior authorization to transfer or import the agents and toxins. The APHIS/CDC Form 2, Request to Transfer Select Agents and Toxins, is used by persons or organizations to request prior authorization of a transfer of Select Agent(s) or Toxin(s) from the Federal Select Agent Program as required by regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). Importation and domestic movement permits are no longer required for public health or animal health Select Agent pathogens. More information regarding Select Agents and Toxins is available at https://www.selectagents.gov.

Persons who offer for transportation or transport Select Agents in commerce in, to, or through the United States must develop and implement security plans for such transportation. A security plan must include an assessment of the possible transportation security risks for materials covered by the security plan and specific measures to reduce or eliminate the assessed risks. At a minimum, a security plan must include measures to address those risks associated with personnel security, en route security, and unauthorized access.

Regulations

United States Department of Transportation. 49 CFR Parts 171–180, Hazardous Materials Regulations. Applies to the shipment of infectious substances in commercial transportation in, to, or through the United States. Information on these regulations is available at https://www.phmsa.dot.gov/hazmat.

United States Postal Service (USPS). 39 CFR Part 20, International Postal Service (International Mail Manual), and Part 111, General Information on Postal Service (Domestic Mail Manual). Regulations on transporting infectious substances through the USPS are codified in Section 601.10.17 of the Domestic Mail Manual and Section 135 of the International Mail Manual. A copy of the Domestic and International Mail Manuals may be obtained from the USPS Postal Explorer website at https://pe.usps.com/DMM300/Index.

Occupational Health and Safety Administration (OSHA). 29 CFR Section 1910.1030, Occupational Exposure to Bloodborne Pathogens. These regulations provide minimal packaging and labeling for blood and body fluid when transported within a laboratory or outside of it. Information may be obtained from your local OSHA office or at https://www.osha.gov.

Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions). International Civil Aviation Organization (ICAO). These regulations apply to the shipment of infectious substances by air and are recognized in the United States and by most countries worldwide. A copy of these regulations may be purchased from the ICAO Document Sales Unit on the ICAO website at https://store.icao.int/ or by email to sales@icao.int.

Dangerous Goods Regulations. International Air Transport Association (IATA). Global standards are detailed in this widely recognized publication on requirements for the transport of biological and chemical hazards. They are issued by IATA, an airline association, based on the ICAO Technical Instructions, and followed by most airline carriers. A copy of these regulations may be purchased from IATA at https://www.iata.org/publications/dgr/Pages/index.aspx or by email to custserv@iata.org.

Importation and Transfers

Regulations governing the transfer of biological agents are designed to ensure that possession of these agents is in the best interest of the public and the nation. These regulations require documentation of personnel and facilities, justification of need, and pre-approval of the transfer by a federal authority. The following regulations apply to this category:

Biological Agent or Vectors of Human Disease Import Permit. 42 CFR Section 71.54. Unless the material meets one of the regulatory exclusions, this regulation requires a permit from the CDC Import Permit Program to import infectious biological agents, infectious substances, and vectors of human disease into the United States. More information is available at the CDC Import Permit Program website at https://www.cdc.gov/cpr/ipp/index.htm.

Transfer of any Select Agents or Toxins requires the intended recipient to be registered with the Select Agent Program and submit an APHIS/CDC Form 2 as required to obtain approval to import the Select Agent or Toxin prior to each importation event (see 42 CFR Part 73, 9 CFR Part 12, and/or 7 CFR Part 330).

Importation of Pathogenic Agents of Livestock, Poultry and Other Animal Diseases and Other Materials Derived from Livestock, Poultry or Other Animals. 9 CFR Part 122. Organisms and Vectors. The USDA, APHIS, Veterinary Services (VS) requires that a permit be issued prior to the importation or domestic transfer (interstate movement) of pathogenic disease agents of livestock, poultry, or other animals. Information may be obtained at 301-851-3300 or from the USDA website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth. Completed permit applications may be submitted electronically at https://www.aphis.usda.gov/permits/learn_epermits.shtml.

Importation of Plant Pests. 7 CFR Part 330. Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage. This regulation requires a permit to move into or through the United States or by interstate any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Information can be obtained by calling 301-851-2357 or at the USDA APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information.

Transfer of USDA Plant Pests

The movement of Plant Pests is regulated under two distinct and separate regulations: (1) 7 CFR Part 331—Possession, Use, and Transfer of Select Agents and Toxins; and (2) 7 CFR Part 330—Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. The regulation found at 7 CFR Part 331 requires an approved Transfer Form (APHIS/CDC Form 2) prior to importation, interstate, or intrastate movement of a Select Agent Plant Pest. In addition, under 7 CFR Part 330, the movement of a Plant Pest also requires a PPQ Form 526 permit for movement in, to, or through the United States, or interstate any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Information can be obtained by calling 301-851-2357 or at the Select Agent Program website at https://www.selectagents.gov.

Export of Human, Animal, and Plant Pathogens and Related Materials; Department of Commerce (DoC); 15 CFR Parts 730–799. This regulation requires that exporters of a wide variety of etiologic agents of human, plant, and animal diseases, including genetic material, and products that might be used for culture of large amounts of agents, will require an export license. Information may be obtained by calling the DoC Bureau of Industry and Security (BIS) at 202-482-4811 or at the DoC BIS website at https://www.bis.doc.gov. Additional web resources include:

1. https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear
2. https://classic.ntis.gov/products/export-regs/

DOT Packaging of Infectious Substances

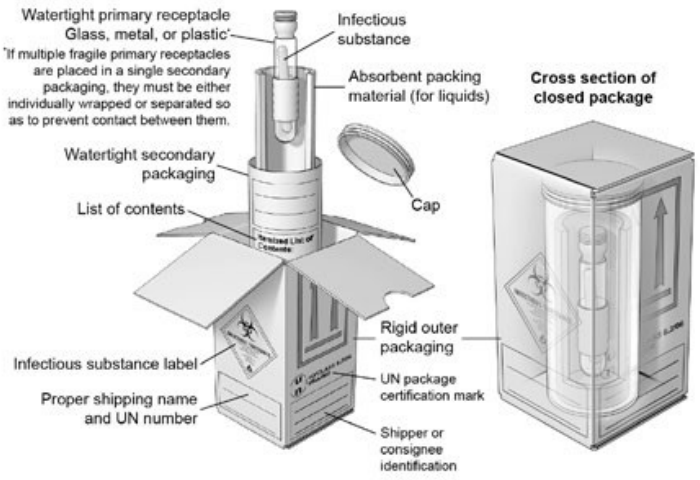
General DOT Packaging Requirements for Transport of Infectious Substances by Aircraft

DOT-compliant packaging is required by domestic and international air carriers for transport of infectious substances. DOT packaging regulations are also the basis for infectious substance packaging designed for motor vehicle, railcar, and vessel transport. The following is a summary of each packaging type and related transportation requirements.

Category A Infectious Substance (UN 2814 and UN 2900): Figure 1. A Category A material is an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Category A infectious substances are assigned to identification number “UN 2814” for substances that cause disease in humans or in both humans and animals, or “UN 2900” for substances that cause disease in animals only.

Figure 1 shows an example of the UN standard triple packaging system for materials known or suspected of being a Category A infectious substance as outlined in the Packaging Instruction of the IATA Dangerous Goods Regulations.[3] The package consists of a watertight primary receptacle or receptacles; a watertight secondary packaging; and a rigid outer packaging of adequate strength for its capacity, mass, and intended use. Note that for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles. A list of contents must be located on or near the secondary packaging. Each surface of the external dimension of the packaging must be 100 mm (3.9 inches) or more. The completed package must pass specific performance tests, including a drop test and a water-spray test, and must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The completed package must also be capable of withstanding, without leakage, temperatures in the range of -40ºC to +55ºC (-40ºF to 131ºF). The completed package must be marked “UN 2814, Infectious substance, affecting humans,” or “UN 2900, Infectious substance, affecting animals,” and labeled with a Division 6.2 (infectious substance) label. In addition, the package must be accompanied by appropriate shipping documentation, including a shipping paper and emergency response information.

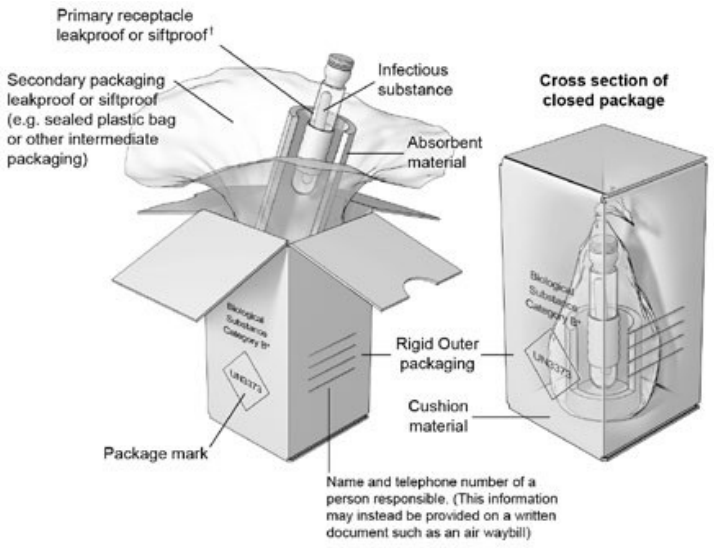
Figure 1. A Category A UN Standard Triple Packaging



Category B Biological specimen (UN 3373): Figure 2. A Category B infectious substance is one that does not meet the criteria for inclusion in Category A. A Category B infectious substance does not cause permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. The proper shipping name for a Category B infectious substance is “UN3373, Biological substance, Category B.”

Figure 2 shows an example of the triple packaging system for materials known or suspected of containing a Category B infectious substance. A Category B infectious substance must be placed in a packaging consisting of a leak-proof primary receptacle, leak-proof secondary packaging, and rigid outer packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches). The packaging must be of good quality and strong enough to withstand the shocks and loadings normally encountered during transportation. For liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles. For aircraft, the primary or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of 95 kPa (0.95 bar, 14 psi). The package must be constructed and closed to prevent any loss of contents that might be caused under normal transportation conditions by vibration or changes in temperature, humidity, or pressure. The completed package must be capable of passing a 1.2 meter (3.9 feet) drop test. The package must be marked with a diamond-shaped marking containing the identification number “UN 3373” and labeled with the proper shipping name “Biological substance, Category B.” In addition, the name, address, and telephone number of a person knowledgeable about the material must be provided on a written document, such as an air waybill, or on the package itself.

Figure 2. A Category B Non-specification Triple Packaging



Intrafacility Specimen and Sample Transfers

Any movement of a pathogen between parts of an institution, which would require transport in a motor vehicle, on public roads, would require compliance with the requirements given previously in this Appendix. However, movement of a pathogen on private roads within the confines of a contiguous facility boundary (e.g., a campus) where public access is restricted is not commercial transportation and, therefore, is not subject to these requirements. If movement of a pathogen is on or crosses a public road, it also is not subject to these requirements if access to the public road is restricted by signals, lights, gates, or similar controls.[4–8]

It is also common to need to move samples or cultures between laboratories, between floors in a building, or by walking samples between buildings. When a sample needs to be moved, care should be taken to minimize the transport through public and office areas. Avoid passenger elevators when possible, using stairs and freight elevators instead. It is recommended that the sample(s) be placed in a sealable bag or container to provide primary leak-proof containment. Place absorbent in the bag or container to absorb any spilled material in the event of a loss. Place the sealed bag or container in a durable, rigid outer container for transport. Disinfect the exterior of the outer container as appropriate depending on the risk posed by the material to be transported. PPE to be worn during transit is based on the institution's risk assessment.

Transfer of specific, high-risk pathogens, even within an organization, may need approval from USDA, CDC, or the Federal Select Agent Program.

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