Packaging Critical Biologic Agents

Co-Editor's Note

To complement the information provided in the summary from the World Courier Symposium, we are republishing below more specific instructions on the packaging and transport of infectious substances and diagnostic specimens. As you will note, the document contains information on numerous web sites where you can obtain the shipping requirements of several federal and international regulatory agencies. To directly access this information, go to http://www.bt.cdc.gov, then click on Laboratory issues in the left-hand column. The first topic listed under “laboratory issues” will be this document.

Ira F. Salkin


1. Definitions
a. Biological agents include infectious agents of humans, plants, and animals, as well as the toxins that may be produced by microbes and by genetic material potentially hazardous by itself or when introduced into a suitable vector. Biologic agents and infectious substances are closely related terms that are found in the transfer and transportation regulations. Biological agents may exist as purified and concentrated cultures but may also be present in a variety of materials such as body fluids, tissues, soil samples, etc.
c. Transportation refers to the packaging and shipping of these materials by air, land, or sea, generally by a commercial conveyance.
d. Transfer refers to the process of exchanging these materials between facilities.

2. General Packaging Requirements for Transport of Biological Agents and Clinical Specimens

The generalized “triple” (primary receptacle, watertight secondary packaging, durable outer packaging) packaging required for a biological agent of human disease or materials that are known or suspected of containing them requires an “Infectious Substance” label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the Department of Transportation (DOT), United States Postal Service (USPS), Public Health Service (PHS), and International Air Transport Association (IATA) regulations.

Clinical specimens with a low probability of containing an infectious agent are also required to be “triple” packaged, but performance tests require only that the package not leak after a 4-foot drop test. DOT, PHS, and IATA require a “clinical specimen” label on the outside of the package.

For information regarding packaging and labeling of infectious substances and clinical specimens in volumes of less than 50 ml in accordance with the provisions of subparagraph 72.3(a) of the regulation on Interstate Shipment of Etiologic Agents (42 CFR, Part 72), consult the BMBL or visit: www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s1.htm

3. Transportation

Regulations on the transportation of biological agents are aimed at ensuring that the public and the workers in the transportation chain are protected from
exposure to any agent that might be in the package. Protection is achieved through:

a. The requirements for rigorous packaging that will withstand rough handling and contain all liquid material within the package without leakage to the outside;

b. Appropriate labeling of the package with the biohazard symbol and other labels to alert workers in the transportation chain to the hazardous contents of the package;

c. Documentation of the hazardous contents of the package should such information be necessary in an emergency situation; and

d. Training of workers in the transportation chain to familiarize them with the hazardous contents enabling response to emergency situations.

4. Regulations

Biological agents and the materials that are known or suspected to contain them are recognized by federal and state governments as hazardous materials, and their transportation and transfer are subject to regulatory control.

a. Interstate Transportation of Biologic Agents
   Public Health Service: 42 CFR Part 72. This regulation is being revised so that it coordinates with other U.S. and international regulations. A copy of the current regulation may be obtained from the Internet at: http://www.cdc.gov/od/ohs.

b. Hazardous Materials Regulations
   Department of Transportation: 49 CFR Parts 171-178. Applies to the shipment of both biological agents and clinical specimens. Information may be obtained from the Internet at: http://www.dot.gov/rules.html.

c. Ability to Mail Etiologic Agents

d. Occupational Exposure to Bloodborne Pathogens
   Occupational Health and Safety Administration (OSHA): 29 CFR Part 1910.1030. Provides minimal packaging and labeling requirements for transport of blood and body fluids within the laboratory and outside of it. Information may be obtained from your local OSHA office or from the Internet at: http://osha.gov.

e. Dangerous Goods Regulations (DGR)
   International Air Transport Association (IATA). These regulations provide packaging and labeling requirements for infectious substances and materials, as well as clinical specimens that have a low probability of containing an infectious substance. These are the regulations followed by the airlines and are derived from the Committee of Experts on the Transport of Dangerous Goods, United Nations Secretariat, and the Technical Instructions for the Transport of Dangerous Goods by air which is provided by the International Civil Aviation Organization (ICAO). A copy of the DGR may be obtained by calling 1-800-716-6326 or through the Internet at: http://www.iata.org, or http://www.who.org.

5. Other Regulations: Transfer

Regulations on the transfer of biological agents are aimed at ensuring that the change in possession of biological materials is in the best interests of the public and the nation. These regulations require documentation of the personnel and facilities, justification of need for the biological agent in the transfer process, and subsequent approval of the transfer process by a federal authority. The following regulations fit in this category:

a. Importation of Etiologic Agents of Human Disease
   42 CFR Part 71 Foreign Quarantine. Part 71.54 Etiologic Agents, Hosts and Vectors. This regulation requires an import permit from the Centers for Disease Control and Prevention for importing etiologic agents of human disease and any materials, including live animals or insects, that may contain them. An application and information on importation permits may be obtained by calling 1-888-CDC-FAXX and enter document number 101000, or on the Internet at: http://www.cdc.gov/od/ohs/biosfry/imprtpem.html.

b. Importation of Biologic Agents of Livestock, Poultry, and Other Animal Diseases
   9 CFR Parts 92, 94, 95 96, 122, and 130. These
regulations require an import permit from the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services to import or domestically transfer etiologic agents of livestock, poultry, other animals, and any materials that might contain these etiologic agents. Information may be obtained at 301-734-3277, or from the Internet at: http://aphisweb.aphis.usda.gov/ncie.

c. 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 import or domestically transfer a plant pest, plant biological agent, or any material that might contain them. Information can be obtained by calling 301-734-3277, or through the Internet at: http://www.aphis.usda.gov/ppq/ppqpermits.html.

d. Transfer of Select Biological Agents of Human Disease
42 CFR Part 72.6 Additional Requirements for Facilities Transferring or Receiving Select Agents. Facilities transferring or receiving select agents must be registered with the CDC and each transfer of a select agent must be documented. Information may be obtained on the Internet at: http://www.cdc.gov/od/ohs/lrsat.

e. Export of Etiologic Agents of Humans, Animals, Plants, and Related Materials
Department of Commerce. 15 CFR Parts 730 to 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 Export Administration at 202-482-4811, or through the Internet at: http://bxa.fedworld.gov or http://www.bxa.doc.gov.

For further information on any provision of transfer regulations contact: Centers for Disease Control and Prevention, Attn: External Activities Program, Mail Stop F-05, 1600 Clifton Road NE, Atlanta, GA 30333, phone 404-639-4418, fax 404-639-2294.

Note that the shipper’s name, address, and telephone number must be on the outer and inner containers. The reader is also advised to refer to additional provisions of the Department of Transportation (49 CFR, Parts 171-180) Hazardous Materials Regulations.

Contact your state health department laboratory director if you represent a laboratory that would like to ship a biologic agent to an advanced capacity laboratory for presumptive or confirmatory identification. Inform the state health department laboratory director as to the identity of the suspected critical biologic agent.