Packaging Critical Biologic Agents

For detailed descriptions of packaging and shipping information, microbiological practices and safety procedures, please refer to *Biosafety in Microbiological and Biomedical Laboratories*, United States Department of Health and Human Services, 4th Ed., edited by J.Y. Richmond and R.W. McKinney, U.S. Government Printing Office, 1999. The BMBL is also available at:

www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s1.htm

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.

b. Critical biologic agent is defined in: *MMW*R:49(RR-4), pp.5-6. Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response, April 21, 2000.

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

Figure 1 (below) shows the generalized "triple" (primary receptacle, water tight secondary packaging, durable outer packaging) packaging required for a biological agent of human disease or materials that are known or suspected of containing them. This packaging requires the "Infectious Substance" label shown in **Figure 2** (below) on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and 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 shall not leak after a four-foot drop test. DOT, PHS, and IATA require a "clinical specimen" label on the outside of the package.

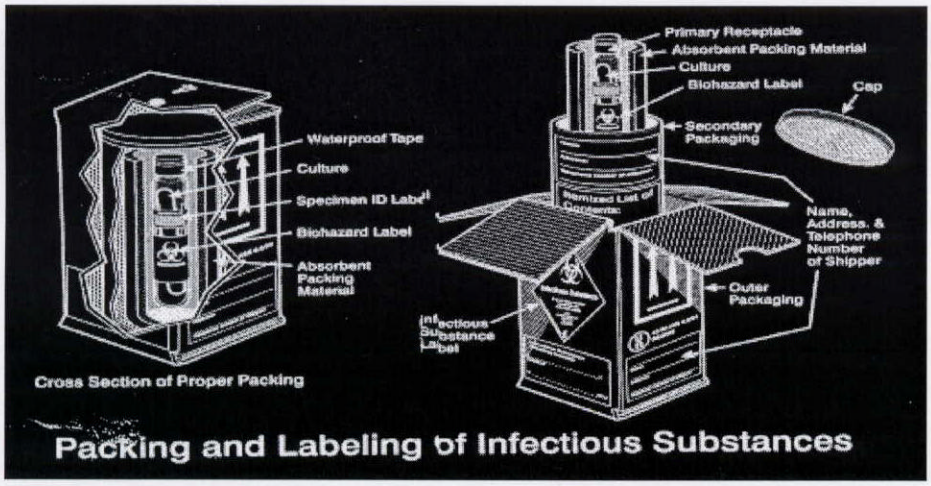

Figure 1. Packing and Labeling of Infectious Substances

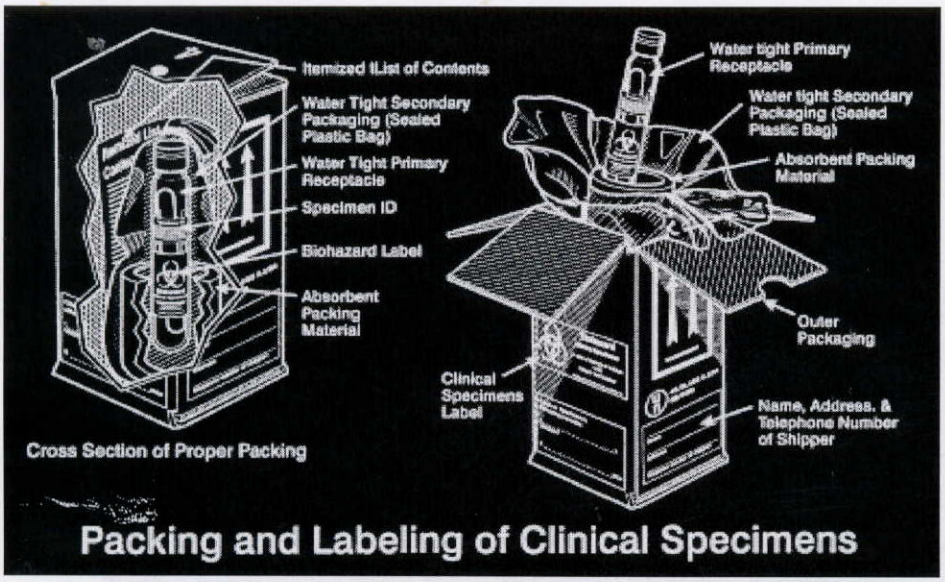

Figure 2. Packing and Labeling of Clinical Specimens

Figures 1 and **2** illustrate the 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). For additional information, 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 the 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 is subject to regulatory control.

a. Interstate Transportation of Biologic Agents

Public Health Service: 42 CFR Part 72. This regulation is in revision to harmonize it with the 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

United States Postal Service: 39 CFR Part 111. Codified in the Domestic Mail Manual 124.38: Etiologic Agent Preparations. A copy of the Domestic Mail Manual may be obtained from the Government Printing Office by calling 1-202-512-1800 or from the Internet at:

http://www.access.gpo.gov

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:

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. These regulations 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 within the best interests of the public and of the nation. These regulations require documentation of the personnel, facilities, and 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/biosfty/imprtper.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 requires 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 which 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 related to Microbe Inotech Labs, Inc.** contact:

Microbe Inotech Laboratories, Inc.
Attn: Dr. Bruce C. Hemming
12133 Bridgeton Square Drive
St. Louis, MO 63044-2616
Telephone: 314-344-3030 or 800-688-9144
Fax: 314-344-3031
e-mail: bhemming@microbeinotech.com

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 N.E.
Atlanta, GA 30333
Telephone: (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 such as the MiL, inc. for presumptive or confirmatory identification. Inform the state health department laboratory director as to the identity of the suspected critical biologic agent.