

(e) *Mixed waste.* When two or more hazardous materials are mixed together, the mixture will be decontaminated and disposed of in accordance with EPA, NRC, State, and Federal regulations for the mixture, or for the most hazardous material.

(f) *Packaging.* Solid waste will be placed in cans, sturdy bags, or boxes. Rigid, puncture-resistant, sealable containers will be used for packaging “sharps.” When wet materials are packaged for disposal, the materials will be placed in a leak-proof container. Heavy waste will be placed in rigid containers ensuring that the burst strength of the container is not exceeded.

(g) *Labeling.* A method of verifying that all items prepared for disposal have been decontaminated will be established for etiologic agent wastes. Mixed waste will be labeled as appropriate to indicate the hazards that must be addressed after decontamination.

(h) *Recordkeeping.* A manifest will be initiated and maintained, where required, to record the disposition and transfer of waste. Applicable Federal, State, and local ordinances will be followed.

Subpart F—Importation, Shipment, and Transport of Etiologic Agents

§ 627.35 Introduction.

The CDC of the Public Health Service (PHS), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Department of Transportation (DOT), the United States Postal Service and the International Air Transport Association (IATA) regulate the importation, shipment, and transportation of etiologic agents. This chapter outlines the minimum administrative requirements the commander or institute director are to follow and gives sources for information on the requirements for importation, packaging, labeling, and shipment of etiologic agents.

§ 627.36 Administration.

The commander or institute director will establish the following controls to ensure that etiologic agents are trans-

ported with proper authorization, controls, and procedures:

(a) Institute policies will be established in writing to ensure that before etiologic agents are acquired or shipped—

(1) The division chief responsible for the area where work with etiologic agents is to be conducted approves all acquisitions or shipments.

(2) The safety officer is informed in writing of the type and amount of any BL-4 or USDA-restricted etiologic agent (listed in HHS publication No. (NIH) 88-8395 or current edition) being received, and the estimated date of arrival.

(3) The recipient of all etiologic agents shipped from an institute will be documented.

(4) The commander or institute director approves all acquisitions and shipments of BL-4 or USDA-restricted etiologic agents.

(5) The commander or institute director approves all requests for shipments to or from foreign countries and to individuals not affiliated with an institution or agency (for example, physicians in private practice).

(6) The Office of The Surgeon General, United States Army, or the Commander, United States Army Materiel Command (AMC) approves the initial acquisition and use of all reference stocks of etiologic agents and transfers between Army RDTE activities in accordance with AR 70-65.

(7) There is full compliance with the regulatory requirements referenced in §§ 627.37, 627.38, 627.39 and 627.40.

(8) The following information regarding the recipient and the intended use of BL-4 and USDA-restricted animal pathogens, will be kept on file for 10 years. This information will also be kept for all shipments to or from foreign countries and to individuals not affiliated with an institution or agency (for example, physicians in private practice).

(i) The requester’s name and address.

(ii) The type and amount of the etiologic agent to be sent.

(iii) The qualifications of the recipient of the etiologic agent.

(iv) The intended use of the etiologic agent.

(v) A statement indicating that the agent is not for human use.

(b) Etiologic agents assigned to biosafety level 1, 2, or 3, approved for shipment, and properly labeled and packaged may be shipped by commercial cargo carriers.

(c) All etiologic agents assigned to BL-4 or USDA-restricted animal pathogens approved for shipment and properly packaged, will be accompanied by a designated courier, or under close supervision of a responsible party who will monitor aspects of the shipment, ensuring that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.

§ 627.37 Importation directives.

Importation of etiologic agents is subject to the Public Health Service Foreign Quarantine Regulations (42 CFR 71.156). Examples of permits authorizing the importation or receipt of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§ 627.38 Shipment directives.

Shipping unmarked and unidentified etiologic agents is prohibited. Etiologic agents will be packaged, labeled, and shipped according to the requirements found in the Interstate Shipment of Etiologic Agents Regulations (42 CFR part 72) and its amendments. The USDA regulations in 9 CFR parts 102 through 104, 122 and the FDA regulations in 21 CFR parts 312 and 600 through 680 will also be followed as applicable. Packaging and labeling requirements for interstate shipment of etiologic agents are summarized and illustrated in appendix D. Permits authorizing the shipment of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§ 627.39 Transportation directives.

The packaging and labeling requirements cited above must be followed for the local transport of etiologic agents and diagnostic specimens by courier or by other delivery services. Similar requirements and restrictions applicable

to the transport of etiologic agents, diagnostic specimens, and biological products by all modes of transportation (that is, air, motor, rail, and water) are imposed by the Department of Transportation (49 CFR part 173), IATA "Dangerous Goods Regulations," the Air Transport Association "Restricted Articles Tariff 6-D," the International Civil Aviation Organization (ICAO), Postal Bulletin No. 21246 "International Mail-Hazardous Materials," 39 CFR, and, the Domestic Mail Manual. When shipments exceed 4 liters, the requirements found in AR 740-32 will be followed.

§ 627.40 Additional requirements.

Additional requirements for importation, shipment, and transportation of infectious agents and hazardous materials that must be followed are contained in the following directives:

(a) AR 40-12, Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces.

(b) AR 70-65, Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities.

§ 627.41 Sources for further information on shipment of etiologic agents.

(a) Guide for Transportation of Hazardous Materials, Vol. 4(1), February 10, 1975. Copies are obtainable from the Office of Research Grants Inquiries, NIH, Department of Health and Human Services, 5333 Westbard Avenue, Bethesda, MD 20205.

(b) The CDC, Office of Biosafety, 1600 Clifton Road N.E., Atlanta, Georgia 30333. Telephone (404) 639-3883, or FTS: 236-3883.

(c) The American Type Culture Collection (ATCC), Packaging and Shipping of Biological Materials at ATCC. Copies may be obtained from the ATCC, 12301 Parklawn Drive, Rockville, MD 20852. Phone (301) 881-2600.

(d) National Committee for Clinical Laboratory Standards (NCCLS), Procedures for the Domestic Handling and Transport of Diagnostic Specimens and