BUMED INSTRUCTION 6210.3

From: Chief, Bureau of Medicine and Surgery
To: All Ships and Stations

Subj: Etiologic agents/biomedical materials; handling of

Ref: (a) SECNAVINST 6210.2/AR 40-12/AFR 161-4 of 24 Oct 1974

Encl: (1) Section 72.25, 42 Code of Federal Regulations 72
(2) Illustration, packaging and labeling requirements, specimens less than 50 ml in volume
(3) Illustration, packaging and labeling requirements, specimens 50-500 ml
(4) Application for Permit to Import or Transport Agents or Vectors of Human Disease, HSM 13.39 (CDC)

1. Purpose. To implement requirements of enclosure (1) and certain provisions of reference (a) which provide for the safe handling of etiologic agents (live microorganisms or their toxins which cause, or may cause human disease) from the time the specimens are prepared for shipment until their arrival at final destination.

2. Scope. The provisions of this instruction apply to all persons in the Department of the Navy.

3. Background. The U.S. Public Health Service revised the Interstate Quarantine Regulations in July 1972 (encl (1)). The revision provides packaging and labeling requirements for etiologic agents. In addition, U.S. Postal Service and U.S. Department of Transportation regulations were similarly revised. The Public Health Service has also changed Foreign Quarantine Regulations to require a special permit label for the importation or transfer of etiologic agents from outside the United States, its commonwealths, territories, and possessions, to any point within these same areas. Shipments from Armed Forces medical facilities and laboratories outside the U.S. to Armed Forces medical facilities and laboratories within U.S. territory are permitted in accordance with appendix B of reference (a). As a condition on granting this permission, the Public Health Service requires that the special permit label be affixed to each shipping container.

4. Definitions. The following definitions are applicable to this instruction:

a. Etiologic agents: See paragraph 1.

b. Diagnostic specimen: Any human or animal material, including but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

c. Biological product: Defined in subparagraph (a)(3) of enclosure (1) and generally means a substance prepared, manufactured, and intended for medical or veterinary investigational use, including immunizing agents and diagnostic specimens.

5. Policy. Persons in the Department of the Navy shall not transport or cause to be transported in interstate traffic or introduce into the U.S. mail or into the United States or its territory any material, including but not limited to diagnostic specimens and biological products, believed to contain an etiologic agent unless the material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation and the package is properly labeled. Shipments from Puerto Rico, Guam, American Samoa, Virgin Islands, the Canal Zone, and the U.S. Trust Territories of the Pacific Islands shall conform to this instruction.

6. Packaging. The packaging requirements stated in paragraph 22c(1) and (2) of reference (a) apply to all shipments, interstate and foreign, made by persons in the Department of the Navy. Proper packaging methods are illustrated in enclosures (2) and (3).

7. Shipping

a. All shipments of etiologic agents must be labeled in accordance with the requirements of enclosure (1) and paragraph 23 of reference (a). The shipment of indigenous etiologic agents and other biomedical materials within the United States, its territories, commonwealths, or possessions require the Etiologic Agent/Biomedical Material label only. All shipments

to the United States from oversea medical facilities and laboratories and all exotic (nonindigenous) agents shipped to or within the United States must be accompanied by the Importation or Transfer Permit label.

b. Label acquisition: It is the responsibility of the receiving facility to acquire the appropriate label.

c. Label availability and shipping coordination: Navy Environmental and Preventive Medicine Units (NAVENPVNTMEDU's) are assigned the responsibility for stocking and controlling the issue of the Importation or Transfer Permit labels for shipment of etiologic agents from one Navy facility to another. Facilities that are to receive the agents shall make application to the nearest NAVENPVNTMEDU for the required label. Permit application forms, enclosure (4), may be obtained from the units. The Etiologic Agent/Biomedical Material labels may be requested from the units or acquired in accordance with paragraph 32.b of reference (a).

(1) List of units and their locations

Navy Environmental and Preventive Medicine
Unit No. 2
Norfolk, VA 23511
AUTOVON: 690-7671
COMMERCIAL: (803) 444-7671
Command Short Title:
NAVENPVNTMEDU 2

Navy Environmental and Preventive Medicine
Unit No. 5
Naval Station, Box 143
San Diego, CA 92136
AUTOVON: 958-1263
COMMERCIAL: (714) 235-1263
Command Short Title:
NAVENPVNTMEDU 5

U.S. Environmental and Preventive Medicine
Unit No. 6
Box 112
FPO San Francisco 96610
AUTOVON: 430-0111
COMMERCIAL: (808) 474-2173 (Honolulu)
Command Short Title:
NAVENPVNTMEDU 6

U.S. Navy Environmental and Preventive Medicine
Unit No. 7
FPO New York 09521
AUTOVON: 625-1110
COMMERCIAL: 605 400 (Naples Italy)
Command Short Title:
NAVENPVNTMEDU 7

d. Notice of delivery. Those etiologic agents listed in paragraph (c)(6) of enclosure (1) shall be transported by registered mail or equivalent system. Receiving activities must acknowledge receipt of shipment immediately upon delivery. If notice of delivery of the package is not received by the sender within 5 days following anticipated delivery, the shipper shall notify immediately by message or telephone the nearest NAVENPVNTMEDU. The NAVENPVNTMEDU, in turn, will take prompt action to locate the package and will notify the Director, Center for Disease Control, if the shipment has not been found within 48 hours.

e. Label security. The officer in charge of each NAVENPVNTMEDU shall designate an officer of his staff to be responsible for providing adequate security of the labels to prevent their possible misuse.

f. Authenticating procedure. Each permit label shall be identified as follows: PHS Permit No. USNEPMU-X-XXX-X. The first digit shall be the unit number followed by the julian date and the sequential number of the permit.

g. Reports. A listing of activities to which labels have been issued and the etiologic agent/biomedical material involved shall be included in the NAVENPVNTMEDU semiannual report. (MED 6200-1, Preventive Medicine Activities, applies.)

h. Oversea medical facilities and laboratories. In addition to strict compliance with the foregoing packaging and shipping requirements, senders of etiologic agents/biomedical materials are cautioned to adhere to existing regulations of the host country. In any case, the standards shall not be less than those required for interstate shipment (see par. 5).

D. L. CUSTIS

Distribution:
SNDL Parts 1 and 2
Marine Corps Codes H and I

Stocked:
CO, NAVPUBFORMCEN
5801 Tabor Ave.
Phila., PA 19120

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333
Telephone: (404) 633-3311, Ext. 3883

TITLE 42—PUBLIC HEALTH

Chapter I—Public Health Service, Department of Health, Education, and Welfare

SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING

PART 72—INTERSTATE QUARANTINE

Subpart C—Shipment of Certain Things

Section 72.25 of Part 72, Title 42, Code of Federal Regulations, is amended to read as follows:

§ 72.25 Etiologic agents.

(a) *Definitions.* As used in this section:

(1) An "etiologic agent" means a viable microorganism or its toxin which causes, or may cause, human disease.

(2) A "diagnostic specimen" means any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

(3) A "biological product" means a biological product prepared and manufactured in accordance with the provisions of 9 CFR Part 10, Licensed Veterinary Biological Products, 42 CFR Part 73, Licensed Human Biological Products, 21 CFR 130.3, *New drugs for investigational use in humans*, 9 CFR Part 103, Biological Products for Experimental Treatment of Animals, or 21 CFR 130.3(a), *New drugs for investigational use in animals*, and which, in accordance with such provisions, may be shipped in interstate traffic.

(b) *Transportation; etiologic agent minimum packaging requirements.* No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material, including but not limited to, diagnostic specimens and biological products, containing, or reasonably believed by such person to contain, an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

(c) *Transportation; etiologic agents subject to additional requirements.* No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material, other than diagnostic specimens and biological products, containing, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged in accordance with the requirements specified in paragraph (b) of this section, and unless, in addition, such material is packaged and shipped in accordance with the requirements specified in subparagraphs (1)–(6) of this paragraph:

BACTERIAL AGENTS

Actinobacillus—all species.
Arizona hinshawii—all serotypes.
Bacillus anthracis.
Bartonella—all species.
Bordetella—all species.
Borrelia recurrentis, B. vincenti.
Brucella—all species.
Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani.
Corynebacterium diphtheriae C, equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale.
Diplococcus (Streptococcus) pneumoniae.
Erysipelothrix insidiosa.
Escherichia coli, all enteropathogenic serotypes.
Francisella (Pasteurella) tularensis.
Haemophilus ducreyi, H. influenzae.
Herellea vaginicola.
Klebsiella—all species and all serotypes.
Leptospira interrogans—all serotypes.
Listeria—all species.
Mima polymorpha.
Morazella—all species.
Mycobacterium—all species.
Mycoplasma—all species.
Neisseria gonorrhoeae, N. meningitidis.
Pasteurella—all species.
Pseudomonas pseudomallei.
Salmonella—all species and all serotypes.
Shigella—all species and all serotypes.
Sphaerophorus necrophorus.
Staphylococcus aureus.
Streptobacillus moniliformis.
Streptococcus pyogenes.
Treponema careteum, T. pallidum, and *T. pertenue.*
Vibrio fetus, V. comma, including biotype El Tor, and *V. parahemolyticus.*
Yersenia (Pasteurella) pestis.

FUNGAL AGENTS

Actinomycetes (including *Nocardia* species, *Actinomyces* species and *Arachnia propionica*).
Blastomyces dermatitidis.
Coccidioides immitis.
Cryptococcus neoformans.
Histoplasma capsulatum.
Paracoccidioides brasiliensis.

VIRAL, RICKETTSIAL, AND CHLAMYDIAL AGENTS

Adenoviruses—human—all types.
Arboviruses.
Coxiella burnetii.
Coxsackie A and *B viruses*—all types.
Cytomegaloviruses.
Dengue virus.
Echoviruses—all types.
Encephalomyocarditis virus.
Hemorrhagic fever agents, including *Crimean hemorrhagic fever (Congo), Junin*, and *Machupo viruses*, and others as yet undefined.
Hepatitis-associated antigen.
Herpesvirus—all members.
Infectious bronchitis-like virus.
Influenza viruses—all types.
Lassa virus.
Lymphocytic choriomeningitis virus.
Marburg virus.
Measles virus.
Mumps virus.
Parainfluenza viruses—all types.
Polioviruses—all types.
Poxviruses—all members.
Psittacosis - Ornithosis - Trachoma-Lymphogranuloma group of agents.
Rabies virus—all strains.
Reoviruses—all types.
Respiratory syncytial virus.
Rhinoviruses—all types.
Rickettsia—all species.
Rubella virus.
Simian viruses—all types.
Tick-borne encephalitis virus complex, including *Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever*, and *Central European encephalitis viruses.*
Vaccinia virus.
Varicella virus.
Variola major and *Variola minor viruses.*
Vesicular stomatis virus.
Yellow fever virus.

(1) *Volume less than 50 ml.* Material shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

(2) *Volume 50 ml. or greater.* Packaging of material in volumes of 50 ml. or more shall include, in addition, a shock absorbent material, in volume at least equal to that of the absorbent material

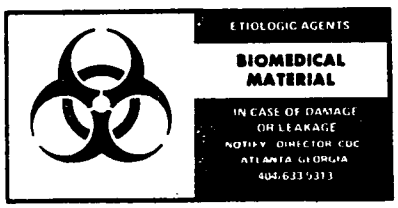
[1] The requirements of this section are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

Enclosure (1)

between the primary and secondary containers, at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 500 ml. of material. However, two or more primary containers whose combined volumes do not exceed 500 ml. may be placed in a single, secondary container. Not more than eight secondary shipping containers may be enclosed in a single outer shipping container. (The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.)

(3) *Dry ice.* If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be so placed that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4) *Labels.* The label for Etiologic Agents/Biomedical Material, except for size and color, must be as shown:



(i) The color of material on which the label is printed must be white and the symbol and printing in red.

(ii) The label must be a rectangle measuring 51 mm. (2 inches) high by 102.5 mm. (4 inches) long.

(iii) The red symbol measuring 38 mm. (1½ inches) in diameter must be centered in a white square measuring 51 mm. (2 inches) on each side.

(iv) Type size of the letters of label shall be as follows:

ETIOLOGIC AGENT	10 pt. rev.
BIOMEDICAL MATERIAL	14 pt.
IN CASE OF DAMAGE OR LEAKAGE	10 pt. rev.
NOTIFY DIRECTOR CDC ATLANTA, GA	8 pt. rev.
404 633 5313	10 pt. rev.

(5) *Damaged packages.* Carriers shall promptly, upon discovery of damage to the package that indicates damage to the primary container, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road NE., Atlanta, GA 30333 (telephone (404) 633-5313), and the sender.

(6) *Registered mail or equivalent system.* Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification to the shipper immediately upon delivery:

Actinobacillus mallei.
Coccidioides immitis.
Francisella (Pasteurella) tularensis.
Hemorrhagic fever agents, including, but not limited to, *Crimean hemorrhagic fever (Congo), Junin, Machupo viruses.*
Herpesvirus simiae (B virus).
Histoplasma capsulatum.
Lassa virus.
Marburg virus.
Pseudomonas pseudomallei.
Tick-borne encephalitis virus complex, including, but not limited to, *Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever,* and *Central European encephalitis viruses, Variola minor* and *Variola major.*
Yersenia (Pasteurella) pestis.

(d) *Notice of delivery; failure to receive.* When notice of delivery of agents containing, or suspected of containing, etiologic agents listed in paragraph (c)(6) of this section is not received by the sender within 5 days following anticipated delivery of the package, the shipper shall notify the Director, Center for Disease Control, 1600 Clifton Road NE., Atlanta, GA 30333 (telephone (404) 633-5313).

(e) *Requirements; variations.* The Administrator may approve variations from the requirements of this section if, upon review and evaluation, he finds that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and makes such findings a matter of official record.

(Sec. 361, 58 Stat. 703; 42 U.S.C. 264)

[FR Doc.72-9687 Filed 6-29-72;8:45 am]

Effective July 30, 1972

PACKAGING AND LABELING OF ETIOLOGIC AGENTS

VOLS less than 50 ml

The Interstate Quarantine Regulations (42 CFR, Part 72.25 Etiologic Agents) was revised July 31, 1972 to provide for packaging and labeling requirements for etiologic agents and certain other materials shipped in interstate traffic.

Figures 1 and 2 diagram the packaging and labeling of etiologic agents in volumes of less than 50 ml. in accordance with the provisions of subparagraph (C) (1) of the cited regulation. Figure 3 illustrates the color and size of the label, described in subparagraph (C) (4) of the regulations, which shall be affixed to all shipments of etiologic agents.

For further information on any provision of this regulation contact:

Center for Disease Control
Attn: Biohazards Control Office
1600 Clifton Road
Atlanta, Georgia 30333
Telephone: 404 – 633-3311

FIGURE 1

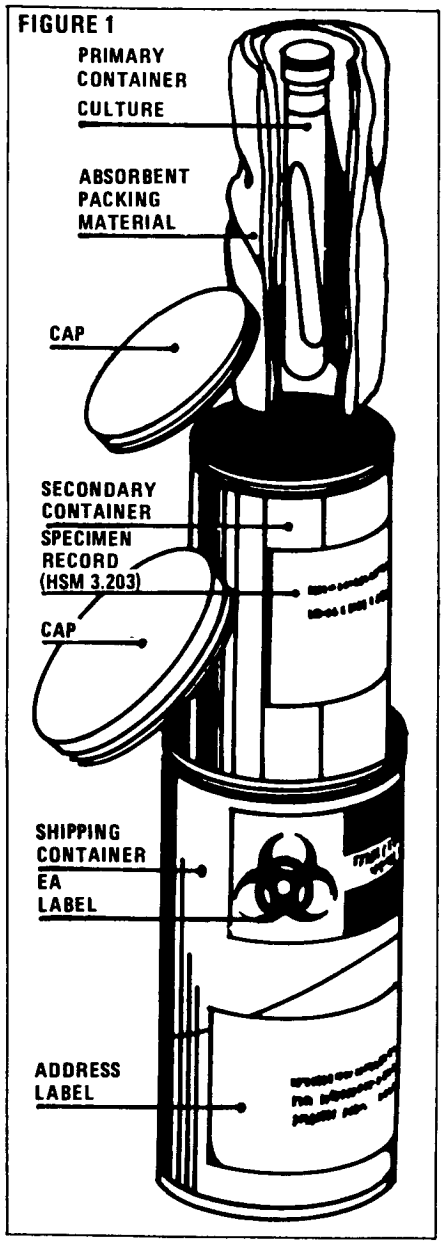
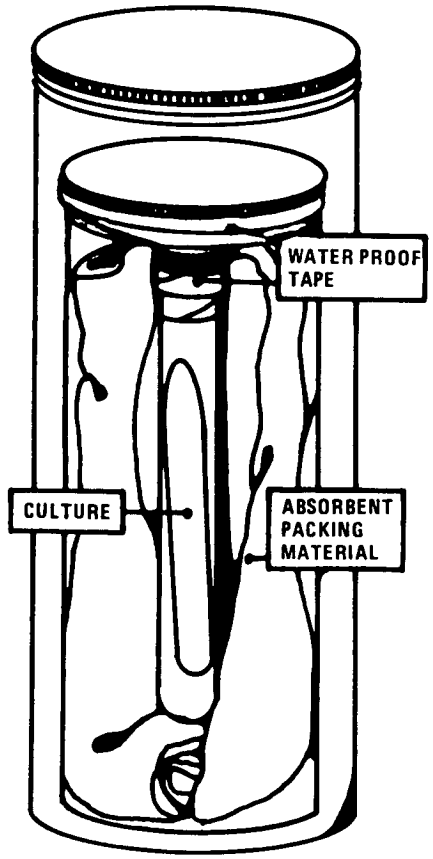


FIGURE 2



CROSS SECTION OF PROPER PACKING

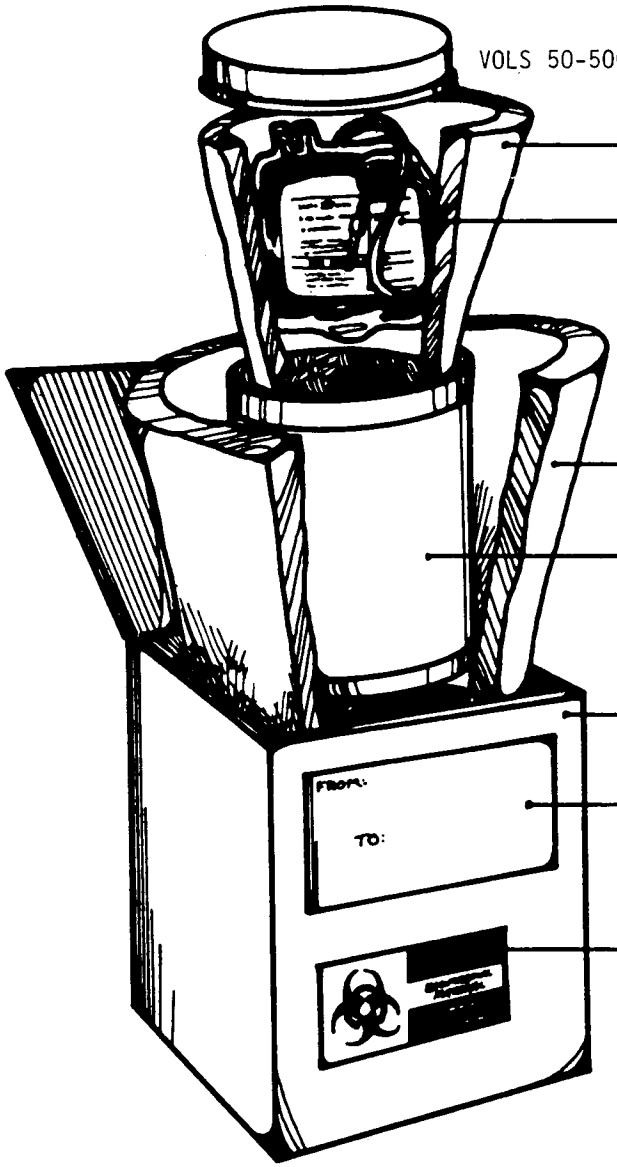
FIGURE 3

ETIOLOGIC AGENTS

BIOMEDICAL MATERIAL

IN CASE OF DAMAGE OR LEAKAGE
NOTIFY DIRECTOR CDC
ATLANTA GEORGIA
404 633-3311

PACKAGING AND LABELING OF ETIOLOGIC AGENTS



*NOTE: Single primary containers may not exceed 500 ml. of material. Two or more primary containers whose combined volumes do not exceed 500 ml. may be enclosed in a single, secondary container. The maximum volume of etiologic agent which may be enclosed in a single outer shipping container shall not exceed 4000 ml.

The Interstate Quarantine Regulations (42 CFR, Part 72.25, Etiologic Agents) was revised July 31, 1972, to provide for packaging and labeling requirements for etiologic agents and certain other materials shipped in interstate traffic. The illustration shows acceptable packaging and labeling of etiologic agents in accordance with subparagraphs (c) (2) and (4) of the cited regulation.

For further information on any provision of this regulation contact:

Center for Disease Control
Attn: Biohazards Control Office
1600 Clifton Road
Atlanta, Georgia 30333

Telephone: 404-633-3311

Enclosure (3)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
CENTER FOR DISEASE CONTROL
FOREIGN QUARANTINE PROGRAM
ATLANTA, GEORGIA 30333

APPLICATION FOR PERMIT TO IMPORT OR TRANSPORT AGENTS OR VECTORS OF HUMAN DISEASE

INSTRUCTIONS: Complete and Submit Original and 1 copy to:
Center for Disease Control, Attn: Foreign Quarantine Program, Atlanta, Georgia 30333

USE ADDITIONAL SHEETS IF NECESSARY.

1. PERSON REQUESTING PERMIT	NAME, ORGANIZATION, ADDRESS:	
2. SOURCE OF MATERIAL	NAME OF SENDER, ORGANIZATION, ADDRESS:	
3. DESCRIPTION OF MATERIAL	NAME, ORIGINAL GEOGRAPHIC AND HOST SOURCE AND CULTURAL HISTORY OF AGENT OR VECTOR:	
4. TYPE OF PERMIT REQUESTED	IMPORTATION INTO U.S. ☐ Single ☐ Multiple	TRANSFER WITHIN THE U.S. ☐ Single ☐ Multiple
	No. of shipments expected to be made within the next 12 months period_____.	
5. SHIPMENT INFORMATION	METHOD OF TRANSPORT: ☐ Mail ☐ Air Freight ☐ Hand Carry ☐ Other _____	U.S. PORT(S) OF ARRIVAL:
6. QUANTITY OF MATERIAL TO BE IMPORTED	INDICATE VOLUME AND TYPE OF INDIVIDUAL CONTAINERS: (Reference 42 CFR 72.25)	
7. PROPOSED USE OF MATERIAL	INDICATE OBJECTIVES AND PROPOSED PLAN OF WORK; COMPLETION DATE; FINAL DISPOSITION OF MATERIAL(S):	
8. ISOLATION AND CONTAINMENT FACILITIES	DESCRIBE AVAILABLE FACILITIES:	
9. TECHNICAL PERSONNEL	QUALIFICATIONS AND EXPERIENCE OF TECHNICAL PERSONNEL:	

I certify that the material will be used in accordance with all Restrictions and Precautions as may be specified in the Permit(s).

10. APPLICANT	SIGNATURE:	DEGREE(S):	11. TITLE:	12. DATE SIGNED:

HSM 13.39 (CDC)
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Enclosure (4)