

Public Health Service, HHS

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APPENDIX A TO PART 72—SELECT AGENTS

AUTHORITY: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

SOURCE: 45 FR 48627, July 21, 1980, unless otherwise noted.

§ 72.1 Definitions.

As used in this part:

Biological product means a biological product prepared and manufactured in accordance with the provisions of 9 CFR parts 102-104 and 21 CFR parts 312 and 600-680 and which, in accordance with such provisions, may be shipped in interstate traffic.

Diagnostic specimen means any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

Etiologic agent means a viable microorganism or its toxin which causes, or may cause, human disease.

Interstate traffic means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

§ 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any ma-

terial including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may 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.

§ 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of § 72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material (other than biological products) known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged, labeled, and shipped in accordance with the requirements specified in paragraphs (a) through (f) of this section:

BACTERIAL AGENTS

Acinetobacter calcoaceticus.
Actinobacillus— all species.
Actinomycetaceae— all members.
Aeromonas hydrophila.
Arachnia propionica.
Arizona hinshawii— all serotypes.
Bacillus anthracis.
Bacteroides spp.
Bartonella— all species.
Bordetella— all species.
Borrelia recurrentis, B. vincenti.
Brucella— all species.
Campylobacter (Vibrio) fetus, C. (Vibrio) jejuni.
Chlamydia psittaci, C. trachomatis.
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.
Edwardsiella tarda.
Erysipelothrix insidiosa.
Escherichia coli, all enteropathogenic serotypes.
Francisella (Pasteurella) Tularensis.
Haemophilus ducreyi, H. influenzae.
Klebsiella— all species and all serotypes.
Legionella— all species and all Legionella-like organisms.
Leptospira interrogans— all serovars.
Listeria— all species.
Mimae polymorpha.
Moraxella— all species.

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Mycobacterium— all species.
Mycoplasma— all species.
Neisseria gonorrhoeae, *N. meningitidis*.
Nocardia asteroides.
Pasteurella— all species.
Plesiomonas shigelloides.
Proteus— all species.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Salmonella— all species and all serotypes.
Shigella— all species and all serotypes.
Sphaerophorus necrophorus.
Staphylococcus aureus.
Streptobacillus moniliformis.
Streptococcus pneumoniae.
Streptococcus pyogenes.
Treponema carenum, *T. pallidum*, and *T. pertenuis*.
Vibrio cholerae, *V. parahemolyticus*.
Yersinia (Pasteurella) pestis, *Y. enterocolitica*.

FUNGAL AGENTS

Blastomyces dermatitidis.
Coccidioides immitis.
Cryptococcus neoformans.
Histoplasma capsulatum.
Paracoccidioides brasiliensis.

VIRAL AND RICKETTSIAL AGENTS

Adenoviruses—human—all types.
Arboviruses—all types.
Coxiella burnetii.
Coxsackie A and B viruses—all types.
Creutzfeldt—Jacob agent
Cytomegaloviruses.
Dengue viruses—all types.
Ebola virus.
Echoviruses—all types.
Encephalomyocarditis virus.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).
Herpesvirus—all members.
Infectious bronchitis-like virus.
Influenza viruses—all types.
Kuru agent.
Lassa virus.
Lymphocytic choriomeningitis virus.
Marburg virus.
Measles virus.
Mumps virus.
Parainfluenza viruses—all types.
Polioviruses—all types.
Poxviruses—all members.
Rabies virus—all strains.
Reoviruses—all types.
Respiratory syncytial virus.
Rhinoviruses—all types.
Rickettsia— all species.
Rochalimaea quintana.
Rotaviruses—all types.
Rubella virus.
Simian virus 40.

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 stomatitis viruses—all types.
White pox viruses.
Yellow fever virus.²

(a) *Volume not exceeding 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 (e.g., paper towel) 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.

(b) *Volume greater than 50 ml.* Packaging of material in volumes of 50 ml. or more shall comply with requirements specified in paragraph (a) of this section. In addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer

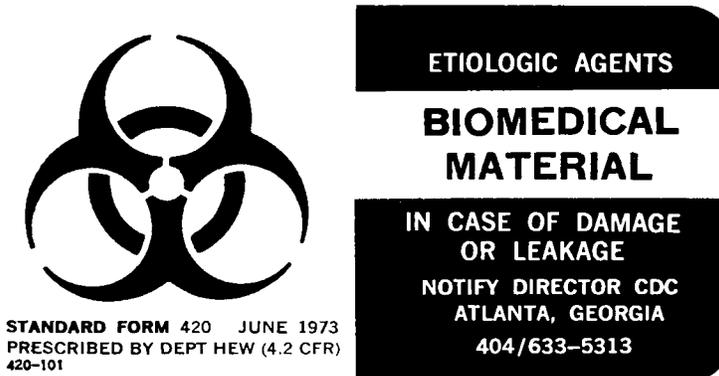
²This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be packaged in accordance with the requirements contained in this part.

shipping container shall not exceed 4,000 ml.

(c) *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 placed so that the secondary container

does not become loose inside the outer shipping container as the dry ice sublimates.

(d)(1) The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label as illustrated and described below:



(2) The color of material on which the label is printed must be white, the symbol red, and the printing in red or white as illustrated.

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

(4) 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.

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

Etiologic agents—10 pt. rev.
Biomedical material—14 pt.
In case of damage or leakage—10 pt. rev.
Notify Director CDC, Atlanta, Georgia—8 pt. rev.
404-633-5313—10 pt. rev.

(e) *Damaged packages.* The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing an Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333,

by telephone: (404) 633-5313. The carrier shall also notify the sender.

(f) *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 of receipt to the sender immediately upon delivery:

Coccidioides immitis.
Ebola virus.
Francisella (Pasteurella) tularensis.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Herpesvirus simiae (B virus).
Histoplasma capsulatum.
Lassa virus.
Marburg virus.
Pseudomonas mallei.
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.
Variola major, Variola minor, and Whitepox viruses.

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*Yersinia (Pasteurella) pestis.*³

§ 72.4 Notice of delivery; failure to receive.

When notice of delivery of materials known to contain or reasonably believed to contain etiologic agents listed in § 72.3(f) is not received by the sender within 5 days following anticipated delivery of the package, the sender shall notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333 (telephone (404) 633-5313).

§ 72.5 Requirements; variations.

The Director, Center for Disease Control, may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and such findings are made a matter of official record.

§ 72.6 Additional requirements for facilities transferring or receiving select agents.

(a) *Registration of facilities.* (1) Prior to transferring or receiving a select agent listed in Appendix A of this part, a facility shall register with a registering entity authorized by the Secretary (paragraph (c) of this section) or be approved by the Secretary as equipped and capable of handling the covered agent at Biosafety Level (BL) 2, 3, or 4, depending on the agent.

(2) Registration will include:

(i) Sufficient information provided by the responsible facility official indicating that the applicant facility, and its laboratory or laboratories, are equipped and capable of handling the agents at BL 2, 3, or 4, depending upon the agent, and the type of work being performed with the agents;

(ii) Inspection of the applicant facility at the discretion of the Secretary or the registering entity in consultation with the Secretary;

³This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be transported in accordance with requirements contained in § 72.3(f).

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(iii) Issuance by the registering entity of a registration number unique to each facility;

(iv) Collection of a periodic site registration fee by the registering entity or the Secretary.

A schedule of fees collected by the Secretary to cover the direct costs (e.g., salaries, equipment, travel) and indirect costs (e.g., rent, telephone service and a proportionate share of management and administration costs) related to administration of this part will be published in the FEDERAL REGISTER and updated annually.

(v) Follow-up inspections of the facility by the registering entity or the Secretary, as appropriate, to ensure the facility continues to meet approved standards and recordkeeping requirements.

(3) Such registration shall remain effective until relinquished by the facility or withdrawn by the Secretary or the registering entity.

(4) The registration may be denied or withdrawn by the registering entity or the Secretary based on:

(i) Evidence that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;

(ii) Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;

(iii) Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans;

(iv) Evidence that the facility has failed to comply with any provisions of this part or has acted in a manner in contravention of this part; or

(v) Failure to pay any required registration fee.

(5) The biosafety standards and requirements for BSL-2, 3, and 4 operations are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition, May 1999 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S.