

section. The notice shall contain a statement of the grounds upon which the revocation is based.

(2) The importer may file an answer within 20 days after receipt of the notice. Answers shall admit or deny specifically, and in detail, each allegation in the notice. Allegations in the notice not denied by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the importer to file an answer within 20 days after receipt of the notice may be deemed an admission of all allegations of fact recited in the notice.

(3) The importer shall be entitled to a hearing with respect to the revocation upon filing a written request, either in the answer or in a separate document, with the Director within 20 days after the effective date of revocation. Failure to request a hearing shall be deemed a waiver of hearing and as consent to the submission of the case to the Director for decision based on the written record. The failure both to file an answer and to request a hearing shall be deemed to constitute consent to the making of a decision on the basis of available information.

(4) As soon as practicable after the completion of any hearing conducted pursuant to the provisions of this section, the Director shall render a final decision. A copy of such decision shall be served on the importer.

(5) An importer's registration which has been revoked may be reinstated by the Director upon inspection, examination of records, conference with the importer, and receipt of information and assurances of compliance with the requirements of this section.

(i) *Other permits.* In addition to the requirements under this section, permits to import certain species of nonhuman primates may also be required under other Federal regulations (50 CFR parts 17 and 23) protecting such species.

(Approved by the Office of Management and Budget under control number 0920-0134)

§ 71.54 Etiological agents, hosts, and vectors.

(a) A person may not import into the United States, nor distribute after im-

portation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

§ 71.55 Dead bodies.

The remains of a person who died of a communicable disease listed in § 71.32(b) may not be brought into a U.S. port unless the body is (a) properly embalmed and placed in a hermetically sealed casket, (b) cremated, or (c) accompanied by a permit issued by the Director.

PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS¹

Sec.

72.1 Definitions.

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

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

72.4 Notice of delivery; failure to receive.

72.5 Requirements; variations.

72.6 Additional requirements for facilities transferring or receiving select agents.

72.7 Penalties.

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

¹The requirements of this part 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.

§ 72.2

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, secreta, 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 material 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:

42 CFR Ch. I (10-1-97 Edition)

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) foetus, 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 insidiosus.
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.
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 careteum, T. pallidum, and T. pertenuae.
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 con-

tainer). 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 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:

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.



STANDARD FORM 420 JUNE 1973
 PRESCRIBED BY DEPT HEW (4.2 CFR)
 420-101

ETIOLOGIC AGENTS

**BIOMEDICAL
 MATERIAL**

IN CASE OF DAMAGE
 OR LEAKAGE

NOTIFY DIRECTOR CDC
 ATLANTA, GEORGIA

404/633-5313

(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.
*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).

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).

§ 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;

(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 requirements for BSL-2, 3, and 4 operations pertaining to this section are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Third Edition, May 1993 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 C.F.R. Part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia, or at the Office of the Federal Register, 800 North Capitol Street N.W., Suite 700, Washington D.C.

(6) Additional specific requirements for handling toxins subject to this part must be met and are found in 29 CFR § 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories."

(b) Appeals.

A decision made by the Secretary or a registering entity to deny or withdraw registration of a particular facility may be appealed to the Secretary. An application for appeal must be received by the Secretary no later than 14 days after the appealing party's application for registration was denied or

no later than 14 days after the appealing party's registration was withdrawn. The application must clearly identify the issues presented by the appeal and fully explain the appealing party's position with respect to those issues. The Secretary may allow the filing of opposing briefs, informal conferences, or whatever steps the Secretary considers appropriate to fairly resolve the appeal.

(c) Authorized registering entities.

(1) The Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select agents are consistent with the requirements contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories," Third Edition.

(2) A registering entity shall maintain:

(i) A database of all facilities formerly and currently registered as BL 2, 3, or 4 and capable of working with agents in Appendix A of this part. The database shall include the name and address of the registered facility, the date the facility was registered, the facility's registration number, and the name and phone number of the responsible facility official.

(ii) A copy of each CDC Form EA-101 transmitted by each transferor registered by that registering entity. Such forms shall be made readily accessible to the Secretary and to appropriate federal law enforcement authorities and/or authorized local law enforcement authorities.

(3) In the event the Secretary authorizes more than one registering entity, or if otherwise necessary, the Secretary may require the establishment of a consolidated database to carry out the provisions of § 72.6(c)(2).

(d) Requests for agents.

(1) Prior to the transfer of any agent contained in Appendix A of this part, a CDC Form EA-101 must be completed for each transfer sought. As specified in CDC Form EA-101, the information provided must include:

(i) The name of the requestor and requesting facility;

(ii) The name of the transferor and transferring facility;

(iii) The names of the responsible facility officials for both the transferor and requestor;

(iv) The requesting facility's registration number;

(v) The transferring facility's registration number;

(vi) The name of the agent(s) being shipped;

(vii) The proposed use of the agent(s); and

(viii) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(2) The form must be signed by the transferor and requestor, and the responsible facility officials representing both the transferring and requesting facilities.

(3) A copy of the completed CDC Form EA-101 must be retained by both transferring and requesting facilities for a period of five (5) years after the date of shipment or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

(4) All CDC forms EA-101 must be produced upon request to appropriate federal and authorized local law enforcement authorities, officials authorized by the Secretary, and officials of the registering entity.

(e) Verification of registration.

(1) Prior to transferring any agent covered by this part, the transferor's responsible facility official must verify with the requestor's responsible facility official, and as appropriate, with the registering entity:

(i) That the requesting facility retains a valid, current registration;

(ii) That the requestor is an employee of the requesting facility; and

(iii) That the proposed use of the agent by the requestor is correctly indicated on CDC Form EA-101.

(2) In the event that any party is unable to verify the information required in paragraph (e)(1) of this section, or there is suspicion that the agent may not be used for the requested purpose, then the party shall immediately notify CDC.

(f) Transfer.

(1) Upon completion of the CDC Form EA-101 and verification of registration, the transferring facility must comply

with the packaging and shipping requirements in this part or other applicable regulations when transferring the agent.

(2) The requesting facility's responsible official must acknowledge receipt of the agent telephonically or otherwise electronically within 36 hours of receipt and provide a paper copy or facsimile transmission of receipt to the transferor within 3 business days of receipt of the agent.

(3) Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed paper copy or facsimile transmission of CDC Form EA-101 within 24 hours to the registering entity (holding that facility's registration), in accordance with § 72.6(c)(2) for filing in a centralized repository.

(g) Inspections.

(1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance with this part. All CDC forms EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities, and/or any consolidated database established in accordance with § 72.6(c)(3), to assure compliance with this part.

(h) Exemptions.

(1) *Exemptions for certain select agents:* Select agents otherwise covered by this part are exempt from its provisions if:

(i) The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with § 72.6(i) after diagnostic, reference, or verification procedures have been completed;

(ii) The agent is a toxin having an LD₅₀ for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins

which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or

(iii) The agent(s) is an exempted strain specified in Appendix A of this part and/or CDC Form EA-101. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents (Appendix A of this part). Individuals seeking additions to the list of exemptions should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future changes to the list of exemptions will be published in the FEDERAL REGISTER for review and comment prior to inclusion on Appendix A of this part.

(2) *Exemption of CLIA certified laboratories:* Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of § 72.6.

(3) *Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory:* Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)

(i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic, reference, verification, or proficiency testing purposes, the *transferor* must:

(A) Provide the following information on CDC Form EA-101:

(1) The name of the requestor and requesting facility;

(2) The name of the transferor and transferring facility;

(3) The name of the transferor's responsible facility official;

(4) The requesting facility's CLIA certification number (which the transferor must verify as valid and current with the registering entity);

(5) The transferring facility's registration number;

(6) The name of the agent(s) being shipped;

(7) The proposed use of the agent(s); and

(8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Verify receipt of the agent with the CLIA laboratory and note such receipt on CDC Form EA-101;

(C) Transmit a copy of the form, signed by the transferrer and the responsible facility official representing the transferring facility, to the registering entity holding the transferring facility's registration; and

(D) Retain a copy of CDC Form EA-101 in accordance with § 72.6(d)(3) and § 72.6(d)(4).

(ii) Prior to receiving a select agent listed in Appendix A of this part from a CLIA laboratory, the *requestor* must be registered in accordance with § 72.6(a) and comply with the following requirements:

(A) Provide the following information on the CDC Form EA-101:

(1) The name of the requestor and requesting facility;

(2) The name of the transferor and transferring facility;

(3) The name of the requestor's responsible facility official;

(4) The transferring facility's CLIA certification number;

(5) The requesting facility's registration number;

(6) The name of the agent(s) being shipped;

(7) The proposed use of the agent(s); and

(8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Upon receiving the agent, note such receipt on CDC Form EA-101;

(C) Transmit a copy of CDC Form EA-101, signed by the requestor and the responsible facility official representing the requesting facility, to the registering entity holding the requesting facility's registration;

(D) Retain a copy of the CDC Form EA-101 in accordance with §§ 72.6(d)(3) and 72.6(d)(4);

(E) Comply with the disposal requirements of § 72.6(i) and all other sections of this part when subsequently transferring the agent.

(i) Agent disposal.

(1) Upon termination of the use of the agent, all cultures and stocks of it will be

(i) Securely stored in accordance with prudent laboratory practices,

(ii) Transferred to another registered facility in accordance with this part, or

(iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

(2) When an agent, previously transferred to a facility in accordance with this part, is consumed or destroyed, the responsible facility official must formally notify the registering entity. Formal notification must be noted on CDC Form EA-101 and a copy kept on record by the responsible facility official for a period of five (5) years and is subject to paragraph (g) of this section.

(j) Definitions. As used in this section:

Facility means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part.

Registering entity means an organization or state agency authorized by the Secretary to register facilities as capable of handling select agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."

Requestor means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

Secretary means the Secretary of the Department of Health and Human Services or her or his designee.

Select agent means a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part. The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic submits.

Single geographic site means a building or complex of buildings at a single mailing address.

Transfer means:

(1) The conveyance or movement from a point or origination to a point of destination either:

(i) From one state or territory to another or;

(ii) Entirely within one contiguous state or territory.

(2) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of §72.6 (d), (e), and (f) provided that:

(i) The intended use of the agent remains consistent with that specified in the most current transfer form; and

(ii) For each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

[61 FR 55197, Oct. 24, 1996]

§72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine or no more than \$500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for

transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

[61 FR 55199, Oct. 24, 1996]

APPENDIX A TO PART 72—SELECT AGENTS

Viruses

1. Crimean-Congo haemorrhagic fever virus
 2. Eastern Equine Encephalitis virus
 3. Ebola viruses
 4. Equine Morbillivirus
 5. Lassa fever virus
 6. Marburg virus
 7. Rift Valley fever virus
 8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
 9. Tick-borne encephalitis complex viruses
 10. Variola major virus (Smallpox virus)
 11. Venezuelan Equine Encephalitis virus
 12. Viruses causing hantavirus pulmonary syndrome
 13. Yellow fever virus
- Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

1. *Bacillus anthracis*
 2. *Brucella abortus*, *B. melitensis*, *B. suis*
 3. *Burkholderia (Pseudomonas) mallei*
 4. *Burkholderia (Pseudomonas) pseudomallei*
 5. *Clostridium botulinum*
 6. *Francisella tularensis*
 7. *Yersinia pestis*
- Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens epsilon toxin*
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD₅₀ for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

RECOMBINANT ORGANISMS/MOLECULES

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

OTHER RESTRICTIONS

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

ADDITIONAL EXEMPTIONS

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*) and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the FEDERAL REGISTER for review and comment prior to inclusion in this Appendix.

[61 FR 55199, Oct. 24, 1996]

PART 75—STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

Sec.

75.1 Background and purpose.

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APPENDIX A TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATION PROGRAMS FOR RADIOGRAPHERS

APPENDIX B TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

APPENDIX C TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

APPENDIX D TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

APPENDIX E TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATION PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

APPENDIX F TO PART 75—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS

APPENDIX G TO PART 75—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, Pub. L. 97-35, 95 Stat. 599-600 (42 U.S.C. 10004).

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

§ 75.1 Background and purpose.

(a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10004, which requires the establishment by the Secretary of Health and Human Services of standards for the accreditation of programs for the education of certain persons who administer radiologic procedures and for the credentialing of such persons.

(b) Section 979 requires the Secretary, after consultation with specified Federal agencies, appropriate agencies of States, and appropriate professional organizations, to promulgate by regulation the minimum standards described above. These standards distinguish between the occupations of (1) radiographer, (2) dental hygienist, (3) dental assistant, (4) nuclear medicine technologist, and (5) radiation therapy technologist. In the interest of public safety and to prevent the hazards of improper use of medical radiation identified by Congress in its determination of the need for standards, the Secretary is also authorized to prepare standards for other occupational groups utilizing ionizing and non-ionizing radiation as he/she finds appropriate. However, the standards set out below are limited to the five occupational groups listed above, utilizing ionizing radiation. Nothing in this accreditation standards is intended to