

§ 72.4

*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.

Government Printing Office, Washington, DC 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop A-13 Atlanta, Georgia, or at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC. The manual is also available on the CDC web site at www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm.

(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," Fourth 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

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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 enti-

ties, 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 transferor 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

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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 trans-

ferred, 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, as amended at 66 FR 45945, Aug. 31, 2001]

§ 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*