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issuing the Federal quarantine, isolation, or conditional release order, or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the Federal quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the individual under Federal quarantine, isolation, or conditional release, or by any authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall upon request be served with a copy of his or her own administrative record in its entirety.

[82 FR 6971, Jan. 19, 2017]

§ 70.18 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law.

(b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

[82 FR 6971, Jan. 19, 2017]

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AUTHORITY: Secs. 215 and 311 of Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

SOURCE: 50 FR 1519, Jan. 11, 1985, unless otherwise noted.

Subpart A—Definitions and General Provisions

§ 71.1 Scope and definitions.

(a) The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or territories (also known as possessions) of the United States. Regulations pertaining to preventing the interstate spread of communicable diseases are contained in 21 CFR parts 1240 and 1250 and 42 CFR part 70.

(b) As used in this part the term:

Airline means any air carrier or foreign air carrier providing air transportation, as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether quarantine, isolation, or conditional release is warranted.

Carrier means a ship, aircraft, train, road vehicle, or other means of transport, including military.

Commander means the pilot in command of an aircraft as defined in 14 CFR 1.1.

Communicable disease means an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment.

Conditional release means surveillance as defined under this part and includes public health supervision through in-person visits by a health official or designee, telephone, or through any elec-

tronic or internet-based means as determined by the Director.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

Contamination means the presence of undesirable substances or material which may contain infectious agents or their toxic products.

Controlled Free Pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

Deratting Certificate means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and deratting of the ship.

Deratting Exemption Certificate means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and exemption from deratting of the ship which is rodent free.

Detention means the temporary holding of a person, ship, aircraft, or other carrier, animal, or thing in such place and for such period of time as may be determined by the Director.

Director means the Director, Centers for Disease Control, Public Health Service, Department of Health and Human Services, or his/her authorized representative.

Disinfection means the killing of infectious agents or inactivation of their toxic products outside the body by direct exposure to chemical or physical agents.

Disinfestation means any chemical or physical process serving to destroy or remove undesired small animal forms, particularly arthropods or rodents, present upon the person, the clothing, or the environment of an individual, or upon animals and carriers.

Disinsection means the operation in which measures are taken to kill the insect vectors of human disease present in carriers and containers.

Educational purpose means use in the teaching of a defined educational program at the university level or equivalent.

Electronic or internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director.

Exhibition purpose means use as a part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

Ill person means an individual:

(i) Who if onboard an aircraft:

(A) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(B) Has a fever that has persisted for more than 48 hours; or

(C) Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the FEDERAL REGISTER.

(ii) Who if onboard a vessel:

(A) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater; or feels warm to the touch; or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing or suspected or confirmed pneumonia, persistent cough or cough with bloody sputum, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury),

persistent vomiting (other than sea sickness), headache with stiff neck; or

(B) Has a fever that has persisted for more than 48 hours; or

(C) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater); or

(D) Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the FEDERAL REGISTER.

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the FEDERAL REGISTER by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

International Health Regulations or *IHR* means the International Health Regulations of the World Health Organization, adopted by the Fifty-Eighth World Health Assembly in 2005, as may be further amended, and subject to the United States' reservation and understandings.

International voyage means:

(i) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or

(ii) In the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

Isolation means the separation of an individual or group who is reasonably believed to be infected with a quarantinable communicable disease from those who are healthy to prevent the spread of the quarantinable communicable disease.

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation

and navigation, or a similar individual with responsibility for a carrier. Consistent with the definition of “operate” in 14 CFR 1.1, “operator” means, with respect to aircraft, any person who uses, causes to use or authorizes to use aircraft, for the purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of aircraft, with or without the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual’s health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

Military services means the U.S. Army, the U.S. Air Force, the U.S. Navy, and the U.S. Coast Guard.

Non-invasive means procedures conducted by an authorized public health worker (*i.e.*, an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

Possession means U.S. territory.

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, ques-

tioning, review of travel documents, records review, and other non-invasive means, to determine the individual’s health status and potential public health risk to others.

Quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who is not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

Quarantinable communicable disease means any of the communicable diseases listed in an Executive Order, as provided under §361 of the Public Health Service Act (42 U.S.C. §264). Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov> and <http://www.archives.gov/federal/register>. If this Order is amended, HHS will enforce that amended order immediately and update that Web site.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases, and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

Scientific purpose means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products.

Secretary means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.

Surveillance means the temporary supervision by a public health official (or designee) of an individual or group,

who may have been exposed to a quarantinable communicable disease, to determine the risk of disease spread.

U.S. port means any seaport, airport, or border crossing point under the control of the United States.

U.S. territory means any territory (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

United States means the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

Vector means any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products that are known to transfer, or are capable of transferring, an infectious biological agent to a human.

[50 FR 1519, Jan. 11, 1985, as amended at 77 FR 75890, Dec. 26, 2012; 82 FR 6973, Jan. 19, 2017]

§ 71.2 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law. (b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

[82 FR 6975, Jan. 19, 2017]

§ 71.3 Designation of yellow fever vaccination centers; Validation stamps.

(a) *Designation of yellow fever vaccination centers.* (1) The Director is responsible for the designation of yellow fever vaccination centers authorized to issue certificates of vaccination. This responsibility is delegated by the Director to a State or territorial health department with respect to yellow fever vaccination activities of non-Federal

medical, public health facilities, and licensed physicians functioning within the respective jurisdictions of a State or territorial health department. Designation may be made upon application and presentation of evidence satisfactory to a State or territorial health department that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of a safe, potent, and pure yellow fever vaccine. Medical facilities of Federal agencies are authorized to obtain yellow fever vaccine without being designated as a yellow fever vaccination center by the Director.

(2) A designated yellow fever vaccination center shall comply with the instruction issued by the Director or by a delegated officer or employee of a State or territorial health department for the handling, storage, and administration of yellow fever vaccine. If a designated center fails to comply with such instruction, after notice to the center, the Director or, for non-Federal centers, a State or territorial health department, may revoke designation.

(b) *Validation stamps.* International Certificates of Vaccination against cholera and yellow fever issued for vaccinations performed in the United States shall be validated by:

- (1) The Seal of the Public Health Service; or
- (2) The Seal of the Department of State; or
- (3) The stamp of the Department of Defense; or
- (4) The stamp issued to the National Aeronautics and Space Administration; or
- (5) The stamp issued by a State or territorial health department; or
- (6) An official stamp of a design and size approved by the Director for such purpose.

§ 71.4 Requirements relating to the transmission of airline passenger, crew, and flight information for public health purposes.

(a) Any airline with a flight arriving into the United States, including any intermediate stops between the flight's origin and final destination, shall make the data elements in paragraph

(b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already available and maintained by the airline, within 24 hours of an order by the Director and in a format available and acceptable to both the airline and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available, middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Airline name;
- (12) Flight number;
- (13) City of departure;
- (14) Departure date and time;
- (15) City of arrival;
- (16) Arrival date and time; and
- (17) Seat number.

(c) No later than February 21, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

(d) Notwithstanding paragraph (a) of this section, any airline with a flight arriving into the United States, including any intermediate stops between the

flight's origin and final destination, shall collect and, within 24 hours of an order by the Director, transmit to the Director the data elements in paragraph (e) of this section, in a format acceptable to the Director, for the passengers or crew who may be at risk of exposure to a communicable disease, for the purposes of public health follow-up, such as health education, treatment, prophylaxis, or other appropriate public health interventions, including travel restrictions.

(e) The data elements referred to in paragraph (d) of this section include, to the extent that such information exists for the individual:

- (1) Full name (last, first, and, if available, middle or others);
- (2) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code);
- (3) Primary contact phone number to include country code;
- (4) Secondary contact phone number to include country code; and
- (5) Email address.

[82 FR 6975, Jan. 19, 2017, as amended at 82 FR 31728, July 10, 2017; 85 FR 7880, Feb. 12, 2020]

§ 71.5 Requirements relating to the transmission of vessel passenger, crew, and voyage information for public health purposes.

(a) The operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10-25), shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already in the operator's possession, within 24 hours of an order by the Director and in a format available and acceptable to both the operator and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available middle or others);

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- (2) Date of birth;
 - (3) Sex;
 - (4) Country of residence;
 - (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
 - (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
 - (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the United States (number and street, city, State, and zip code; as applicable);
 - (8) Primary contact phone number to include country code;
 - (9) Secondary contact phone number to include country code;
 - (10) Email address;
 - (11) Vessel operator;
 - (12) Vessel name;
 - (13) Voyage number;
 - (14) Embarkation port and date;
 - (15) Disembarkation port and date;
 - (16) All port stops; and
 - (17) Cabin number.
- (c) No later than February 21, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

[82 FR 6975, Jan. 19, 2017]

Subpart B—Measures at Foreign Ports

§ 71.11 Bills of health.

A carrier at any foreign port clearing or departing for any U.S. port shall not be required to obtain or deliver a bill of health.

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Subpart C—Notice of Communicable Disease Prior to Arrival

§ 71.20 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures, at U.S. ports of entry or other locations, through non-invasive procedures as defined in section 71.1 to detect the potential presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

[82 FR 6975, Jan. 19, 2017]

§ 71.21 Report of death or illness.

(a) The master of a ship destined for a U.S. port shall report immediately to the quarantine station at or nearest the port at which the ship will arrive, the occurrence, on board, of any death or any ill person among passengers or crew (including those who have disembarked or have been removed) during the 15-day period preceding the date of expected arrival or during the period since departure from a U.S. port (whichever period of time is shorter).

(b) The commander of an aircraft destined for a U.S. airport shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew.

(c) In addition to paragraph (a) of this section, the master of a ship carrying 13 or more passengers must report 24 hours before arrival the number of cases (including zero) of acute gastroenteritis (AGE) in passengers and crew recorded in the ship's medical log during the current cruise. All cases of acute gastroenteritis (AGE) that occur after the 24 hour report must

also be reported not less than 4 hours before arrival.

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

[50 FR 1519, Jan. 11, 1985, as amended at 82 FR 31729, July 10, 2017]

Subpart D—Health Measures at U.S. Ports: Communicable Diseases

§ 71.29 Administrative records relating to quarantine, isolation, or conditional release.

(a) The administrative record of an individual under quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order, or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the individual under Federal quarantine, isolation, or conditional release, or by an authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall, upon request, be served with a copy of his or her own administrative record in its entirety.

[82 FR 6975, Jan. 19, 2017]

§ 71.30 Payment for care and treatment.

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and condi-

tional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the Director's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual for the time period beginning when the Director refers the individual to the hospital or medical facility and ends when, as determined by the Director, the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary

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for the safe medical transport of the individual.

[82 FR 6975, Jan. 19, 2017]

§ 71.31 General provisions.

(a) Upon arrival at a U.S. port, a carrier will not undergo inspection unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States, as may exist when the carrier has on board individual(s) reportable in accordance with § 71.21 or meets the circumstances described in § 71.42. Carriers not subject to inspection under this section will be subject to sanitary inspection under § 71.41 of this part.

(b) The Director may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease. The Director may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

§ 71.32 Persons, carriers, and things.

(a) Whenever the Director has reason to believe that any arriving person is infected with or has been exposed to any of the communicable diseases listed in an Executive Order, as provided under section 361(b) of the Public Health Service Act, he/she may isolate, quarantine, or place the person under surveillance and may order disinfection or disinfestation, fumigation, as he/she considers necessary to prevent the introduction, transmission or spread of the listed communicable diseases. Executive Order 13295, of April 4, 2003, as provided under section 361 of the Public Health Service Act (42 U.S.C. 264), and as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov> and <http://www.archives.gov/federal-register>. If this Order is amended, HHS will enforce that amended order immediately and update this reference.

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(b) Whenever the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease, he/she may require detention, disinfection, disinfestation, fumigation, or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases.

[68 FR 17559, Apr. 10, 2003, as amended at 77 FR 75891, Dec. 26, 2012]

§ 71.33 Persons: Isolation and surveillance.

(a) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for persons who are apprehended or held in isolation or quarantine under this subpart.

(b) The Director may require isolation where surveillance is authorized in this subpart whenever the Director considers the risk of transmission of infection to be exceptionally serious.

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and submit to surveillance, including electronic and internet-based monitoring as required by the Director or by the State or local health department having jurisdiction over the areas to be visited, and report for such medical examinations as may be required.

(2) Inform the Director prior to departing the United States or prior to traveling to any address other than that stated as the intended destination.

(d) From time to time the Director may, in accordance with section 322 of the Public Health Service Act, enter into agreements with public or private medical or hospital facilities for providing care and treatment for persons detained under this part.

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

[50 FR 1519, Jan. 11, 1985; 50 FR 3910, Jan. 29, 1985; 82 FR 6976, Jan. 19, 2017]

§ 71.34 Carriers of U.S. military services.

(a) Carriers belonging to or operated by the military services of the United States may be exempted from inspection if the Director is satisfied that they have complied with regulations of the military services which also meet the requirements of the regulations in this part. (For applicable regulations of the military services, see Army Regulation No. 40-12, Air Force Regulation No. 161-4, Secretary of the Navy Instruction 6210.2, and Coast Guard Commandant Instruction 6210.2).

(b) Notwithstanding exemption from inspection of carriers under this section, animals or articles on board shall be required to comply with the applicable requirements of subpart F of this part.

§ 71.35 Report of death or illness on carrier during stay in port.

The master of any carrier at a U.S. port shall report immediately to the quarantine station at or nearest the port the occurrence, on board, of any death or any ill person among passengers or crew.

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

§ 71.36 Medical examinations.

(a) The Director may require that an individual arriving into the United States undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release.

(b) The Director shall promptly arrange for the medical examination to be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require that an individual provide information and undergo such testing, as may be reasonably necessary, to diagnose or confirm the presence, absence, or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected, based on the results of a medical examination, may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

[82 FR 6976, Jan. 19, 2017]

§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is exposed to or infected with a quarantinable communicable disease;

(4) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(5) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(6) An explanation that if a medical examination is required as part of the Federal order that the examination will be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the

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Federal order may be published or posted in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.

[82 FR 6976, Jan. 19, 2017]

§ 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

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(f) The Director's written Federal order shall be promptly served on the individual, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

[82 FR 6976, Jan. 19, 2017]

§ 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.

(a) The Director shall, as soon as practicable, arrange for a medical review upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under 71.38 and following the issuance and service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual subject to Federal quarantine, isolation, or conditional release may authorize an advocate (*e.g.*, an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director shall appoint representatives at government

expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he/she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in the medical review pertaining to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should continue. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the

individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individual's and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual or the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the

holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

[82 FR 6976, Jan. 19, 2017]

§ 71.40 Suspension of the right to introduce and prohibition of the introduction of persons into the United States from designated foreign countries or places for public health purposes.

(a) The Director may prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease, by issuing an order in which the Director determines that:

(1) By reason of the existence of any quarantinable communicable disease in a foreign country (or one or more political subdivisions or regions thereof) or place there is serious danger of the introduction of such quarantinable communicable disease into the United States; and

(2) This danger is so increased by the introduction of persons from such country (or one or more political subdivisions or regions thereof) or place that a suspension of the right to introduce such persons into the United States is required in the interest of public health.

(b) For purposes of this section:

(1) *Introduction into the United States* means the movement of a person from a foreign country (or one or more political subdivisions or regions thereof) or place, or series of foreign countries or places, into the United States so as to bring the person into contact with persons or property in the United States, in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with a quarantinable

communicable disease, even if the quarantinable communicable disease has already been introduced, transmitted, or is spreading within the United States;

(2) *Prohibit, in whole or in part, the introduction into the United States of persons* means to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States, or physically expelling from the United States some or all of the persons;

(3) *Serious danger of the introduction of such quarantinable communicable disease into the United States* means the probable introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease;

(4) The term *Place* includes any location specified by the Director, including any carrier, as that term is defined in 42 CFR 71.1, whatever the carrier's flag, registry, or country of origin; and

(5) *Suspension of the right to introduce* means to cause the temporary cessation of the effect of any law, rule, decree, or order pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States.

(c) Any order issued by the Director under this section shall include a statement of the following:

(1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons shall be prohibited;

(2) The period of time or circumstances under which the introduction of any persons or class of persons into the United States shall be prohibited;

(3) The conditions under which that prohibition on introduction shall be effective in whole or in part, including any relevant exceptions that the Director determines are appropriate;

(4) The means by which the prohibition shall be implemented; and

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

(d) When issuing any order under this section, the Director shall, as practicable under the circumstances, consult with all Federal departments or agencies whose interests would be impacted by the order. The Director shall, as practicable under the circumstances, provide the Federal departments or agencies with a copy of the order before issuing it. In circumstances when it is impracticable to engage in such consultation before taking action to protect the public health, the Director shall consult with the Federal departments or agencies as soon as practicable after issuing his or her order, and may then modify the order as he or she determines appropriate. In addition, the Director may, as practicable under the circumstances, consult with any State or local authorities that he or she deems appropriate in his or her discretion.

(1) If the order will be implemented in whole or in part by State and local authorities who have agreed to do so under 42 U.S.C. 243(a), then the Director shall explain in the order the procedures and standards by which those authorities are expected to aid in the enforcement of the order.

(2) If the order will be implemented in whole or in part by designated customs officers (including any individual designated by the Department of Homeland Security to perform the duties of a customs officer) or Coast Guard officers under 42 U.S.C. 268(b), or another Federal department or agency, then the Director shall, in coordination with the Secretary of Homeland Security or other applicable Federal department or agency head, explain in the order the procedures and standards by which any authorities or officers or agents are expected to aid in the enforcement of the order, to the extent that they are permitted to do so under their existing legal authorities.

(e) This section does not apply to:

(1) Members of the armed forces of the United States and associated per-

sonnel if the Secretary of Defense provides assurance to the Director that the Secretary of Defense has taken or will take measures such as quarantine or isolation, or other measures maintaining control over such individuals, to prevent the risk of transmission of the quarantinable communicable disease into the United States; or

(2) Other United States government employees or contractors on orders abroad, or their accompanying family members who are on their orders or are members of their household, if the Director receives assurances from the relevant head of agency and determines that the head of the agency or department has taken or will take, measures such as quarantine or isolation, to prevent the risk of transmission of a quarantinable communicable disease into the United States.

(f) This section shall not apply to U.S. citizens, U.S. nationals, and lawful permanent residents.

(g) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[85 FR 56458, Sept. 11, 2020]

Subpart E—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection

§ 71.41 General provisions.

Carriers arriving at a U.S. port from a foreign area shall be subject to a sanitary inspection to determine whether there exists rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable disease.

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§ 71.42 Disinfection of imports.

When the cargo manifest of a carrier lists articles which may require disinfection under the provisions of this part, the Director shall disinfect them on board or request the appropriate customs officer to keep the articles separated from the other cargo pending appropriate disposition.

§ 71.43 Exemption for mails.

Except to the extent that mail contains any article or thing subject to restrictions under subpart F of this part, nothing in the regulations in this part shall render liable to detention, disinfection, or destruction any mail conveyed under the authority of the postal administration of the United States or of any other Government.

§ 71.44 Disinsection of aircraft.

(a) The Director may require disinsection of an aircraft if it has left a foreign area that is infected with insect-borne communicable disease and the aircraft is suspected of harboring insects of public health importance.

(b) Disinsection shall be the responsibility of the air carrier or, in the case of aircraft not for hire, the pilot in command, and shall be subject to monitoring by the Director.

(c) Disinsection of the aircraft shall be accomplished immediately after landing and blocking.

(1) The cargo compartment shall be disinsected before the mail, baggage, and other cargo are discharged.

(2) The rest of the aircraft shall be disinsected after passengers and crew deplane.

(d) Disinsection shall be performed with an approved insecticide in accordance with the manufacturer's instructions. The current list of approved insecticides and sources may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333.

§ 71.45 Food, potable water, and waste: U.S. seaports and airports.

(a) Every seaport and airport shall be provided with a supply of potable water from a watering point approved by the Commissioner of Food and Drugs, Food and Drug Administration, in accordance with standards established in title

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21, Code of Federal Regulations, parts 1240 and 1250.

(b) All food and potable water taken on board a ship or aircraft at any seaport or airport intended for human consumption thereon shall be obtained from sources approved in accordance with regulations cited in paragraph (a) of this section.

(c) Aircraft inbound or outbound on an international voyage shall not discharge over the United States any excrement, or waste water or other polluting materials. Arriving aircraft shall discharge such matter only at servicing areas approved under regulations cited in paragraph (a) of this section.

§ 71.46 Issuance of Deratting Certificates and Deratting Exemption Certificates.

Valid Deratting Certificates or Deratting Exemption Certificates are not required for ships to enter a U.S. seaport. In accordance with Article 17 of the International Health Regulations, the Public Health Service may perform rodent infestation inspections and issue Deratting Certificates and Deratting Exemption Certificates.

§ 71.47 Special provisions relating to airports: Office and isolation facilities.

Each U.S. airport which receives international traffic shall provide without cost to the Government suitable office, isolation, and other exclusive space for carrying out the Federal responsibilities under this part.

§ 71.48 Carriers in intercoastal and interstate traffic.

Carriers, on an international voyage, which are in traffic between U.S. ports, shall be subject to inspection as described in §§ 71.31 and 71.41 when there occurs on board, among passengers or crew, any death, or any ill person, or when illness is suspected to be caused by insanitary conditions.

Subpart F—Importations

§ 71.50 Scope and definitions.

(a) The purpose of this subpart is to prevent the introduction, transmission, and spread of communicable human

disease resulting from importations of various animal hosts or vectors or other etiological agents from foreign countries into the United States.

(b) In addition to terms in § 71.1, the terms below, as used in this subpart, shall have the following meanings:

Animal product or *Product* means the hide, hair, skull, teeth, bones, claws, blood, tissue, or other biological samples from an animal, including trophies, mounts, rugs, or other display items.

Authorized veterinarian means an individual who has an advanced degree relevant to the practice of veterinary medicine, has a valid license or accreditation, and is authorized to practice animal medicine in the exporting country.

Cat means any domestic cat (*Felis catus*).

Death certificate means an official government document that certifies that a death has occurred and provides identifying information about the deceased, including (at a minimum) name, age, and sex. The document must also certify the time, place, and cause of death (if known). If the official government document is not written in English, then it must be accompanied by an English language translation of the official government document, the authenticity of which has been attested to by a person licensed to perform acts in legal affairs in the country where the death occurred. In lieu of a death certificate, a copy of the Consular Mortuary Certificate and the Affidavit of Foreign Funeral Director and Transit Permit, shall together constitute acceptable identification of human remains.

Dog means any domestic dog (*Canis familiaris*).

Educational purpose means use in the teaching of a defined educational program at the university level or equivalent.

Exhibition purpose means use as part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open

to the general public except for reasonable vacation and retraining periods.

Histopathology means the study of changes in human or animal tissues caused by disease.

Human remains means a deceased human body or any portion of a deceased human body, except:

(i) Clean, dry bones or bone fragments; human hair; teeth; fingernails or toenails; or

(ii) A deceased human body and portions thereof that have already been fully cremated prior to import; or

(iii) Human cells, tissues or cellular or tissue-based products intended for implantation, transplantation, infusion, or transfer into a human recipient.

Importer means any person importing or attempting to import an item regulated under this subpart.

In transit means animals that are located within the United States, whether their presence is anticipated, scheduled, or not, as part of the movement of those animals between a foreign country of departure and foreign country of final destination without clearing customs and officially entering the United States.

In-Transit Shipment means a cargo shipment originating in a foreign country that is moved through one or more U.S. ports while transiting through the United States to a third-country destination. In-transit shipments pass through a U.S. port of entry and a U.S. port of exit, which may be in the same location, or which may involve numerous stopping points.

Isolation when applied to animals means the separation of an ill animal or ill group of animals from individuals, or other animals, or vectors of disease in such a manner as to prevent the spread of infection.

Leak-proof container means a container that is puncture-resistant and sealed in such a manner as to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping, such as

(i) A double-layered plastic, puncture-resistant body bag (*i.e.*, two sealed body bags, one inside the other);

(ii) A casket with an interior lining certified by the manufacturer to be leak-proof and puncture-resistant; or

(iii) A sealed metal body-transfer case.

Licensed veterinarian means an individual who has obtained both an advanced degree and valid license to practice animal medicine.

Microchip means an implanted radio-frequency device placed under the skin of an animal that contains a unique identification tag that meets the International Standards Organization (ISO) compatibility through ISO 11784 or ISO 11785, or similar technologies as approved by the Director.

Necropsy means an animal autopsy in which the cause of death may be determined through the examination and collection, post-mortem, of tissues, organs, or bodily fluids.

Official government veterinarian means a veterinarian who performs work on behalf of an exporting country's government and can verify the license or credentials of an authorized veterinarian.

Person means any individual or partnership, firm, company, corporation, association, organization, or similar legal entity, including those that are not-for-profit.

Quarantine when applied to animals means the practice of separating live animals that are reasonably believed to have been exposed to a communicable disease, but are not yet ill, in a setting where the animal can be observed for evidence of disease, and where measures are in place to prevent transmission of infection to humans or animals.

Render noninfectious means treating an animal product (e.g., by boiling, irradiating, soaking, formalin fixation, or salting) in such a manner that renders the product incapable of transferring an infectious biological agent to a human.

Scientific purpose means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products.

You or your means an importer, owner, or an applicant.

(c) Any provision of this subpart held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this subpart and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[77 FR 75891, Dec. 26, 2012, as amended at 85 FR 42741, July 15, 2020; 89 FR 41837, May 13, 2024]

§ 71.51 Dogs and cats.

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

Animal means, for purposes of this section, any domestic cat (*Felis catus*) or domestic dog (*Canis familiaris*).

CDC dog import form means an OMB-approved form submitted to CDC through an online portal that includes the importer's name and contact information; description of the dog, including microchip number and current photographs of the dog's face and body; purpose of importation; travel information, including dates of departure and arrival, country of departure, countries the dog has been physically present in within the last six months, and U.S. port of entry; and other information as described in CDC technical instructions.

CDC dog import permit means a document issued by CDC granting approval to import a dog into the United States from a DMRVV-restricted country. To receive a permit, eligible importers submit information to CDC that includes the importer's name and contact information; description of the dog, including microchip number and current photographs of the dog's face and body; purpose of importation; travel information, including dates of departure and arrival, country of departure, countries the dog has been physically present in within the last six months, and U.S. port of entry; and other information as described in CDC technical instructions.

CDC-registered animal care facility means a facility registered by CDC for

the purpose of providing veterinary care and housing to animals imported into the United States.

Certification of dog arriving from DMRVV-free or DMRVV low-risk country means the OMB-approved form that together with other records may be used by an importer to demonstrate that a dog has been only in DMRVV-free or DMRVV low-risk countries during the six months before the dog's arrival in the United States.

Certification of foreign rabies vaccination and microchip means the Office of Management and Budget (OMB)-approved form that must be:

(i) completed by an authorized veterinarian, which may include an official government veterinarian, in the exporting country; and

(ii) reviewed and signed by an official government veterinarian in the exporting country attesting that the information listed is true and correct.

Certification of U.S.-issued rabies vaccination means the OMB-approved form that must be completed by a U.S. Department of Agriculture (USDA)-Accredited Veterinarian and endorsed by a USDA Official Veterinarian prior to a dog's departure from the United States in order to demonstrate compliance with admissibility requirements upon the dog's return to the United States from a DMRVV high-risk country.

Conditional release, when applied to an animal, means the temporary release of an animal from the custody of a carrier or a CDC-registered animal care facility into the care of a licensed veterinarian approved by the Director, for the purpose of receiving emergency medical care or a public health evaluation, pending an admissibility determination or removal of the animal from the United States. The licensed veterinarian must return conditionally released animals immediately to the custody of the carrier or the CDC-registered animal care facility upon the conclusion of such medical care or evaluation.

Confinement, when applied to an animal, means restriction to a building or other enclosure at a U.S. port or other location approved by the Director, including *en route* to a destination, separate from other animals, and from persons except for contact necessary for

its care. If the animal is allowed out of the enclosure, it must be muzzled and kept on a leash.

DMRVV means dog-maintained rabies virus variant and includes any rabies virus variant that is known or suspected to have an enzootic transmission cycle in which dogs are essential for the maintenance of the viral variant. This includes epidemiologic situations in which dogs are the only recognized reservoir species, as well as situations in which dogs and other species (typically wildlife) both play epidemiologically relevant roles in maintaining enzootic transmission.

DMRVV-free country means a country determined by the Director as not having DMRVV present based on internationally accepted standards.

DMRVV high-risk country means a country determined by the Director as having high risk for DMRVV transmission based on factors such as the presence and geographic distribution of the virus, or low quality of or low confidence in rabies surveillance systems or dog vaccination programs. A list of the DMRVV high-risk countries is available on CDC's website.

DMRVV low-risk country means a country determined by the Director as having low risk for DMRVV transmission based on factors such as the virus being limited to a localized area, adequacy of surveillance and dog vaccination programs to prevent further geographic distribution of the virus, and the virus being in a controlled status with the country's heading toward eventual DMRVV-free status.

DMRVV-restricted country means a country from which the import of dogs into the United States has been prohibited or otherwise restricted. Designation of a DMRVV-restricted country may be based on the country's export of dogs infected with DMRVV to any other country within a timeframe determined by the Director or based on the country's lacking adequate controls, as determined by the Director, to monitor and prevent the export of dogs to the United States with falsified or fraudulent rabies vaccination credentials, inaccurate or invalid rabies vaccination documentation, or other fraudulent, inaccurate, or invalid importation documents.

Flight parent means any person transporting one or more animals on behalf of an importer for purposes of resale, adoption, or transfer of ownership. A flight parent is typically solicited through social media and may be compensated (including through goods and services, *e.g.*, complimentary airplane ticket, paid baggage fees, other paid fees) or be uncompensated. If required by USDA, flight parents must possess all required Federal licenses or registrations to transport animals.

Importer for purposes of this section means any person importing or attempting to import an animal into the United States, including an owner or a person acting on behalf of an importer, such as a broker registered with U.S. Customs and Border Protection (CBP) or a flight parent. If required by USDA, an individual transporting an animal on behalf of an importer, including a flight parent must possess all required Federal licenses or registrations to transport animals.

Owner means owner or agent.

SAFE TraQ means CDC's System for Animal Facility Electronic Tracking of Quarantine or other system as approved by the Director for tracking pre-clearance management (*e.g.*, quarantine, medical examinations, vaccinations, diagnostic testing, screening, and travel information) of animals arriving in the United States through a CDC-registered animal care facility.

Serologic Testing, when applied to an imported animal, means a rabies antibody titration test performed by a CDC-approved rabies laboratory using a CDC-approved technique. The serology sample must be drawn, submitted, and tested in accordance with CDC technical instructions. The current list of CDC-approved laboratories is available online on CDC's website. CDC will update its website as needed.

USDA-Accredited Veterinarian shall have the same definition as *Accredited Veterinarian* under 9 CFR 160.1.

USDA Official Veterinarian means the Animal and Plant Health Inspection Service (APHIS) veterinarian who is assigned by the USDA Administrator to supervise and perform the official work of APHIS in any U.S. State or several U.S. States.

(b) *Authorized U.S. airports for dogs and cats.* (1) Cats may arrive at and be admitted into the United States through any U.S. airport.

(2) Dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries and with documentation confirming that they have been only in DMRVV low-risk or DMRVV-free countries during the last six months may arrive at and be admitted into the United States through any U.S. airport.

(3) Dogs that have a valid certification of U.S.-Issued rabies vaccination form may arrive at and be admitted into the United States through any U.S. airport.

(4) Dogs that have been in a DMRVV high-risk country within the last six months and have a valid certification of foreign rabies vaccination and microchip form must arrive at and may be admitted only through a U.S. airport with a CDC quarantine station (also known as a U.S. port health station) and a CDC-registered animal care facility.

(5) Dogs that have been in a DMRVV high-risk country within the last six months that arrive at an unauthorized U.S. airport or that arrive without a valid certification of U.S.-issued rabies vaccination or certification of foreign rabies vaccination and microchip form shall be denied admission and returned to their countries of departure via air pursuant to paragraph (v) of this section.

(6) The current list of U.S. airports with CDC-registered animal care facilities is available on CDC's website. CDC will update the list as needed.

(c) *Authorized U.S. land ports for dogs and cats.* (1) Cats may arrive at and be admitted into the United States through any U.S. land port.

(2) Dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries and with documentation confirming that they have been only in DMRVV-free or DMRVV low-risk countries during the last six months may arrive at and be admitted into the United States through any U.S. land port.

(3) Dogs that have a valid certification of U.S.-issued rabies vaccination form may arrive at and be admitted

into the United States through any U.S. land port.

(4) Dogs that have been in a DMRVV high-risk country within the last six months and do not have a valid certification of U.S.-issued rabies vaccination form are not authorized to enter the United States through any U.S. land port and shall be denied admission into the United States.

(d) *Authorized U.S. seaports for dogs and cats.* (1) Cats may arrive at and be admitted into the United States through any U.S. seaport.

(2) Dogs arriving to the United States from DMRVV low-risk or DMRVV-free countries and with documentation confirming that they have been only in DMRVV-free or DMRVV low-risk countries during the last six months may arrive at and be admitted into the United States through any U.S. seaport.

(3) Dogs that have a valid certification of U.S.-issued rabies vaccination form may arrive at and be admitted into the United States through any U.S. seaport.

(4) Dogs that have been in a DMRVV high-risk country within the last six months and do not have a valid certification of U.S.-issued rabies vaccination form are not authorized to enter the United States through any U.S. seaport and shall be denied admission into the United States.

(5) Notwithstanding paragraph (d)(4) of this section, a dog meeting the definition of a “service animal” under 14 CFR 382.3 that has been in a DMRVV high-risk country within the last six months and was vaccinated against rabies in a foreign country may be admitted through a U.S. seaport if:

(i) The dog accompanies an “individual with a disability” as defined under 14 CFR 382.3; and

(ii) The dog has a valid and complete certification of foreign rabies vaccination and microchip form and a valid serologic titer from a CDC-approved laboratory.

(e) *Limitation on U.S. ports for dogs and cats.* (1) The Director may limit the times, U.S. ports, or conditions under which dogs or cats may arrive at and be admitted to the United States based on an importer’s, CDC-registered animal care facility’s, or carrier’s failure

to comply with the provisions of this section or as needed to protect the public’s health. If the Director determines a limitation is required, the Director will notify importers, CDC-registered animal care facilities, and carriers in writing of the specific times, U.S. ports, or conditions under which dogs and cats may be permitted to arrive at and be admitted to the United States.

(2) CBP will prescribe the time, place, and manner in which dogs are presented upon arrival at a port of entry, which may include prohibiting dogs from being presented within the Federal Inspection Station.

(f) *Age requirement for all dogs.* (1) All dogs presented for admission into the United States must be at least six (6) months old at the time of their arrival into the United States.

(2) Dogs arriving into the United States that are not at least six (6) months old at the time of their arrival shall be denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(g) *Microchip requirements for all dogs.* (1) All dogs presented for admission into the United States must have a microchip implanted prior to arrival at the U.S. port.

(2) The microchip must have been implanted on or before the date the current rabies vaccine was administered. Rabies vaccines administered prior to the implantation of a microchip are invalid.

(3) The microchip number must be documented on the certification of foreign rabies vaccination and microchip form, the certification of U.S.-issued rabies vaccination form, or if the dog is arriving from a DMRVV low-risk or DMRVV-free country, documented on one of the forms listed in paragraph (u)(2) of this section and all accompanying veterinary records. The microchip number must also be documented on the CDC dog import form.

(4) Importers must consent to the scanning of the dogs’ microchip by CDC quarantine public health officers, CDC-registered animal care facility staff, or their representatives, upon the dogs’ arrival at a U.S. port.

(5) Dogs arriving in the United States without a microchip, with a microchip

that cannot be detected, with a microchip that does not match the accompanying documentation, or if the importer refuses to have the dogs' microchip scanned, shall be denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(h) *CDC dog import form for all dogs.*

(1) All importers of dogs must submit a complete and accurate CDC dog import form to CDC via a CDC-approved system prior to the dogs arriving in the United States. This includes accompanied or unaccompanied dogs arriving by air, land, or sea regardless of where the dogs originated or whether arriving as cargo, checked-baggage, or hand-carried baggage. This excludes dogs that are transiting through the United States without making an entry in accordance with paragraph (cc) of this section.

(2) Dogs that arrive without a receipt confirming that the CDC dog import form was submitted before the dogs' arrival in the United States may be denied admission and returned to their country of departure pursuant to paragraph (v) of this section, regardless of the value of the shipment.

(3) Dogs arriving by air without a receipt confirming that the CDC dog import form was submitted before the dogs' arrival in the United States may be held in the care of a CDC-registered animal care facility, on a space-available basis, for up to 24 hours after their arrival. If the dogs arrive at an airport without a CDC-registered animal care facility or if the animal care facility lacks space to house the dogs, the dogs may be held in the care of a licensed veterinarian approved by CDC for up to 24 hours after their arrival until the *CDC Dog Import Form* is filed. The importer (or airline if the importer abandons the animal) is responsible for making all necessary arrangements with a CDC-registered animal care facility or a veterinary clinic (if the CDC-registered animal care facility is unavailable at the airport or lacks space to house the dogs), including arranging transportation to the facility. The airline may require reimbursement from an importer for any associated costs incurred by the airline on the importer's behalf.

(4) Dogs arriving by sea without a receipt confirming submission of a CDC dog import form may be held on board the vessel until the form is filed. The vessel's owner or operator may require reimbursement from an importer for any associated costs incurred by the vessel's owner or operator on the importer's behalf.

(5) Dogs arriving by land without a receipt confirming submission of a CDC dog import form shall be denied admission and returned immediately to the dogs' country of departure, but such denial does not prevent the importer from reapplying for admission of the dogs after the form is filed.

(6) A receipt confirming submission of the CDC dog import form must accompany all dogs departing foreign locations for travel to the United States. For dogs departing from foreign airports to the United States, the airline must deny boarding to dogs unless the importer has presented this receipt prior to boarding.

(7) Airlines, unless granted a waiver in accordance with paragraph (dd) of this section, are required to create a bill of lading for all dogs arriving in the United States prior to the dogs' arrival. This includes dogs transported as cargo, checked-baggage, or hand-carried baggage. If granted a waiver to the bill of lading requirement, the airline's handling and transport of the dogs must be consistent with the terms of that waiver.

(8) Unless being transported by an airline for which a waiver to the bill of lading requirement has been granted pursuant to paragraph (dd) of this section, dogs arriving by air for which a bill of lading has not been filed prior to their arrival in the United States (or if the airline's handling and transport of the dogs is inconsistent with the terms of the waiver) shall be denied admission and returned to their country of departure pursuant to paragraph (v) of this section.

(i) *Inspection requirements for admission of all dogs and cats.* (1) All animals arriving at a U.S. port shall be inspected upon arrival, and only those animals that show no signs of communicable disease as defined in 42 CFR 71.1 shall be admitted into the United States.

(2) All animals presented for admission into the United States may be subject to additional examination and disease surveillance screening for the purpose of communicable disease surveillance. Ill animals may be required to undergo additional diagnostic testing prior to release of the animal; such testing is not considered surveillance screening.

(3) The Director may require confinement of an animal and examination by a veterinarian when necessary to determine whether the animal is admissible into the United States, for instance, if dental examination would assist in determining the animal's age.

(4) Importers who refuse to consent to inspection, examination, disease surveillance screening, or diagnostic testing of the animal upon arrival shall have the animal denied admission and returned to its country of departure pursuant to paragraph (v) of this section.

(j) *Examination by a USDA-accredited veterinarian and confinement of exposed dogs and cats or those that appear unhealthy.* (1) If an animal, upon inspection, does not appear to be in good health (e.g., it has signs such as emaciation, lesions of the skin, discharge of the eyes or nose, coughing, sneezing, nervous system disturbances, inability to stand or walk, difficulty breathing, jaundice, vomiting, or diarrhea), or appears healthy but, during shipment, may have been exposed to a sick or dead animal (including an animal other than a dog or cat) suspected of having a communicable disease, the Director may require prompt confinement and veterinary examination.

(2) In the case of animals that appear unhealthy or those that were potentially exposed and arriving by air or sea, the Director may require the airline or vessel's master or operator to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. In the case of animals that appear unhealthy or those that were potentially exposed and arriving by land, the Director may deny admission, but such denial does not prevent the importer from reapplying for admission after providing the Director with satisfactory evidence that a licensed veteri-

narian has examined the animal and administered any tests or treatment as needed to ensure the animal does not have a communicable disease.

(3) Carriers shall maintain a record of sickness of animals occurring while *en route* to the United States and shall submit the record to the CDC quarantine station with jurisdiction for the U.S. port.

(4) Animals that become sick while *en route* or on arrival shall be separated from other animals (including animals other than dogs or cats) as soon as the sickness is discovered and shall be held in confinement pending any necessary examination as determined by the Director.

(5) Airlines (in the case of arrivals by air) or the masters or operators of vessels (in the case of arrivals by sea) shall immediately arrange for confinement and medical evaluation of any ill or injured animals at a CDC-registered animal care facility or CDC-approved veterinary facility (if a CDC-registered animal care facility is not available) which, in the judgment of the Director, affords protection against transmission of any communicable disease, and suitable housing in accordance with the Animal Welfare Act (7 U.S.C. 2131 *et seq.*, as may be amended). In the case of ill or injured animals arriving by land, the Director may deny admission, but such denial does not prevent the importer from reapplying for admission after providing the Director with satisfactory evidence of confinement (as needed) and examination by a licensed veterinarian.

(6) The airline or vessel's master or operator shall immediately thereafter arrange for transportation of any ill or injured animals by a CBP-bonded transporter to the CDC-registered animal care facility or other CDC-approved veterinary facility (if a CDC-registered animal care facility is not available) for confinement and medical evaluation. The airline or vessel's master or operator shall arrange to have ill or injured animals transported in a way that does not expose transportation personnel or the public to communicable diseases.

(7) The Director will consider the findings of the examination and tests

in determining whether the animal may have a communicable disease.

(8) The importer shall bear the expenses of transportation, confinement, examination, tests, and treatment under this paragraph. If an importer fails to arrange for or pay for such expenses or cooperate with any CDC-mandated public health evaluations, then the animal will be considered abandoned, and the carrier shall assume financial responsibility pursuant to paragraph (aa) of this section.

(9) Confinement shall be subject to conditions specified by the Director to protect the public's health.

(10) CDC may request that CBP conditionally release animals for medical evaluation and treatment in emergency or exigent circumstances. Animals eligible for conditional release shall remain under the legal custody of the carrier or CDC-registered animal care facility for the purpose of receiving veterinary medical care. If such animals are conditionally released to a CDC-approved veterinary facility (if a CDC-registered animal care facility is not available or cannot provide the level of care needed), then the animal must be immediately returned to the custody of the carrier or CDC-registered animal care facility once medical treatment is no longer required or upon request by either CDC or CBP.

(11) If an importer (or carrier if the animal is abandoned by the importer) opts to have an animal euthanatized (*e.g.*, under circumstances where the animal is fatally ill or injured), the importer or carrier shall promptly communicate this decision to CDC in writing and prior to euthanasia. Euthanasia does not relieve importers or carriers of the obligation to arrange and pay for testing and necropsy required by CDC.

(k) *Veterinary examination, revaccination against rabies, and quarantine at a CDC-registered animal care facility for foreign-vaccinated dogs from DMRVV high-risk countries.* (1) All dogs arriving into the United States that have been in DMRVV high-risk countries within the last six months and that do not have a valid certification of U.S.-issued rabies vaccination form shall undergo veterinary examination and revaccina-

tion against rabies at a CDC-registered animal care facility upon arrival.

(2) The importer is responsible for making all arrangements relating to the examination, revaccination, and quarantine (if applicable) at a CDC-registered animal care facility prior to the dog's arrival in the United States. The costs of examination, vaccination, and quarantine (if applicable) shall be borne by the importer and not at the government's expense.

(3) Prior to granting a reservation, CDC-registered animal care facilities must ensure they have received the following:

(i) The completed certification of foreign rabies vaccination and microchip form;

(ii) Serologic test results (if applicable) obtained from a CDC-approved laboratory on a blood sample drawn, submitted, and tested in accordance with CDC's technical instructions;

(iii) Photos of the dogs' teeth to assist with age verification;

(iv) The travel itinerary for the dogs confirming that the dogs will be arriving only at a U.S. airport with a CDC-registered animal care facility and will not be arriving at any other U.S. port; and

(v) A receipt confirming submission of the CDC dog import form.

(4) Importers must present documentation to airlines confirming their reservation at a CDC-registered animal care facility prior to their dogs boarding a flight to the United States. Airlines must deny boarding to dogs if the importer fails to present such documentation.

(5) Airlines must deny boarding to any foreign-vaccinated dog that has been in a DMRVV high-risk country within the last six months for which the importer has not presented a receipt confirming submission of the CDC dog import form and proof of a reservation at a CDC-registered animal care facility, or that is being presented for travel to an unauthorized U.S. airport.

(6) The airline shall arrange for dogs to be transported by a CBP-bonded transporter to the CDC-registered animal care facility immediately upon arrival at the U.S. airport.

(7) The dogs shall remain in the custody of the CDC-registered animal care facility until the following requirements are met:

(i) Veterinary health examination by a USDA-accredited veterinarian for signs of illness. All illnesses must be documented in SAFE TraQ. CDC will review these illness case reports and determine admissibility prior to the dog's release. Suspected or confirmed communicable diseases, including the presence of ectoparasites (*i.e.*, ticks and fleas), must be reported to CDC prior to release of the dog;

(ii) Confirmation of microchip number;

(iii) Confirmation of age through dental examination by a USDA-accredited veterinarian;

(iv) Vaccination against rabies with a USDA-licensed rabies vaccine that is administered by a USDA-accredited veterinarian; and

(v) Confirmation of adequate rabies serologic titer from a CDC-approved laboratory. Blood samples for serologic tests must be drawn within a timeframe as specified in CDC technical instructions. Dogs that arrive without an adequate rabies serologic test results from a CDC-approved laboratory, or with a serologic test result drawn outside the acceptable timeframe, or with serologic test results outside acceptable parameters, shall be housed at the CDC-registered animal care facility for a 28-day quarantine period following administration of the USDA-licensed rabies vaccine.

(1) *Registration or renewal of CDC-registered animal care facilities.* (1) A facility must register with and receive written approval from the Director to function as a CDC-registered animal care facility before housing any live dog imported into the United States. Applications and all required documents must be submitted to cdcanimalimports@cdc.gov.

(2) The CDC-registered animal care facility must be located within 35 miles of a CDC quarantine station.

(3) To register or renew a registration certificate, a facility must submit the following documents to CDC:

(i) A completed registration/application form;

(ii) A statement of intent that describes the number and types of animals the facility can safely house at any one time, including the number of animals that can be housed in the quarantine area;

(iii) Written standard operating procedures that include all elements required in paragraphs (k) through (q) of this section;

(iv) A copy of all required Federal, State, or local registrations, licenses, and/or permits; a facility must have a USDA Class H intermediate handlers registration (and any additional class licenses or registrations as deemed appropriate by USDA) and a CBP Facilities Information and Resource Management System (FIRMS) code; and

(v) A self-certification signed by the owner or manager of the CDC-registered animal care facility stating that the facility is in compliance and agrees to continue to comply with the regulations in this section.

(3) Upon receiving the documentation required by this section, the Director will review the application and either grant or deny the application for registration as a CDC-registered animal care facility. Applications that are denied may be appealed under paragraph (r) of this section.

(i) Before issuing a registration, the Director may inspect any animal health record, facility, vehicle, or equipment to be used in management, examination, and clearance of imported animals. Thereafter, animal health records, facilities, vehicles, and equipment used in importing animals may be inspected during annual site inspection visits or when otherwise needed to protect the public's health.

(ii) CDC may conduct unannounced inspections of facilities seeking to register or renew their status as a CDC-registered animal care facility or when otherwise needed to protect the public's health.

(iii) CDC inspections will be based on USDA Animal Welfare regulation standards (9 CFR parts 1, 2, and 3) and other standards as outlined in CDC's *Technical Instructions for CDC-registered Animal Care Facilities*.

(iv) Unless revoked in accordance with paragraph (r) of this section, a registration certificate issued under

this section is effective for two years beginning from the date CDC issues the registration certificate.

(v) A CDC-registered animal care facility must apply to CDC for renewal of the registration certificate not less than 60 days and not more than 90 days before the existing registration expires.

(4) The Director may deny an application to register, renew, or reinstate a facility as a CDC-registered animal care facility if the registrant has had a previous registration revoked in accordance with paragraph (r) within the last five years.

(5) All CDC-registered animal care facilities must comply with the requirements of paragraphs (k) through (q) of this section.

(m) *Record-keeping requirements at CDC-registered animal care facilities.* (1) A CDC-registered animal care facility must retain records regarding each imported animal for three years after the release or return of the animal. Each record must include:

(i) the bill of lading (or other alternative documentation if the airline has been granted a waiver under paragraph (dd) of this section) for the shipment;

(ii) the name, address, phone number, and email address of the importer and owner (if different from the importer);

(iii) the number of animals in the shipment;

(iv) the identity of each animal in each shipment, including name, microchip number, date of birth, sex, breed, and coloring;

(v) the airline, flight number, date of arrival, and port of arrival of the shipment; and

(vi) veterinary medical records for the animal, including:

(A) Certification of foreign rabies vaccination and microchip form and rabies serology obtained before arrival in the United States (if applicable);

(B) the USDA-licensed rabies vaccine administered upon arrival;

(C) veterinary examination records upon arrival and while in quarantine;

(D) rabies serology performed while in quarantine in the United States (if applicable);

(E) all diagnostic test results performed during quarantine; and

(F) necropsy reports for imported animals that die while in the care of

the CDC-registered animal care facility.

(2) A CDC-registered animal care facility must maintain records electronically in SAFE TraQ.

(i) Copies of all records must be entered directly into or uploaded into SAFE TraQ;

(ii) Records must be uploaded and complete prior to the animal's release from the facility (or for necropsy results within 30 days of an animal's death); and

(iii) CDC will audit records remotely as needed and in-person during site inspection visit(s) at the facility.

(n) *Worker protection plan and personal protective equipment (PPE).* (1) A CDC-registered animal care facility must establish and maintain a worker protection plan with standards comparable to those in the Occupational Safety and Health Administration's *Recommended Practices for Safety and Health Programs* and the National Association of Public Health Veterinarians (NASPHV) *Compendium of Veterinary Standard Precautions for Zoonotic Disease Prevention in Veterinary Personnel*.

(2) In addition to complying with the requirements of this section, a facility must comply with all relevant Federal and State requirements relating to occupational health and safety.

(3) Rabies pre-exposure prophylaxis is required for workers who handle imported animals with signs of illness or in quarantine, and for staff who perform necropsies of imported animals. Rabies pre-exposure prophylaxis must be administered in accordance with the Advisory Committee on Immunization Practices guidelines for pre-exposure prophylaxis vaccination to prevent human rabies.

(4) Post-exposure procedures that provide potentially exposed workers with direct and rapid access to a medical consultant are required.

(5) Procedures for documenting the frequency of worker training, including for those working in the quarantine area, are required.

(6) As part of the worker protection plan, a facility must establish, implement, and maintain hazard evaluation and worker communication procedures that include the following:

(i) Descriptions of known communicable disease and injury hazards associated with handling animals;

(ii) The need for PPE when handling animals and training in the proper use of PPE, including re-training and reinforcement of appropriate use;

(iii) Procedures for disinfection or safe disposal of garments, supplies, equipment, and waste; and

(iv) Procedures for reporting to CDC within 48 hours suspected or confirmed communicable diseases in facility workers associated with handling imported animals.

(o) *CDC-registered animal care facility standard operating procedures, requirements, and equipment standards for crating, caging, and transporting live animals.* (1) Equipment standards for crating, caging, and transporting live animals must be in accordance with USDA Animal Welfare regulation standards (9 CFR parts 1, 2, and 3) and International Air Transport Association standards.

(2) Animals must not be removed from crates during transport.

(3) Used PPE, bedding, and other potentially contaminated material must be removed from the ground transport vehicle upon arrival at the animal care facility and disinfected in a manner that would destroy potential pathogens of concern or safely disposed of in a manner that prevents the spread of communicable disease.

(p) *Health reporting and veterinary service requirements for animals at CDC-registered animal care facilities.* (1) A CDC-registered animal care facility must provide the following services for each animal upon arrival and ensure that each animal meets CDC entry requirements prior to release from the facility:

(i) veterinary examination by a USDA-accredited veterinarian within one business day of arrival;

(ii) verification of microchip and confirmation that the microchip number matches the animal's health records;

(iii) verification of an animal's age via a dental examination or, if dental examination cannot be reliably performed, verification through another CDC-approved diagnostic method (*e.g.*, ocular lens examination, radiographs);

(iv) revaccination against rabies using a USDA-licensed vaccine; and

(v) confirmation of a valid serology test from a CDC-approved laboratory on a sample drawn from a dog prior to arrival within a timeframe and results within parameters as specified in CDC technical instructions, or completion of a 28-day quarantine at the CDC-registered animal care facility after administration of the USDA-licensed rabies vaccine.

(2) A CDC-registered animal care facility must provide the following services upon the occurrence of any morbidity or mortality in an imported animal in the facility:

(i) Immediate isolation of the animal and implementation of infection prevention and control measures in accordance with industry standards and CDC technical instructions if a communicable disease is suspected.

(ii) Notification to CDC within 24 hours of the arrival of an ill animal or occurrence of any illness or death occurring in an animal.

(iii) Examination by a USDA-accredited veterinarian immediately upon detection of illness and diagnostic testing to determine the cause of illness. All costs associated with examination and diagnostics are the responsibility of the importer.

(iv) For any animal that dies or is euthanized due to fatal illness or injury, necropsy (gross and histopathologic examination are required), and any subsequent infectious disease testing based on gross or histopathology findings or as determined by CDC, to determine the cause of death. The importer is responsible for all costs associated with necropsy and testing.

(v) Suspected or confirmed communicable diseases, including the presence of ectoparasites (*i.e.*, ticks and fleas), must be reported to CDC within 24 hours of identification.

(3) Upon completion of the quarantine period and before a facility releases any animal from quarantine, the facility must ensure that the facility's USDA-accredited veterinarian has verified the health status of the animal.

(4) Any report required under this paragraph must be uploaded to SAFE TraQ prior to the release of the animal.

(q) *Quarantine requirements for animals at CDC-registered animal care facilities.* (1) A CDC-registered animal care facility must maintain a quarantine area for holding animals when quarantine is required. Foreign-vaccinated dogs that have been in a DMRVV high-risk country within six months of arrival must be quarantined for 28 days after revaccination with a USDA-licensed rabies vaccine at the facility if they do not have a valid rabies serologic test from a CDC-approved laboratory. CDC may also require quarantine or extend the quarantine period if a facility or CDC finds or suspects that an animal is infected with, or has been exposed to, a communicable disease or if CDC determines that additional diagnostic testing is warranted.

(2) For any quarantine area established or maintained under this section, a facility must establish, implement, maintain, and adhere to standard operating procedures that meet the following physical security requirements:

(i) The CDC-registered animal care facility must be locked and secure, with access limited to authorized and trained personnel.

(ii) A CDC-registered animal care facility must limit access to animal quarantine areas to authorized personnel responsible for the transport, care, or treatment of the animals.

(3) During the quarantine period, a CDC-registered animal care facility must monitor animals for signs of any communicable disease, including, but not limited to, signs consistent with rabies, brucellosis, leptospirosis, leishmaniasis, or ecto- or endoparasites.

(4) If any animals appear ill during quarantine, the CDC-registered animal care facility must, in accordance with paragraphs (p)(2)(i) through (v) of this section, ensure appropriate evaluation, monitoring, and treatment. Suspected or confirmed communicable diseases in animals must be reported to CDC within 24 hours.

(5) A CDC-registered animal care facility must not knowingly release any ill animal from quarantine under paragraph (q)(3) of this section without prior consultation with and written approval from CDC.

(6) Quarantined animals must be housed in such a manner that they do not expose other quarantined animals or non-quarantined animals (including animals other than dogs or cats) to potentially infectious materials, including soiled bedding, caging, and other potentially contaminated items. Animals in quarantine may not be housed together.

(7) If CDC notifies a CDC-registered animal care facility of any evidence that animals have been exposed to a communicable disease, the facility must, at the facility's expense (subject to reimbursement by the importer or carrier (in case of abandonment)), implement or cooperate in the CDC's implementation of additional measures to rule out the spread of suspected communicable disease before releasing an animal or shipment of animals from quarantine, including examination, additional diagnostic procedures, treatment, detention, extended quarantine, isolation, seizure, or destruction of exposed animals.

(8) A CDC-registered animal care facility must establish, implement, and adhere to standard operating procedures for safe handling and necropsy of any animal that dies in quarantine.

(r) *Revocation and reinstatement of a CDC-registered animal care facility's registration.* (1) The Director may revoke a CDC-registered animal care facility's registration if the Director determines that the facility has failed to comply with any applicable provisions of this section, the facility's standard operating procedures, USDA Animal Welfare standards (9 CFR parts 1, 2, and 3), or other standards as outlined in CDC's *Technical Instructions for CDC-registered Animal Care Facilities*.

(2) CDC will send the CDC-registered animal care facility a notice of revocation stating the grounds upon which the proposed revocation is based.

(3) If the CDC-registered animal care facility wishes to contest the revocation, the facility must file a written response to the notice within five business days after receiving the notice.

(4) As part of the response, a CDC-registered animal care facility may request that the Director review the written record.

(5) If a CDC-registered animal care facility fails to file a response within five business days, all of the grounds listed in the proposed revocation will be deemed admitted, in which case the notice shall constitute final agency action, unless the Secretary, within one business day, decides to excuse the facility's failure to respond on a timely basis.

(6) If a CDC-registered animal care facility's response is timely, the Director will review the registration, the notice of revocation, the response, and make a decision in writing based on the written record.

(7) As soon as practicable after completing the written record review, the Director will issue a decision in writing that shall constitute final agency action, unless the Secretary, within one business day, decides to review the Director's decision. The Director will provide the facility with a copy of the written decision.

(8) The Director may reinstate a revoked registration after inspecting the facility, examining its records, conferring with the facility, and receiving information and assurance from the facility of compliance with the requirements of this section.

(s) *Requirement for the certification of foreign rabies vaccination and microchip form to import foreign-vaccinated dogs from DMRVV high-risk countries.* (1) Importers of foreign-vaccinated dogs from DMRVV high-risk countries must submit the certification of foreign rabies vaccination and microchip form to the CDC-registered animal care facility in order to make a reservation at that facility.

(2) Importers must present documentation confirming the dog's reservation at a CDC-registered animal care facility to the airline prior to boarding and to CBP upon arrival at a U.S. port for admission of foreign-vaccinated dogs from DMRVV high-risk countries.

(3) The certification of foreign rabies vaccination and microchip form must be truthful and accurate, completed in English, and include:

(i) The name of the person importing the dog (consignee), physical address, phone number, email address, passport number, and date of birth;

(ii) The owner's name, phone number, and email address;

(iii) The destination address (physical address) where the dog will reside upon arrival in the United States;

(iv) The dog's name, breed, sex, date of birth or approximate age if the date of birth is unknown, and color or markings of the dog;

(v) Rabies vaccination information for the dog administered within a time-frame and in accordance with the vaccination schedule as specified in CDC technical instructions;

(vi) Rabies vaccine product information (product name, manufacturer, lot number, and product expiration date);

(vii) Rabies vaccine expiration date (date when next vaccine is due), which must be after the dog's date of arrival at a U.S. port;

(viii) Microchip number and microchip implant date, which must be on or before the date of administration of the most recent rabies vaccination included on this form;

(ix) The name, license number or official stamp, address, telephone number, email address, and signature of the authorized veterinarian or official government veterinarian that examined the dog in the exporting country; and

(x) The name, address, official seal or stamp, and signature of an official government veterinarian attesting that the authorized veterinarian is licensed or authorized to practice veterinary medicine in the exporting country and further attesting that the information listed on the form is true and correct.

(4) Importers who fail or refuse to present the certification of foreign rabies vaccination and microchip form or present a form that is untruthful, inaccurate, and incomplete may result in the dog being denied admission and returned to the country of departure pursuant to paragraph (v) of this section.

(t) *Requirement for Certification of U.S.-Issued Rabies Vaccination form for importers seeking to import U.S.-vaccinated dogs from DMRVV high-risk countries.* (1) Importers returning to the United States with a U.S.-vaccinated dog that has been in a DMRVV high-risk country within the last six months may present their dog for admission without a rabies serologic test from a CDC-approved laboratory, without the

dog undergoing veterinary examination (unless ill, injured, or exposed), and without revaccination against rabies or quarantine at a CDC-registered animal care facility upon arrival under the following circumstances:

(i) The importer presents a certification of U.S.-issued rabies vaccination form that is truthful, complete, and accurate.

(ii) The importer presents a valid certification of U.S.-issued rabies vaccination form that sufficiently and reliably demonstrates that a USDA-licensed rabies vaccine was administered within a timeframe and age parameters as specified in CDC technical instructions.

(2) The certification of U.S.-issued rabies vaccination form must have been completed and endorsed prior to the dog leaving the United States and cannot be completed upon arrival at a U.S. port or after the dog has left the United States.

(3) Importers returning to the United States from a DMRVV high-risk country with their U.S.-vaccinated dog that are unable to meet the requirements of this paragraph shall have the dog treated as if it was vaccinated in a foreign country in accordance with the provisions of paragraphs (k) and (s) of this section or, alternatively, have the dog denied admission and returned to the country of departure pursuant to the paragraph (v) of this section.

(4) If an importer fails to immediately (within 24 hours of arrival) arrange for the dog's return to the country of departure, then the animal will be considered abandoned pursuant to paragraph (aa) of this section.

(u) *Requirement for proof that a dog has been only in DMRVV low-risk or DMRVV-free countries.* (1) Dogs arriving, including those returning to the United States, from a DMRVV low-risk or DMRVV-free country may be admitted into the United States subject to the requirements in this section if the importer submits written documentation satisfactory to the Director that for the six months before arrival, the dog has been only in DMRVV low-risk or DMRVV-free countries.

(2) For purposes of paragraph (u)(1) of this section, written documentation satisfactory to the Director shall include any one of the following:

(i) A valid certification of foreign rabies vaccination and microchip form if completed in a DMRVV-free or DMRVV low-risk country and the dogs are arriving into the United States from the same DMRVV-free or DMRVV low-risk country as that listed on the form. This form must be completed by an authorized veterinarian, which may include an official government veterinarian, and must be certified by an official government veterinarian in the exporting country;

(ii) A valid certification of U.S.-issued rabies vaccination form completed by a USDA-accredited veterinarian and endorsed by a USDA official veterinarian;

(iii) A valid USDA export certificate if the certificate is issued to allow the dogs to travel to a DMRVV-free or DMRVV low-risk country and the dogs are returning to the United States from the same DMRVV-free or DMRVV low-risk country as that listed on the export certificate. The form must be completed by a USDA-accredited veterinarian and endorsed by a USDA official veterinarian;

(iv) A valid foreign export certificate from a DMRVV-free or DMRVV low-risk country that has been certified by an official government veterinarian in that country. The export certificate must be accompanied by veterinary records (such as the European Union pet passport) or proof of payment for veterinary services establishing that veterinary services were performed in the exporting country at least six months before traveling to the United States;

(v) A certification of dog arriving from DMRVV-free or DMRVV low-risk country form if accompanied by veterinary records or proof of payment for veterinary services establishing that veterinary services were performed in the same DMRVV-free or DMRVV low-risk country at least six months before travel to the United States. This form must be completed by an authorized veterinarian, which may include an official government veterinarian, and must be certified by an official government veterinarian in the exporting country; or

(vi) Other records or documents satisfactory to the Director that CDC may

establish through technical instructions and publish on its website.

(v) *Denial of admission of dogs and cats.* (1) The following categories of animals are inadmissible to the United States:

(i) Any dog arriving from a DMRVV low-risk or DMRVV-free country without written documentation satisfactory to the Director that the dog has been only in DMRVV low-risk or DMRVV-free countries during the six months prior to the attempted entry, or if the Director reasonably suspects fraud.

(ii) Any dog that is not accompanied by a receipt confirming that a CDC dog import form has been submitted to CDC through a CDC-approved system.

(iii) Any dog arriving by air for which a bill of lading, including an air waybill, has not been created by the airline prior to the dog's arrival in the United States (regardless of the value of the shipment) unless the airline transporting the dog has been granted a waiver pursuant to paragraph (dd) of this section and the airline's handling and transport of the dog is consistent with the terms of that waiver.

(iv) Any unvaccinated or foreign-vaccinated dog arriving by land to the United States if the dog has been in a DMRVV high-risk country within the last six months.

(v) Any unvaccinated or foreign-vaccinated dog arriving by sea to the United States if the dog has been in a DMRVV high-risk country within the last six months, except for a foreign-vaccinated dog qualifying as a service animal and meeting the standards set forth in paragraph (d)(5) of this section.

(vi) Any animal imported by an importer who refuses to comply with the requirements (if applicable) for disease surveillance screening, microchip scanning, veterinary examination, diagnostics tests to rule out communicable diseases, revaccination, providing proof of sufficient rabies serologic tests, or quarantine (if applicable) at a CDC-registered animal care facility or other CDC-approved facility (if a CDC-registered animal care facility is not available) upon arrival.

(vii) Any dog that has been in a DMRVV high-risk country within the last six months and arrives without a

valid certification of U.S.-issued rabies vaccination form or a valid certification of foreign rabies vaccination and microchip form.

(viii) Any foreign-vaccinated dog that has been in a DMRVV high-risk country within the last six months and does not arrive via air at a U.S. airport with a CDC quarantine station and a CDC-registered animal care facility, except for a foreign-vaccinated dog arriving by sea that qualifies as a service animal and meets the standards set forth in paragraph (d)(5) of this section.

(ix) Any dog imported from a DMRVV high-risk country that arrives without a reservation at a CDC-registered animal care facility (if applicable).

(x) Any dog from a DMRVV-restricted country that arrives without a valid CDC dog import permit.

(xi) Any dog, regardless of country of departure, if the Director reasonably suspects fraud in any documentation required for admission or if such documentation is otherwise untruthful, inaccurate, or incomplete.

(xii) Any animal, regardless of country of departure, that poses a public health risk, including animals that appear unhealthy upon arrival or demonstrate signs or symptoms of communicable disease.

(xiii) Any dog under six months of age that arrives in the United States.

(xiv) Any dog that arrives in the United States without a microchip or without its microchip number documented on the importation paperwork required by CDC.

(2) An importer must meet the admission requirements of all U.S. government agencies for the admission of an animal into the United States. Satisfaction of CDC's requirements for the admission of animals does not fulfill the admission requirements of other U.S. government agencies.

(w) *Dogs and cats awaiting an admissibility determination or return to their country of departure.* (1) Animals arriving by air that are denied admission and awaiting return to their country of departure or awaiting a determination as to their admissibility must be held in a CDC-registered animal care facility or other CDC-approved facility (if a CDC-registered animal care facility is

not available) in such a way as to prevent the potential spread of communicable diseases.

(2) An airline must arrange to transport an animal arriving by air to a CDC-registered animal care facility (or other boarding, kennel, or veterinary clinic approved by CDC if a CDC-registered animal care facility is not available) if the animal is denied admission and is awaiting return to its country of departure or is awaiting a determination of its admissibility. If the animal is apparently healthy, the airline must transport the animal (by a CBP-bonded transporter) within 12 hours of its arrival.

(3) An airline must immediately report an obviously ill or injured animal (*e.g.*, the animal is unable to stand, has difficulty breathing, is bleeding, has broken bones or disfigured limbs, or is experiencing seizures, vomiting, or discharge from the nose, mouth, or eyes) arriving into the United States to the CDC quarantine station of jurisdiction. The airline must immediately arrange to transport an obviously ill or injured animal by a CBP-bonded transporter to a CDC-registered animal care facility or veterinary clinic as directed by CDC.

(4) Animals arriving by sea that are denied admission must remain on the vessel while awaiting return to the country of departure.

(x) *Disposal or disposition of dogs and cats denied admission to the United States.* (1) Animals shall be subject to such additional requirements as authorized under this part or 42 CFR part 70 as may be deemed necessary by the Director to protect the public's health, including suspension of entry under §71.63.

(2) Animals denied admission to the United States that were transported to the United States via air must be returned by the airline to the country of departure at the importer's expense on the next available outbound flight (no later than 72 hours after arrival), regardless of airline or route, if fit to travel. Pending the animal's return, the animal shall be detained at the importer's expense in the custody of the carrier at a CDC-registered animal care facility (or other boarding, kennel, or veterinary clinic approved by CDC if a

CDC-registered animal care facility is not available).

(3) Animals denied admission to the United States that were transported to the United States via sea shall be re-embarked immediately by the vessel's master or operator and returned to their country of departure on the next voyage.

(4) Animals denied admission to the United States that were transported to the United States via land shall be returned immediately by importer or carrier to their country of departure.

(5) If an animal is not fit to travel, poses a public health risk, or would pose a risk to other animals, then the carrier shall arrange for the animal to be transported to a CDC-registered animal care facility or a CDC-approved veterinary clinic (if a CDC-registered animal care facility is not available) for housing and treatment by a licensed veterinarian until approved for travel by CDC or humanely euthanized (*e.g.*, under circumstances where the animal is fatally ill or injured) by a licensed veterinarian. The importer shall be responsible for all costs associated with the denial, veterinary evaluation, care, or disposal of the animal. If the importer refuses to pay for any costs associated with the denial, evaluation, care, or disposal of the animal, then it will be considered abandoned, and the carrier shall assume custody and financial responsibility for these costs.

(6) If humane euthanasia is recommended by a veterinarian or chosen by an importer or carrier (*e.g.*, under circumstances where the animal is fatally ill or injured), the animal must be euthanized by a U.S.-licensed veterinarian in accordance with American Veterinary Medical Association guidelines. Euthanasia does not relieve carriers or importers of the obligation to arrange and pay for testing and necropsy required by CDC.

(7) The Director may grant temporary extensions of returns for animals that are not fit for travel as determined by a CDC veterinarian, but the importer (or carrier in the case of abandonment) must arrange for the return of the animal to its country of departure as soon as CDC notifies the carrier that the animal is fit for travel.

(8) The requirements of this paragraph shall additionally apply to dogs or cats abandoned by the importer prior to the dogs' or cats' admission into the United States. A dog or cat may be deemed abandoned pursuant to the provisions of paragraph (aa) of this section.

(9) Carriers must provide transportation to/from and holding at a CDC-registered animal care facility or another CDC-approved facility (if a CDC-registered animal care facility is not available) while the animal is pending an admissibility determination, undergoing veterinary evaluation or care, or upon denial of entry. Carriers may require reimbursement from an importer for any costs incurred on behalf of the importer.

(10) Importers must comply with CDC requirements for the return of an animal or for the veterinary assessment of an animal. Refusal to cooperate, including refusal to pay any associated veterinary fees, will result in the animal being considered abandoned by the importer, and custody of the animal will be transferred to the carrier who will assume financial responsibility for costs relating to the denial, evaluation, care, or disposal of the animal.

(11) A carrier may enter into contractual arrangements with an importer or a third party relating to the expenses of returning an animal to its country of departure, for veterinary care, or otherwise disposing of an animal, provided that no government costs are incurred. The return of an animal to its country of departure or the initiation of veterinary care shall not be delayed while the carrier attempts to enter into or negotiate contractual arrangements.

(12) The provisions of this paragraph may be applied to importers of animals and to carriers transporting such animals in circumstances where an animal is denied entry at a land port or seaport of the United States and the animal cannot be immediately returned to its country of departure (*e.g.*, because it is unfit to travel).

(y) *Appeals of CDC denials to admit a dog or a cat upon arrival into the United States.* (1) If CDC denies admission to an animal upon arrival, then the im-

porter may appeal that denial to the Director.

(2) The importer must submit the appeal in writing to the Director, stating the reasons for the appeal and demonstrating that there is a genuine and substantial issue of fact in dispute.

(3) The importer must submit the appeal within one (1) business day of the denial by emailing CDCAnimalImports@cdc.gov.

(4) Submitting an appeal will not delay the return of the animal to the country of departure.

(5) The Director will issue a written response to the appeal, which shall constitute final agency action, unless the Secretary, within one (1) business day, decides to review the Director's decision.

(z) *Record of death of dogs and cats en route to the United States and disposition of dead animals.* (1) Carriers shall maintain a record of the death of animals occurring while *en route* to the United States and shall submit the record to the CDC quarantine station of jurisdiction for the U.S. port upon arrival.

(2) Animals that become sick or die *en route* or are identified as sick or dead upon arrival shall be separated from other animals (including animals other than dogs or cats) as soon as the sickness or death is discovered and shall be held in confinement pending any necessary examination as determined by the Director. Sick animals shall be examined pursuant to the provisions of paragraph (j) of this section or disposed of pursuant to the provisions of paragraph (x) of this section.

(3) The carrier shall arrange for any animals that die *en route* to the United States or that die while detained pending determination of their admissibility to undergo a necropsy (gross and histopathologic examination are required), and any subsequent infectious disease testing based on gross or histopathology findings or as determined by CDC. The carrier or CDC-registered animal care facility must contact the CDC quarantine station of jurisdiction prior to transporting an animal for necropsy to determine whether rabies testing is required. In the event an importer abandons an animal, the carrier will become the owner and shall

assume responsibility for all expenses described in this paragraph.

(4) The carrier shall send copies of the final necropsy report and all test results to the CDC quarantine station of jurisdiction.

(5) Pursuant to paragraphs (p) and (x) of this section, the importer is responsible for costs associated with the necropsy, testing, and disposal of the body. In the event an importer abandons an animal, then pursuant to paragraph (aa) of this section, the carrier will become the owner and shall assume responsibility for all expenses described in this paragraph.

(aa) *Abandoned shipments of dogs and cats.* (1) In the event an importer abandons an animal under this section, the carrier will become the owner and shall assume responsibility for all expenses described in this section.

(2) An animal shipment will be deemed abandoned under the following circumstances:

(i) when explicitly stated by the importer verbally or in writing to the carrier, CDC, or CBP; or

(ii) if the importer fails to cooperate with or respond to the carrier's attempts to comply with the provisions of this section within 24 hours; or

(iii) if the importer refuses payment within 24 hours for CDC-mandated examinations, testing, holding, or treatment needed to ensure the safe importation of dogs and cats into the United States.

(bb) *Sanitation of cages and containers of dogs and cats.* When the Director finds that the cages or other containers of animals arriving in the United States are in an unsanitary or other condition that may constitute a communicable disease risk, the animals shall not be admitted in such containers unless the carrier has the containers cleaned and disinfected or the animals are removed and placed in clean containers in accordance with USDA and, in the case of airlines, the International Air Transport Association shipping requirements. Discarded containers must be cleaned and disinfected or destroyed in accordance with carrier policies. CDC may require documentation of container disinfection or destruction by the carrier.

(cc) *Requirements for in-transit shipments of dogs and cats.* (1) In-transit shipments of live animals are not eligible for release into the United States and may only be transported as cargo and not as hand-carried baggage or checked/excess baggage.

(2) In-transit shipments must be maintained under continuous confinement with USDA APHIS oversight on board a conveyance until export, or off-loaded and maintained under continuous confinement and APHIS oversight at a USDA APHIS-preapproved holding facility with a CBP-issued FIRMS code while awaiting a connecting conveyance, and then loaded and maintained under USDA APHIS oversight on board the connecting conveyance until export.

(3) The provisions of this section shall apply to animals transiting through the United States from one foreign country to another, except as provided below:

(i) Animals that appear healthy but have been exposed to a sick or dead animal (including an animal other than a dog or cat) suspected of having a communicable disease are not required to undergo examination or tests as provided in paragraph (j) of this section if the Director determines that the conditions under which the animals are being transported afford adequate protection against introduction of communicable disease into the United States.

(ii) The certification of foreign rabies vaccination and microchip form, certification of U.S.-issued rabies vaccination form, certification of dog arriving from DMRVV-free or DMRVV low-risk country form, or CDC dog import form is not required for dogs that are transported by aircraft and are being transited through the United States if retained in the custody of the airline under conditions that would prevent transmission of communicable diseases.

(iii) There is no minimum age requirement for dogs that are transported by aircraft and are being transited through the United States if retained in the custody of the airline under conditions that would prevent transmission of communicable diseases.

(iv) A microchip is not required for dogs that are transported by aircraft and are being transited through the United States if retained in the custody of the airline under conditions that would prevent transmission of communicable diseases.

(dd) *Bill of lading and other airline requirements for dogs.* (1) Airlines are required to create a bill of lading, which includes air waybills (AWB), for all dogs arriving in the United States prior to arrival. This includes dogs transported as cargo, checked-baggage, or hand-carried baggage.

(2) Airlines that lack the technical ability to generate a bill of lading to transport dogs as checked baggage or as hand-carried baggage may request a waiver from CDC by emailing cdcanimalimports@cdc.gov.

(i) The airline's request for a waiver must be accompanied by a written standard operating procedure (SOP) describing how the airline will ensure care, transportation, and housing for any ill, injured, or abandoned animals in the absence of a bill of lading. The SOP must also identify and provide the location of a CDC-registered animal care facility or other suitable alternative approved by CBP and CDC that will provide care and suitable housing for any ill, injured, or abandoned animals prior to any animals being transported to the United States.

(ii) As a condition of granting a waiver, CDC may require the airline to obtain the services of a licensed U.S. customs broker who will be responsible for coordinating on behalf of the airline the entry and clearance of any dogs imported into the United States, including compliance with CDC's requirements relating to the admission of dogs.

(iii) As a condition of granting a waiver, CDC may require the airline to provide a timetable and identify steps that the airline will take to develop the technical capacity to generate an AWB (or another suitable alternative to an AWB) to transport dogs as cargo, checked-baggage, or hand-carried baggage.

(iv) The Director may revoke a waiver granted to an airline upon notice to the airline and a finding that an airline has acted inconsistent with the terms

of the waiver, including any provision of its SOP.

(v) CDC may publish additional technical instructions on its website for airlines seeking a waiver from the bill of lading requirement.

(3) Any dog arriving by air for which a bill of lading, including an AWB, has not been created by the airline prior to the dog's arrival in the United States will be denied admission and returned to the country of departure pursuant to paragraph (v) of this section, unless the airline transporting the dog has been granted a waiver and the airline's handling and transport of the dog are consistent with the terms of that waiver.

(4) Airlines must deny boarding to any dogs for which the importer: has not presented to the airline before boarding a receipt confirming submission of the CDC dog import form; if the dogs are scheduled to arrive at a different U.S. port than the one listed on the receipt of the CDC dog import form; or if the dogs presented for travel do not match the description on the receipt of the CDC dog import form.

(5) For U.S.-vaccinated dogs that have been in a DMRVV high-risk country within the last six months, airlines must deny boarding unless the importer presents prior to boarding a valid certification of U.S.-issued rabies vaccination form or if the dogs presented for travel do not match the description on the certification of U.S.-issued rabies vaccination form.

(6) For foreign-vaccinated dogs that have been in a DMRVV high-risk country within the last six months, airlines must deny boarding unless the importer presents documentation to the airline before boarding of a reservation at a CDC-registered animal care facility and the dog is scheduled to arrive in the United States at the U.S. airport where the CDC-registered animal care facility is located.

(7) For dogs from DMRVV-free or DMRVV low-risk countries, airlines must deny boarding unless the importer before boarding presents documentation as described in paragraphs (g)(2) and (u)(2) demonstrating that the dog is over six months of age, has a microchip, and has been only in

DMRVV low-risk or DMRVV-free countries during the last six months. Airlines must also deny boarding if the dog presented for travel does not match the description on the documents presented by the importer for travel.

(8) A representative of an airline transporting live dogs into the United States must be on-site at the U.S. airport and available to coordinate the entry/clearance of the dogs with Federal government officials until all live dogs transported on an arriving flight into the United States have either been cleared for entry or arrangements have been made to transport the dogs to a CDC-registered animal care facility or other facility (*e.g.*, veterinary clinic or kennel) approved by CDC pending an admissibility determination.

(ee) *Order prohibiting carriers from transporting dogs and cats.* (1) If the Director determines that a carrier has endangered the public health of the United States by acting or failing to act to prevent the introduction of DMRVV, as would occur through failure to comply with any applicable provisions of this section, the Director may issue an order revoking the carrier's permission to transport live animals into the United States, which shall be served on the carrier's owner or operator.

(2) The Director may rescind the order after inspecting the carrier's facilities; examining its records; conferring with the carrier's owners or operators, its contractors, or staff; or receiving information and written assurances from the carrier owner or operator that it has taken remedial steps to ensure future compliance with the requirements of this section.

(3) A carrier owner or operator may appeal a revocation of a carrier's permission to transport live animals into the United States. The appeal shall be in writing, addressed to the Director, state the reasons for the appeal, and demonstrate that there is a genuine and substantial issue of fact in dispute. The appeal must be submitted via email to CDCAnimalImports@cdc.gov.

(4) As soon as practicable after completing the written record review, the Director will issue a decision in writing that shall constitute final agency ac-

tion, unless the Secretary, within one business day, decides to review the Director's decision. The Director will serve the carrier with a copy of the written decision.

(ff) *Prohibition on imports of dogs from DMRVV-restricted countries.* (1) The Director may prohibit or otherwise restrict the import of dogs into the United States from certain countries designated as DMRVV-restricted countries. CDC will maintain a list of DMRVV-restricted countries based on the countries' prior export of dogs infected with DMRVV to any other countries within a time frame determined by CDC or based on inadequate controls, as determined by CDC, in the countries to monitor and prevent the export of dogs to the United States with falsified or fraudulent rabies vaccine credentials, invalid rabies vaccination certificates, or other fraudulent, inaccurate, or invalid exportation/importation documents.

(2) DMRVV-restricted countries may be subject to additional restrictions, including a complete prohibition on the importation of dogs into the United States from those countries as needed to prevent the reintroduction of DMRVV.

(3) The Director may maintain such additional restrictions or prohibitions in place until the Director is satisfied that the DMRVV-restricted country has established sufficient controls to prevent the reintroduction of DMRVV into the United States, including measures to prevent the use of falsified or fraudulent vaccine credentials or invalid rabies vaccination certificates.

(4) The addition or removal of DMRVV-restricted countries from the list shall be announced through notice in the *FEDERAL REGISTER*, and a list will be maintained on CDC's website.

(5) Notwithstanding the prohibition on imports of dogs from DMRVV-restricted countries, the Director may allow the importation of dogs for scientific purposes, when used as service animals (as defined in 14 CFR 382.3) for individuals with disabilities, or in furtherance of an important government interest. In such instances CDC will issue a CDC dog import permit for the importation of dogs from DMRVV-restricted countries. Instructions for how

to apply for a permit will be included in CDC technical instructions.

(gg) *Request for issuance of additional fines or penalties.* (1) CDC may request that CBP, pursuant to 19 U.S.C. 1592 and 19 U.S.C. 1595a, issue additional fines, citations, or penalties to importers, brokers, or carriers when the Director has reason to believe that an importer, broker, or carrier has violated any of the provisions of this section or otherwise engaged in conduct contrary to law.

(2) CDC may request that the U.S. Department of Justice investigate, and if determined appropriate based on the outcome of such investigation, prosecute any person who the Director has reason to believe may have violated Federal law, including by forcibly assaulting, resisting, opposing, impeding, intimidating, or interfering with a U.S. government employee while engaged in or on account of the performance of their official duties in violation of 18 U.S.C. 111, by obstructing an agency proceeding in violation of 18 U.S.C. 1505, or by otherwise engaging in conduct contrary to law.

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

[50 FR 1519, Jan. 11, 1985, as amended at 89 FR 41837, May 13, 2024]

§ 71.52 Turtles, tortoises, and terrapins.

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

Turtles includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order *Testudinata*, class *Reptilia*, except marine species (Families *Dermochelidae* and *Cheloniidae*).

(b) *Importation; general prohibition.* Except as otherwise provided in this section, live turtles with a carapace length of less than 4 inches and viable turtle eggs may not be imported into the United States.

(c) *Exceptions.* (1) Live turtles with a carapace length of less than 4 inches and viable turtle eggs may be imported into the United States, provided that such importation is not in connection with a business, and the importation is limited to lots of fewer than seven live turtles or fewer than seven viable turtle eggs, or any combinations of such

turtles and turtle eggs totaling fewer than seven, for any entry.

(2) Seven or more live turtles with a carapace length of less than 4 inches, or seven or more viable turtle eggs or any combination of turtles and turtle eggs totaling seven or more, may be imported into the United States for bona fide scientific or educational purposes or for exhibition when accompanied by a permit issued by the Director.

(3) The requirements in paragraphs (c)(1) and (c)(2) of this section shall not apply to the eggs of marine turtles excluded from these regulations under § 71.52(a).

(d) *Application for permits.* Applications for permits to import turtles, as set forth in paragraph (c)(2) of this section, shall be made by letter to the Director, and shall contain, identify, or describe, the name and address of the applicant, the number of specimens, and the common and scientific names of each species to be imported, the holding facilities, the intended use of the turtles following their importation, the precautions to be undertaken to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria, and any other information and assurances the Director may require.

(e) *Criteria for issuance of permits.* A permit may be issued upon a determination that the holder of the permit will isolate or otherwise confine the turtles and will take such other precautions as may be determined by the Director to be necessary to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria and on condition that the holder of the permit will provide such reports as the Director may require.

(f) *Interstate Regulations.* Upon admission at a U.S. Port, turtles and viable turtle eggs become subject to Food and Drug Administration Regulations (21 CFR 1240.62) regarding general prohibition.

(g) *Other permits.* Permits to import certain species of turtles may 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)

§ 71.53 Requirements for importers of nonhuman primates.

(a) *Purpose.* The purpose of this section is to prevent the transmission of communicable disease from nonhuman primates (NHPs) imported into the United States, or their offspring, to humans. The regulations in this section are in addition to other regulations promulgated by the Secretary to prevent the introduction, transmission, and spread of communicable diseases under 42 CFR part 71, subpart A and 42 CFR part 70.

(b) *Scope.* This section applies to any person importing a live NHP into the United States, including existing importers, any person applying to become a registered importer, and any person importing NHP products.

(1) Importers must make their facilities, vehicles, equipment, and business records, including employee health records and animal health records, used in the importation of NHPs, available to HHS/CDC for inspection during operating business days and hours, and at other necessary and reasonable times, to enable HHS/CDC to ascertain compliance with the regulations in this section.

(2) Nothing in this section supersedes or preempts enforcement of emergency response requirements imposed by statutes or other regulations.

(c) *Acronyms, initialisms, and definitions.*

(1) For the purposes of this section:

AAALAC means the Association for Assessment and Accreditation of Laboratory Animal Care International.

AZA means the Association of Zoos and Aquariums.

CITES means the Convention on International Trade in Endangered Species.

ELISA means enzyme-linked immunosorbent assay, a type of laboratory test that measures antibodies or detects antigens for specific pathogens.

HHS/CDC means U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, or an authorized representative acting on its behalf.

IACUC means Institutional Animal Care and Use Committee.

MOT means mammalian old tuberculin, a biological product used as a di-

agnostic tool in the evaluation for mycobacterial (TB and related bacteria) infections.

NIOSH means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

PPE means personal protective equipment, such as gloves, respirators, and other devices used in preventing the spread of communicable diseases.

SOPs means standard operating procedures.

TB means tuberculosis.

TST means tuberculin skin test.

USDA means United States Department of Agriculture.

(2) For purposes of this section, the terms listed below shall have the following meanings:

Animal act means any use of NHPs, including offspring, for entertainment in which the NHPs are trained to perform some behavior or action and are part of a routinely scheduled show, performance, or exhibition, open to the general public.

Breeding colony means a facility where NHPs, including offspring, are maintained for reproductive purposes.

Broker means a person or organization within the United States that acts as an official agent of an exporter of NHPs from another country, or as an intermediary between such an exporter and an importer of NHPs.

Cohort means a group of NHPs imported together into the United States.

Director means the Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, or an authorized representative.

Educational purpose means the use of NHPs, including offspring, in the teaching of a defined educational program at the university level or equivalent.

Exhibition purposes means the use of NHPs, including offspring, as part of a public display open to the general public during routinely scheduled hours in a facility that meets or exceeds AZA accreditation standards.

Importer means any person importing, or attempting to import, a live NHP into the United States, including an

applicant to become a registered importer. Within the meaning of this section, “importer” includes any person maintaining a facility or institution housing NHPs during quarantine. Within the meaning of this section, “importer” also includes the agent of any animal act, laboratory, or zoo that is subject to or carries out responsibilities in accordance with the regulations in this section.

In transit means NHPs located within the United States that are not intended for import, whether scheduled or not, as part of the movement of those NHPs between a foreign country of departure and foreign country of final destination.

Lab or laboratory means a facility in the United States accredited by AAALAC or licensed by USDA, conducting research using NHPs, having foreign based facilities, and intending to transfer or transferring one or more NHPs that were originally part of an institutionally approved, ongoing protocol, from its foreign-based facility into its United States facility for purposes related to that specific research project.

Licensed veterinarian means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association’s Council on Education, or has a certificate issued by the American Veterinary Medical Association’s Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the HHS/CDC; and has received training and/or experience in the care and management of nonhuman primates.

Medical consultant means an occupational health physician, physician’s assistant, or registered nurse, who is knowledgeable about the risks to human health associated with NHPs.

Nonhuman primate or NHP means all nonhuman members of the Order Primates.

NHP product or Product means skulls, skins, bodies, blood, tissues, or other biological samples from a nonhuman primate, including trophies, mounts, rugs, or other display items.

Offspring means the direct offspring of any live NHPs imported into the

United States and the descendants of any such offspring.

Old World Nonhuman Primate means all nonhuman primates endemic to Asia or Africa.

Pathogen means any organism or substance capable of causing a communicable disease.

Permitted purpose means the use of NHPs for scientific, educational, or exhibition purposes as defined in this section.

Person means any individual or partnership, firm, company, corporation, association, organization, including a not-for-profit organization, such as a sanctuary, or other legal entity.

Quarantine means the practice of isolating live NHPs for at least 31 days after arrival in a U.S. quarantine facility where the NHPs are observed for evidence of infection with communicable disease, and where measures are in place to prevent transmission of infection to humans or NHPs within the cohort.

Quarantine facility means a facility used by a registered importer of NHPs for the purpose of quarantining imported NHPs.

Quarantine room means a room in a registered import facility for housing imported NHPs during the quarantine period.

Scientific purposes means the use of NHPs including offspring for research following a defined protocol and other standards for research projects as normally conducted at the university level.

Zoo means:

(1) Within the United States, an AZA-accredited and professionally maintained park, garden, or other place in which animals are kept for public exhibition and viewing; or

(2) Outside of the United States, a professionally maintained park, garden, or other place in which animals are kept for public exhibition and viewing that meets or exceeds the accrediting standards of the AZA.

Zoonotic disease means any infectious agent or communicable disease that is capable of being transmitted from animals (both wild and domestic) to humans.

(d) *General prohibition on importing nonhuman primates.* (1) A person may

not import live NHPs into the United States unless the person is registered with HHS/CDC as a NHP importer in accordance with this section.

(2) A person may only import live NHPs into the United States for:

(i) Permitted purposes, as defined under paragraph (c)(2) of this section; or

(ii) Use in breeding colonies, provided that all offspring will be used only as replacement breeding stock or for permitted purposes.

(3) A person may not accept, maintain, sell, resell, or otherwise distribute imported NHPs (including their offspring) for use as pets, as a hobby, or as an avocation with occasional display to the general public.

(e) *Disposal of prohibited or excluded NHPs.* (1) HHS/CDC may seize, examine, isolate, quarantine, export, treat, or destroy any NHP if:

(i) It is imported through a location other than an authorized port of entry;

(ii) It is imported for other than permitted purposes;

(iii) It is maintained, sold, resold, or distributed for other than permitted purpose;

(iv) It is imported by a person who is not a registered importer; or

(v) It is otherwise deemed to constitute a public health threat by the Director.

(2) For any NHP arriving in the United States through an unauthorized location, for other than the permitted purposes, or by a person who is not a registered importer, the person attempting to import that NHP, must, as approved by the Director and at the person's own expense, do one of the following:

(i) Export or arrange for destruction of the NHP, or

(ii) Donate the NHP for a scientific, educational, or exhibition purpose after quarantine at a HHS/CDC-registered facility.

(3) If the person attempting to import a NHP fails to dispose of the NHP by one of the options described in paragraph (e)(2) of this section, the Director will dispose of the NHP at the person's expense.

(4) Pending disposal of any prohibited or excluded NHPs, the NHP will be de-

tained at the person's expense at a location approved by the Director.

(f) *Authorized ports of entry for live NHPs.* (1) An importer may import live NHPs into the United States only through a port of entry where a HHS/CDC quarantine station is located. The list of current HHS/CDC quarantine stations can be found at <http://www.HHS/CDC.gov/quarantine/QuarantineStations.html>.

(2) In the event that the importer is unable to provide for entry at a port where a HHS/CDC quarantine station is located, the importer may only import live NHPs into the United States through another port of entry if the Director provides advance written approval.

(3) If prior written approval is not obtained from the Director, the importer and excluded NHPs will be subject to the provisions of paragraph (e) of this section.

(g) *Registration or renewal of importers.* Before importing any live NHP into the United States, including those that are part of an animal act or those involved in zoo-to-zoo or laboratory-to-laboratory transfers, an importer must register with and receive written approval from the Director.

(1) To register, or to renew a registration certificate, as an importer, a person must submit the following documents to HHS/CDC:

(i) A completed registration/application form;

(ii) A completed statement of intent that describes the number and types of NHPs intended for import during the registration period, the intended permitted purposes for which the NHPs will be imported;

(iii) Written SOPs that include all elements required in paragraphs (h) through (n) of this section;

(iv) A copy of all federal, state, or local registrations, licenses, and/or permits; and

(v) A signed, self-certification stating that the importer is in compliance with the regulations contained in this section and agrees to continue to comply with the regulations in this section.

(2) Upon receiving the documentation required by this section, the Director will review the application and either

grant or deny the application for registration as an importer. Applications that are denied may be appealed under paragraph (u) of this section.

(i) Before issuing a registration, the Director may inspect any business record, facility, vehicle, or equipment to be used in importing NHPs.

(ii) Unless revoked in accordance with paragraph (t) of this section, a registration certificate issued under this section is effective for two years beginning from the date HHS/CDC issues the registration certificate.

(iii) An importer must apply to HHS/CDC for renewal of the registration certificate not less than 30 days and not more than 60 days before the existing registration expires.

(3) All importers must comply with the requirements of paragraphs (h) through (n) of this section.

(h) *Documentation.* An importer must develop, and document compliance with, a written policy that states imported NHPs, including their offspring, will only be used and distributed for permitted purposes.

(1) An importer must collect or create a record of the intended purpose of importation for each imported NHP and the purpose must comply with one of the permitted purposes. An importer must retain written certifications demonstrating that the NHPs and their offspring will continue to be used for permitted purposes for three years after the distribution or transfer of the NHP.

(2) An importer must retain records regarding each distribution of imported NHPs. Each record must include the identity of any recipients, the number and identity of each NHP in each shipment or sale, and the dates of each shipment or sale, for three years after the distribution or transfer of the NHP.

(3) An importer must maintain these records in an organized manner, either electronically or in a central location that is at or in close proximity to the NHP facility to allow HHS/CDC to easily inspect the records during HHS/CDC site visits during regular business hours or within one hour of such visits. If records are maintained electronically, they must be time-dated in a manner that cannot be altered, and redundant back-up copies must be made in a manner that protects against loss.

(4) Before distributing or transferring an imported NHP, an importer must:

(i) Communicate to the recipients of NHPs, in writing, the restrictions and definitions of permitted purposes; and

(ii) Obtain written certifications from the intended recipient that the NHPs will be used and distributed only for permitted purposes.

(i) *Worker protection plan and personal protective Equipment.* (1) In addition to complying with the requirements of this section, an importer must comply with all relevant federal and state requirements relating to occupational health and safety.

(2) Importers must have a written worker protection plan for anyone whose duties may result in exposure to NHPs, including procedures for appropriate response measures in the event of an emergency. An importer must adhere to the plan and SOPs and must ensure that each worker covered under the plan also adheres to it and all pertinent SOPs.

(3) An importer must contact HHS/CDC immediately by telephone, text, or email, as specified in the importer's SOP, to report any instance of a worker exposed to a zoonotic illness and must include instructions for contacting HHS/CDC in its worker protection plan.

(4) A worker protection plan must include the following:

(i) Procedures to protect and train transport workers in how to avoid and respond to zoonotic disease exposures associated with NHPs, including procedures for appropriate responses in the event of a vehicle crash or other emergency during transport;

(ii) Hazard evaluation and worker communication procedures that adhere to those in paragraph (i)(5) of this section;

(iii) PPE requirements that adhere to those in paragraph (i)(6) of this section;

(iv) TB-control requirements that adhere to those in paragraph (i)(7) of this section;

(v) If applicable, SOPs that adhere to requirements relating to macaques as described in paragraph (i)(8) of this section;

(vi) An infection-prevention program, including infection-prevention methods requiring, at a minimum, PPE and

workplace practices for preventing infection among workers whose duties may result in exposure to NHPs and:

(A) SOPs that include requirements for preventing workplace infection from potentially contaminated needles or other sharp instruments and that, at a minimum, prohibit workers from recapping used needles by hand; removing needles by hand; or otherwise bending, breaking, or manipulating used needles by hand.

(B) SOPs requiring that used disposable syringes and needles, scalpel blades, and other sharp items be placed in puncture-resistant containers kept as close to the work site as practical and disinfected and/or disposed of as hazardous waste.

(C) SOPs requiring that removable, disposable PPE be autoclaved, incinerated, or otherwise disposed of as biohazardous waste. Nondisposable clothing worn in the quarantine facility must be disinfected on site before laundering.

(D) An infection-prevention program that requires NHP handlers to cleanse all bites, scratches, and/or mucosal surfaces or abraded skin exposed to blood or body fluids immediately and thoroughly.

(E) Infection-prevention procedures that require workers to immediately flush their eyes with water for at least 15 minutes following an exposure of blood or body fluids to the eye.

(vii) Post-exposure procedures that provide potentially exposed workers with direct and rapid access to a medical consultant including:

(A) Procedures ensuring that exposed workers have direct and immediate access to a medical consultant who has been previously identified in the SOPs to HHS/CDC.

(B) For potential exposures to herpes B virus, post-exposure procedures that require the routing of diagnostic specimens to the National B Virus Resource Center located at Georgia State University in Atlanta, Georgia, or another location as specified by HHS/CDC.

(viii) Procedures for documenting the frequency of worker training, including for those working in the quarantine facility.

(5) As part of the worker protection plan described in this paragraph (i), an

importer must establish, implement, and maintain hazard evaluation and worker communication procedures that include the following:

(i) A description of the known zoonotic disease and injury hazards associated with handling NHPs;

(ii) The need for PPE when handling NHPs and training in proper use of PPE, including re-training and reinforcement of appropriate use;

(iii) Procedures for monitoring workers for signs of zoonotic illness, including procedures that ensure reporting to HHS/CDC by telephone, text, or email within 24 hours of the occurrence of illness in any worker suspected of having a zoonotic disease; and

(iv) Procedures for disinfection of garments, supplies, equipment, and waste.

(6) As part of the worker protection plan described in this paragraph (i), an importer must identify the PPE required for each task or working area. Additionally, in this part of the worker protection plan, an importer must ensure the following:

(i) Any required PPE must be available to workers when needed;

(ii) Workers in direct contact with NHPs must wear the following:

(A) Gloves of sufficient thickness to reduce the risk of cuts, scratches, and punctures;

(B) At a minimum, disposable NIOSH-approved N95 respirators, in compliance with OSHA 29 CFR §1910.134, which requires a respiratory protection program;

(C) Face shields or eye protection; and

(D) Outer protective clothing when opening crates, removing foreign materials from crates, feeding NHPs, removing dead NHPs, or handling bedding materials.

(iii) Workers handling crates or pallets containing NHPs must wear the following:

(A) Elbow-length, reinforced leather gloves or equivalent gloves that prevent penetration of splinters, other crating materials, or debris;

(B) Outer protective clothing;

(C) Waterproof shoes or boots;

(D) NIOSH-approved respiratory protection that is compliant with OSHA regulations at 29 CFR 1910.134, and;

(E) Face shields or eye protection.

(iv) Workers whose faces may come within 5 feet of an NHP must wear disposable NIOSH-approved N95 respirators and either face shields or eye protection to protect against aerosol or droplet transmission of pathogens;

(v) Workers must remove disposable PPE and discard as a biohazard; and

(vi) Workers must not drink, eat, or smoke while physically handling NHPs or cages, crates, or other materials from such NHPs.

(7) For TB protection, an importer must ensure the following:

(i) Workers in a facility housing NHPs must have a baseline evaluation for TB prior to working with NHPs and an evaluation at least annually;

(ii) Prompt and direct access to a medical consultant who is capable of performing the evaluation and maintaining records for such tests;

(iii) If an NHP is found to have laboratory-confirmed TB, any worker who had previously entered any room where a confirmed NHP has been housed must promptly undergo a post-exposure TB evaluation and

(A) If that test is negative, the worker must undergo another TB evaluation 3 months later; and

(B) If either test is reactive, the worker must be referred for medical evaluation; and

(C) The HHS/CDC must be immediately notified of the results of the medical evaluation by telephone, text, or email as specified in the importer's SOPs.

(iv) Compliance with exposure-control planning elements under 29 CFR 1910.1030 for workers who will have parenteral and other contact with blood or other potentially infectious material from NHPs and compliance with the respiratory protection requirements in 29 CFR 1910.134.

(8) For importation of macaques, an importer must develop, implement and adhere to a written PPE program to prevent herpes B virus transmission. The program must be based on a thorough hazard assessment of all work procedures, potential routes of exposure (*e.g.*, bites, scratches, or mucosal exposures), and potential adverse health outcomes.

(9) An importer must keep records of all serious febrile illnesses (fever greater than 101.3 degrees Fahrenheit [38.5 degrees Celsius] for more than 48 hours) in workers having exposure to NHPs in transit or in quarantine. The record must be kept by the importer as part of the worker's administrative records. The importer must promptly notify HHS/CDC by telephone, text, or email if such an illness occurs. An importer must ensure that the medical consultant providing care is informed that the patient works with and/or has been exposed to NHPs.

(j) *SOP requirements and equipment standards for crating, caging, and transporting live nonhuman primates.* Equipment standards for crating, caging, and transporting live NHPs must be in accordance with USDA Animal Welfare regulation standards (9 CFR parts 1, 2, and 3) and International Air Transport Association standards, and an importer must establish, implement, maintain, and adhere to SOPs that ensure the following requirements are met:

(1) Any crate used to transport NHPs must be free of sharp projections that could scratch or otherwise injure workers or NHPs.

(2) Glass items must not be used for feeding or watering NHPs during transport.

(3) NHPs must only be removed from crates in an approved quarantine facility under the supervision of a licensed veterinarian.

(4) NHPs must not be removed from crates during transport.

(5) Upon arrival into the United States, only an importer or an authorized representative may receive the NHPs from a conveyance (*e.g.*, airplane, ship). The importer must establish an emergency contingency plan in the unlikely event they are unable to meet the shipment.

(6) All reusable items must be decontaminated between uses.

(7) At all times during transport, crates containing NHPs must be separated by a physical barrier from workers, other individuals, and all other animals and cargo, or by a spatial barrier greater than 5 feet, that prevents contamination of cargo or individuals with bodily fluids, feces, or soiled bedding.

(8) At all times during transport, individuals traveling with the shipment must be protected from shared air of NHPs to prevent the transmission of zoonotic diseases. Airflow must be unidirectional from NHP transport workers to NHPs or, if any air is recirculated to the NHP transport workers, it must be HEPA-filtered. If a ventilation system is not in place, all NHP transport workers must wear respiratory protection.

(9) If traveling by plane, crates containing NHPs should be loaded in the cargo hold last and removed first, must be placed on plastic that prevents spillage onto the deck of the plane, and must be placed on pallets or double crated to ensure separation from other cargo.

(10) Workers, as well as NHPs, must be protected from communicable disease exposures at any facility used en route, including transportation holding facilities. An importer must maintain a description of any transportation holding facilities and document the communicable disease prevention measures taken to protect workers at facilities used en route.

(11) For each import, documentation must be made of the communicable disease-prevention procedures to be carried out in every step of the chain of custody, from the time of embarkation of the NHPs at the country of origin until arrival at the quarantine facility.

(12) Procedures to ensure that aircraft, ship, vehicles, and related equipment are decontaminated following transport.

(13) Used PPE, bedding, and other potentially contaminated material must be removed from the ground transport vehicle upon arrival at the quarantine facility and disposed of as biohazardous waste.

(k) *Ground transport vehicles.* An importer must establish, implement, maintain, and adhere to SOPs for ground transport vehicles transporting NHPs that meet the following requirements.

(1) Ground transport vehicles must have a separate cargo compartment with separate heating, ventilation, and air-conditioning systems.

(2) The interior surfaces of ground transport vehicle cargo compartments

must be of smooth construction, easy to clean and disinfect.

(3) Used PPE, bedding, and other potentially contaminated material must be removed from the ground transport vehicle upon arrival at the quarantine facility and disposed of as biohazardous waste by a licensed facility.

(4) Ground transport vehicle cargo compartments must be large enough to allow safe stowage of NHP crates in a manner that allows ready access to each NHP during transit without unloading any crates.

(5) After transport of the NHP shipment from the port of entry to the quarantine facility, the importer must notify HHS/CDC in writing, text message, or email as specified within the SOP, within 48 hours of the time the shipment arrived at the quarantine facility.

(6) As part of the notification of arrival in paragraph (k)(5) of this section, an importer must inform HHS/CDC whether suspected or confirmed transmission or spread of communicable disease occurred during transport, including notification of NHPs that died, became ill, or were injured during transport, or malfunctions associated with disease-mitigation procedures or equipment.

(l) *Quarantine facilities.* (1) The requirements of this paragraph (l) relating to quarantine facilities do not apply to laboratory-to-laboratory transfers or zoo-to-zoo transfers that are in compliance with paragraphs (p)(2) and (q)(2) of this section, respectively.

(2) An importer must maintain a quarantine facility for holding a cohort during the required quarantine period. NHPs must be quarantined for 31 days after arrival at the importer's quarantine facility. HHS/CDC may extend the quarantine period if an importer or HHS/CDC finds or suspects that an NHP is infected with, or has been exposed to, a zoonotic disease, or if an importer or HHS/CDC finds a need for additional diagnostic testing.

(i) For any quarantine facility established or maintained under this section, an importer must establish, implement, maintain, and adhere to SOPs that meet the following physical security requirements:

(A) The facility must be locked and secure, with access limited to authorized, trained, and knowledgeable personnel.

(B) An importer must limit access to NHP quarantine areas to authorized personnel who are responsible for the transport, study, care, or treatment of the NHPs.

(ii) An importer must keep the number of workers involved in the care, transport, and inspection of NHPs to the minimum necessary to perform these functions.

(iii) The facility must be designed and operated in such a manner as to allow for adequate disinfecting.

(iv) The facility must have adequate equipment and space for discarding and disinfecting all equipment, clothing, and caging.

(v) Each heating ventilation and air-conditioning unit in the quarantine facility must be designed so that there is no mixing of air among quarantine rooms and each quarantine room must remain under negative air pressure in relationship to the common hallway or anteroom(s) adjacent to the quarantine room.

(vi) Each quarantine room must have air flow indicators (pressure gauges or visual flow indicators) that are affixed outside the quarantine room that indicate the direction of airflow into or out of quarantine rooms and adjoining common hallways and anterooms.

(3) An importer must establish, implement, maintain, and adhere to SOPs for handling, monitoring, and testing NHPs in quarantine that meet the following requirements:

(i) An importer must ensure that all NHPs are identified individually with a unique number or alphanumeric code permanently applied to the NHP by tattoo, microchip, or other permanent identifier before importation or after the 31-day quarantine. Tattoos, microchips, or other permanent identifiers must not be applied during the quarantine period.

(ii) Health certificates, shipping documents, and NHP health records must include the number or code required in paragraph (1)(3)(i) of this section, as well as the age, sex, and species of the NHP.

(iii) An importer must ensure NHPs are confined in a squeeze-back cage whenever possible and that any individual NHP is anesthetized, tranquilized, or otherwise restrained before handling.

(iv) A description of handling and transporting samples. For any procedure involving the use of a syringe, a separate, disposable needle and syringe must be used, including a sterile needle and syringe for withdrawing medication from any multi-dose vials (*e.g.*, ketamine).

(v) Before any contaminated item is removed from a quarantine facility, an importer must ensure that all NHP waste, bedding, uneaten food, or other possibly contaminated items are disinfected, autoclaved, or double-bagged for disposal as biomedical waste by a licensed facility.

(vi) All cages, feeding bottles, reusable items, and other contaminated items must be disinfected between uses and before disposal.

(vii) Any equipment used for infusion of NHPs must be autoclaved or incinerated, as appropriate.

(viii) During the quarantine period, an importer must monitor NHPs for signs of any zoonotic illness, including signs consistent with yellow fever, monkeypox, or filovirus disease.

(A) If any NHP appears ill during quarantine, an importer must monitor that NHP for signs of zoonotic illness, including filovirus disease, and ensure appropriate treatment.

(B) If an Old World NHP displays signs suggestive of filovirus infection (*e.g.*, diarrhea with melena or frank blood, bleeding from external orifices or petechiae, or suffusive hemorrhage), and survives, an importer must collect serum samples on day 31 of quarantine and test these samples for antibodies to filovirus while the entire cohort remains in quarantine. An importer must test the serum for immunoglobulin G (IgG) antibodies to filovirus by using an ELISA methodology, or other method approved by HHS/CDC.

(C) An importer must not knowingly request a release from HHS/CDC of any ill NHP from quarantine under paragraph (1)(4) of this section.

(ix) For each NHP in a quarantine facility, an importer must administer at

least three TSTs on the eyelid using old mammalian tuberculin (MOT), with at least 2 weeks between tests, before the NHP is released from import quarantine. TSTs must be read and recorded at 24, 48, and 72 hours, and a grading scale for interpretation of these tests must be listed in an SOP for TB testing.

(A) An importer must ensure that any cohort with positive or suspicious TST reaction remains in quarantine and receives at least five additional TSTs (each administered at least two weeks apart) following removal of the last affected NHP.

(B) The validity of TB test results may be compromised if during quarantine an NHP contracts a viral illness, including measles; is treated with steroids; or is immunized. An importer must document such occurrence(s) and hold the NHPs until they have recovered from the illness or are no longer on treatment, and for a recommended time after recovery (to be determined in consultation with HHS/CDC, depending on the illness or treatment in question) before TB tests are performed.

(C) An importer must retain records of all TSTs performed during the lifetime of each NHP at the facility housing the NHP until the NHP is transferred to another facility. These records must accompany the NHP during moves to other facilities.

(x) An importer must ensure that different cohorts of NHPs are quarantined in separate quarantine rooms.

(A) If mixing of cohorts should occur, an importer must treat the mixed cohort as a single cohort.

(B) All NHPs within that mixed cohort must remain in quarantine until each NHP in that mixed cohort has completed the minimum 31-day quarantine period.

(C) Quarantined NHPs must be housed in such a manner that they do not expose non-quarantined NHPs to non-filtered air and other potentially infectious materials, including soiled bedding, caging, and other potentially contaminated items.

(4) Before releasing a NHP from quarantine, an importer must obtain written permission from HHS/CDC. HHS/CDC may permit the release of a cohort

from quarantine when all the following conditions have been met:

(i) The 31-day quarantine period, including any required extension of quarantine, has been completed.

(ii) HHS/CDC has confirmed receipt of written notification of the health status of the NHPs in the shipment from the quarantine facility's licensed veterinarian as required by paragraph (m)(4) of this section.

(iii) HHS/CDC confirms that the importer has addressed and resolved to HHS/CDC's satisfaction any NHP or worker communicable disease issues that were reported to HHS/CDC during shipment.

(5) If HHS/CDC notifies an importer of any evidence that NHPs have been exposed to a zoonotic disease, the importer must, at the importer's expense, implement or cooperate in the HHS/CDC's implementation of additional measures to rule out the spread of suspected zoonotic disease before releasing a shipment from quarantine, including examination, additional diagnostic procedures, treatment, detention, isolation, seizure, or destruction of exposed animals.

(6) An importer must establish, implement, and adhere to SOPs for safe handling and necropsy of any NHP that dies in quarantine. The SOPs must ensure the following:

(i) The carcass of the NHP must be placed in a waterproof double-bag and properly stored for necropsy, specimen collection, autoclaving and/or incineration, and disposal;

(ii) A necropsy must be performed by a veterinary pathologist or state-licensed veterinarian. Each necropsy report must address all major organ systems and incorporate clinical history and laboratory findings;

(iii) Necropsy and appropriate laboratory testing of the NHP must document the cause of death and/or rule out zoonotic illness;

(iv) Necropsy must be performed under biosafety level 3 (BSL3) or enhanced biosafety level 2 "plus" (BSL2 +) to protect against exposure to highly infectious agents;

(v) Any samples of tissues, blood, serum, and/or transudates (bodily fluid) collected during necropsy must be retained until the NHP shipment has

been released from quarantine by HHS/CDC, in case other testing is required by HHS/CDC;

(vi) Fresh and formalin-fixed tissue specimens, including tracheobronchial lymph node, liver, lung, and spleen, regardless of necropsy findings, must be collected for laboratory examination;

(vii) Any granulomatous lesions found in any NHP at necropsy, regardless of whether TB in the NHP was previously suspected, must be submitted to a laboratory for laboratory examination for acid-fast bacilli and for mycobacterial culture; and

(viii) In the event that an Old World NHP dies or is euthanized for any reason other than trauma or unexpected adverse environmental conditions during quarantine, liver tissue for filovirus antigen by using the antigen-capture ELISA method must be submitted to a qualified laboratory for testing. The laboratory should provide documentation of test validation and records of ongoing quality assurance.

(m) *Health reporting requirements for nonhuman primates.* (1) An importer must notify HHS/CDC of the events listed in this paragraph (m) by telephone, text, or email.

(2) An importer must notify HHS/CDC within 24 hours of the occurrence of any morbidity or mortality of NHPs in quarantine facilities, or following a zoo-to-zoo or laboratory-to-laboratory transfer.

(3) For any morbidity or mortality from time of embarkation from country of origin to release from HHS/CDC quarantine, an importer must report the circumstances to HHS/CDC promptly, including the cause of death for each NHP.

(4) Upon completion of the quarantine period and before an importer releases any NHP, cohort, or mixed cohort from quarantine, the importer must ensure that the quarantine facility's licensed veterinarian notifies HHS/CDC in writing of the health status of the shipment.

(5) An importer must notify HHS/CDC within 24 hours if any NHP tests positive for filovirus virus antigen or antibody.

(6) An importer must report to HHS/CDC within 24 hours, any positive or suspicious TST results, necropsy find-

ings, or laboratory results. Any report required under this section must include a copy or summary of the individual NHP's health records.

(n) *Recordkeeping and reporting requirements for importing NHPs.* (1) Before authorizing the import of any NHPs, an importer must be in compliance with all applicable elements of the importer's SOPs.

(2) At least seven days before importing a shipment of NHPs, an importer must notify HHS/CDC in writing or by email of the impending shipment and provide the following information:

(i) The importer's name and address;

(ii) Number and species of NHPs being imported;

(iii) Description of crates;

(iv) Means of individually identifying NHPs;

(v) Origin of NHPs, including the country, the exporter, and the exporter's address;

(vi) Use of NHPs under paragraph (h) of this section;

(vii) Specific itinerary with names, dates, flights, times, airports, sea ports, and responsible parties to contact at every step of travel, including all ground transportation;

(viii) Port of entry;

(ix) If arriving by flight, the name of the airline and its flight number;

(x) If arriving by vehicle, the name of the vehicle's owner and its license plate number;

(xi) If arriving by ship, the name of the ship and its vessel number;

(xii) Name and address of the destination quarantine facility;

(xiii) Name, address, and contact information for shipper, if other than the importer;

(xiv) If applicable, name, address, and contact information for broker in the United States;

(xv) Name, address, and contact information for the person(s) responsible for off-loading NHPs in the United States;

(xvi) Name, address, and contact information for any party responsible for ground transportation from port of entry to quarantine facility;

(xvii) Expected quarantine facility, if different from the importer;

(xviii) Master air waybill number for shipment;

(xix) CITES permit number and expiration date.

(o) *Animal acts.* (1) All animal acts must be registered with HHS/CDC under paragraph (g) of this section. In addition to the requirements in paragraph (g) of this section, which incorporates the requirements in paragraphs (h) through (m), an importer must provide:

(i) A description of the animal act that includes each NHP.

(ii) Brochures, advertising materials, and/or documentation of recent or planned animal act performances.

(iii) A current list of all NHPs in the animal act, indicating each NHP's name, species, sex, age, distinguishing physical description, and unique identifier such as a tattoo, microchip, or other permanent identifier.

(iv) Prior to entry or re-entry into the United States, specific itinerary with names, dates, flights, times, airports, sea ports, and responsible parties to contact at every step of travel, including all ground transportation.

(v) A description, diagram, and photographs of the facilities where the importer houses the NHPs in the animal act in the United States, including illustrations of the primate caging and/or enclosures; the relationship of these cages or enclosures to other structures on the property and adjoining properties; whether the primate facilities are open to the air or fully enclosed; and the physical security measures of the facility.

(vi) Documentation signed by a licensed veterinarian describing the physical exam performed on each NHP in the animal act. Such examinations must be performed at least once a year. The physical exam must include the following:

(A) Routine complete blood counts, clinical chemistries, fecal exams, and any additional testing indicated by the physical exam.

(B) At least once a year, TB testing with MOT and interpreted as stated in paragraph (1)(3)(ix) of this section;

(C) NHPs with positive TST results must be evaluated for potential antituberculosis chemotherapy in consultation with HHS/CDC.

(D) If the NHP is a chimpanzee, serology and antigen testing for hepatitis B,

serology for hepatitis C, and any additional titers must be performed as indicated by clinical history or exam. A chimpanzee found serologically positive for hepatitis B and/or hepatitis C is ineligible for entry or re-entry into the United States, unless confirmatory evidence signed by a licensed veterinarian shows that there is no hepatitis B or hepatitis C virus present in the NHP.

(vii) SOPs for transporting the NHPs internationally, including the shipping crates or enclosures, the type of conveyance, and measures to minimize human exposure to the NHPs.

(viii) A copy of a negative TST conducted within the past 12 months, or medical documentation that the individual is free of clinically active TB, for each trainer and/or handler.

(ix) A copy of each SOP for responding to suspected zoonotic diseases.

(x) If macaques are in the animal act, an SOP for responding to potential herpes B-virus exposures.

(p) *Zoo-to-zoo transfers.* (1) Persons who will only be importing live NHPs into the United States through transfer from one zoo to another must comply with all the elements listed in paragraphs (g), (h), (n), (i)(1) through (5), (i)(6)(i), (i)(6)(v), (i)(6)(vi), (i)(7) through (9); (j)(1), (j)(2), (j)(5), (j)(10) through (12); (k)(5) and (k)(6); and (m)(1), (m)(2), (m)(5), and (m)(6) of this section.

(2) If a zoo is importing one or more NHPs into the United States from another zoo, the recipient zoo must, before the transfer, submit the following information for approval by HHS/CDC:

(i) A copy of each NHP's veterinary medical records, including regular testing for TB from the previous zoo for HHS/CDC's approval. The medical record should include a positive identification of the NHP, such as a tattoo, microchip, or photograph.

(ii) A copy of a current health certificate, including documentation of a negative TB test, signed by a state licensed veterinarian within 14 days of the transfer stating that the NHP(s) appear healthy and are free from communicable diseases; and

(iii) Documentation which verifies that the recipient zoo is registered in accordance with this section, and

(iv) A specific itinerary with names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel, including all ground transportation.

(3) Persons importing live NHPs that are transferred from one zoo to another, who are not able to meet the requirements listed in paragraphs (p)(2)(i) and (ii) of this section, must comply with all the elements in paragraphs (g), (h), (i), (j), (k), (l), (m), and (n) of this section.

(q) *Laboratory-to-laboratory transfers.*

(1) A laboratory transferring NHPs on an established research protocol from its foreign-based facility to its U.S.-based laboratory must comply with all the elements listed in paragraphs (g), (h), (i), (j), (k), and (n) of this section; and paragraphs (m)(1), (m)(2), (m)(5), and (m)(6) of this section.

(2) If a lab is receiving one or more NHPs for purposes related to an ongoing research project from another established research facility outside the United States, the recipient facility must, before the transfer, submit the following to HHS/CDC for approval:

(i) A copy of each NHP's veterinary medical records, including regular testing for TB from the previous lab for HHS/CDC's approval. The medical record should include a positive identification of the NHP, such as a tattoo, microchip, or photograph.

(ii) A copy of a current health certificate(s), including documentation of a negative TST, signed by a state-licensed veterinarian within 14 days of the transfer stating that the NHP(s) appear healthy and are free from communicable diseases; and

(iii) Documentation of the ongoing IACUC-approved research project and the reason the NHP needs to be transported to the U.S. laboratory facility.

(iv) A specific itinerary with names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel, including all ground transportation.

(3) Persons importing live NHPs that are transferred from one lab to another, who are not able to meet the requirements listed in paragraphs (q)(2)(i), (ii), and (iii) of this section, must comply with all the elements in

paragraphs (g), (h), (i), (j), (k), (l), (m), and (n) of this section.

(r) *In transit shipments of NHPs.* (1) Before arrival into the United States, brokers of in transit shipments must notify HHS/CDC of all scheduled in transit shipments of NHPs not intended for import into the United States and provide the following information:

(i) Number and species of NHPs in the shipment;

(ii) Origin of NHPs, including the country, the exporter, and the exporter's address;

(iii) Name and full address of the final destination quarantine facility in the importing country;

(iv) Means of individually identifying NHPs, if required by the importing country;

(v) A specific itinerary while in the United States including names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel within the United States, including all ground transportation;

(vi) Description of crates;

(vii) SOPs describing procedures to protect and train transport workers from exposure to communicable disease while handling NHPs;

(viii) SOPs describing procedures to prevent contamination of other articles and cargo during transit, including physical separation of crates from other cargo;

(ix) SOPs describing procedures to decontaminate aircraft, ships, vehicles, and related equipment following transport; and

(x) Proposed use, if any, of in transit holding facilities and steps to be taken to protect workers, as well as NHPs, from communicable disease exposure at each facility to be used en route.

(2) While located in the United States, in transit shipments must be housed and cared for in a manner consistent with requirements for NHPs intended for import into the United States as specified in paragraphs (j) and (k) of this section.

(s) *Revocation and reinstatement of an importer's registration.* (1) If the Director determines that an importer has failed

to comply with any applicable provisions of this section, including the importer's SOPs, the Director may revoke the importer's registration.

(2) HHS/CDC will send the importer a notice of revocation stating the grounds upon which the proposed revocation is based.

(i) If the importer wishes to contest the revocation, the importer must file a written response to the notice within 20 calendar days after receiving the notice.

(A) As part of the response, an importer may request that the Director review the written record.

(B) If an importer fails to file a response within 20 calendar days, all of the grounds listed in the proposed revocation will be deemed admitted, in which case the notice shall constitute final agency action.

(ii) [Reserved]

(3) If an importer's response is timely, the Director will review the registration, the notice of revocation, and the response, and make a decision in writing based on the written record.

(4) As soon as practicable after completing the written record review, the Director will issue a decision in writing that shall constitute final agency action. The Director will serve the importer with a copy of the written decision.

(5) The Director may reinstate a revoked registration after inspecting the importer's facility, examining its records, conferring with the importer, and receiving information and assurance from the importer of compliance with the requirements of this section.

(t) *Nonhuman primate products.* (1) NHP products may be imported without obtaining a permit under this section if accompanied by documentation demonstrating that the products have been rendered noninfectious using one of the following methods:

(i) Boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers, or teeth is removed; or

(ii) Gamma irradiation at a dose of at least 20 kilo Gray at room temperature (20 °C or higher); or

(iii) Soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium

carbonate, Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours; or

(iv) Soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 liters water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

(v) In the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate, Na₂CO₃);

(vi) Formalin fixation; or

(vii) Another method approved by HHS/CDC.

(viii) Fully taxidermied products are considered rendered noninfectious, and so do not require a permit from the Director.

(2) NHP products that have not been rendered noninfectious are considered to pose a potential human health risk and may only be imported under the following circumstances:

(i) The product must be accompanied by a permit issued by the Director. Requests for permits should be accompanied by an explanation of the product's intended use and a description of how the product will be handled to ensure that it does not pose a zoonotic disease threat to humans. The Director will review the request for a permit, and accompanying materials, and issue a decision that shall constitute final agency action.

(ii) The product may only be imported for bona fide scientific, educational, or exhibition purposes.

(iii) A permit will only be issued if the product will be received by a facility equipped to handle potentially infectious NHP materials.

(iv) The product must comply with any other applicable federal requirements, including those relating to packaging, shipping, and transport of potentially infectious, biohazardous substances as well as those for select agents pursuant to 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121.

(u) *Appeal of denial for a permit to import.* If the HHS/CDC denies your request for a permit under this section, you may appeal that denial to the HHS/CDC Director.

(1) You must submit your appeal in writing to the HHS/CDC Director, stating the reasons for the appeal and demonstrating that there is a genuine and substantial issue of fact in dispute.

(2) You must submit the appeal within 5 business days after you receive the denial.

(3) HHS/CDC will issue a written response to the appeal, which shall constitute final Agency action.

(v) *Filovirus testing fee.* (1) Non-human primate importers shall be charged a fee for filovirus testing of non-human primate liver samples submitted to the Centers for Disease Control and Prevention (CDC).

(2) The fee shall be based on the cost of reagents and other materials necessary to perform the testing; the use of the laboratory testing facility; irradiation for inactivation of the sample; personnel costs associated with performance of the laboratory tests; and administrative costs for test planning, review of assay results, and dissemination of test results.

(3) An up-to-date fee schedule is available from the Division of Global Migration & Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333. Any changes in the fee schedule will be published in the FEDERAL REGISTER.

(4) The fee must be paid in U.S. dollars at the time that the importer submits the specimens to HHS/CDC for testing.

[78 FR 11538, Feb. 15, 2013]

§ 71.54 Import regulations for infectious biological agents, infectious substances, and vectors.

(a) The following definitions apply to this section:

Animal. Any member of the animal kingdom except a human including an animal product (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws).

Diagnostic specimen. Specimens of human and animal matter (including tissue, blood, body discharges, fluids, excretions or similar material), or environmental samples.

Genomic material. Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) comprising the genome or organism's

hereditary information, that may be single-stranded or double-stranded, and in a linear, circular, or segmented configuration and may be positive sense (same polarity as mRNA), negative sense, or ambisense (mixture of the two).

Infectious biological agent. A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.

Infectious substance. Any material that is known or reasonably expected to contain an infectious biological agent.

Select agents and toxins. Biological agents and toxins that could pose a severe threat to public health and safety as listed in 42 CFR 73.3 and 73.4.

Vector. Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.

(b) Unless excluded pursuant to paragraph (f) of this section, a person may not import into the United States any infectious biological agent, infectious substance, or vector unless:

(1) It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC). The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.

(2) The importer is in compliance with all of the permit requirements and conditions that are outlined in the permit issued by the CDC.

(3) The importer has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance,

and/or vector to be imported, and the level of risk given its intended use.

(4) The importer takes measures to help ensure that the shipper complies with all applicable legal requirements concerning the packaging, labeling, and shipment of infectious substances.

(c) If noted as a condition of the issued permit, subsequent transfers of any infectious biological agent, infectious substance or vector within the United States will require an additional permit issued by the CDC.

(d) A permit is valid only for:

(1) The time period and/or term indicated on the permit, and

(2) Only for so long as the permit conditions continue to be met.

(e) A permit can be denied, revoked or suspended if:

(1) The biosafety measures of the permit holder are not commensurate with the hazard posed by the infectious biological agent, infectious substance, or vector, and the level of risk given its intended use; or,

(2) The permit holder fails to comply with all conditions, restrictions, and precautions specified in the permit.

(f) A permit issued under this part is not required for an item if:

(1) It is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.

(2) With the exception of bat or nonhuman primate specimens, it is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent and is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious.

(3) With the exception of live bats or bat or nonhuman primate products, it is an animal or animal product being imported for educational, exhibition, or scientific purposes and is accompanied by documentation confirming that the animal or animal product is not known to contain (or suspected of containing) an infectious biological agent or has been rendered noninfectious.

(4) It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.

(5) It is a product that is cleared, approved, licensed, or otherwise authorized under any of the following laws:

(i) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), or

(ii) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or

(iii) The Virus-Serum-Toxin Act (21 U.S.C. 151–159).

(6) It is an animal or animal product listed in 42 CFR Part 71 and its importation has been authorized in accordance with 42 CFR 71.52, 71.53, or 71.56.

(g) To apply for a permit, an individual must:

(1) Submit a signed, completed CDC Form 0.753 (Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States) to the HHS/CDC Import Permit Program.

(2) Have in place biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use.

(h) Issuance of a permit may be contingent upon an inspection of the importer's facility by the CDC to evaluate whether the importer's biosafety measures (e.g., physical structure and features of the facility, and operational and procedural safeguards) are commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector, and the level of risk given its intended use.

(i) Denial, suspension, or revocation of a permit under this section may be appealed to the CDC Director. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the denial, suspension, or revocation of the permit. HHS/CDC will issue a written response to the appeal, which shall constitute final agency action.

[78 FR 7678, Feb. 4, 2013]

§ 71.55 Importation of human remains.

(a) Human remains imported into the United States, or in transit within the United States and not intended for import, must be fully contained within a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements.

(b) The provisions of 42 CFR 71.54 shall apply to all imported human remains known to contain or reasonably suspected of containing an infectious biological agent.

(c) Unless accompanied by a permit issued under 42 CFR 71.54, human remains imported into the United States must meet one of the following requirements:

(1) Human remains imported for burial, entombment, or cremation must:

(i) Be consigned directly to a licensed mortuary, cemetery, or crematory for immediate and final preparation prior to burial, entombment, or cremation; and

(ii) Unless embalmed, be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(2) Human remains imported for medical examination or autopsy must:

(i) Be consigned directly to an entity authorized to perform such functions under the laws of the applicable jurisdiction prior to subsequent burial, entombment, or cremation; and

(ii) Unless embalmed, be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(3) Human remains imported for any other purpose, unless embalmed, must be accompanied by an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(d) The Director may suspend the importation of human remains under 42 CFR 71.63 if the Director designates the foreign country and determines that such an action is necessary to protect the public health.

[85 FR 42741, July 15, 2020]

§ 71.56 African rodents and other animals that may carry the monkeypox virus.

(a) *What actions are prohibited? What animals are affected?* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in the previous sentence) at 404-498-1633.

(ii) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals

and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. Your request must be limited to scientific, exhibition, or educational purposes.

(iii) We will respond in writing to all requests, and we also may impose conditions in granting an exemption. If we deny your request, you may appeal that denial. Your appeal must be in writing and be submitted to the CDC official whose office denied your request, and you must submit the appeal within two business days after you receive the denial. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

(3) The prohibitions in paragraph (a) of this section do not apply to products derived from rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or products derived from any other animal whose importation the Director has prohibited by order if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the monkeypox virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies; and they may be imported without written permission from CDC.

(b) *What actions can CDC take?* (1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

- (i) Issue an order causing an animal to be placed in quarantine,
- (ii) Issue an order causing an animal to be re-exported,
- (iii) Issue an order causing an animal to be destroyed, or
- (iv) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order causing an animal to be quarantined, re-exported, or destroyed will be in writing.

(c) *How do I appeal an order?* If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

[68 FR 62369, Nov. 4, 2003]

§ 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.

(a) The Director may suspend the entry into the United States of animals, articles, or things from designated foreign countries (including political subdivisions and regions thereof) or places whenever the Director determines that such an action is necessary to protect the public health and upon a finding that:

(1) There exists in a foreign country (including one or more political subdivisions and regions thereof) or place a communicable disease the introduction, transmission, or spread of which would threaten the public health of the United States; and

(2) The entry of imports from that country or place increases the risk that the communicable disease may be introduced, transmitted, or spread into the United States.

(b) The Director shall designate the foreign countries or places and the period of time or conditions under which the introduction of imports into the United States shall be suspended. The Secretary or Director will coordinate in advance with other Federal agencies that have overlapping authority in the regulation of entry of animals, articles, or other things, as may be necessary to implement and enforce this provision.

[82 FR 6978, Jan. 19, 2017]