

Public Health Service, HHS

§ 71.1

71.56 African rodents and other animals that may carry the monkeypox virus.

71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.

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