AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING

PART 70—INTERSTATE QUARANTINE

Sec.
70.1 General definitions.
70.2 Measures in the event of inadequate local control.
70.3 All communicable diseases.
70.4 Report of disease.
70.5 Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.
70.6 Apprehension and detention of persons with quarantinable communicable diseases.
70.7 Responsibility with respect to minors, wards, and patients.
70.8 Members of military and naval forces.
70.9 Vaccination clinics.
70.10 Public health prevention measures to detect communicable disease.
70.11 Report of death or illness onboard aircraft operated by an airline.
70.12 Medical examinations.
70.13 Payment for care and treatment.
70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.
70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.
70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.
70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.
70.18 Penalties.

AUTHORITY: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); section 361–369, PHS Act, as amended (42 U.S.C. 264–272); 31 U.S.C. 9701.

SOURCE: 65 FR 49908, Aug. 16, 2000, unless otherwise noted.

§ 70.1 General definitions.

As used in this part, terms shall have the following meaning:

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 Federal quarantine, isolation, or conditional release is warranted.

CDC means the Centers for Disease Control and Prevention, Department of Health and Human Services.

Communicable diseases means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

Communicable period means the period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

Communicable stage means the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual.

Conditional release 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 and includes public health supervision through in-person visits, telephone, or through electronic or Internet-based monitoring.

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.

Conveyance means an aircraft, train, road vehicle, vessel (as defined in this section) or other means of transport, including military.

Director means the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.

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 or supervising health authority.

Ill person means an individual who:

(1) 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

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

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

Incubation period means the time from the moment of exposure to an infectious agent that causes a communicable disease until signs and symptoms of the communicable disease appear in the individual or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear. For a quarantinable communicable disease, incubation period means the precommunicable stage.

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.

Interstate traffic (1) Means:

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(ii) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(iii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

Isolation means the separation of an individual or group 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 conveyance. 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 an aircraft, for the purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of an 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.

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.

Precommunicable stage means the stage beginning upon an individual's earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage.

Public health emergency as used in this part means:

(1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or

(2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or

(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or

(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or

(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

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

Qualifying stage is statutorily defined (42 U.S.C. 264(d)(2)) to mean:

(1) The communicable stage of a quarantinable communicable disease; or

(2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

Quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who are 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 section 361 of the Public Health Service Act. 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.

Reasonably believed to be infected, as applied to an individual, means specific articulable facts upon which a public

health officer could reasonably draw the inference that an individual has been exposed, either directly or indirectly, to the infectious agent that causes a quarantinable communicable disease, as through contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector, and that as a consequence of the exposure, the individual is or may be harboring in the body the infectious agent of that quarantinable communicable disease.

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.

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.

State means any of the 50 states, plus the District of Columbia.

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.

Vessel means any passenger-carrying, cargo, or towing vessel exclusive of:

Fishing boats including those used for shell-fishing;

Tugs which operate only locally in specific harbors and adjacent waters;

Barges without means of self-propulsion;

Construction-equipment boats and dredges; and

Sand and gravel dredging and handling boats.

[65 FR 49908, Aug. 16, 2000, as amended at 77 FR 75884, Dec. 26, 2012; 82 FR 6968, Jan. 19, 2017]

§ 70.2 Measures in the event of inadequate local control.

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

§ 70.3 All communicable diseases.

A person who has a communicable disease in the communicable period shall not travel from one State or possession to another without a permit from the health officer of the State, possession, or locality of destination, if such permit is required under the law applicable to the place of destination. Stop-overs other than those necessary for transportation connections shall be considered as places of destination.

§ 70.4 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

§ 70.5 Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

(a) The following provisions are applicable to any individual under a Federal order of isolation, quarantine, or conditional release with regard to a quarantinable communicable disease or to any individual meeting the requirements of paragraph (d), (e), or (f) of this section:

(1) Except as specified under the terms of a Federal conditional release order, no such individual shall travel in interstate traffic or from one State or U.S. territory to another without a

written travel permit issued by the Director.

(2) Requests for a travel permit must state the reasons why the travel is being requested, mode of transportation, the places or individuals to be visited, the precautions, if any, to be taken to prevent the potential transmission or spread of the communicable disease, and other information as determined necessary by the Director to assess the individual's health condition and potential for communicable disease spread to others.

(3) The Director will consider all requests for a permit and, taking into consideration the risk of introduction, transmission, or spread of the communicable disease, may condition the permit upon compliance with such precautionary measures as the Director shall prescribe. The Director shall respond to a request for a permit within 5 business days.

(4) An individual to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances, as required by its terms.

(5) An individual who has had his/her request for a permit denied, or who has had a travel permit suspended or revoked, may submit a written appeal to the Director (excluding the CDC official who denied, suspended, or revoked the permit). The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Director (excluding the CDC official who denied, suspended, or revoked the permit) within 10 calendar days of the denial, suspension, or revocation of the permit. The Director (excluding the CDC official who denied, suspended, or revoked the permit) will issue a written response to the appeal within 3 business days, which shall constitute final agency action.

(b) The operator of any conveyance operating in interstate traffic shall not:

(1) Accept for transportation any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release, unless such an individual presents a permit issued by the Director or a copy of the Federal conditional release order authorizing such travel;

(2) Transport any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release in violation of any of the terms or conditions prescribed in the travel permit or conditional release order issued by the Director.

(c) Whenever a conveyance operating in interstate traffic transports an individual under a Federal order or travel permit, the Director may require that the operator of the conveyance submit the conveyance to inspection, sanitary measures, and other measures, as the Director deems necessary to prevent the possible spread of communicable disease.

(d) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals traveling entirely intrastate and to conveyances that transport such individuals upon the request of a State or local health authority of jurisdiction. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(e) The Director may additionally apply the provisions in paragraphs (a) through of this section (c) to individuals traveling interstate or entirely intrastate and to conveyances that transport such individuals whenever the Director makes a determination under 42 CFR 70.2 that based on the existence of inadequate local control such measures are needed to prevent the spread of any of the communicable diseases from such State or U.S. territory to any other State or U.S. territory.

(f) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals under a State or local order, or written agreement, for quarantine, isolation, or conditional release and to conveyances that may transport such individuals, upon the request of a State

or local health authority of jurisdiction or whenever the Director makes a determination of inadequate local control under 42 CFR 70.2. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(g) The Director may exempt individuals and non-public conveyances, such as ambulances, air ambulance flights, or private vehicles, from the requirements of this section.

[82 FR 6970, Jan. 19, 2017]

§ 70.6 Apprehension and detention of persons with quarantinable communicable diseases.

(a) The Director may authorize the apprehension, medical examination, quarantine, isolation, or conditional release of any individual for the purpose of preventing the introduction, transmission, and spread of quarantinable communicable diseases, as specified by Executive Order, based upon a finding that:

(1) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and is moving or about to move from a State into another State; or

(2) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and constitutes a probable source of infection to other individuals who may be moving from a State into another State.

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

[82 FR 6971, Jan. 19, 2017]

§ 70.7 Responsibility with respect to minors, wards, and patients.

A parent, guardian, physician, nurse, or other such person shall not transport, or procure or furnish transportation for any minor child or ward, patient or other such person who is in the communicable period of a communicable disease, except in accordance with provisions of this part.

§ 70.8 Members of military and naval forces.

The provisions of §§ 70.3, 70.4, 70.5, 70.7, and this section shall not apply to members of the military or naval forces, and medical care or hospital beneficiaries of the Army, Navy, Veterans' Administration, or Public Health Service, when traveling under competent orders: *Provided*, That in the case of persons otherwise subject to the provisions of § 70.5 the authority authorizing the travel requires precautions to prevent the possible transmission of infection to others during the travel period.

§ 70.9 Vaccination clinics.

(a) The Director may establish vaccination clinics, through contract or otherwise, authorized to administer vaccines and/or other prophylaxis.

(b) A vaccination fee may be charged for individuals not enrolled in Medicare Part B to cover costs associated with administration of the vaccine and/or other prophylaxis. Such fee is to be collected at the time that the vaccine is administered. The vaccination fee, if imposed, is shown in the following table:

Vaccine	Effective dates	Amount
Fluarix	[1] 1/25/05	[2] $25.00

[1] Continuing for one year.
[2] $7.00 for the vaccine and $18.00 for administration.

[70 FR 3493, Jan. 25, 2005]

§ 70.10 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures at U.S. airports, seaports, railway stations, bus terminals, and other locations where individuals may gather to engage in interstate travel, through non-invasive procedures determined appropriate by the Director to detect the 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 6971, Jan. 19, 2017]

§ 70.11 Report of death or illness onboard aircraft operated by an airline.

(a) The pilot in command of an aircraft operated by an airline who is conducting a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to the Director the occurrence onboard of any deaths or the presence of ill persons among passengers or crew and take such measures as the Director may direct to prevent the potential spread of the communicable disease, provided that such measures do not affect the airworthiness of the aircraft or the safety of flight operations.

(b) The pilot in command of an aircraft operated by an airline who reports in accordance with paragraph (a) of this section shall be deemed to satisfy the reporting obligation under 42 CFR 70.4.

[82 FR 6971, Jan. 19, 2017]

§ 70.12 Medical examinations.

(a) The Director may require an individual to undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release for a quarantinable communicable disease.

(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 an individual to provide information and undergo such testing as may be reasonably necessary to diagnose or confirm the presence 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 6971, Jan. 19, 2017]

§ 70.13 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 conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the CDC'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 (*i.e.*, 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 or group for the time period beginning when the Director refers the individual or group 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 for the individual's safe medical transport.

[82 FR 6971, Jan. 19, 2017]

§ 70.14 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 in the qualifying stage of a quarantinable communicable disease;

(4) An explanation of the factual basis underlying the Director's reasonable belief that the individual is moving or about to move from one State into another or constitutes a probable source of infection to others who may be moving from one State into another;

(5) 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;

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

(7) 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 Federal order may be published or posted in a conspicuous location if the Federal order is 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 this section shall affect the constitutional or statutory rights of individuals to obtain judicial review of their Federal detention.

[82 FR 6971, Jan. 19, 2017]

§ 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

(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 and serve 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.

(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 the Federal order is 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 6971, Jan. 19, 2017]

§ 70.16 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 section 70.15 and following the 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 in a qualifying stage.

(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 under 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 (excluding the CDC official who issued the quarantine, isolation, or conditional release order) 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 or 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 that pertain 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 be rescinded, continued, or modified. 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 authorized 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 individuals 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 and 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 6971, Jan. 19, 2017]

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

(a) The administrative record of an individual under Federal 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 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]

PART 71—FOREIGN QUARANTINE

Subpart A—Definitions and General Provisions

Sec.
71.1 Scope and definitions.
71.2 Penalties.
71.3 Designation of yellow fever vaccination centers; Validation stamps.
71.4 Requirements relating to the transmission of airline passenger, crew, and flight information for public health purposes.
71.5 Requirements relating to the transmission of vessel passenger, crew, and voyage information for public health purposes.

Subpart B—Measures at Foreign Ports

71.11 Bills of health.

Subpart C—Notice of Communicable Disease Prior to Arrival

71.20 Public health prevention measures to detect communicable disease.
71.21 Report of death or illness.

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

71.29 Administrative records relating to quarantine, isolation, or conditional release.
71.30 Payment for care and treatment.
71.31 General provisions.
71.32 Persons, carriers, and things.
71.33 Persons: Isolation and surveillance.
71.34 Carriers of U.S. military services.
71.35 Report of death or illness on carrier during stay in port.
71.36 Medical examinations.
71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.
71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).
71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.
71.40 Prohibiting the introduction of persons from designated foreign countries and places into the United States.

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

71.41 General provisions.
71.42 Disinsection of imports.
71.43 Exemption for mails.
71.44 Disinsection of aircraft.
71.45 Food, potable water, and waste: U.S. seaports and airports.
71.46 Issuance of Deratting Certificates and Deratting Exemption Certificates.
71.47 Special provisions relating to airports: Office and isolation facilities.
71.48 Carriers in intercoastal and interstate traffic.

Subpart F—Importations

71.50 Scope and definitions.
71.51 Dogs and cats.
71.52 Turtles, tortoises, and terrapins.
71.53 Requirements for importers of nonhuman primates.
71.54 Import regulations for infectious biological agents, infectious substances, and vectors.
71.55 Importation of human remains.
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 electronic 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, questioning, 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);

(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.

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 conditional 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

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.

(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

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.

(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 Prohibiting the introduction of persons from designated foreign countries and places into the United States.

(a) The Director may prohibit the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions and regions thereof) or places, only for such period of time that the Director deems necessary for the public health, by issuing an order in which the Director determines that:

(1) By reason of the existence of any 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 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 introduction of such persons into the United States is required in the interest of the public health.

(b) For purposes of this section:

(1) *Introduction into the United States* of persons from a foreign country (or one or more political subdivisions or regions thereof) or place 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 in the United States, or so as to cause the contamination of property in the United States, in a manner that the Director determines to present a risk of transmission of a communicable disease to persons or property, even if the communicable disease has already been introduced, transmitted, or is spreading within the United States;

(2) *Serious danger of the introduction of such communicable disease into the United States* means the potential for introduction of vectors of the communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the communicable disease; and

(3) 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 nationality.

(c) In any order issued under this section, the Director shall designate the foreign countries (or one or more political subdivisions or regions thereof) or places; the period of time or circumstances under which the introduction of any persons or class of persons into the United States shall be suspended; and the conditions under which that prohibition on introduction, in whole or in part, shall be effective, including any relevant exceptions that the Director determines are appropriate.

(d) Before issuing any order under this section, the Director may coordinate with State and local authorities and other Federal departments or agencies as he deems appropriate in his 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 may 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 officers of the Department of Homeland Security with U.S. Customs and Border Protection, who exercise the authorities of customs officers) 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 members of the armed forces of the United States and associated personnel for whom the Secretary of Defense provides assurance to the Director that the Secretary of Defense, through measures such as quarantine, isolation, or other measures maintaining control over such individuals, is preventing the risk of transmission of a communicable disease into the United States.

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

[85 FR 16566, Mar. 24, 2020]

EFFECTIVE DATE NOTE: At 85 FR 56458, Sept. 11, 2020, § 71.40 was revised, effective Oct. 13, 2020. For the convenience of the user, the revised text is set forth as follows:

§ 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 personnel 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.

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.

§ 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 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.

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.

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 schedule for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

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.

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.

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.

[77 FR 75891, Dec. 26, 2012, as amended at 85 FR 42741, July 15, 2020]

§ 71.51 Dogs and cats.

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

Cat means all domestic cats.

Confinement means restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

Dog means all domestic dogs.

Owner means owner or agent.

Valid rabies vaccination certificate means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.

(2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.

(3) Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.

(4) Bears the signature of a licensed veterinarian.

(b) *General requirements for admission of dogs and cats*—(1) *Inspection by Director*. The Director shall inspect all dogs and cats which arrive at a U.S. port, and admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1.

(2) *Examination by veterinarian and confinement of dogs and cats*. When, upon inspection, a dog or cat does not appear to be in good health on arrival (e.g., it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the Director may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The Director will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities which in the judgment of the Director will afford protection against any communicable disease. The owner shall bear the expense of confinement. Confinement shall be subject to conditions specified by the Director to protect the public health.

(3) *Record of sickness or death of dogs and cats and requirements for exposed animals*. (i) The carrier responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine station at the U.S. port upon arrival. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered, and shall be held in confinement pending any necessary examination as determined by the Director.

(ii) When, upon inspection, a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no evidence that the animal may be infected with a communicable disease. The provisions of paragraph (b)(2) of this section shall be applicable to the examination or tests.

(4) *Sanitation*. When the Director finds that the cages or other containers of dogs or cats arriving in the United States are in an insanitary or other condition that may constitute a communicable disease hazard, the dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected.

(c) *Rabies vaccination requirements for dogs*. (1) A valid rabies vaccination certificate is required at a U.S. port for admission of a dog unless the owner submits evidence satisfactory to the Director that:

(i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free (a current list of rabies-free countries may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333); or

(ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country determined by the Director to be rabies-free; or

(iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

(2) Regardless of the provisions of paragraph (c)(1) of this section, the Director may authorize admission as follows:

(i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but must be confined until at least 30 days have elapsed since the date of vaccination;

(ii) If the dog is less than 3 months of age, it may be admitted, but must be confined until vaccinated against rabies at 3 months of age and for at least 30 days after the date of vaccination;

(iii) If the dog is 3 months of age or older, it may be admitted, but must be confined until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at a U.S. port. It must be kept in confinement for at least 30 days after the date of vaccination.

(3) When a dog is admitted under paragraph (c)(2) of this section, the Director shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.

(d) *Certification requirements.* The owner shall submit such certification regarding confinement and vaccination prescribed under this section as may be required by the Director.

(e) *Additional requirements for the importation of dogs and cats.* Dogs and cats shall be subject to such additional requirements as may be deemed necessary by the Director or to exclusion if coming from areas which the Director has determined to have high rates of rabies.

(f) *Requirements for dogs and cats in transit.* The provisions of this section shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:

(1) Dogs and cats that appear healthy, but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as provided in paragraph (b)(3) of this section if the Director determines that the conditions under which they are being transported will afford adequate protection against introduction of communicable disease.

(2) Rabies vaccination is not required for dogs that are transported by aircraft or ship and retained in custody of the carrier under conditions that would prevent transmission of rabies.

(g) *Disposal of excluded dogs and cats.* A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exportation, it shall be detained at the owner's expense in the custody of the U.S. Customs Service at the U.S. port.

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

§ 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 diagnostic 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 detained 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 than 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 (l)(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 (l)(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 findings, 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 (l)(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, Na_2CO_3) 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, Na_2CO_3);

(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]

PART 72 [RESERVED]

PART 73—SELECT AGENTS AND TOXINS

Sec.

73.0 Applicability and related requirements.
73.1 Definitions.
73.2 Purpose and scope.
73.3 HHS select agents and toxins.
73.4 Overlap select agents and toxins.
73.5 Exemptions for HHS select agents and toxins.
73.6 Exemptions for overlap select agents and toxins.
73.7 Registration and related security risk assessments.
73.8 Denial, revocation, or suspension of registration.
73.9 Responsible Official.
73.10 Restricting access to select agents and toxins; security risk assessments.
73.11 Security.
73.12 Biosafety.
73.13 Restricted experiments.
73.14 Incident response.
73.15 Training.
73.16 Transfers.
73.17 Records.
73.18 Inspections.
73.19 Notification of theft, loss, or release.
73.20 Administrative review.
73.21 Civil money penalties.

AUTHORITY: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

SOURCE: 70 FR 13316, Mar. 18, 2005, unless otherwise noted.

§ 73.0 Applicability and related requirements.

All individuals and entities that possess SARS-CoV, Lujo virus, or Chapare virus must provide notice to CDC regarding their possession of SARS-CoV, Lujo virus, or Chapare virus on or before December 4, 2012. Currently registered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all the requirements of this part by December 4, 2012. All previously unregistered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all of the requirements of this part by April 3, 2013.

[77 FR 61110, Oct. 5, 2012, as amended at 77 FR 71702, Dec. 4, 2012]

§ 73.1 Definitions.

For purposes of this part:

Administrator means the Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS) means the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General means the Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Conotoxins means short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$, whereas:

(1) C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges;
(2) The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB;
(3) X_1 = any amino acid(s) or Des-X;
(4) X_2 = Asparagine or Histidine;
(5) P = Proline;
(6) A = Alanine;
(7) G = Glycine;
(8) X_3 = Arginine or Lysine;
(9) X_4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan;
(10) X_5 = Tyrosine, Phenylalanine, or Tryptophan;
(11) X_6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine;
(12) X_7 = Any amino acid(s) or Des X; and
(13) ''Des X'' = ''an amino acid does not have to be present at this position.'' For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS means the Department of Health and Human Services.

HHS Secretary means the Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin means a biological agent or toxin included in § 73.3.

Information security means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(1) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information authenticity;

(2) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) Availability, which means ensuring timely and reliable access to and use of information.

Occupational exposure means any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties.

Overlap select agent and/or toxin means a biological agent or toxin listed in § 73.4 and 9 CFR part 121.4.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Proficiency testing means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Recombinant nucleic acids means:

(1) Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

Responsible Official means the individual designated by an entity with the

authority and control to ensure compliance with the regulations in this part.

Security barrier means a physical structure that is designed to prevent entry by unauthorized persons.

Select agent and/or toxin means unless otherwise specified, all of the biological agents or toxins listed in §§ 73.3 and 73.4.

Specimen means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

State means any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Synthetic nucleic acids means:

(1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (*i.e.*, synthetic nucleic acids) or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means all of the States.

USDA means the United States Department of Agriculture.

Validated inactivation procedure means a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Viability testing protocol means a protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

Verification means the demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61110, Oct. 5, 2012; 82 FR 6290, Jan. 19, 2017]

§ 73.2 Purpose and scope.

This part implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

§ 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) HHS select agents and toxins:

Abrin
Bacillus cereus Biovar *anthracis**
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]

[1] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-

Coxiella burnetii
Crimean-Congo hemorrhagic fever virus
Diacetoxyscirpenol
Eastern equine encephalitis virus
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza virus)
Ricin
Rickettsia prowazekii
SARS coronavirus (SARS-CoV)
Saxitoxin
South American hemorrhagic fever viruses:
  Chapare
  Guanarito
  Junin
  Machupo
  Sabia
Staphylococcal enterotoxins (subtypes A–E)
T–2 toxin
Tetrodotoxin
Tick-borne encephalitis virus
  Far Eastern subtype
  Siberian subtype
Kyasanur Forest disease virus
Omsk haemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

(c) Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and/or Synthetic Organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any of the toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) HHS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any HHS select agent or toxin that is in its naturally occurring environment provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable HHS select agents or nontoxic HHS toxins.

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary to be effectively inactivated or

---

CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; ''Des X'' = ''an amino acid does not have to be present at this position.'' For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to CDC. A written decision granting or denying the request will be issued.

(7) Except as required in § 73.16(l), the aggregate amount of the toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not, at any time, exceed the following amounts: 1000 mg of Abrin; 1 mg of Botulinum neurotoxins; 100 mg of Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$); 10,000 mg of Diacetoxyscirpenol; 1000 mg of Ricin; 500 mg of Saxitoxin; 100 mg of Staphylococcal enterotoxins (subtypes A–E); 10,000 mg of T–2 toxin; or 500 mg of Tetrodotoxin. Provided that,

(i) The toxin is transferred only after the transferor uses due diligence and documents the identification of the recipient and the legitimate need (*e.g.*, prophylactic, protective, bona fide research, or other peaceful purpose) claimed by the recipient to use such toxin. Information to be documented includes, but is not limited to, the recipient identity information, including the recipient's name, institution name, address, telephone number and email address; name of the toxin and the total amount transferred; and the legitimate need claimed by the recipient. Notwithstanding the provisions of paragraph (d) of this section, the HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

(ii) Reports to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in this part.

(8) An animal inoculated with or exposed to an HHS select toxin.

(9) An HHS select toxin identified in an original food sample or clinical sample.

(10) For those laboratories that are not exempt under § 73.5(a) and § 73.6(a), Botulinum neurotoxin that is produced as a byproduct in the study of Botulinum neurotoxin producing species of *Clostridium* so long as the toxin has not been intentionally cultivated, collected, purified, or otherwise extracted, and the material containing the toxin is rendered non-toxic and disposed of within 30 days of the initiation of the culture.

(11) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with state and Federal regulations within seven calendar days of the conclusion of patient care.

(12) Any South American genotypes of Eastern Equine Encephalitis Virus and any West African Clade of Monkeypox virus provided that the individual or entity can identify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/*.

(2) If an excluded attenuated strain or modified toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts

and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any HHS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus cereus* Biovar *anthracis*, Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, Ebola viruses, *Francisella tularensis*, Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 70 FR 61049, Oct. 20, 2005; 73 FR 61365, Oct. 16, 2008; 73 FR 64554, Oct. 30, 2008; 77 FR 61110, Oct. 5, 2012; 79 FR 26861, May 12, 2014; 81 FR 63143, Sept. 14, 2016; 82 FR 6290, Jan. 19, 2017]

§ 73.4 Overlap select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) Overlap select agents and toxins:

*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

(c) Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and/or Synthetic Organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.

(2) Recombinant and/or synthetic nucleic acids that encode for the toxic form(s) of any overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment provided that the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable overlap select agents or nontoxic overlap toxins.

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary or Administrator to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to CDC or APHIS. A written decision granting or denying the request will be issued.

(7) An overlap select toxin identified in an original food sample or clinical sample.

(8) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with state and Federal regulations within seven calendar days of the conclusion of patient care.

(9) Any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC provided that the individual or entity can identify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent, or a select toxin modified to be less potent or toxic, may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/*.

(2) If an excluded attenuated strain or modified toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary or Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary or Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus anthracis*, *Burkholderia mallei* and *Burkholderia pseudomallei* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the overlap select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the select agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by the submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008; 77 FR 61111, Oct. 5, 2012; 79 FR 26861, May 12, 2014; 82 FR 6291, Jan. 19, 2017]

§ 73.5 Exemptions for HHS select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification of the select agent or toxin (except for Botulinum neurotoxin and/or *Staphylococcal* enterotoxin (Subtypes A–E)), or within 30 calendar days after identification of Botulinum neurotoxin and/or *Staphylococcal* enterotoxin (Subtypes A–E), the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) Unless otherwise directed by the HHS Secretary, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven calendar days after delivery of patient care by health care professionals has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

(i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus cereus* Biovar *anthracis*,, Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, Ebola viruses, *Francisella tularensis*, Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or Yersinia pestis. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be

submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary may exempt from the requirements of this part an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008; 77 FR 61112, Oct. 5, 2012; 82 FR 6292, Jan. 19, 2017]

§ 73.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within seven calendar days after identification, the select agent or toxin is transferred in accordance with §73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) Unless otherwise directed by the HHS Secretary or Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with §73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven calendar days after delivery of patient care by health care professionals has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Burkholderia mallei* and *Burkholderia pseudomallei*. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with §73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary, after consultation with Administrator, may exempt from the requirements of this part an investigational product that is, bears, or contains an overlap select agent or toxin, may be exempted when such product is being used in an investigation authorized under any Federal

Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. The HHS Secretary may extend the exemption once for additional 30 days.

(f) Upon request of the Administrator, the HHS Secretary may exempt an individual or entity from the requirements, in whole or in part, of this part for 30 calendar days if the Administrator has granted the exemption for agricultural emergency. The HHS Secretary may extend the exemption once for an additional 30 calendar days.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008; 77 FR 61112, Oct. 5, 2012; 79 FR 26862, May 12, 2014;82 FR 6292, Jan. 19, 2017]

§ 73.7 Registration and related security risk assessments.

(a) Unless exempted under § 73.5, an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary. Unless exempted under § 73.6 or 9 CFR part 121.6, an individual or entity shall not possess, use, or transfer overlap select agents or toxins, without a certificate of registration issued by the HHS Secretary and Administrator.

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxin currently in its possession.

(c) As a condition of registration, each entity must designate an individual to be its Responsible Official. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the Responsible Official.

(d)(1) As a condition of registration, the following must be approved by the HHS Secretary or Administrator based on a security risk assessment by the Attorney General:

(i) The individual or entity,

(ii) The Responsible Official, and

(iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions:[1]

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

[1] These conditions may apply to more than one individual.

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) To apply for a certificate of registration that covers only HHS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC. To apply for a certificate of registration that does not cover only HHS select agents or toxins (*i.e.*, covers at least one overlap select agent and/or toxin, or covers any combination of HHS select agents and/or toxins and USDA select agents and/or toxins), an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC or APHIS, but not both.

(f) Prior to the issuance of a certificate of registration, the Responsible Official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(g) The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(h) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the Responsible Official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(i) A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.

(2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(j) An entity must immediately notify CDC or APHIS if it loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.

(k) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

(l) A certificate of registration will be valid for a maximum of three years.

[70 FR 13316, Mar. 18, 2005, as amended at 82 FR 6292, Jan. 19, 2017]

§ 73.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

(1) The individual or entity, the Responsible Official, or an individual who

owns or controls the entity is within any of the categories described in 18 U.S.C. 175b,

(2) The individual or entity, the Responsible Official, or an individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5),

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(3) The individual or entity does not meet the requirements of this part, or

(4) It is determined that such action is necessary to protect public health and safety.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order,

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release, and

(3) Comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 73.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

§ 73.9 Responsible Official.

(a) An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must:

(1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General,

(2) Be familiar with the requirements of this part,

(3) Have authority and responsibility to act on behalf of the entity,

(4) Ensure compliance with the requirements of this part,

(5) Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan, and

(6) Ensure that annual inspections are conducted for each registered space where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented.

(7) Ensure that individuals are provided the contact information for the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any biosafety or security concerns related to select agents and toxins.

(8) Investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation or viable agent removal method failure to CDC or APHIS.

(9) Review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training

must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.

(b) An entity may designate one or more individuals to serve as an alternate Responsible Official, who acts for the Responsible Official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.

(c) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*,, *Bacillus cereus* Biovar *anthracis*,'' Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium, Burkholderia mallei, Burkholderia pseudomallei Francisella tularensis*, Ebola viruses, , Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis*. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(3) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(d) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 82 FR 6292, Jan. 19, 2017]

§ 73.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) A person with a valid approval from the HHS Secretary or Administrator to have access to select agents and toxins may request, through his or her Responsible Official, that the HHS Secretary or Administrator provide their approved access status to another registered individual or entity for a specified period of time. A Responsible Official must immediately notify the Responsible Official of the visited entity if the person's access to select agents and toxins has been terminated.

(f) An individual's security risk assessment may be expedited upon written request by the Responsible Official and a showing of good cause (e.g., public health or agricultural emergencies, national security, or a short term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(g) An individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b,

(h) An individual's access approval may be denied, limited, or revoked if:

(1) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime specified in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power (as defined in 50 U.S.C. 1801), or

(2) It is determined such action is necessary to protect public health and safety.

(i) An individual may appeal the HHS Secretary's decision to deny, limit, or revoke access approval under § 73.20.

(j) Access approval is valid for a maximum of three years.

(k) The Responsible Official must immediately notify CDC or APHIS when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control,

(2) Contain provisions for the control of access to select agents and toxins including the safeguarding of animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

(3) Contain provisions for routine cleaning, maintenance, and repairs,

(4) Establish procedures for removing unauthorized or suspicious persons,

(5) Describe procedures for addressing loss or compromise of keys, keycards, passwords, combinations, etc. and protocols for changing access permissions or locks following staff changes,

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records, and

(7) Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

(8) Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of such activity.

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which manage security for the registered space are isolated or have controls that permit only authorized and authenticated users;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (*e.g.*, servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agents and toxins is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to spaces

registered under this part or records in § 73.17;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the requirements of section 17 of this part are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the HHS Secretary or Administrator,

(2) Allow individuals not approved for access from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, or other activities not related to select agents or toxins only when continuously escorted by an approved individual if the potential for access to select agents or toxins exists,

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (e.g., card access system, lock boxes),

(4) Inspect all suspicious packages before they are brought into or removed from the area where select agents or toxins are used or stored,

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release,

(6) Require that individuals with access approval from the HHS Secretary or Administrator refrain from sharing with any other person their unique means of accessing a select agent or toxin (e.g., keycards or passwords),

(7) Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official:

(i) Any loss or compromise of keys, passwords, combination, etc.,

(ii) Any suspicious persons or activities,

(iii) Any loss or theft of select agents or toxins,

(iv) Any release of a select agent or toxin, and

(v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised, and

(vi) Any loss of computer, hard drive or other data storage device containing information that could be used to gain access to select agents or toxins.

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) Entities must conduct complete inventory audits of all affected select agents and toxins in long-term storage when any of the following occur:

(1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;

(2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or

(3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.

(f) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:

(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;

(2) Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's

safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and

(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:

(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;

(ii) The training of employees with access to Tier 1 select agents and toxins on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability; and

(iii) The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

(4) Entities with Tier 1 select agents and toxins must prescribe the following security enhancements:

(i) Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General, have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessment;

(ii) Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee;

(iii) Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment;

(iv) A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. One of the security barriers must be monitored in such a way as to detect intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.) The final barrier must limit access to the select agent or toxin to personnel approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.

(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;

(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;

(vii) For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space;

(viii) The entity must:

(A) Determine that the response time for security forces or local police will not exceed 15 minutes where the response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier or;

(B) Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional release, or unauthorized access. The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier.

(5) Entities that possess Variola major virus and Variola minor virus must have the following additional security requirements:

(i) Require personnel with independent unescorted access to Variola major or Variola minor virus to have a Top Secret security clearance;

(ii) Require Variola major or Variola minor virus storage locations to be under the surveillance of closed circuit television that is monitored;

(iii) After hours access procedures for Variola major or Variola minor virus must require notification of the entity's security staff prior to entry into the Variola laboratory and upon exit;

(iv) Require that observation zones be maintained in outdoor areas adjacent to the physical barrier at the perimeter of the entity and be large enough to permit observation of the activities of people at that barrier in the event of its penetration;

(v) Provide for a minimum of four barriers for the protection of the Variola major or Variola minor virus, one of which must be a perimeter fence;

(vi) Require a numbered picture badge identification subsystem to be used for all individuals who are authorized to access Variola major or Variola minor without escort;

(vii) Require the use, at all times, of properly trained and equipped security force personnel able to interdict threats identified in the site specific risk assessment;

(viii) Identify security force personnel designated to strengthen onsite response capabilities, and that will be onsite and available at all times to carry out their assigned response duties;

(ix) Provide for security patrols to periodically check external areas of the registered areas to include physical barriers and building entrances;

(x) Require that all on-duty security force personnel shall be capable of maintaining continuous communication with support and response assets by way of security operations center;

(xi) Require that Variola major and Variola minor material in long term storage be stored in tamper-evident systems;

(xii) Require that all spaces containing working or permanent Variola major or Variola minor stocks be locked and protected by an intrusion alarm system that will alarm upon the unauthorized entry of a person anywhere into the area;

(xiii) Require that alarms required pursuant to this section annunciate in a continuously manned security operations center located within the facility; and

(xiv) Require that the security operations center shall be located within a building so that the interior is not visible from the perimeter of the protected area.

(g) In developing a security plan, an individual or entity should consider the document entitled, ''Security Guidance for Select Agent or Toxin Facilities.'' This document is available on the National Select Agent Registry at *http://www.selectagents.gov/*.

(h) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 79 FR 26862, May 12, 2014; 82 FR 6293, Jan. 19, 2017]

§ 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions:

(1) The hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety

containers; and engineering controls and other facility safeguards;

(3) Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material; and

(4) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider:

(1) The CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.'' This document is available on the National Select Agent Registry Web site at *http://www.selectagents.gov*.

(2) The ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,'' (NIH Guidelines). This document is available on the National Select Agent Registry Web site at *http://www.selectagents.gov*.

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

(e) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the HHS Secretary:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] <100 ng/kg body weight.

(b) The HHS Secretary may revoke approval to conduct any of the experiments in paragraph (a) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(c) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 79 FR 26862, May 12, 2014]

§ 73.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment.[2] The incident response plan must be coordinated with any entity-wide plans, kept in the

[2] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

workplace, and available to employees for review. The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, and other natural and manmade events.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

(d) The incident response plan must also contain the following information:

(1) The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.),

(2) The name and contact information for the building owner and/or manager, where applicable,

(3) The name and contact information for tenant offices, where applicable,

(4) The name and contact information for the physical security official for the building, where applicable,

(5) Personnel roles and lines of authority and communication,

(6) Planning and coordination with local emergency responders,

(7) Procedures to be followed by employees performing rescue or medical duties,

(8) Emergency medical treatment and first aid,

(9) A list of personal protective and emergency equipment, and their locations,

(10) Site security and control,

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge, and

(12) Decontamination procedures.

(e) Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures:

(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and

(2) The incident response plan must describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins.

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or

toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

(d) The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (*e.g.*, laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

[77 FR 61114, Oct. 5, 2012, as amended at 82 FR 6293, Jan. 19, 2017]

§ 73.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer.[4]

(b) A transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all requirements in this part,

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred, or

(iii) Is transferring the select agent or toxin from outside the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the HHS Secretary may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under this part under conditions prescribed by the HHS Secretary.

(e) To obtain authorization for transfer, APHIS/CDC Form 2 must be submitted.

(f) After authorization is provided by APHIS or CDC, the packaging of the select agent(s) and toxin(s) is performed by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins and is in compliance with all applicable laws concerning packaging.

(g) The sender must comply with all applicable laws governing packaging and shipping.

(h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and

[4] This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

(i) The recipient must submit a completed APHIS/CDC Form 2 within two business days of receipt of a select agent or toxin.

(j) The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.

(k) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).

(l) A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of § 73.3(d) must:

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*e.g.*, prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

(2) Report to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in § 73.3(d) of this part.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61115, Oct. 5, 2012; 79 FR 26862, May 12, 2014; 82 FR 6294, Jan. 19, 2017]

§ 73.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (e.g., strain designation, GenBank Accession number, etc.),

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) Where stored (e.g., building, room, and freezer or other storage container),

(iv) When moved from storage and by whom and when returned to storage and by whom,

(v) The select agent used, purpose of use, and, when applicable, final disposition,

(vi) Records created under § 73.16 and 9 CFR 121.16 (Transfers),

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient, and

(viii) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release),

(2) An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics,

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.),

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom,

(v) Where stored (e.g., building, room, and freezer or other storage container),

(vi) When moved from storage and by whom and when returned to storage and by whom including quantity amount,

(vii) Records created under § 73.16 and 9 CFR part 121.16 (Transfers),

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient,

(ix) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release), and

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom,

(4) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator,

(5) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry,

(6) Accurate, current records created under § 73.9 and 9 CFR part 121.9 (Responsible Official), § 73.11 and 9 CFR part 121.11 (Security), § 73.12 and 9 CFR part 121.12 (Biosafety), § 73.14 and 9 CFR part 121. 14 (Incident response), and § 73.15 and 9 CFR part 121.15 (Training), and

(7) A written explanation of any discrepancies.

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61115, Oct. 5, 2012; 82 FR 6294, Jan. 19, 2017]

§ 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

§ 73.19 Notification of theft, loss, or release.

(a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,

(iii) An estimate of the time during which the theft or loss occurred,

(iv) The location (building, room) from which the theft or loss occurred, and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss.

(2) A completed APHIS/CDC Form 3 must submitted within seven calendar days.

(b) Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity released,

(iii) The time and duration of the release,

(iv) The environment into which the release occurred (e.g., in building or outside of building, waste system),

(v) The location (building, room) from which the release occurred,

(vi) The number of individuals potentially exposed at the entity,

(vii) Actions taken to respond to the release, and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

§ 73.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision.

(c) The HHS Secretary's decision constitutes final agency action.

[77 FR 61115, Oct. 5, 2012]

§ 73.21 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board have been delegated authority to conduct hearings and to render decisions in accordance with 42 CFR part 1005 with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to

exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The Departmental Appeals Board of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

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

Sec.
75.1 Background and purpose.
75.2 Definitions.
75.3 Applicability.
APPENDIX A TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIOGRAPHERS
APPENDIX B TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS
APPENDIX C TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS
APPENDIX D TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS
APPENDIX E TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS
APPENDIX F TO PART 75—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS
APPENDIX G TO PART 75—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

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

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

§ 75.1 Background and purpose.

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

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

§ 75.2 Definitions.

All terms not defined herein shall have the meaning given them in the Act. As used in this part:

Accreditation, as applied to an educational program, means recognition, by a State government or by a nongovernmental agency or association, of a specialized program of study as meeting or exceeding certain established qualifications and educational standards. As applied to a health care or educational institution, *accreditation* means recognition, by a State government or by a nongovernmental agency or association, of the institution as meeting or exceeding certain established standards or criteria for that type of institution.

Act means the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10001–10008.

Continuing competency means the maintenance of knowledge and skills and/or demonstrated performance that are adequate and relevant to professional practice needs.

Credentialing means any process whereby a State Government or nongovernmental agency or association grants recognition to an individual who meets certain predetermined qualifications.

Dental hygienist means a person licensed by the State as a dental hygienist.

Dental assistant means a person other than a dental hygienist who assists a dentist in the care of patients.

Educational program means a set of formally structured activities designed to provide students with the knowledge and skills necessary to enter an occupation, with evaluation of student performance according to predetermined objectives.

Energized laboratory means any facility which contains equipment that generates ionizing radiation. This does not include facilities for training students when the equipment is not powered to emit ionizing radiation, e.g., practice in setting controls and positioning of patients.

Formal training means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

Ionizing radiation means any electromagnetic or particulate radiation (X-rays, gamma rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles) which interacts with atoms to produce ion pairs in matter.

Licensed practitioner means a licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic.

Licensure means the process by which an agency of State government grants permission to persons meeting predetermined qualifications to engage in an occupation.

Nuclear medicine technologist means a person other than a licensed practitioner who prepares and administers radio-pharmaceuticals to human beings and conducts *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes.

Permit means an authorization issued by a State for specific tasks or practices rather than the entire scope of practice in an occupation.

Radiation therapy technologist means a person other than a licensed practitioner who utilizes ionizing radiation-generating equipment for therapeutic purposes on human subjects.

Radiographer means an individual other than a licensed practitioner who (1) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits ionizing radiation, and (2) is delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed. Radiographers are distinguished from personnel whose use of diagnostic procedures is limited to a few specific body sites and/or standard procedures, from those personnel in other clinical specialties who may occasionally be called upon to assist in diagnostic radiology, and from those technicians or assistants whose activities do not, to any significant degree, determine the site or dosage of radiation to which a patient is exposed.

Radiologist means a physician certified in radiology by the American Board of Radiology or the American Osteopathic Board of Radiology.

§ 75.3 Applicability.

(a) *Federal Government*. Except as provided in section 983 of the Act, the credentialing standards set out in the Appendixes to this part apply to those individuals who administer or propose to administer radiologic procedures, in each department, agency and instrumentality of the Federal Government as follows:

(1) *Radiographer Standards* apply to all individuals who are radiographers as defined in § 75.2 and who are not practitioners excepted by the Act.

(2) *Nuclear Medicine Technologist Standards* apply to all individuals who are nuclear medicine technologists as

defined in §75.2, who perform *in vivo* nuclear medicine procedures, and who are not practitioners excepted by the Act. For purposes of this Act, any administration of radiopharmaceuticals to human beings is considered an *in vivo* procedure.

(3) *Radiation Therapy Technologist Standards* apply to all individuals who perform radiation therapy and who are not practitioners excepted by the Act.

(4) *Dental Hygienist Standards* apply to all dental hygienists who perform dental radiography.

(5) *Dental Assistant Standards* apply to all dental assistants who perform dental radiography.

(6) The following persons are deemed to have met the requirements of these standards:

(i) Persons employed by the Federal government as radiologic personnel prior to the effective date of this regulation and who show evidence of current or fully satisfactory performance or certification of such from a licensed practitioner:

(ii) Uniformed military personnel who receive radiologic training from or through the Armed Forces of the United States and who meet standards established by the Department of Defense or components thereof, provided that those standards are determined by such Department or component to offer equivalent protection of patient health and safety:

(iii) Foreign national employed by the Federal government in positions outside of the United States who show evidence of training, experience, and competence determined by the employing agency to be equally protective of patients health and safety; and

(iv) Persons first employed by the Federal government as radiologic personnel after the effective date of this regulation who (*a*) received training from institutions in a State or foreign jurisdiction which did not accredit training in that particular field at the time of graduation, or (*b*) practiced in a State or foreign jurisdiction which did not license that particular field or which did not allow special eligibility to take a licensure examination for those who did not graduate from an accredited educational program; provided that such persons show evidence of training, experience, and competence determined by the Office of Personnel Management or the employing agency to be equally protective of patient health and safety.

(7) The following persons are exempted from these standards:

(i) Persons who are trained to perform, or perform, covered radiologic procedures in emergency situations which preclude use of fully qualified personnel; and

(ii) Students in approved training programs.

(8) A department, agency, or instrumentality of the Federal government may, after consultation with the Secretary, use alternative criteria which it determines would offer equivalent protection of patient health and safety.

(b) *States*. The States may, but are not required to, adopt standards for accreditation and credentialing that are consistent with the standards set out in the appendixes to this part.

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

A. Description of the Profession

The radiographer shall perform effectively by:

1. Applying knowledge of the principles of radiation protection for the patient, self, and others.
2. Applying knowledge of anatomy, positioning, and radiographic techniques to accurately demonstrate anatomical structures on a radiograph.
3. Determining exposure factors to achieve optimum radiographic technique with a minimum of radiation exposure to the patient.
4. Examining radiographs for the purpose of evaluating technique, positioning, and other pertinent technical qualities.
5. Exercising discretion and judgment in the performance of medical imaging procedures.
6. Providing patient care essential to radiologic procedures.
7. Recognizing emergency patient conditions and initiating lifesaving first aid.

B. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and

grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals;

(c) Medical schools;

(d) Postsecondary vocational/technical schools and institutions; and

(e) Other acceptable institutions which meet comparable standards.

3. The sponsoring institutions and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affilitate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

C. Instructional Facilities

1. *General*. Appropriate classroom and clinical space, modern equipment, and supplies for supervised education shall be provided.

2. *Laboratory*. Energized laboratories utilized for teaching purposes shall be certified as required for compliance with Federal and/or State radiation safety regulations. The use of laboratories shall be governed by established educational objectives.

3. *Reference Materials*. Adequate up-to-date scientific books, periodicals, and other reference materials related to the curriculum and profession shall be readily accessible to students.

D. Clinical Education

1. The clinical phase of the educational program shall provide an environment for supervised competency-based clinical education and experience and offer a sufficient and well-balanced variety of radiographic examinations and equipment.

2. An acceptable ratio of students to registered technologists shall be maintained in the clinical teaching environment.

3. A clinical instructor(s), who shall be responsible for supervising students according to objectives, shall be identified for each primary clinical education center.

4. The maximum student enrollment shall not exceed the capacity recommended on the basis of volume and variety of radiographic procedures, resources, and personnel available for teaching purposes.

5. In programs where didactic and clinical experience are not provided in the same institution, accreditation shall be given only to the institution responsible for admissions, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the students in the clinical setting are educational. There shall be a uniform contract between the accredited institution and each of its affiliate hospitals, clearly defining the responsibilities and obligations of each.

E. Curriculum

1. The structure of the curriculum shall be based on not less than two calendar years of full-time study or its equivalent.

2. Instruction shall follow a planned outline that includes:

(a) The assignment of appropriate instructional materials;

(b) Classroom presentations, discussions and demonstrations; and

(c) Examinations in the didactic and clinical aspects of the program.

3. All professional courses, including clinical education, must include specific curriculum content that shall include, but shall not be limited to:

(a) Introduction to radiologic technology;

(b) Medical ethics;

(c) Imaging;

(d) Radiographic processing technique;

(e) Human structure and function;

(f) Medical terminology;

(g) Principals of radiographic exposure;

(h) Radiographic procedures;

(i) Principles of radiation protection;

(j) Radiographic film evaluation;

(k) Methods of patient care;

(l) Pathology;

(m) Radiologic physics; and

(n) Radiation biology.

Related subjects added to the professional curriculum shall meet the requirements of the degree-granting institution.

F. Finances

Financial resources for operation for the educational program shall be assured through regular budgets, gifts, grants, endowments, or fees.

G. Faculty

1. *Program Director*. A program director shall be designated who is credentialed in radiography. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiography shall not be adversely affected by educationally unrelated functions.

(a) *Minimum qualifications*. A minimum of two years of professional experience and proficiency in instructing, curriculum design, program planning, and counseling.

(b) *Responsibilities*. (1) The program director, in consultation with the medical director/advisor (G. 2.) shall be responsible for the organization, administration, periodic review, records, continued development, and general policy and effectiveness of the program.

(2) Opportunities for continuing education shall be provided for all faculty members.

2. *Medical Director/Medical Advisor*—(a) *minimum qualifications*. The medical director/

medical advisor shall be a qualified radiologist, certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

(b) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for their achievement.

3. *Instructors.* All instructors shall be qualified through academic preparation and experience to teach the assigned subjects.

H. Students

ADMISSION

(a) Candidates for admission shall satisfy the following minimum requirements: Completion of four years of high school; successful completion of a standard equivalency test; or certification of equivalent education by an organization recognized by the United States Department of Education. Courses in physics, chemistry, biology, algebra, and geometry are strongly recommended.

(b) The number of students enrolled in each class shall be commensurate with the most effective learning and teaching practices and should also be consistent with acceptable student-teacher ratios.

I. Records

Records shall be maintained as dictated by good educational practices.

NOTE: Educational programs accredited by an organization recommended by the United States Department of Education are considered to have met these standards.

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

A. Sponsorship

Sponsorship must be by an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. The formal training in dental radiography may be a part of a total program of dental hygiene education accredited by an organization recognized by the United States Department of Education.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental hygiene education programs or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental hygienists must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental hygienists to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: Interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: Sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Hygienists have the opportunity to develop competence in making radiographs. Faculty supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice where there is not direct supervision by faculty.

—Dental hygienists must demonstrate knowledge of radiation safety measures before making radiographs and, where possible, should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity which approved the training program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards. Under existing licensure provisions in all States, becoming a dental hygienist requires graduation from a dental hygiene education program accredited by an organization recognized by the United States Department of Education. In lieu of this requirement, Alabama accepts graduation from a State-approved preceptorship program.

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

A. Sponsorship

Sponsorship must be an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: Defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised

clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. Dental radiography training may be freestanding (as a continuing education course offered by State dental/dental auxiliary societies, or by dental/dental auxiliary education programs); or be a part of an educational program in dental assisting. Such dental assisting education programs may be accredited by an organization recognized by the United States Department of Education; or located in a school accredited by an institutional accrediting agency recognized by the United States Department of Education or approved by the State agency responsible for secondary and postsecondary education, or approved by a Federal agency conducting dental assistant education in that Agency.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental assisting education programs, or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental assistants must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental assistants to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics*. Curriculum content should include: Historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology*. Curriculum content should include: interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection*. Curriculum content should include: sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality*. Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques*. Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques*. Curriculum content should include: Solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting*. Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Assistants have the opportunity to develop competence in making radiographs. The clinical experience may be conducted in the dental office in which the Dental Assistant is employed or is serving an externship. Faculty and/or employing dentist supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice when there is not direct supervision by faculty and/or the employing dentist.

—Dental Assistants must demonstrate knowledge of radiation safety measures before making radiographs, and where possible should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs

and radiographic surveys, including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity (or Federal agency where appropriate) which approves the educational program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

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

A. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals and clinics;

(c) Laboratories;

(d) Medical schools;

(e) Postsecondary vocational/technical schools and institutions; and

(f) Other acceptable institutions which meet comparable standards.

3. The sponsoring institution and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

4. Responsibilities of the sponsor and each affiliate for program administration, instruction, supervision, etc., must be carefully described in written affiliation agreements.

B. Curriculum

Instruction must follow a plan which documents:

1. A structured curriculum including clinical education with clearly written syllabi which describe learning objectives and competencies to be achieved. The curriculum shall be based on not less than one calendar year of full-time study or its equivalent.

2. The minimum professional curriculum that includes the following:

(a) Methods of patient care;

(b) Radiation safety and protection;

(c) Nuclear medicine physics;

(d) Radiation physics;

(e) Nuclear instrumentation;

(f) Statistics;

(g) Radionuclide chemistry;

(h) Radiopharmacology;

(i) Departmental organization and function;

(j) Radiation biology;

(k) Nuclear medicine *in vivo* and *in vitro* procedures;

(l) Radionuclide therapy;

(m) Computer applications; and

(n) Clinical practicum.

3. Assignment of appropriate instructional materials.

4. Classroom presentations, discussions, and demonstrations.

5. Supervised practice, experience, and discussions. This shall include the following:

(a) Patient care and patient recordkeeping;

(b) Participation in the quality assurance program;

(c) The preparation, calculation, identification, administration, and disposal of radiopharmaceuticals;

(d) Radiation safety techniques that will minimize radiation exposure to the patient, public, fellow workers, and self;

(e) The performance of an adequate number and variety of imaging and non-imaging procedures; and

(f) Clinical correlation of nuclear medicine procedures.

6. Evaluation of student's knowledge, problem-solving skills, and motor and clinical competencies.

7. The competencies necessary for graduation.

C. Resources

1. The program must have qualified program officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. The following program officials must be identified:

(a) *Program Director*—(1) *Responsibilities*. The program director of the educational program shall have overall responsibility for the organization, administration, periodic review, continued development, and general effectiveness of the program. The director shall provide supervision and coordination to the instructional staff in the academic and clinical phases of the program. Regular visits to the affiliates by the program director must be scheduled.

(2) *Qualifications*. The program director must be a physician or nuclear medicine technologist. The program director must demonstrate proficiency in instruction, curriculum design, program planning, and counseling.

(b) *Medical Director*—(1) *Responsibilities*. The medical director of the program shall provide competent medical direction and shall participate in the clinical instruction. In multiaffiliate programs each clinical affiliate must have a medical director.

(2) *Qualifications*. The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board(s) of Nuclear Medicine, or Pathology, or Radiology, or possess suitable equivalent qualifications.

(c) *Clinical Supervisor*. Each clinical affiliate must appoint a clinical supervisor.

(1) *Responsibilities*. The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical affiliate.

(2) *Qualifications*. The clinical supervisor must be a technologist credentialed in nuclear medicine technology.

2. *Instructional Staff*—(a) *Responsibilities*. The instructional staff shall be responsible for instruction in the didactic and/or clinical phases of the program. They shall submit course outlines for each course assigned by the program director; evaluate students and report progress as required by the sponsoring institution; and cooperate with the program director in the periodic review and upgrading of course material.

(b) *Qualifications*. The instructors must be qualified, knowledgeable, and effective in teaching the subjects assigned.

(c) *Instructor-to-student ratio*. The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional development*. Accredited programs shall assure continuing education in the health profession or occupation and ongoing instruction for the faculty in curriculum design and teaching techniques.

3. Financial resoures for continued operation of the educational program must be assured.

4. *Physical Resources*. (a) *General*. Adequate classrooms, laboratories, and other facilities shall be provided.

(b) *Equipment and Supplies*. Modern nuclear medicine equipment, accurately calibrated, in working order, and meeting applicable Federal and State standards, if any, must be available for the full range of diagnostic and therapeutic procedures as outlined in the curriculum.

(c) *Reference Materials*. Reference materials appropriate to the curriculum shall be readily accessible to students.

(d) *Records*. Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources*. Instructional aids such as clinical materials, reference materials, demonstration and other multimedia materials must be provided.

D. Students

ADMISSION REQUIREMENTS

Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent. They shall have completed postsecondary courses in the following areas:

(1) Human anatomy and physiology;

(2) Physics;

(3) Mathematics;

(4) Medical terminology;

(5) Oral and written communications;

(6) General chemistry; and

(7) Medical ethics.

Prerequisites may be completed during nuclear medicine training. Educational institutions such as junior colleges, universities, and technical vocational institutes may provide these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., two to four years).

E. Operational Policies

Students may not take the responsibility nor the place of qualified staff. However, students may be permitted to perform procedures after demonstrating proficiency, with careful supervision.

F. Continuing Program Evaluation

1. Periodic and systematic review of the program's effectiveness must be documented.
2. One element of program evaluation shall be the initial employment of graduates of the program.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

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

A. Sponsorship

1. Educational programs may be established in:
(a) Community and junior colleges, senior colleges, and universities;
(b) Hospitals, clinics, or autonomous radiation oncology centers meeting the criteria for major cancer management centers or meeting demonstrably equivalent standards;
(c) Medical schools; and
(d) Postsecondary vocational/technical schools and institutions.
2. The sponsoring institution and affiliates, if any, must be accredited by recognized agencies or meet equivalent standards. When more than one clinical education center is used, each must meet the standards of a major cancer management center.
3. When didactic preparation and supervised clinical education are not provided in the same institution, accreditation must be obtained by the sponsoring institution for the total program. This institution will be the one responsible for admission, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the student in the clinical setting are educational. There shall be a uniform, written, affiliation agreement between the accredited institution and each clinical education center, clearly defining the responsibilities and obligations of each.

B. Curriculum

Educational programs of 24 months and 12 months or their equivalents may be developed. A 24-month program shall admit those candidates with a high school diploma (or equivalent) as outlined in D.1. The 12-month program shall be designed for those students admitted with backgrounds as outlined in D.2.
Instruction must follow a plan which documents:
1. A structured curriculum with clearly written course syllabi which describe competencies and learning objectives to be achieved. The curriculum shall include but not necessarily be limited to the following:
(a) Orientation to radiation therapy technology;
(b) Medical ethics and law;
(c) Methods of patient care;
(d) Medical terminology;
(e) Human structure and function;
(f) Oncologic pathology;
(g) Radiation oncology;
(h) Radiobiology;
(i) Mathematics;
(j) Radiation physics;
(k) Radiation protection;
(l) Radiation oncology technique;
(m) Radiographic imaging; and
(n) Clinical dosimetry.

The curriculum must include a plan for well-structured competency-based clinical education.

2. Assignment of appropriate instructional materials.
3. Classroom presentations, discussions, and demonstrations.
4. Supervised clinical education and laboratory practicum.
5. Evaluation of students to assess knowledge, problem-solving skills, and motor and clinical competencies.
6. Program graduates must demonstrate competencies including, but not limited to, the following:
(a) Practice oral and written communications;
(b) Maintain records of treatment administered;
(c) Perform basic mathematical functions;
(d) Demonstrate knowledge of human structure, function, and pathology;
(e) Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
(f) Provide basic patient care and cardiopulmonary resuscitation;
(g) Deliver a planned course of radiation therapy;
(h) Verify physician's prescribed course of radiation therapy and recognize errors in computation;
(i) Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;

(j) Produces and utilize immobilization and beam directional devices;

(k) Prepare commonly used brachytherapy sources;

(l) Demonstrate knowledge of methods of calibration of equipment, and quality assurance;

(m) Prepare isodose summations;

(n) Detect malfunctioning equipment;

(o) Apply rules and regulations for radiation safety, and detect defects which might pose a radiation hazard;

(p) Understand the function of equipment and accessories;

(q) Demonstrate knowledge of methods of continuing patient evaluation (follow up);

(r) Apply wedge and compensating filters;

(s) Recognize patients' clinical progress, complications, and demonstrate knowledge of when to withhold treatment until consultation with the physician; and

(t) Interact with patients and families concerning the physical and psychological needs of patients.

C. Resources

1. *Program Officials*. The program must have a qualified program official or officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. A program director is necessary; other program officials may be required.

(a) *Program Director*—(1) *Responsibilities*.

—The director of the educational program shall be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiation therapy technology shall not be adversely affected by educationally unrelated functions.

—In a college-sponsored program, or a hospital-sponsored multiple affiliate program, the program director shall be an employee of the sponsoring institution. A schedule of regular affiliate visits must be maintained.

(2) *Qualifications*.

—Must be a technologist qualified in radiation therapy technology and educational methodologies.

—Must be credentialed in radiation therapy technology or possess suitable equivalent qualifications.

—Must have at least two years' experience as an instructor in an accredited educational program.

(b) *Clinical Supervisor*. Each clinical education center shall appoint a clinical supervisor.

(1) *Responsibilities*. The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical education center.

(2) *Qualifications*. Must be a technologist, with suitable experience, qualified in radiation therapy technology and educational methodologies and must be credentialed in radiation therapy technology.

(c) *Medical Director/Medical Advisor*—

(1) *Responsibilities*. The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for achievement.

(2) *Qualifications*. The medical director/medical advisor shall be a qualified radiation oncologist certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

2. *Instructional Staff*— (a) *Responsibilities*. The instructional staff shall be responsible for submitting course outlines for each course assigned by the program director; evaluating students and reporting progress as required by the sponsoring institution; and cooperating with the program director in the periodic review and upgrading of course material.

(b) *Qualifications*. The instructors must be individually qualified, must be effective in teaching the subjects assigned, and must meet the standards required by the sponsoring institution.

(c) *Instructor-to-Student Ratio*. The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional Development*. Programs shall have a policy that encourages continuing education in radiation therapy technology and assures ongoing instruction for the faculty in curriculm design and teaching strategies.

3. *Financial Resources*. Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources*—(a) *General*. Adequate classrooms, laboratories, and other facilities shall be provided. All affiliated institutions shall provide space required for these facilities.

(b) *Equipment and Supplies*. Appropriate modern equipment and supplies in sufficient quantities shall be provided.

(c) *Laboratory*. Energized laboratories must meet Federal and/or State radiation and safety regulations.

(d) *Reference Materials*. An adequate supply of up-to-date books, periodicals, and other reference materials related to the curriculum and the profession shall be readily available to students.

(e) *Records*. Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources*. Instructional aids such as clinical materials, reference materials, and demonstration and other multimedia materials must be provided.

D. Students

ADMISSION

1. Applicants must be high school graduates (or equivalent) with an educational background in basic science and mathematics.

2. For admission to a 12-month program, the candidate must satisfy one of the following requirements:

(a) Graduation from an accredited or equivalent program in radiography.

(b) Successful completion or challenge of courses in the following prerequisite content areas:

—Radiation physics;
—Human structure and function;
—Radiation protection;
—Medical ethics and law;
—Methods of patient care;
—Medical terminology; and
—Mathematics.

(c) Successful demonstration of the following competencies:

—Practice oral and written communications;
—Perform basic mathematical functions;
—Demonstrate knowledge of human structure and function;
—Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
—Provide basic patient care and cardiopulmonary resuscitation;
—Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;
—Apply rules and regulations for radiation safety, detect defects which might pose a radiation hazard, and maintain control, if a radiation accident occurs; and
—Interact with patients and families concerning patients physical and psychological needs.

E. Continuing Program Evaluation

1. A process for periodic and systematic review of the program's effectiveness must be documented and reflected in policies.

2. Program evaluation shall include the employment performance of recent graduates.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

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

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

A. Licensure

1. Only eligible applicants who have passed the licensure examination shall be licensed as Radiographers, Nuclear Medicine Technologists, or Radiation Therapy Technologists.

2. Licenses shall be renewed at periodic intervals.

B. Eligibility

1. For regular eligibility to take the licensure examination, applicants shall have successfully completed an accredited program of formal education in radiography, nuclear medicine technology, or radiation therapy technology.

2. Special eligibility to take the licensure examination shall be provided for applicants whose training and/or experience are equal to, or in excess of, those of a graduate of an accredited educational program.

C. Examination

A criterion-referenced examination in radiography, nuclear medicine technology, or radiation therapy technology shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The licensed Radiographer, Nuclear Medicine Technologist, or Radiation Therapy Technologist shall maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.

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

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

Currently, Dental Hygienists are credentialed through individual State licensure processes, all of which include assessment of competence in dental radiography. In all States, Dental Hygienists are required to be licensed prior to practicing. The existing State dental hygiene licensure processes meet the intent and purpose of the Consumer-Patient Radiation Health and Safety Act of 1981 and the standards for licensing Dental Hygienists in dental radiography set forth below.

A. Licensure/Permit

1. To those who have passed a licensure or designated dental radiography examination, a license or permit shall be issued by the State entity responsible for credentialing dental personnel.

2. Licenses or permits shall be renewed at periodic intervals.

B. Eligibility

1. An individual shall provide proof of graduating student status or graduation from an accredited or approved dental hygiene or dental assisting education program.

2. For dental assistants, special eligibility to take the examination shall be provided to applicants with appropriate combinations of training and/or experience.

C. Examination

A criterion-referenced examination in dental radiography shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The Dental Hygienist or Dental Assistant shall be required to maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.