

§ 71.53 Requirements for importers of nonhuman primates.

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

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

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

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

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

(1) For the purposes of this section:

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

AZA means the Association of Zoos and Aquariums.

CITES means the Convention on International Trade in Endangered Species.

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

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

IACUC means Institutional Animal Care and Use Committee.

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

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

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

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

SOPs means standard operating procedures.

TB means tuberculosis.

TST means tuberculin skin test.

USDA means United States Department of Agriculture.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

United States and the descendants of any such offspring.

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

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

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

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

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

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

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

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

Zoo means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) A completed registration/application form;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Face shields or eye protection; and

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

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

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

(B) Outer protective clothing;

(C) Waterproof shoes or boots;

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

(E) Face shields or eye protection.

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

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

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

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

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

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

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

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

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

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

(iv) Compliance with exposure-control planning elements under 29 CFR 1910.1030 for workers who will have percutaneous 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.

(1) *Quarantine facilities.* (1) The requirements of this paragraph (1) 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

from quarantine when all the following conditions have been met:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) The importer's name and address;

(ii) Number and species of NHPs being imported;

(iii) Description of crates;

(iv) Means of individually identifying NHPs;

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

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

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

(viii) Port of entry;

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

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

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

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

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

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

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

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

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

(xviii) Master air waybill number for shipment;

(xix) CITES permit number and expiration date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) Means of individually identifying NHPs, if required by the importing country;

(v) A specific itinerary while in the United States including names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel within the United States, including all ground transportation;

(vi) Description of crates;

(vii) SOPs describing procedures to protect and train transport workers from exposure to communicable disease while handling NHPs;

(viii) SOPs describing procedures to prevent contamination of other articles and cargo during transit, including physical separation of crates from other cargo;

(ix) SOPs describing procedures to decontaminate aircraft, ships, vehicles, and related equipment following transport; and

(x) Proposed use, if any, of in transit holding facilities and steps to be taken to protect workers, as well as NHPs, from communicable disease exposure at each facility to be used en route.

(2) While located in the United States, in transit shipments must be housed and cared for in a manner consistent with requirements for NHPs intended for import into the United States as specified in paragraphs (j) and (k) of this section.

(s) *Revocation and reinstatement of an importer's registration.* (1) If the Director determines that an importer has failed

to comply with any applicable provisions of this section, including the importer's SOPs, the Director may revoke the importer's registration.

(2) HHS/CDC will send the importer a notice of revocation stating the grounds upon which the proposed revocation is based.

(i) If the importer wishes to contest the revocation, the importer must file a written response to the notice within 20 calendar days after receiving the notice.

(A) As part of the response, an importer may request that the Director review the written record.

(B) If an importer fails to file a response within 20 calendar days, all of the grounds listed in the proposed revocation will be deemed admitted, in which case the notice shall constitute final agency action.

(ii) [Reserved]

(3) If an importer's response is timely, the Director will review the registration, the notice of revocation, and the response, and make a decision in writing based on the written record.

(4) As soon as practicable after completing the written record review, the Director will issue a decision in writing that shall constitute final agency action. The Director will serve the importer with a copy of the written decision.

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

(t) *Nonhuman primate products.* (1) NHP products may be imported without obtaining a permit under this section if accompanied by documentation demonstrating that the products have been rendered noninfectious using one of the following methods:

(i) Boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers, or teeth is removed; or

(ii) Gamma irradiation at a dose of at least 20 kilo Gray at room temperature (20 °C or higher); or

(iii) Soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium

carbonate, Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours; or

(iv) Soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 liters water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

(v) In the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate, Na₂CO₃);

(vi) Formalin fixation; or

(vii) Another method approved by HHS/CDC.

(viii) Fully taxidermied products are considered rendered noninfectious, and so do not require a permit from the Director.

(2) NHP products that have not been rendered noninfectious are considered to pose a potential human health risk and may only be imported under the following circumstances:

(i) The product must be accompanied by a permit issued by the Director. Requests for permits should be accompanied by an explanation of the product's intended use and a description of how the product will be handled to ensure that it does not pose a zoonotic disease threat to humans. The Director will review the request for a permit, and accompanying materials, and issue a decision that shall constitute final agency action.

(ii) The product may only be imported for bona fide scientific, educational, or exhibition purposes.

(iii) A permit will only be issued if the product will be received by a facility equipped to handle potentially infectious NHP materials.

(iv) The product must comply with any other applicable federal requirements, including those relating to packaging, shipping, and transport of potentially infectious, biohazardous substances as well as those for select agents pursuant to 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121.

(u) *Appeal of denial for a permit to import.* If the HHS/CDC denies your request for a permit under this section, you may appeal that denial to the HHS/CDC Director.

(1) You must submit your appeal in writing to the HHS/CDC Director, stating the reasons for the appeal and demonstrating that there is a genuine and substantial issue of fact in dispute.

(2) You must submit the appeal within 5 business days after you receive the denial.

(3) HHS/CDC will issue a written response to the appeal, which shall constitute final Agency action.

(v) *Filovirus testing fee.* (1) Non-human primate importers shall be charged a fee for filovirus testing of non-human primate liver samples submitted to the Centers for Disease Control and Prevention (CDC).

(2) The fee shall be based on the cost of reagents and other materials necessary to perform the testing; the use of the laboratory testing facility; irradiation for inactivation of the sample; personnel costs associated with performance of the laboratory tests; and administrative costs for test planning, review of assay results, and dissemination of test results.

(3) An up-to-date fee schedule is available from the Division of Global Migration & Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333. Any changes in the fee schedule will be published in the FEDERAL REGISTER.

(4) The fee must be paid in U.S. dollars at the time that the importer submits the specimens to HHS/CDC for testing.

[78 FR 11538, Feb. 15, 2013]

§ 71.54 Import regulations for infectious biological agents, infectious substances, and vectors.

(a) The following definitions apply to this section:

Animal. Any member of the animal kingdom except a human including an animal product (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws).

Diagnostic specimen. Specimens of human and animal matter (including tissue, blood, body discharges, fluids, excretions or similar material), or environmental samples.

Genomic material. Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) comprising the genome or organism's

hereditary information, that may be single-stranded or double-stranded, and in a linear, circular, or segmented configuration and may be positive sense (same polarity as mRNA), negative sense, or ambisense (mixture of the two).

Infectious biological agent. A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.

Infectious substance. Any material that is known or reasonably expected to contain an infectious biological agent.

Select agents and toxins. Biological agents and toxins that could pose a severe threat to public health and safety as listed in 42 CFR 73.3 and 73.4.

Vector. Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.

(b) Unless excluded pursuant to paragraph (f) of this section, a person may not import into the United States any infectious biological agent, infectious substance, or vector unless:

(1) It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC). The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.

(2) The importer is in compliance with all of the permit requirements and conditions that are outlined in the permit issued by the CDC.

(3) The importer has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance,