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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

RIN 0920-AA23

Docket No. HHS/CDC-2011-0001

Control of Communicable Disease; Foreign - Requirements for Importers of Nonhuman Primates (NHP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final Rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is amending regulations for the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of Macaca fascicularis (cynomolgus), Chlorocebus aethiops (African green), and Macaca mulatta (rhesus) monkeys to all NHPs with the

exception of the filovirus testing requirement. Filovirus testing will only be required for Old World NHPs in quarantine that have illness consistent with filovirus infection or that die for any reason other than trauma during quarantine. HHS/CDC is also finalizing a provision to reduce the frequency at which importers of cynomolgus, African green, and rhesus monkeys are required to renew their special permits (from every 180 days to every 2 years). HHS/CDC is incorporating existing guidelines into the regulations and adding new provisions to address the following: NHPs imported as part of an animal act; NHPs imported or transferred by zoological societies; the transfer of NHPs from approved laboratories; and non-live imported NHP products. Finally, HHS/CDC is also requiring that all NHPs be imported only through ports of entry where a HHS/CDC quarantine station is located.

DATES: This final rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

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I. Background

A. What is the Risk to Human Health from NHPs?

NHPs, particularly those recently captured in the wild, may harbor agents infectious to humans. Although such infectious agents, if present, are usually detectable in the NHP's blood, they also may be detected in secreted bodily fluids such as urine, feces, or saliva. Due to the nature of the job, persons working in temporary and long-term holding facilities and those involved in transporting NHPs (e.g., cargo handlers and inspectors) are especially at risk for infection. NHPs are a potential source of pathogens and communicable or zoonotic disease that may be fatal to humans, including filoviruses, hepatitis, herpes B virus, tuberculosis (TB), and parasitic infections (National Research Council, 2003). Quarantine requirements for imported NHPs are designed to reduce this communicable disease risk.

B. What is the Legal Authority for this Rulemaking?

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) authorizes the Secretary of the Department of Health and Human Services (HHS) to make and enforce regulations as may be necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one State or possession to another. Section 361 of the PHSA also provides that, as the Secretary deems necessary, such regulations may provide for inspection and destruction of animals or articles found to be infected or contaminated as a source of dangerous infection. Section 361 of the PHSA serves as the primary legal authority for 42 CFR 71.53, regarding the importation of NHPs.

Section 368 of the PHSA (42 U.S.C. 271) sets forth penalties for violations of any regulations prescribed under section 361 of the PHSA. Under section 368(a) of the PHSA, any person who violates a regulation prescribed under section 361 of the PHSA may be punished by a fine up to \$1,000 or by imprisonment for up to 1 year, or both [42 U.S.C. 271(a)]. These penalties are strengthened under the sentencing classification provisions of 18 U.S.C. sections 3559 and 3571, which provide for more strict penalties for criminal violations that would otherwise be

classified as Class A misdemeanors. Individuals may be punished by a fine of up to \$100,000 per violation not resulting in the death of an individual, or up to \$250,000 per violation resulting in the death of an individual [18 U.S.C. 3559, 3571(b)]. Organizations may be fined up to \$200,000 per violation not resulting in the death of an individual and \$500,000 per violation resulting in the death of an individual [18 U.S.C. 3559, 3571(c)]. These penalties are criminal in nature and would thus be imposed by a court, not administratively by HHS or HHS/CDC.

C. What is the History of this Rulemaking?

To address the risk NHPs pose to humans, since October 10, 1975, HHS/CDC has prohibited the importation of NHPs except for scientific, educational, or exhibition purposes (42 CFR 71.53). NHP importers have been required to register with HHS/CDC, renew this registration every 2 years, and hold NHPs in quarantine for a minimum of 31 days following entry into the United States. Importers also must maintain records on imported NHPs; immediately report illness suspected of being communicable to humans; and make their facilities, vehicles, equipment, and business records used in the importation of NHPs available to HHS/CDC 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.

Additional requirements for importers of NHPs have been developed and implemented in response to specific public health threats, including interim guidelines for handling NHPs during transit and quarantine (HHS/CDC Update: Ebola-Related, 1990) issued following a 1990 incident involving identification of Ebola virus (Reston strain) among NHPs imported from the Philippines. As a result of this incident, HHS/CDC concluded that cynomolgus, African green, and rhesus monkeys were capable of being an animal host or vector of filovirus which may pose a threat to human health. On April 20, 1990, HHS/CDC published a notice in the Federal Register requiring a special permit for importing cynomolgus, African green, and rhesus monkeys (55 FR 15210, April 20, 1990), with enhanced requirements for the granting of a special permit to import these species, including submitting a plan to HHS/CDC every 180 days describing specific isolation, quarantine, and disease control measures and detailing measures to be carried out at every step of the chain of custody, from embarkation at the country of origin, through delivery of the NHPs and the completion of the required quarantine period. Importers also were required to describe and implement testing

procedures for all quarantined NHPs to rule out the possibility of filovirus infection.

Over time, HHS/CDC revised components of the special permit requirement in response to surveillance findings and the development of improved laboratory tests. HHS/CDC informed covered importers of these changes by letter in 1991 (Roper, 1991). The special permit notice required filovirus antigen-capture testing on specimens from any NHP that died during quarantine for reasons other than trauma, and filovirus antibody testing of a serum sample taken at the end of quarantine before a cohort is released from quarantine on any NHPs that recover from illness consistent with a possible filovirus infection during quarantine (Tipple, 1996).

On July 30, 1993, HHS/CDC published guidelines in the Morbidity and Mortality Weekly Report (MMWR) for TB testing requirements for NHPs, following the recognition of TB in up to 2% of imported NHPs and the risk for TB infection posed to caretakers (HHS/CDC, 1993). These published requirements included provisions for recordkeeping to track and trace NHPs and for use of personal protective equipment (PPE) by NHP handlers to prevent transmission of TB (HHS/CDC, 1993). Since publishing the guidelines in the MMWR, HHS/CDC has required a minimum of three negative

tuberculin skin tests (TSTs) administered at 2-week intervals, on each imported NHP before approving release of any NHPs from quarantine.

On February 12, 2013, HHS/CDC published a final rule at 78 FR 9828 establishing a user fee for filovirus testing of all nonhuman primates that die during the HHS/CDC-required 31-day quarantine period for any reason other than trauma. This provision was initially designated in the NPRM at § 71.53(j). Because HHS/CDC had already published its proposal for a filovirus user fee, we did not solicit or receive additional comment on this proposal through this current rulemaking. Through today's final rule, we are renumbering the filovirus user fee provision as § 71.53(v). HHS/CDC is making this non-substantive change to increase the functionality and ease of use of these regulations.

II. Summary of the Proposed Rule Requirements

In the January 5, 2011, NPRM, HHS/CDC proposed to continue, in § 71.53(d), the long-standing general prohibition on importing NHPs, and to reflect, in § 71.53(e), its authority to require disposal of prohibited or excluded NHPs. HHS/CDC also proposed a list of definitions specific to modern importation principles and practices for NHPs, including adding new definitions and

revising existing ones, to add clarity to the provisions regulating the importation of NHPs.

Additionally, HHS/CDC proposed to expand the isolation, quarantine, and worker protection requirements; and to expand the registration process described in the special permit requirements for cynomolgus, African green, and rhesus monkeys to all importations of NHPs. HHS/CDC intended that the proposed changes would simplify importer registration procedures and provide an enhanced measure of worker and NHP safety against known and emerging zoonotic diseases.

HHS/CDC intended to achieve its regulatory objectives through a performance-based standard focusing on desired characteristics of the regulated activities, rather than a prescriptive standard for conducting those activities. The Agency endeavored to allow regulated entities flexibility in choosing how to meet the standard's goals and objectives.

To extend the public health benefits of the special permit requirements regarding identifying filovirus infections, HHS/CDC proposed extending filovirus testing to include all Old World NHPs in quarantine that have illness consistent with filovirus infection or that die for any reason other than trauma during quarantine. This

requirement was proposed because Old World NHPs are susceptible to filovirus infection and they originate from areas of the world where filoviruses have caused fatal disease in NHPs. Consequently, surveillance for filovirus infection would include not just the species covered under the special permit requirements, but all newly imported Old World primates (unpublished data, HHS/CDC; Formenty, et al., 1999; Rollin, et al., 1999, Rouquet, et al., 2005; Leroy, et al., 2004).

Also in keeping with the special permit requirements, HHS/CDC proposed under paragraph (h) to require that NHP importers develop a written policy for ensuring that imported NHPs and their offspring would be used and distributed only for the permitted purposes defined in the regulation. HHS/CDC proposed requiring importers to keep written certifications that would follow the NHP for life and demonstrate the continued use of the NHPs and any offspring only for permitted purposes. The intended purpose of this requirement was to ensure that NHPs are not diverted into the pet trade, subsequently placing individuals at risk of contracting zoonotic diseases that NHPs may carry.

Under proposed paragraph (h) importers would be required to maintain these records in an organized manner,

and in a central location, which is at or in close proximity to the NHP facility, to allow HHS/CDC to inspect the records during regular business hours or within one hour of HHS/CDC site visits. Proposed § 71.53(g)(1) would require any importer to establish, implement, and maintain documentation and standard operating procedures (SOPs) associated with the importation of NHPs. HHS/CDC's proposal included performance-based requirements for worker education concerning risks, exposure notification and reporting, PPE, development of SOPs, TB and other diagnostic testing, post-exposure procedures, and other requirements for the development and implementation of a plan sufficient, as determined by HHS/CDC, for protecting workers from the risks associated with handling NHPs.

The proposed rule contained quarantine provisions, including a 31-day period of quarantine at a U.S. quarantine facility, with possible extensions of quarantine if the NHPs showed infection with certain communicable diseases, if the importer or HHS/CDC suspected that an NHP was infected with certain communicable diseases, or if the importer or HHS/CDC determined that there was a need for additional diagnostic testing. Additionally, HHS/CDC proposed to eliminate the 31-day quarantine requirement and associated restrictions for transfers of NHPs into the

United States between Association of Zoos and Aquariums (AZA)-accredited zoos. HHS/CDC proposed a similar quarantine exception for transfers of NHPs from laboratories accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or its equivalent, if the laboratory has a foreign-based and a U.S.-based facility and the NHP is part of an ongoing research project. The proposed procedures and standards contained in § 71.53(l) were based on procedures and standards of the National Research Council (NRC), HHS/CDC biosafety guidelines, current knowledge of infectious agent transmission routes, and experience gained from investigating filovirus infection outbreaks (HHS/CDC, 1996; HHS/CDC, 1989).

Other quarantine requirements proposed in § 71.53(l) addressed routine veterinary medical care and screening for zoonotic diseases of NHPs in quarantine, management of illnesses and deaths of unknown etiology, written protocols for the evaluation and diagnostic testing of suspect cases of zoonotic disease in NHPs, and improved surveillance and testing procedures in NHP quarantine and research facility settings. The proposed requirements for SOPs and equipment for crating, caging, and transporting NHPs in § 71.53(j) outlined the requirements that the importer must meet,

either directly or by contractual or other arrangement, to ensure safe handling of NHPs during transportation. The proposed procedures included preventing contamination of other articles and cargo during transportation; providing physical separation of crates from other cargo; and ensuring decontamination of aircraft, ships, vehicles, and related equipment following NHP transport. In addition, in § 71.53(f), HHS/CDC proposed to restrict entry of NHPs into the United States to those ports of entry where HHS/CDC quarantine stations are located, except in limited circumstances approved in advance by HHS/CDC. In § 71.53(k), HHS/CDC proposed that an importer establish, implement, maintain, and adhere to SOPs for ground vehicles to ensure the safe transport of NHPs to quarantine facilities, and ensure that pre-quarantined NHPs posed no risk to human health. Under proposed § 71.53(m), an importer would have to notify HHS/CDC of certain events listed in the paragraph within the designated time period. For example, proposed § 71.53(m)(6) would require an importer to report to HHS/CDC within 48 hours any positive or suspicious TST results, necropsy findings, or laboratory results. In addition to the NHP health-reporting requirements in § 71.53(m), HHS/CDC proposed 19 general

reporting and recordkeeping requirements in § 71.53(n), with which the importer would have to comply.

Paragraph (g) *Registration or Renewal of Importers* requires all animal acts to comply with requirements in § 71.53(h) through (n). HHS/CDC proposed additional requirements for animal acts entering and re-entering the United States under proposed § 71.53(o). Under proposed paragraph (o)(1) of the animal act provision, a foreign-based importer would have to provide additional information and documentation to help identify the individual NHP and to describe the conditions under which the NHPs are housed in the United States, and maintain documentation signed by a licensed veterinarian attesting to the results of physical examinations for NHPs. Under proposed paragraph (o)(2) of that provision, the importer of a U.S.-based animal act would meet additional specified requirements when the animals re-enter the United States.

For those NHPs entering the United States under the zoo-to-zoo and laboratory-to-laboratory transfers exception, proposed § 71.53(p) and (q) set requirements for the recipient zoo or laboratory within the United States, including registration, submission of veterinary medical records that document an NHP's current and past health history, accreditation standards, and equivalency standards

for zoos and aquariums. HHS/CDC also proposed requirements for brokers in the United States handling in-transit shipments of NHPs that have a layover or are detained or delayed at a U.S. airport. Finally, HHS/CDC proposed new procedures for revocation and reinstatement of an importer's registration [§ 71.53(s)] as well as requirements for importing untreated NHP products such as carcasses, trophies, blood, and other biological samples were proposed under § 71.53(t).

III. Comment Summary and Responses

A. General Opposition and Support

HHS/CDC received public comments from 23 individuals and entities to the January 5, 2011, NPRM. One commenter opposed the rule in its entirety, asserting that all imports of NHPs should be banned, irrespective of the purpose for which the NHP was imported. However, if such imports were permitted, this commenter said we should require a physical inspection of the importer's premise, the importer's fingerprints and picture identification, and posting of the importer's application forms on the web for public inspection.

HHS/CDC response. HHS/CDC is obligated to regulate animal imports to best protect public health and is

satisfied that this final rule achieves this goal. Further, HHS/CDC maintains a very efficient and effective registration and oversight program for the importation of NHPs and the protection of public health, which includes a thorough review of all records and unannounced inspection of the premises in which the NHPs are kept during quarantine. We do not believe the addition of fingerprinting or picture identification is necessary or would improve oversight. Further, an importer's application contains proprietary information and therefore would not be appropriate for public display.

Several commenters expressed support for portions of the proposed rule. Eight commenters approved of extending the import requirements for special permit NHP importers to all importers, and four supported extending the period for permit renewal from 6 months to 2 years. Four commenters also supported easing the quarantine restrictions for zoo-to-zoo transfers of NHPs between zoos accredited by the AZA or an equivalent organization, and laboratory-to-laboratory transfers where the importer can document that the animals are part of a research project following Institutional Animal Care and Use Committee (IACUC)-approved protocols. One commenter supported the proposal to import shipments of

NHPs only through ports of entry with HHS/CDC quarantine stations, and another supported the animal act provisions.

HHS/CDC Response. HHS/CDC has reviewed and considered all details of these comments and will discuss each in turn.

B. Public Comments Regarding Purpose and Scope

One commenter said that we should broaden the purpose provision in § 71.53(a) to include not only preventing the transmission of communicable disease and pathogens from imported NHPs to humans, but also preventing the importation of diseases and pathogens themselves.

HHS/CDC Response. NHPs are only one of the imports that HHS/CDC regulates to prevent the introduction of communicable disease. Specifically, the importation of pathogens is regulated under 42 CFR 71.54, Etiological agents, hosts, and vectors. Further, the HHS/CDC Director has broad general authority under 42 CFR 71.32(b) to take measures with regard to any carrier, article, or thing that may be contaminated with a communicable disease. Therefore, HHS/CDC does not believe it necessary to broaden the purpose and scope of this section.

This same commenter said we should broaden the scope provision in § 71.53(b) to include post-importation recipients of NHPs and the offspring of these NHPs, arguing

that the proposal placed "an unreasonable indirect enforcement burden on registered importers" by requiring them to question their customers' intended use of the importer's products. The commenter recommended requiring prospective recipients of post-importation NHPs and their offspring to register with HHS/CDC, and maintain records regarding the use, distribution, and disposition of these animals.

HHS/CDC Response. Under § 71.53, HHS/CDC regulates the initial importation of NHPs into the United States. To be approved to register as an importer, an importer must agree to only distribute NHPs for a permitted purpose. The requirement that an importer retain records of distribution allows HHS/CDC to monitor this agreement to ensure importers are adhering to the distribution restrictions. Therefore, HHS/CDC believes that the current practice of holding the initial importer responsible for the transfer of an NHP for a permitted purpose is sufficient to protect the public's health and will remain in place.

Finally, a commenter suggested requiring that "sanctuaries" obtain a U.S. Department of Agriculture (USDA) license, HHS/CDC registration, or both, if the sanctuary is to receive or possess previously imported NHPs. The commenter asserted that such entities "must

agree not otherwise (to) dispose (of) or distribute said primates."

HHS/CDC Response. HHS/CDC does not have the authority to require USDA to issue a license to an individual or entity. A "sanctuary" would fall under the definition of "person," which means such entities fall under § 71.53(b) and the general prohibition in § 71.53 (d) against receiving, maintaining, or distributing an NHP for other than a permitted purpose. For clarity, we have revised the definition of "person" in § 71.53(c) to explicitly include not-for-profit organizations, such as sanctuaries. Finally, we note that in keeping with current practices, any "person" may submit an application to HHS/CDC to become a registered importer, including a sanctuary.

C. Public Comments Regarding Definitions

One commenter supported the definition of "education and scientific purposes," saying that they had experienced problems with importers abusing the concept and endeavoring to bring NHPs into the United States by claiming the animals were purchased for a thesis. This commenter said that the proposed definition would "prevent such an abuse." However, this commenter also noted that our proposed definition of "trophy" was broader than the same definition

of this term in 50 CFR 23.74(b). Whereas the U.S. Fish and Wildlife Service (USFWS) defines a trophy as "items taken as a result of sport-hunting," the commenter asserted that HHS/CDC's proposed definition included any such items "purchased abroad that are display items," and noted that under the Convention on International Trade in Endangered Species (CITES), only an item resulting from a "personal sport-hunt" would be a trophy.

HHS/CDC Response. Regarding the comment on CITES requirements for any product defined by that agency as a "sports-hunted trophy," we note that today's final rule provisions do not negate other federal requirements. However, we note, too, that our mandate to protect public health is different from the CITES program objective and requires targeting a broader class of imported NHP products. However, CDC agrees that our proposed definition of "trophy" may cause confusion among the regulated communities; therefore, we have introduced a new definition for product that includes sports-hunted trophies. Under this final rule, a "product" is defined as "skulls, skins, bodies, blood, tissues, or other biological samples from a nonhuman primate, including trophies, mounts, rugs, or other display items."

Any untreated NHP product poses a risk to human health, irrespective of whether the product is a trophy from a "personal sport-hunt" or from commercial or other activity, and would require the importer to obtain a permit from HHS/CDC before bringing the product into the United States. To import any NHP product, an importer must render the product noninfectious under a HHS/CDC approved method, or obtain a permit in advance from the Director of HHS/CDC.¹

Other commenters addressed the definitions in § 71.53(c). Two argued that we should change the definition of "zoonotic disease" because the proposed definition was inconsistent with the background information in the NPRM and with the medical dictionary definition of the term. Instead, these commenters suggested we define the term as "any infectious agent or communicable disease that is able to be transmitted from animals, both wild and domestic, to humans."

Another commenter suggested revising four proposed definitions. First, the commenter recommended revising "broker" by adding "of NHP from another country, or as an intermediary between such an" immediately following "official agent of an exporter" and before "exporter and an

¹ <http://www.HHS/CDC.gov/animalimportation/lawsregulations/nonhuman-primates/nprm/questions-answers-importers.html>

importer of NHPs." Second, the commenter recommended a new definition of "cohort" as "a shipment or shipments of NHP that shared a confined space or close proximity (within 5 feet) during import into the United States and/or transit to the importer quarantine facility." Third, for clarity and specificity, this commenter said we should consider changing the term "in transit" to "in international transit" or "in international transit within the U.S." Asserting that the definition for "offspring" lacked documentation criteria, the commenter suggested the fourth change of specifying minimum verification documentation in the definition.

HHS/CDC Response. To clarify many of the terms used in § 71.53, HHS/CDC has adopted most of the above commenter's suggestions. We did not change the term "in transit" because we believe the definition adequately specifies and clarifies HHS/CDC's intent.

A fifth commenter suggested adding a definition of "unusually high morbidity," which the commenter argued was inadequately defined in the proposed documentation requirements in §§ 71.53(i) and 71.53(l). This same commenter said that in the notification requirements in § 71.53(m), "the definition of 'severe' illness in this section is ambiguous."

HHS/CDC Response. Regarding the comment on defining “unusually high morbidity,” we note that HHS/CDC did not propose use of the term in the regulatory text and therefore we do not believe that it is necessary to define it. Regarding the comment on notification requirements in § 71.53 (m), HHS/CDC has removed “severe illness” from this provision in the final rule to alleviate any ambiguity.

D. Public Comments Regarding Prohibition on Importing NHPs

Two commenters said we should expand the general prohibition on importing NHPs in § 71.53(d). One argued that expanding the prohibition would relieve the burdensome requirements imposed on importers. This commenter suggested adding a provision to prohibit persons from receiving “post-importation NHPs” unless the recipient was registered with HHS/CDC under § 71.53, and a provision like paragraph (d)(2) for importers, but instead addressed “post-importation” recipients of NHPs.

HHS/CDC Response. As noted above, under § 71.53, HHS/CDC regulates the initial importation of NHPs into the United States. To be approved to register as an importer, an importer must agree to only distribute NHPs for a permitted purpose. The requirement that an importer retain records of distribution allows HHS/CDC to monitor this

agreement to ensure importers are adhering to the distribution restrictions. Therefore, the current practice of holding the initial importer responsible for the initial transfer of an NHP for a permitted purpose will remain in place.

One commenter suggested that we should expressly prohibit the importation of wild and feral NHPs because these animals represent serious risks to public health and animal welfare.

HHS/CDC Response. In § 71.53(d) of the final rule, HHS/CDC retains the general prohibition on the importation of live NHPs except for certain limited purposes. No matter its origin, there can be no question of an NHP coming into the United States without prior HHS/CDC review and issuance of a registration certificate, regardless of whether the animal is caught in the wild or raised in captivity, because live NHPs present the same potential for infectious disease outbreaks. Under § 71.53(g), each NHP importer must obtain registration from HHS/CDC before importing these animals.

HHS/CDC notes that since we established quarantine restrictions for NHPs in 1975, the number of HHS/CDC-registered NHP importers went from 140 (according to a 1989 review) to 27 in 1999 (Roberts, 2008), and the mortality

rates for NHPs imported under a special permit during shipment and quarantine went from 20 percent to less than 1 percent (Roberts, 2008; DeMarcus, 1999) and has remained there (ILAR, 2006). These data indicate the efficacy of our certification process for NHP importers. Further, allowing NHP imports for specific and limited purposes under HHS/CDC authorization is consistent with the Executive Order 13656 section 1 directive of protecting public health with the "least burdensome tools for achieving regulatory ends."

E. Public Comments Regarding Authorized Points of Entry

Comments were received regarding the proposal in § 71.53(f) to require importation of live NHPs into the United States only through ports of entry with a HHS/CDC quarantine station, unless the importer received advance written approval from HHS/CDC for some other port of entry. One commenter asked that the preamble to the final rule discuss requirements in 50 CFR part 14 for NHP importers to obtain from USFWS a port-exception permit before a shipment entered the United States at Detroit, Dulles, El Paso, Minneapolis, San Diego, or San Juan. This commenter also noted that there are no USFWS staff at the port of entry in Philadelphia.

HHS/CDC Response. HHS/CDC is adopting the proposal that, absent prior approval, a shipment of live NHPs into the United States must come through ports of entry with a HHS/CDC quarantine station. In response to the comment on USFWS's requirements under 50 CFR part 14, in promulgating this final rule, HHS/CDC does not intend to supersede - and believes that these requirements are not inconsistent with - any applicable USFWS or USDA regulation nor any applicable state regulation. An importer must have a CITES permit to bring NHPs into the United States, and an importer in violation of otherwise applicable regulations is prohibited from importing NHPs. We will continue working with federal partners at ports of entry to ensure that the administrative burden on partner agencies is not unreasonable.

Another commenter opposed what they viewed as an exception for NHP shipments entering the United States at "certain border crossing[s] from Canada and Mexico." Such an exception, asserted the commenters, ran contrary to our stated purpose for the port-of-entry requirement. These commenters said further that including shipments coming from U.S. border countries in the paragraph (f) requirement was logical, would have little economic impact given the few importers who ship NHPs across those borders, and would

maintain public health and safety at the cost of a small inconvenience to importers.

HHS/CDC Response. HHS/CDC notes that there is no exception in the final rule from the port-of-entry requirement for over-the-road (OTR) shipments of NHPs coming from Canada or Mexico. A person importing NHPs from those countries either must bring the animals through ports of entry with a HHS/CDC quarantine station, or obtain prior Agency approval for bringing the shipment through an alternate U.S. port of entry. Further, HHS/CDC maintains public health safety through direct oversight of the importation, because a candidate for registration certification or renewal must allow HHS/CDC to inspect records, facilities, transport vehicles, and equipment during operating days and hours, and at other necessary and reasonable times. (See § 71.53(b)(1) and (g)(2)(i).)

F. Public Comments Regarding Importer Licensing Requirements

Commenters addressed the application and permit renewal proposals in § 71.53(g). Two commenters opposed eliminating the 180-day registration renewal requirement for special permit holders. Presenting several examples of alleged noncompliance and Animal Welfare Act violations by

"top NHP importation companies in the United States," one commenter argued that reducing government oversight of companies "with documented histories of noncompliance" would pose a serious threat to public health. Further, argued the commenter, there was no evidence in the record that the species subject to special permit requirements (cynomolgus, African green, and rhesus monkeys) present less of a threat to human health than they did when we first established the requirements in 1990. The same commenter asserted we failed to make the case that moving to a 2-year renewal period would be in the best interest of public health.

HHS/CDC Response. HHS/CDC is adopting the proposal to extend the time for special permit renewal from every 180 days to every 2 years. We believe that the concern about the reduction in government oversight is misplaced, because registration is only part of the oversight of importers. Importers must continue to notify HHS/CDC of all shipments and we will continue to perform regular site visits, including the review of importer SOPs.

Indeed, there is constant communication between HHS/CDC and importers. Further, extending the renewal period is consistent with the directive in Executive Order

13653 section 1 that we apply the least burdensome tools for achieving regulatory ends.

An individual commenter suggested changes to three of the proposed paragraphs in (g)(1). The first suggestion was to change paragraph (g)(1)(ii) to state that an applicant must submit a completed statement of the intended permitted purpose for which an NHP is imported and must name any "intended prospective post-importation recipients." The second was to remove the requirement in proposed (g)(1)(iii) for applicants to submit "a copy of all" SOPs. The final suggestion was to add in proposed (g)(1)(iv) a requirement for applicants to submit "copies of all Federal, State, or local registrations."

HHS/CDC Response. HHS/CDC does not believe it is reasonable to require importers to submit "prospective" recipients of NHPs. HHS/CDC routinely audits importer records to verify that distribution is for permitted purposes. As part of this oversight, HHS/CDC will continue to require importers to submit copies of all SOPs. However, in response to the commenter's third suggestion, the final rule will require a copy of all federal, state, or local registrations, licenses, and/or permits.

Another commenter said that HHS/CDC should require applicants for an importer license or license renewal to

submit the documentation required under § 71.53(i) for worker protection and § 71.53(l) quarantine facilities as part of the permit application process.

HHS/CDC Response. We have added clarifying language to the title and throughout § 71.53(g) of the final rule to make it clear that the same documentation is needed to apply for registration or renewing a registration certificate for importing NHPs.

G. Public Comments Regarding Recordkeeping, Reporting, and Notification Requirements

Several commenters discussed various proposed recordkeeping, reporting, and notification requirements in § 71.53(h), (i), (k), (m), and (n).

An individual suggested that we change paragraph § 71.53(h) to require that importers develop and document compliance with a written policy; revise § 71.53(h)(2) to require that importers collect or create records of the intended purpose for imported NHPs and maintain records regarding each distribution of imported primates; and clarify in § 71.53(h)(3) how an importer must authenticate electronic records, if HHS/CDC would permit such records.

HHS/CDC Response. Each HHS/CDC-registered NHP importer is subjected to periodic, mandatory site visits. During

these site visits, HHS/CDC staff assesses compliance with recordkeeping requirements. Importers are also required to provide HHS/CDC staff with an intended-use statement for each NHP that was distributed following HHS/CDC quarantine. Failure to comply with these recordkeeping requirements may result in suspension or forfeiture of an importer's HHS/CDC registration. HHS/CDC also agrees that there should be a requirement for time-dating of electronic records in a manner that cannot be altered, and for back-up copies of such records. We have revised § 71.53(h)(3) accordingly.

One commenter expressed general support for the proposed reporting requirements and asked that we notify USFWS if we receive disease reports from importers that might raise concerns about its wildlife inspections.

HHS/CDC Response. With regard to the commenter's request that USFWS "receive disease reports from importers that might raise concerns about its wildlife inspections," HHS/CDC routinely informs USFWS of ongoing potentially life-threatening disease outbreaks occurring among USFWS-licensed facilities.

The same commenter strongly recommended that HHS/CDC require tattoos or microchip numbers for NHPs to better identify animals involved in a transfer or transaction.

HHS/CDC Response. Paragraph (1)(3)(i) of this final rule requires importers to ensure that all NHPs are identified individually with a unique number or alphanumeric code permanently applied to the NHP. However, consistent with our intent to set performance-based requirements, the rule does not require one specific identification yet allows the importer to select a "tattoo, microchip, or other permanent identifier." This requirement ensures that NHPs may be identified in any transfer or transaction.

The January 2011 NPRM specifically solicited public comment on how long records should be maintained by the importer, e.g., for the expected life of the NHP. One commenter said that, as written, § 71.53(h) failed to indicate how long an importer must maintain documentation, and suggested a retention period similar to existing USDA requirements (i.e., 3 years after disposition). Two commenters asserted that the retention period under paragraph (h) should be at least for the life of the animal, plus a post-mortem period to investigate disease outbreaks or rules violations. One commenter agreed that the retention period for § 71.53(h) documentation should be for the life of the NHP.

HHS/CDC Response. HHS/CDC agrees with commenters' concern that there should be a specified period for which an importer must keep the written certifications required under § 71.53(h)(1), and has revised the final rule to specify the period of record retention as 3 years after distribution or transfer of the animal. In § 71.53(h)(2) of the final rule, HHS/CDC also clarifies its intention for importers to maintain records regarding each distribution of primates for the required 3-year period, including information identifying each animal in a shipment. We believe these retention periods are sufficient for protecting public health and tracking NHPs after their release from quarantine, and that it is overly burdensome to require record retention for the life of an NHP and a period after death, as some commenters suggested.

Another commenter asked whether importers must document the intended purpose for the life of the NHP, what the effects would be if there were subsequent movements of the NHP within the United States, and whether paragraph (h) applied to offspring of imported NHPs.

HHS/CDC Response. HHS/CDC has revised § 71.53(h) to state expressly that an importer must develop and document compliance with a written policy for use and distribution of NHPs and their offspring. Paragraph (h)(1) also makes

clear that it is the importer's obligation to collect a signed record of the intended purpose for which NHPs are imported from the customer, and to take reasonable steps to ensure that its customers will use NHPs in accordance with Part 71. These records must be retained for three years after distribution. The original importer is not responsible for documenting subsequent movements of the NHP beyond the initial transfer. Again, this is a codification of the accepted current practice that importers only distribute NHPs for scientific, educational, or exhibition purposes as defined in this final rule.

One commenter requested clarification on proposed required certifications under paragraph (h)(5), and asked how HHS/CDC would monitor, track, and record these certifications; how often the importer should provide us with certifications; and how subsequent movement of NHPs and their offspring would affect the certifications.

Another commenter said they were uncertain whether the sellers needed to verify the authority of the person who certifies use of primates at the purchasing institution, and said they were against imposing a requirement on the seller other than maintaining certification from the consignee.

HHS/CDC Response. Regarding the comment on how we would receive and track certifications under proposed § 71.53(h)(5) (not adopted under the final rule), we note that the intent of the final requirements under paragraph (h) is for the importer to retain the records, not to send them to HHS/CDC. HHS/CDC will review certifications in person and regularly through an audit process yet does not expect importers to certify the authority of the signatory beyond normal due diligence. An example of due diligence would be for the importer to include a statement of authority on the certification form.

Two commenters commented on the proposed requirement in § 71.53(i)(3) on notification to HHS/CDC of a worker's exposure to a zoonotic illness. The commenters said we should change this provision to make it consistent with other, similar reporting requirements. Specifically, said the commenters, the provision should read, "An importer must immediately contact HHS/CDC by telephone, SMS text, or e-mail, as specified in the importer's standard operating procedures, 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." For the same reason, the commenters suggested revising the sentence on notification in § 71.53(i)(9) to read as follows: "The

importer must promptly notify HHS/CDC by telephone, SMS text, or e-mail as specified in the importer's standard operating procedures if such illness occurs."

These same commenters suggested revising § 71.53(k)(5) to permit notifying HHS/CDC of the arrival of an NHP shipment by SMS text or email as specified in the importer's SOPs. They also requested that HHS/CDC should permit written notice by email in notification requirements before authorizing the import of NHPs in § 71.53(n)(2).

HHS/CDC Response. HHS/CDC agrees with the commenters and has revised the text of the final rule to expressly permit notifying the Agency by telephone, text message, or email of worker exposure to a zoonotic illness.

Other commenters addressed the proposed health reporting requirements in § 71.53(m). One commenter questioned the proposal in paragraph (m)(4) that an importer must notify HHS/CDC if the mortality of an NHP cohort exceeds 5 percent. The commenter said this threshold could preclude the earliest detection of outbreaks or identification of associations between cases, and argued that we should establish an evidence-based, risk-averse threshold through epidemiological analysis and other available data.

Regarding the proposal in paragraph (m) (7) that an importer notify HHS/CDC within 48 hours if an NHP exhibits signs of TB, four commenters asserted the reporting period should be 24 hours. These commenters said that because TB is extremely communicable and highly dangerous to humans, it was "nonsensical" to have a reporting period that is double that for reporting other zoological diseases. The commenter said that although paragraph (m) stated proposed notification requirements for six events, the failure to define what would constitute a "severe" illness made the provision ambiguous, and difficult to either comply with or enforce.

HHS/CDC Response. In § 71.53(m) (2), the final rule requires notifying the Agency of any morbidity or mortality of animals in quarantine, rather than of "severe illness or death" as proposed. Similarly, § 71.53(m) (4) of the final rule removes the 5 percent threshold for notifying HHS/CDC of morbidity or mortality in a shipment between embarkation from the county of origin through release from quarantine in the United States. Instead, as with paragraph (m) (2), the rule requires notification of any morbidity or mortality during the period described. As to the comment that we set an evidenced-based threshold for reporting mortality, we noted previously that the mortality rates for

special permit process NHPs during shipment and quarantine has been less than 1 percent over the last 5 years (Roberts, 2008; DeMarcus, 1999). Therefore, requiring notification of any morbidity or mortality sets a conservative, evidence-based reporting standard. Further, we have set a more conservative 24-hour requirement in § 71.53(m)(7) for notifying the Agency of positive or suspicious TST results as most protective of human health. All notification periods in § 71.53(m) are now 24 hours.

These commenters also suggested that notification requirements in proposed § 71.53(p)(2)(i) and (ii) for zoo-to-zoo transfers mirror the requirements for laboratory-to-laboratory transfers in proposed § 71.53(q)(2)(i) and (ii).

HHS/CDC Response. HHS/CDC agrees that notification requirements should be the same for laboratory-to-laboratory transfers as for zoo-to-zoo transfers and has edited the text of the final rule accordingly.

H. Public Comments Regarding Worker Protection Requirements

Commenters addressed the training, notification, and SOP requirements in proposed § 71.53(i). One commenter said HHS/CDC should specify a maximum interval between training sessions. Two commenters said we should require employee training on post-exposure procedures when the employee is

hired and at least annually thereafter. One commenter suggested that worker training include contingency plans to prevent exposure to NHPs during transit.

HHS/CDC Response. HHS/CDC agrees with the comment that worker training requirements should specify when workers should receive initial training and the maximum acceptable interval between trainings. NHP workers should receive initial training when they are hired or before receiving a shipment of NHPs, and refresher training at least annually. However, because each facility varies in size and importation frequency, we have decided to evaluate training frequency upon review of importer application and SOPs, in keeping performance based standard of review. This policy of review also addresses another commenter's concern for refresher training on post-exposure procedures. As stated in § 71.53(i)(4)(i), worker protection plan training must include how to avoid and respond to disease exposures associated with NHPs. Plans for refresher and contingency training should also be included in these SOPs.

One commenter fully supported the proposed plans for importers, and especially noted his or her appreciation of the worker PPE requirements for employees who handle live NHPs, which the commenter said, would benefit USFWS inspectors. This commenter added a request that we notify

the USFWS-Office of Law Enforcement of our concerns with their inspectors who might be responsible for inspecting a shipment of wildlife later found to be a source of TB exposure.

HHS/CDC Response. We will continue to work with and communicate with our federal partners whose employees may be exposed to NHPs while inspecting animal shipments to ensure awareness of any health concerns, including the potential for exposure to TB. We note that USFWS inspectors, as with all individuals, should be wearing appropriate eye and respiratory protection when handling or within five feet of the live NHP shipments.

Another commenter asked why we recommended hepatitis B vaccine rather than hepatitis A vaccine, asserting that animals frequently arrive in quarantine with naturally occurring positive titers of hepatitis A, and that hepatitis A is a disease commonly found throughout the world, including the United States.

HHS/CDC Response. In the NPRM, CDC did not recommend specific vaccines as part of the worker protection plan. HHS/CDC recommends that all workers who are at high risk of exposure to NHPs be current on routine vaccinations, in accordance with good public health practice and as

reflected in the Advisory Committee on Immunization Practices² recommendations.

I. Public Comments Regarding Equipment, Transfer/Transport, and Handling

Commenters discussed the proposed requirements in § 71.53(j) and § 71.53(k) for NHP equipment, processing, transport, and identification. An individual commenter made several comments concerning these proposed provisions. The commenter described as "unrealistic" the proposed requirement in paragraph (j)(5) that only an importer or an authorized representative could receive a shipment of NHPs. For airplanes, said the commenter, a plane will not wait if there is no one present who has authority to take receipt of the shipment under this requirement. Instead, said the commenter, HHS/CDC should require a contingency plan to address Agency concerns.

HHS/CDC Response. HHS/CDC made a number of changes to the final rule in response to comments on the proposed standard operating requirements and equipment standards for crating, caging, and transporting live NHPs. We have deleted proposed paragraph (j)(4), and renumbered proposed

²<http://www.HHS/CDC.gov/vaccines/recs/acip>

paragraphs (j)(5) through (j)(13) as (j)(4) through (j)(12) in the final rule. Paragraph (j)(4) of the final rule requires an importer to establish an emergency contingency plan in the unlikely event that the importer or its representative is unable to meet the conveyance transporting an NHP shipment. This change makes clear HHS/CDC's intent that importers should anticipate and plan for contingencies.

Similarly, the commenter described as "unrealistic" our proposal in paragraph (j)(8) that during NHP transport, recirculated air in the NHP compartment must be HEPA-filtered, given that neither planes nor commercial OTR trucks commonly are equipped with such air-filter systems for cargo. Regarding our proposal in paragraph (j)(9) concerning cargo loading of NHP shipments, this individual said importers have little control over aircraft loading procedures, and cannot enforce loading requirements. The individual suggested we work with the International Air Transport Association (IATA). For paragraph (j)(11), the commenter suggested beginning the provision with, "For each importation itinerary," arguing that without this language, we would require monitoring and certification during each shipment. Finally, regarding paragraphs (j)(13) and (k)(3), this individual suggested we expressly require the removal

of potentially contaminated material from ground transport vehicles "upon arrival at the quarantine facility," and the appropriate disposal of biohazardous waste.

HHS/CDC Response. HHS/CDC recognizes that while the importer may not have control over how a plane is loaded at the port of destination, importer SOPs should include information for training of airport cargo handlers regarding the importance of loading NHPs into aircraft to assure that no contamination of other cargo occurs and that any issues with the shipment be easily determined and corrected. Further, we have revised the requirement proposed in paragraph (j)(8) (codified in the final rule as paragraph (j)(7)) to give importers the option of either ensuring an adequate ventilation system is in place, with HEPA filtration for airflow circulating between NHPs and passengers traveling with a shipment of live NHPs, or providing NHP transport workers with respiratory PPE if there is not an adequate ventilation system. The Agency believes this change makes the provision less prescriptive while offering adequate protection against transmitting zoonotic diseases from NHPs to humans traveling on the same conveyance.

We have also revised proposed paragraph (j)(11) (paragraph (j)(10) of the final rule) to make clear that

before beginning operations, or "for each import," importers must establish and document the communicable disease-prevention SOPs to be carried out throughout the chain of custody. In final rule paragraph (j)(12), HHS/CDC has adopted the commenter suggestion to state expressly that importers must ensure SOPs for both the removal from transport vehicles and proper disposal of biohazardous waste following a shipment of live NHPs.

An individual said we should consider requiring at least two transport workers for over-the-road (OTR) NHP shipments, written contingency plans, and signage on the transport vehicle warning the public to call a designated number before entering a vehicle transporting live NHPs. The commenter suggested further that we require OTR shippers to register with HHS/CDC and undergo training specific to transport workers. Another commenter suggested having OTR transporters register with HHS/CDC. This same commenter also suggested GPS-equipped vehicles that meet "certain minimum standards," and with operators possessing "all applicable licenses/permits to operate as a commercial transporter."

HHS/CDC Response. In response to the comment that we require two transport workers per OTR transport shipment of NHPs, and that these transport workers and vehicles be

subject to certain additional requirements, we note that HHS/CDC has not traditionally regulated transport workers, but rather NHP importers. Accordingly, we believe that continuing to regulate NHP importers, rather than placing new requirements on transport workers is the best way to protect public health. However, we agree with the commenter that importers should plan for contingencies in OTR transport, and have revised § 71.53(i)(4)(i) to clarify that worker protection plans should address procedures for responding to emergencies during transport.

J. Public Comments Regarding Quarantine Facility Requirements

Commenters addressed the proposed provisions on quarantine requirements in § 71.53(l) for importers not otherwise exempted under this provision (i.e., authorized zoo-to-zoo and lab-to-lab transfers).

Two commenters commented on the proposed air-handling system requirements in § 71.53(l)(2)(v) and (vi) that would mandate a separate system for each quarantine room, which would remain under negative pressure relative to the common hallway or anterooms. One commenter said the requirement needed further explanation, given that inhibiting air mixture between rooms could be accomplished with separate

exhaust equipment for each room or a dedicated exhaust system that pools adjacent rooms. The commenter noted that exhaust systems are on emergency generator power and supply-side air to quarantine rooms is often provided with a common HVAC (heating, ventilation, and air conditioning) system. Regarding the airflow indicator, the other commenter asked whether it would suffice to confirm negative pressure in the wards and no air circulation out of the ward, if the importer mounted a pressure monitor in the wall indicating negative pressure in the ward compared to the exterior.

HHS/CDC Response. HHS/CDC agrees with the commenter's concerns above and has edited the text of the final rule to better explain the intent of the provision.

One commenter asked whether under proposed § 71.53(1)(3)(iii), HHS/CDC should permit veterinary discretion within a quarantine room to use nets or gloves to recapture a small NHP rather than anesthetizing or tranquilizing the animal "before handling." The commenter said that the proposed text would preclude the use of these alternative capture methods - even where experienced personnel would be involved in the recapture - and the size, species, or clinical soundness of the animal would warrant a non-chemical restraint.

HHS/CDC Response. To address the comment that HHS/CDC should permit the use of methods other than anesthesia or tranquilizer before handling a live NHP, we have revised § 71.53(1)(3)(iii) to allow handling where an animal is "otherwise restrained." Because anesthetizing or tranquilizing a live animal before handling is most protective of human health and safety, those are the preferred methods under the regulation. However, we recognize that using an alternative restraint method may be appropriate where the restraint is part of the facility's SOPs and is the last resort for obtaining quick capture and veterinary handling of a live NHP.

There were several observations and suggestions from commenters concerning the proposed necropsy and diagnostic testing requirements under § 71.53(1), with most commenters addressing TB testing and procedures. One commenter recommended replacing the proposed TB testing procedures. Another commenter said that current TB testing methods used in NHP screening are inadequate, and that the proposed changes to these methods "do not go far enough" to protect public and NHP health and welfare. And another commenter suggested we reconsider the decision to rely on TB skin testing using the mammalian old tuberculin (MOT) method. The commenter said that skin testing is "a poorly

performing test in many NHPs," that the current requirements for multiple testing at 2-week intervals is "physiologically demanding" on the animals, and that there is an inherent risk to animals and humans each time an NHP must be immobilized for such testing. The same commenter argued alternatively for "currently available confirmatory tests, which can be utilized in conjunction with skin testing, minimizing repeat immobilization procedures."

Another commenter said that there is a diagnostic TB test other than the intradermal TST and HHS/CDC's failure to recognize the alternative test has hampered sales. The commenter asserted that the alternative test permits use of the same blood sample drawn during a health examination and provides results in minutes rather than days. This commenter said that TST measured only cell-mediated immunity, which might be suppressed in a latent infection, and that combining TST with measures of humoral immune response would increase diagnostic power and could reduce the possibility of failing to detect latent infection during quarantine. This commenter further asserted that there was no proof of TST working in all NHP species, that there is no requirement to test new production batches of TST on primates, and that imposing the same testing requirements on all NHPs is an approach based on tradition,

not scientific merit. Another commenter also objected to maintaining the TST, saying that given the poor reliability of TST results in NHPs, we should strengthen the proposed requirements to reflect the best available science and practices for test methods and regimens.

Yet another commenter recommended "replacing the (proposed) tuberculin testing procedures." The commenter also said that rather than rely solely on "poorly-performing screening tests in quarantine," HHS/CDC should require "currently available confirmatory tests and then rigorous, ongoing bio-security and surveillance once in the managed zoo collection." Noting the proposed requirement for including in the SOPs a grading scale interpretation of TSTs for NHPs in quarantine, this commenter suggested removing this requirement from § 71.53(1)(3)(ix), and instead, grading reactive animals in import quarantine either as negative or positive. The commenter asserted that although quarantine facilities might use such a scale during import quarantine, many "do not recognize 'questionable' responses," and prefer to err "on the side of caution." Similarly, another commenter said it preferred to grade reactions for animals in import quarantine as positive or negative. The commenter asserted that that the TB test itself is imperfect, and that "any range of

abnormal display may be seen on an individual that is truly infected."

HHS/CDC Response. HHS/CDC does not accept the assertions that there are currently TB tests more appropriate than the required MOT, but believes that a more improved test may be developed in the future. The currently approved test for the diagnosis of TB in NHPs is the TST performed using MOT, 0.1cc injected intradermally in the palpebrum and observed at 24, 48, and 72 hours (ILAR, 1980). Other TB tests have been evaluated but it has been noted that "no single screening test will meet all the requirements for surveillance and diagnosis of TB in nonhuman primates. Instead, the use of several tests in combination can increase the overall sensitivity and specificity of screening and surveillance programs and likely represents the future of TB testing in nonhuman primates" (Lerche, 2008). HHS/CDC will continue to require the TST until an improved testing procedure is developed.. Until then, if test results are positive, the importer may elect a battery of tests to confirm the TST finding, and in consultation with HHS/CDC, may choose either to treat or euthanize the animals. Further, concerning grading scales for animals with "questionable" responses, HHS/CDC appreciates that many NHP importers consider any MOT

reaction as positive. Again, our regulations are influenced by the ILAR guidelines (ILAR, 1980), which do allow subjecting NHPs to further testing in a "suspect" case of TB. HHS/CDC believes that it is permissible for an importer to interpret the TST according to the importer's approved standard operating procedure and to do further diagnostic testing for NHPs with a suspect TB reaction as defined by the SOP.

A commenter noted that paragraph (1)(3) should spell out steps for removing samples from the quarantine ward to perform laboratory analyses.

HHS/CDC Response. In response to the commenter's observation that there was no language in the proposed rule describing procedures for removing samples from the quarantine ward, HHS/CDC has added a requirement in § 71.53(1)(3)(iv) for importers to describe procedures for handling and transporting such samples.

Three commenters noted that proposed § 71.53(1)(3)(viii)(B) would require antibody testing for animals surviving quarantine and displaying signs suggestive of a filovirus infection, but that paragraph (1)(6)(viii) of the provision would require performing filovirus testing using the antigen-capture enzyme-linked immunosorbent assay (ELISA) method on the liver of any

animal that dies or is euthanized for reasons other than trauma. The commenters suggested we modify § 71.53(1)(6)(viii) to require antigen-capture testing of liver tissue only from animals that died or were euthanized and exhibited potential signs of a filovirus infection.

HHS/CDC Response. In accordance with the intent of the provision, HHS/CDC has clarified the proposed language in § 71.53(1)(6)(viii) to specify that antigen-capture testing is required for NHPs that die or are euthanized for any other reason than trauma or adverse environmental conditions.

A commenter asked whether an exemption from a BSL3 type quarantine still would require adhering to proposed paragraphs § 71.53(i), (j) and (k). The commenter suggested worker protection, crating, and transport at a BSL1 or BSL2 for NHPs with well-documented medical histories prior to import. Also, this commenter and another asked HHS/CDC to clarify the apparent inconsistency between proposed § 71.53(1)(6)(ii), requiring performance of a necropsy under biosafety level (BSL)3 containment, and § 71.53(1)(6)(iv), requiring necropsy under BSL3 or BSL2 containment.

HHS/CDC Response. To address commenter requests for clarification regarding the appropriate biosafety level

procedures for necropsy requirements under § 71.53(1)(6), we deleted the reference to BSL3 in paragraph (1)(6)(ii). We revised paragraph (1)(6)(iv) to require BSL3 or BSL2+ precautions for necropsies only. However, HHS/CDC acknowledges that all NHPs pose a potential risk to human health and should therefore be handled while wearing recommended PPE, as dictated in the approved SOPs. BSL2+ is a hybrid level of precautions that requires at least the use of a BSL2 facility with BSL3 containment equipment and practices. (HHS/CDC and NIH, 2007).

An individual commented that we should modify or delete proposed § 71.53(1)(3)(vii)(C) that would prohibit an importer from releasing an animal from quarantine if the importer knows or has reason to suspect the NHP has a zoonotic exposure or infection. The commenter said we should not consider zoonotic agents such as herpes B virus in the same category as TB, yellow fever, or filovirus.

HHS/CDC Response. HHS/CDC has also revised paragraph § 71.53(1)(3)(viii)(C) as the commenter requested to clarify that an importer must not request a release of an NHP from quarantine if the animal is "visibly ill."

Referencing proposed paragraphs § 71.53(i)(5), (j)(6), (j)(12) and (13), (k)(3), and (l)(2); a commenter said we should clarify acceptable procedures for disinfecting,

autoclaving, or disposing of animal wastes, bedding, and uneaten food. The commenter also said we should clarify disinfection requirements for vehicles. This same commenter said that when dealing with imports of large species or large numbers of primates, the cost of disposing of bedding and medical wastes could be prohibitive for zoos, and autoclaving could be impractical or impossible.

HHS/CDC Response. Regarding the commenter's request that HHS/CDC clarify acceptable procedures for disinfecting animal wastes, bedding, and uneaten food, we note that all methods that meet the performance-based standard will be considered. One example for handling of animal waste, bedding, and uneaten food other than autoclaving or disposal by a biohazard company would be to put the waste into the sanitary sewer system. Also, trucks can be cleaned of gross debris to be properly disposed of and then sprayed or fogged with a tuberculocidal, virucidal, or bactericidal disinfectant for an adequate contact time and then cleaned.

K. Public Comments Regarding Requirements for Veterinarians and Veterinary Pathologists

The January 2011 NPRM specifically asked for feedback on what factors should be taken into consideration in the determination of whether a veterinarian is sufficiently

"experienced" in the care of NHPs and what constitutes a "qualified" laboratory. A few commenters discussed the requirements for veterinarians and veterinary pathologists. One commenter said that in requiring quarantine facilities to have access to a qualified veterinarian, proposed § 71.53(i) and (l) should specify that such personnel be on duty and on site during business hours; and that there be appropriate veterinary coverage for evenings, weekends, and holidays. This commenter said further that the requirements should specify a number of available and qualified veterinarians commensurate with the number of NHPs.

HHS/CDC Response. While HHS/CDC may agree that these are good requirements for a facility, these do not help to define qualifications of a veterinarian. Thus, no changes were made to § 71.53(i) and (l) based upon these comments.

A commenter asserted that the rule should include as minimum requirements for veterinarians: a current veterinary license, USDA accreditation, and experience with NHPs. Another commenter also stated that HHS/CDC should define "qualified veterinarian" similar to USDA.

HHS/CDC response. HHS/CDC agrees that these would be the ideal minimal requirements for a licensed veterinarian working with NHPs. In response, we have added a definition for licensed veterinarian to the text of the regulation to

clarify that these individuals must have experience working with NHPs.

A commenter asked why HHS/CDC would require a veterinary pathologist to have a state license, which would preclude other qualified professionals from conducting procedures such as necropsy. The commenter said that because veterinary pathologists do not "practice," most do not obtain or maintain state licenses. The commenter also suggested that we require the performance of necropsies by a board-certified veterinary pathologist or a state-licensed veterinarian.

HHS/CDC response. HHS/CDC agrees that requiring a veterinary pathologist to perform necropsy is not always necessary and may be too limiting to an NHP import facility, but that just any state-licensed veterinarian may not be familiar with the public health risk associated with performing necropsies on imported NHPs. We have removed "state-licensed veterinary pathologist" from § 71.53(1)(6)(ii) and edited the language to reflect a requirement for the performance of necropsies by a veterinary pathologist or a state-licensed veterinarian with knowledge and experience with the disease risks associated with performing these necropsies. Additionally, the veterinary pathologist or licensed veterinarian must be

familiar with the precautions and level of containment that should be used to perform these necropsies.

L. Public Comments Regarding Zoo-to-zoo and Laboratory-to-laboratory Transfers; Animal Acts

Some commenters addressed the proposed requirements for zoo-to-zoo and laboratory-to-laboratory transfers in § 71.53(1)(1), which would exempt these entities from the quarantine facility requirements in this provision provided that the transfer complied with proposed § 71.53(p)(2) and § 71.53(q)(2). After stating their strong support for paragraph (p)(2), one commenter recommended following proposed risk-reduction procedures irrespective of whether quarantine is required.

HHS/CDC Response. Regarding the recommendation for a defined disease risk assessment for NHPs imported by AZA-accredited zoos, HHS/CDC does not believe further risk reduction procedures are necessary, because a zoo must conform to AZA standards as a condition of being excepted from otherwise applicable quarantine requirements.

In response to the commenter's request that we clarify HHS/CDC criteria for determining that a zoo outside the United States is "AZA equivalent," HHS/CDC will consider a facility as meeting this standard if it is accredited by an

organization that has standards comparable to those in the AZA Accreditation Standards and Related Policies.³ These standards include performance-based procedures addressing appropriate veterinary care, quarantine and necropsy, and public exposure to animals. This approach allows individual institutions to decide on the best procedures within their institutional capabilities to reach the desired results.

Another commenter requested that we clarify the § 71.53(p)(2) proposed exemption from the 31-day quarantine provision in § 71.53(l)(1) for zoo-to-zoo transfers. The commenter stated that importers involved in zoo-to-zoo transfers of NHPs still would have to comply with proposed §§ 71.53(i) (worker protection and PPE), 71.53(j) (SOPs for NHP crating, caging, and transport), and 71.53(k) (ground transport requirements). The same commenter asserted that as written, these subsections indicate that if an NHP with a known medical history were the subject of a zoo-to-zoo transfer, the animal still would be handled under BSL3 protocols until its arrival at a U.S. zoo, where it then would be exempt from any type of quarantine. The commenter said there appeared to be an inconsistency.

³ <http://www.aza.org/uploadedFiles/Accreditation/Accreditation%20Standards.pdf>.

HHS/CDC Response. HHS/CDC clarifies the intent of the regulation by emphasizing that qualified zoos and labs under paragraphs (p) and (q) are not exempt from the worker protection, ground transportation, or SOP requirements under this regulation. Further, the only BSL2+ or BSL3 requirements in this regulation are for necropsies. However, HHS/CDC acknowledges that all NHPs pose a potential risk to human health and should therefore be handled while wearing recommended PPE, as dictated in the approved SOPs.

One commenter said it was unclear why there was inconsistency in the standards for documentation of negative TB tests for animal acts, zoo-to-zoo transfers, and laboratory-to-laboratory transfers. The commenter suggested that the standard for all three should be the higher one, which is the laboratory-to-laboratory transfer standard. Two commenters suggested that we have the same standard for medical records and certificates for zoo-to-zoo and laboratory-to-laboratory transfers from outside the United States.

HHS/CDC Response. Regarding the differing TB standards for zoo-to-zoo, laboratory-to-laboratory, and animal acts, HHS/CDC believes the commenter may have misinterpreted the proposed provisions. Neither the proposed language nor

final rule language specifies a more stringent standard for one group. However, each group will be expected to present documentation of regular TB testing and good health.

One commenter recommended that NHPs imported through AZA-accredited zoos go through a defined risk assessment and decision analysis before importation and release from quarantine. This commenter also asked what criteria HHS/CDC would use to determine that a zoo outside the United States was an AZA-equivalent zoo.

HHS/CDC Response. Although we are easing some of the quarantine requirements for zoo-to-zoo and laboratory-to-laboratory transfers, these entities still will be regulated and required to follow risk-reduction procedures. Further, as explained in the regulatory analyses section for this rule, importers transferring NHPs between qualifying zoos and qualifying laboratories already are regulated by USDA, may be bound by the Public Health Service (PHS) policy for humane treatment of laboratory animals, and must meet guidelines for animal care and occupational health and safety from accrediting organizations. For zoos, that means providing a quarantine facility for animals new to the collection. Considering all these factors, we believe that our registration, records, and oversight requirements; the requirements of accrediting

organizations; and oversight by other federal entities provides health and safety assurance equivalent to what the 31-day quarantine period provides for other importers.

One commenter opposed § 71.53(p)(2) and § 71.53(q)(2) provisions permitting NHP transfers between laboratories without subjecting the animals to "certain testing and quarantine requirements." More specifically, the commenter said the proposed change would result in risks to public health and animal health and welfare, and would create the potential for abuse. Another commenter also opposed easing quarantine requirements for laboratory-to-laboratory transfers of NHPs. Citing published papers to support the proposition that neither new shipments nor established colonies of NHPs are immune from infectious diseases, the commenter said we should not eliminate quarantine requirements for any reason.

HHS/CDC Response. HHS/CDC disagrees with these commenters and emphasizes that such transfers will not be without oversight. For laboratory-to-laboratory transfers of NHPs, importers must have protocols approved by the IACUC, a self-regulating entity required under U.S. law for institutions using laboratory animals for research and instruction. Further, the importer must demonstrate that the animals are part of long-term, established studies with

specific study protocols. Sending laboratories must submit records showing TB testing, number of NHPs, current health certificates, documentation of the research project, and travel itineraries.

One commenter said that because NHPs in zoos and in many professional animal acts live in uncontrolled environments where interaction with humans may be unlimited, imported NHPs in zoo populations and animal acts leaving and then returning to the United States should have no special import exemptions. This commenter suggested maintaining the 31-day quarantine requirements for both categories of NHPs. Two commenters both agreed we should maintain the quarantine period for zoo-to-zoo transfers.

HHS/CDC Response. HHS/CDC agrees with the comment that transfers of NHP from facilities outside the United States should be subject to the same medical records and health certificate requirements - irrespective of whether the transfer is between qualified zoos or laboratories. Although these groups will not be required to undergo the 31-day quarantine, these importers still are subject to registration with the Agency before bringing animals into the United States. The final rule will also hold importers of U.S.-based animal acts to the same requirements for entry as foreign-based animal acts; all such NHPs will be

subject to a quarantine period regardless of where the animals are based.

M. Public Comments Regarding NHP Products

One commenter said we should better define “the scope, requirements or duration” of the permit process to help importers of NHP blood and tissue samples ensure that shipments of such products would not be degraded or destroyed and lose their scientific value. The commenter questioned the necessity for further permit requirements given that importers of these products already must obtain a CITES permit.

HHS/CDC Response. Under § 71.53(t), Nonhuman primate products, importers are required to obtain a permit from HHS/CDC prior to shipment of these products. However, this final rule does not change the current and longstanding practice of obtaining such a permit. HHS/CDC recognizes the need for timely shipment of such products and will expedite all requested permits to ensure that no products are degraded or destroyed.

Two commenters made remarks on proposed requirements for permits for importing NHP products, including blood and biological samples. One commenter asked us to indicate that

a HHS/CDC permit covers NHP products not intended for commercial use.

HHS/CDC Response. In response, a HHS/CDC permit is required and will cover any NHP product (personal or commercial) unless it has been rendered noninfectious, as defined in the final text of the regulation.

A commenter asked us also to clarify that although a product importer may not need a HHS/CDC permit for some products, there may be other non-HHS/CDC permits required for import. Asserting that proposed § 71.53(t) would cover blood and tissue samples from NHPs, another commenter noted that importing these materials already requires holding a CITES permit, which HHS/CDC may use to track these importers and materials.

HHS/CDC Response. At present, HHS/CDC does not have the resources to track permits issued by other federal agencies. Furthermore, such outside permits are reviewed and issued for purposes other than to protect public health.

The commenter also noted that the requirement to render biological samples noninfectious could destroy their scientific value. This commenter further asked whether formalin-treated NHP tissues and slides containing such tissue would require a permit for importation. The same

commenter said it was important to distinguish between formalin-fixed tissue and histological preparations of slides and blocks from formalin-fixed tissue. The commenter described slides and blocks as subject to disinfecting in the form of serial exposure to extractive solvents (e.g., alcohol) and heat during tissue processing and block preparation. It said that penetration of thin slices of tissue used on slides permits excellent penetration of solvents, and that the preparation of paraffin-embedded blocks and slides provides a physical barrier that minimizes potential exposure. The commenter said that these materials are for scientific purposes, that knowledgeable people handle the materials in laboratories equipped for handling potentially infectious samples from humans or animals, and that the value of permits for such materials is questionable. The commenter said that should HHS/CDC require importers of blood and tissue samples to obtain a permit, that it must define and structure the process to avoid delays that may adversely affect the scientific quality of samples.

HHS/CDC Response. As noted earlier, although some importers of NHP products are subject to the CITES program, HHS/CDC's mandate is to protect public health, and any untreated NHP product poses a risk to human health.

However, items which may be compromised by rendering them noninfectious may still enter the United States if accompanied by a HHS/CDC-issued permit. Under § 71.53(t)(1) of the final rule, we lay out the conditions for importing noninfectious products into the United States. In § 71.53(t)(2) of the final rule, we clarify that it may be permissible to import infectious blood and tissue samples for bona fide scientific, educational, and exhibition purposes under conditions set out in that provision. Timely requests for importing these products are processed expeditiously. As the final rule makes clear in § 71.53(t)(1), an NHP product importer may use formalin fixation or any method approved by HHS/CDC to render products noninfectious.

N. Public Comments Regarding Appeals

Regarding the appeals process in proposed § 71.53(u), four commenters asserted that the proposed time for appeal was too short, the process was undefined, and a rationale for so short a period was absent. Commenters suggested expanding appeals to 5 days.

HHS/CDC Response. HHS/CDC agrees that importers who are denied a permit should have more time to appeal the denial. Therefore, § 71.53(u)(2) extends the time for

appeal from 2 to 5 days. Regarding the process itself, we believe that an appeal of a permit denial to the HHS/CDC Director is unambiguous and provides sufficient procedural safeguards against erroneous permit denials.

O. Public Comments Regarding HHS/CDC Monitoring and Enforcement

An individual commenter stated that our proposal said little about facility inspection, importer compliance, number of personnel, program funding, and enforcement actions. The commenter questioned how we would ensure consistent monitoring and enforcement. Another commenter referenced what it called "obvious disincentives" for reporting noncompliance by overseas suppliers and shippers, and the apparent lack of a mechanism for HHS/CDC to assess compliance before an NHP shipment arrives in the United States. Calling the proposed procedures in § 71.53(j) "inadequate," and given what the commenter said was the failure of NHP breeding farms outside the United States to match our health and welfare standards, this commenter said we should "directly monitor" NHP overseas operations. This commenter suggested that the Agency take a direct, active role in risk management, by follow the approach the United

Kingdom now employs. In the alternative, said the commenter, we could prohibit NHP imports altogether.

HHS/CDC Response. HHS/CDC does not have the authority to regulate foreign NHP facilities. However, enforcement of the regulations for U.S. facilities will remain as it is currently, and the same penalties apply for violations. For compliance and inspections, HHS/CDC will continue to make unannounced visits for U.S.-based importers, as these importers must make records, facilities, vehicles, and equipment available for HHS/CDC inspection during operating business days and hours, and at other necessary and reasonable times.

Another commenter asked whether inspection of NHP importers would include importers of blood and tissue samples, and asked what criteria we would use for such inspections.

HHS/CDC Response. Because of the extensive resources that would be required for such inspections, the Agency will not perform site visits but will rely on HHS/CDC quarantine station inspections of incoming shipments for compliance with these requirements.

Another commenter also suggested we add "employee health and safety records" and "animal health records" to

the list of things an importer must make available for HHS/CDC inspection.

HHS/CDC Response. HHS/CDC agrees with this comment and has inserted the suggested language into paragraph (b)(1).

Regarding a change in the special permit-renewal period from every 180 days to every two years, one commenter said this change would "vastly reduc[e] regulatory oversight of importers" without evidence that the health risk posed by these importers has changed. This commenter further asserted that we provided no justification for changing the renewal period other than easing the \$84/year burden on the regulated community, and that such a goal alone is insufficient "to justify the serious threat to the public posed by relaxing standards for importation of these species of NHPs."

HHS/CDC Response. HHS/CDC believes that the commenter's concern about the reduction in government oversight is misplaced. We did not propose a reduction in oversight, but in administrative burden. Importers must continue to notify HHS/CDC of all shipments, and the Agency will continue to perform regular site visits, including the review of importer standard operating procedures. Indeed, there is constant communication between HHS/CDC and importers. Extending the renewal period for special permit

species will not result in less oversight, and is consistent with the directive in Executive Order 13653 section 1 that we apply the least burdensome tools for achieving regulatory ends. Further, although one objective of this rule is to reduce the compliance burden on special permit species importers; the principal goals of this rulemaking are to extend special permit species requirements to all NHP imports, to improve Agency oversight through a general requirement that NHP shipments enter the United States through ports of entry with a HHS/CDC quarantine facility, and to codify existing guidelines. We have extended the registration renewal period for special permit species importers not just to reduce the burden on the regulated community, as the commenter asserts, but because the reduction and continuing low morbidity and mortality rates for these species in transit and quarantine demonstrate that a 2-year renewal period would be sufficiently protective of public health.

Concerning the change in timeframe for renewal of importer licenses, HHS/CDC would like to emphasize that we have incorporated all provisions of the old 180-day permit requirement into the new regulation and have strengthened these requirements by requiring filovirus testing on all Old World Monkeys. All currently registered importers of

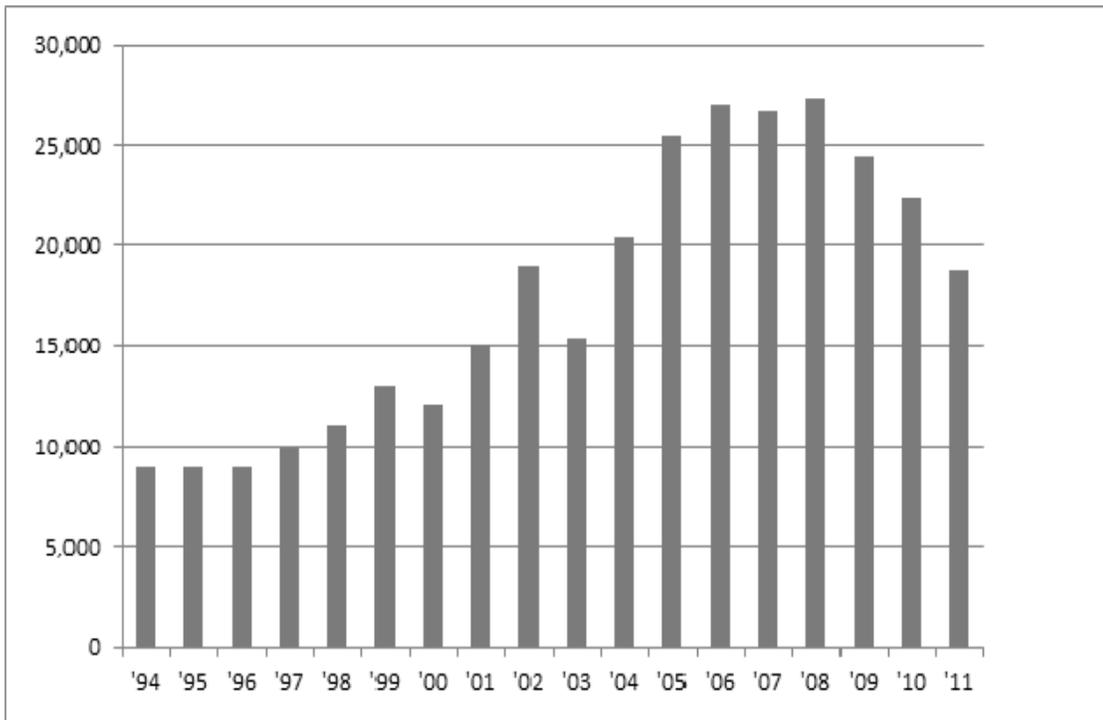
the three special-permit species (cynomolgus and rhesus macaques, and African green monkeys) have been importing these animals since the special permit first went into effect in 1990. There have been no legal challenges to any of the provisions of the special permit. We received only positive feedback from the public during the comment period for the NPRM. Compliance with provisions of the 180-day special permit has been excellent. Any potential for misinterpretation of the provisions is identified during the at-least biannual review of the importer's standard operating procedures and annual site visits.

The NHP import industry has changed vastly during the 22 years since the 180-day special permit final rule was promulgated. Before the requirements of the special permit were introduced, there were hundreds of NHP importers and high levels of NHP mortality during import. Many of these operations were poorly equipped and quickly dropped out of the industry in response to the special permit regulation and other HHS/CDC-mandated provisions concerning tuberculosis. Currently there are only 24 NHP importers registered with CDC: 11 commercial importers; 7 zoos; 4 national primate research centers; 1 university; 1 private research facility. This number has decreased from 27 registered importers in 2004. There are now only 8

importers who routinely import NHP covered by the special permit.

The number of NHPs imported annually has decreased dramatically over the last several years, as shown in the Figure 1 below.

Figure 1.



Factors for this decrease include difficulties encountered in international transportation of NHPs (fewer airlines allow transport each year), as well as decreased demand.

When an importer requests renewal of the special permit, the importer submits an e-mail, and CDC re- authorizes the special permit, provided there have been no

changes in the importer's standard operating procedures and no uncorrected procedural violations. In the last 8 years of program oversight, there has never been an instance where a special permit has not been renewed promptly. Any deficiencies on the part of the importer are: noted during quarantine station oversight when the shipment reaches the United States; self-reported during quarantine by the importer; picked up on biannual review of the importer's registration application; or identified during routine site visits. All special permit NHP importers are visited annually.

HHS/CDC's rulemaking is in keeping with Executive Order 13563, Improving Regulation and Regulatory Review, which states that regulations must "identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. [The regulations] must take into account benefits and costs, both quantitative and qualitative." Renewing the special permits every 180 days expends taxpayer resources (i.e., staff time) to review and approve renewal applications, when there is no current evidence to suggest that such a frequency of scrutiny contributes appreciably to protecting public health. As stated above, regulations should impose the smallest reasonable burden on the regulated entities in order to

accomplish the purpose of the regulations; we are acting in the spirit of that principle by reducing the burden on the NHP importers because there is no evidence that requiring them to renew their special permits every 180 days is necessary to accomplish the purpose of the regulations.

It is our opinion based on extensive experience that the 180-day special permit final rule was promulgated during a much different phase of the import industry. Changes in the industry since then lead us to believe firmly that it has no appreciable benefits public health benefits over a two-year timeframe.

An individual asked how we will monitor compliance and apply penalties for brokers given there were no apparent requirements for them to register with HHS/CDC under § 71.53(r).

HHS/CDC Response. Although there is no requirement for brokers to register with the Agency, under § 71.53(r), brokers must notify HHS/CDC of in transit shipments before the shipments arrive in the United States, which includes providing detailed information on the animals; the in transit itinerary; equipment used in transport, housing and decontamination procedures; and other performance-based procedures to reduce the risk of exposing the public to health hazards presented by NHPs. Further, the same

penalties apply to brokers as to other entities subject to these regulations.

P. Miscellaneous Comments

Asserting that proposed reporting of NHP illnesses and deaths upon arrival and in quarantine would reveal "only a fraction" of morbidity and mortality for these animals, a commenter asked that we provide an analysis of such cases from the recent past before continuing with this rulemaking. The commenter said we should report on the precise nature of illnesses and deaths, and include laboratory and post-mortem results. According to one comment, such an analysis would ensure that the public appreciated and understood any risks and benefits of the changes we proposed.

HHS/CDC Response. HHS/CDC disagrees with this comment. All morbidity and mortality in a shipment of NHPs upon arrival and during the 31-day quarantine period is reported to (and recorded by) HHS/CDC. Illness reports and necropsy reports are reviewed before any NHPs are released from the required quarantine. Additionally, veterinary medical records are reviewed during the regular, unannounced site visits.

One commenter recommended that in the final rule preamble or the rule itself, we discuss whether the rule would apply retroactively to NHPs imported before issuance of the final rule. The agency expressed particular interest in rule provisions addressing an importer's ability to maintain, sell, resell, or otherwise distribute imported NHPs or the offspring of imported NHPs.

HHS/CDC Response. Regarding the question of retroactive applicability, HHS/CDC notes that the new rule does not apply to animals or the offspring of animals imported into the country before 1975. For decades, there have been prohibitions on importing NHPs except for scientific, exhibition, or educational purposes; or for using the offspring of imported NHPs for reasons other than scientific, exhibition, or educational purposes. The revised rule continues these prohibitions.

IV. Alternatives Considered

Executive Order 13563 recommends that the regulatory impact analysis consider all feasible alternatives to current practice and the rule as proposed. The main impact of the rule is to unify existing regulations and codify and professional guidance regarding infection control and worker safety procedures to prevent transmitting pathogens

from NHPs to humans. As explained in **II. Summary of the Proposed Rule Requirements**, HHS/CDC proposed a number of changes in the NPRM that would achieve its regulatory objectives through performance-based standards rather than promulgating prescriptive standards for importers. HHS/CDC endeavored to allow regulated entities flexibility in choosing how to meet the standards. We have provided flexibility regarding recordkeeping requirements, standard operating procedures, and worker protection requirements.

HHS/CDC reviewed the 31-day quarantine requirement and associated restrictions for transfers of NHPs into the United States between Association of Zoos and Aquariums (AZA)-accredited zoos and proposed to eliminate that requirement. Similarly, HHS/CDC proposed a quarantine exception for transfers of NHPs from laboratories accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or its equivalent, if the laboratory has a foreign-based and a U.S.-based facility and the NHP is part of an ongoing research project.

V. Regulatory Analyses

A. Executive Orders 12866 and 13563

HHS/CDC has examined the impacts of the proposed rule under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993) and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011). Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following bars: quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose approaches that maximize benefits; support regulations that protect public health and safety; and minimize the impact of regulation. HHS/CDC has analyzed the rule as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) and that the rule will not create enough change in current practice to have a measurable, quantifiable impact.

This rule is not being treated as a significant regulatory action as defined by Executive Order 12866. As such, it

has not been reviewed by the Office of Management and Budget. This regulatory action is not a major rule under the Congressional Review Act. In our screening analysis under the Regulatory Flexibility Act, HHS/CDC also concludes that the rule will not have a significant economic impact on a substantial number of small entities.

HHS/CDC has determined that the main impact of the rule will be to unify existing regulations and codify professional guidance regarding infection control and worker safety procedures to prevent transmitting pathogens from NHPs to humans. All stakeholders involved in the importation and maintenance of NHPs will now be subject to the same set of rules and guidelines. This rule combines a disparate set of professional recommendations and rules that were published or established in various formats between 1975 and 1993 (see C. What is the History of this Rulemaking?). This rule clarifies definitions of terms and requirements for developing plans and SOPs for quarantine, other operations, personnel training, and worker health programs prior to importation of NHPs; although the rule does not add new terms or requirements. The regulation also allows stakeholders to exercise their own good judgment in implementing the regulatory guidelines through

performance-based standards, rather than dictating prescriptive compliance.

The rule impact will be unification of existing rules and codification professional guidance. The rule will create qualitative costs and benefits for all NHP importation stakeholders and the United State public as explained below.

Benefits. There are benefits to the rule that accrue to: 1) the public in the form of protecting public health; 2) business stakeholders in the form of investment protection and a reduction in time needed to be spent on regulatory compliance leading to a benefit of avoided costs; 3) the NHP workforce; and 4) the scientific community.

Public health benefits:

- Reduction in risk of transmission of a variety of zoonotic infections including filoviruses, TB, herpes B virus, and parasites
- Entry through quarantine stations where qualified personnel examine the NHP to ascertain any potential exposure to the public through direct contact or contaminated cargo

- Certifying the health of NHPs in animal acts will reduce the risk of spectators coming in contact with ill animals

Business stakeholders benefits (reduction in time spent on regulatory compliance, or avoided costs, and investment protection):

- Investment protection - Certifying the health of NHP will reduce the potential transmission of disease between NHP and reduce the costs to the business of caring for other ill animals, or in the worst case, stop the loss of investment through death
- Regulatory reduction (avoided cost) - The registration renewal time for all NHPs will now be 2 years. Previously, importers of cynomolgus, African green, and rhesus monkeys were required to renew their special permit registration every 180 days, or two times a year. According to HHS/CDC records, special-permit holders are about a third of all NHP importers (20 of a total of 60). This is a four-fold reduction in paperwork for registration renewal for about a third of all NHP importers
- Regulatory reduction (avoided cost) - More specific definitions and uniform application of rules and standards will make it much easier for businesses to reliably

forecast the time they need to spend complying with regulation

- Regulatory reduction (avoided cost) - The rule eradicates the 31-day quarantine period for animals being transferred between zoos and laboratories when the facilities have been approved by professional organizations (AZA for zoos and AAALAC for laboratories). CDC professionals indicate that there are between three and five such transfers a year. Professional opinion and discussion with zoos and laboratories indicates that this would result in avoided costs of about \$500 to \$1,800 per transfer, depending on the facility costs for quarantine.

Scientific benefits:

- Obstacles to the movement of highly endangered NHPs will be removed to protect the species
- Controlled entry of NHPs for long-term research will be allowed when the research can only be performed in United States laboratories

NHP workers benefits:

- The regulation now defines the types of personal protective gear that workers must wear in order to protect

the worker from the potential transmission of infectious agents

- Guidelines for regular TB testing have been established to ensure that workers are tested and diagnosed in a timely manner
- Guidelines are now established for access to medical care in the event of zoonotic-human illness transmission to ensure that workers are tested and diagnosed in a timely manner

Costs. The current regulation is primarily definitional and changes very little actual current practice. The only part of the new regulation that will create an additional cost will be the requirement that all NHPs being imported enter the country through a port of entry or airport with a quarantine station. At the current time the majority of, as much as 95% according to CDC subject matter experts, of NHPs enter the country at ports with quarantine stations because they arrive on airlines that frequent those ports of entry. The remaining NHPs that are transported into the United States come in by truck across smaller border crossings between Mexico and the United States or Canada and the United States. Professionals in CDC's Quarantine Branch estimate that this amounts to approximately one

shipment per year, or less than 5% of all NHP imported to the United States. HHS/CDC also notes that arrangements can be made in advance for alternative ports of entry if the importers contact HHS/CDC. Thus, HHS/CDC believes there is very little additional cost impact to the importer.

Cost-Benefit comparison. Benefits and avoided costs as enumerated in the benefits section appear to outweigh the additional transportation cost of additional travel for one or two importers each year that will need to enter through points with quarantine station.

B. Paperwork Reduction Act Analysis

HHS/CDC has determined that this rule contains data collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3420). HHS/CDC already has approval from OMB for the collection of registration information from importers and record keeping requirements under OMB Control No. 0920-0134: Foreign Quarantine Regulations (expiration date July 31, 2015).

In addition, HHS/CDC has approval from OMB under OMB Control No. 0920-0263: Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (expiration date June 30, 2014) to collect data from importers who wish to apply for a special permit to import non-human primates.

C. Federalism Impact

Under Executive Order 13132, if the rule would limit or preempt State authorities, then a Federalism analysis is required. The agency must consult with State and local officials to determine whether the rule would have a substantial direct effect on State or local governments, as well as whether it would either preempt State law or impose a substantial direct cost of compliance.

In accordance with section 361(e) of the PHSA [42 U.S.C. 264(e)], nothing in this rule would supersede any provisions of State or local law except to the extent that such a provision conflicts with this rule. For example, the rule would not prevent a State from taking stronger measures to deal with infected or possibly infected NHPs or to cover additional species. Further, our rule will not supersede state requirements not in conflict with the federal rule's provisions. However, in accordance with section 361(e) of the PHSA, any state or local law that

would permit any activity prohibited under this rule would conflict with this rule and, therefore, would be superseded. The rule would not have a substantial direct effect on State or local governments or impose a substantial direct cost of compliance on them.

D. Environmental Impact

In the absence of an applicable categorical exclusion, the Director, HHS/CDC, has determined that provisions amending 42 CFR 71.53 will not have a significant impact on the human environment.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act at 2 U.S.C. 1532 requires that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more (adjusted for inflation) in any given year. This rule is not expected to result in any one-year expenditure that would exceed this amount, therefore HHS/CDC has not prepared a table of quantified costs and benefits.

F. Plain Language Act of 2010

Under Public Law 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

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Centers for Disease Control and Prevention and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Fifth Edition, 2007; U.S. Government Printing Office, Washington, DC, March 31, 2008.

List of Subjects in 42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Centers for Disease Control and Prevention amends 42 CFR part 71 as follows:

PART 71-FOREIGN QUARANTINE

1. The authority citation for 42 CFR part 71 continues to read as follows:

Authority: Sec. 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 243), secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

2. Revise § 71.53 to read as follows:

§ 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 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 e-mail 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.

(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.

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

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

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

(v) Each heating ventilation and air-conditioning unit in the quarantine facility must be designed so that there is no mixing of air among quarantine rooms and each quarantine room must remain under negative air pressure in

relationship to the common hallway or anteroom(s) adjacent to the quarantine room.

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

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

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

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

(iii) An importer must ensure NHPs are confined in a squeeze-back cage whenever possible and that any individual

NHP is anesthetized, tranquilized, or otherwise restrained before handling.

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

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

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

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

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

(A) If any NHP appears ill during quarantine, an importer must monitor that NHP for signs of zoonotic

illness, including filovirus disease, and ensure appropriate treatment.

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

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

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

(A) An importer must ensure that any cohort with positive or suspicious TST reaction remains in quarantine

and receives at least five additional TSTs (each administered at least two weeks apart) following removal of the last affected NHP.

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

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

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

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

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

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

(4) Before releasing a NHP from quarantine, an importer must obtain written permission from HHS/CDC. HHS/CDC may permit the release of a cohort from quarantine when all the following conditions have been met:

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

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

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

(5) If HHS/CDC notifies an importer of any evidence that NHPs have been exposed to a zoonotic disease, the importer must, at the importer's expense, implement or cooperate in the HHS/CDC's implementation of additional

measures to rule out the spread of suspected zoonotic disease before releasing a shipment from quarantine, including examination, additional diagnostic procedures, treatment, detention, isolation, seizure, or destruction of exposed animals.

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

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

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

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

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

(v) Any samples of tissues, blood, serum, and/or transudates (bodily fluid) collected during necropsy must

be retained until the NHP shipment has been released from quarantine by HHS/CDC, in case other testing is required by HHS/CDC;

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

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

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

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

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

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

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

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

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

Dated: February 6, 2013. _____

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

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