

Requirements for the Importation of Nonhuman Primates into the United States

Request for OMB approval of a Revision Information Collection with OMB
Control No. 0920-0263 (Expiring 8/31/2020)

July 27, 2020

Supporting Statement A

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- **Goal of the study:** To continue regulatory oversight of nonhuman primate importers through registration, reregistration, evaluation of standard operating procedures, receiving pre-shipment notification, reviewing requests for releasing shipments from CDC quarantine, and overseeing filovirus testing of nonhuman primates (NHP) when required.
- **Intended use of the resulting data:** To ensure that NHP importers are meeting CDC regulatory requirements



The Centers for Disease Control and Prevention (CDC) is requesting approval for a set of adjustments to the previously approved burden total for this information collection. The adjustments are as follows:

Adjustments:

Based on the number of registered importers processed by CDC, CDC is adjusting upward two of the information collections within this submission:

- Nonhuman Primate Importer Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(k), (n).
- Nonhuman Primate Importer Quarantine release 71.53(l).

Changes:

CDC is proposing a reformatting and changes to CDC 75.10A Registration Form for NHP Importation to clarify for respondents the information that should be submitted. This results in no changes in respondent burden.

CDC is adding the following information collections to delineate between specific information collections under the regulations at 42 CFR 71.53(m):

- Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m) (no form)
- Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m)

CDC is removing information collections, because CDC is not using the Partner Government Agency Message Set functionality within the Automated Commercial Environment:

- CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates
- CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products
- Documentation of Non-infectiousness 71.53(t)

The total number of hours requested for this information collection total 185, which is a decrease of 737 hours.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The purpose of this submission is to request a revision of a currently approved data collection “**Requirements for the Importation of Nonhuman Primates into the United States**” that expires 08/31/2020. OMB approval is requested for three years.

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment 1) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Existing regulations governing quarantine activities authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals, including nonhuman primates (42 CFR 71.53) (Attachment 3) and etiologic agents in order to protect the public’s health. These practices and procedures ensure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting requirements, as well as a minimum of interference with trade and travel.

The regulations found at 42 CFR 71.53 authorize this information collection and include reporting and recordkeeping requirements pertaining to the importation of animals, specifically nonhuman primates.

Beginning in 1989, numerous monkeys imported into the U.S. were found to have been infected with a filovirus related to the Ebola virus from Africa. This virus has been isolated directly from cynomolgus monkey blood and tissues, and antibody to the virus has been detected in cynomolgus, African green, and rhesus monkeys.

On January 19, 1990, CDC published interim guidelines for handling non-human primates during transit and quarantine in the “Morbidity and Mortality Weekly Report.” Based on additional developments during the next two months, CDC notified all importers in a letter dated March 15, 1990 that compliance with these isolation and quarantine standards was a mandatory condition for continued registration as an importer of non-human primates under 42 CFR 71. On March 23, 1990, an announced public meeting was held in Atlanta, Georgia, to allow all interested parties to comment concerning (1) actions taken to date to prevent the importation of filoviruses into the United States and their transmission to animal handlers; (2) the potential impact of the imposition of a temporary ban on the importation into the United States of cynomolgus monkeys; and (3) additional disease control measures.

On April 4, 1990, CDC reported that four animal handlers at a quarantine facility in the United States had demonstrated serologic evidence of recent infection with the strain of this virus isolated from infected cynomolgus monkeys. Serologic evidence indicated that approximately 5-10% of cynomolgus, African green, and rhesus monkeys coming into the United States had previously been infected with a filovirus – regardless of their origins in Africa or Asia (Philippines, Indonesia, and China).

Considering the available information, the Director of CDC concluded that these three species are capable of being an animal host or vector of human disease. He further concluded that until further information can be obtained about the risk of human illness following infection and about the means of

transmission of filoviruses from monkeys to humans, public health practice requires that more stringent precautions be applied to the importation of these three species.

On April 20, 1990, after considering information presented during and following the March 23rd public meeting and other relevant information, the Director of CDC established a special permit procedure (55 FR 15210) (Attachment 4) under the authority of Sections 361-368 of the Public Health Service Act and 42 CFR 71.53. To receive a special permit to import cynomolgus, African green, and/or rhesus monkeys, a registered importer of non-human primates must submit to the Director of CDC a written plan detailing the steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving non-human primates. This plan must be submitted to the Director of CDC at least 30 days prior to the proposed importation. The plan is evaluated by the Director of CDC and additional information or clarification may be requested if needed. Importation cannot occur until receipt of written approval of the plan by the Director of CDC.

Since May 1990, CDC has monitored the arrival and/or uncrating of certain shipments of non-human primates imported under the special permit program. In February 2013, CDC promulgated two regulations pertaining to the importation of nonhuman primates. The first rule, Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples (Attachment 5), outlines a process by which importers can send liver tissues to CDC from primates that die during importation from reasons other than trauma (2/12/2013, Vol.78, No. 29, p. 9828). CDC performs these tests due to the absence of a private sector option. The second rule, Requirements for Importers of Nonhuman Primates (Attachment 6) consolidates into 42 CFR 71.53, the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (2/15/2013, Vol. 78, No. 32 /p. 11522). It also obviated requirements for the special permit, reducing much of the respondent burden. CDC feels these regulatory changes balance the public health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

2. Purpose and Use of Information Collection

Under 42 CFR 71.53, CDC collects information pertaining to imported nonhuman primates. This information enables CDC to evaluate compliance with pre-arrival shipment notification requirements, ascertain the number and species of imported nonhuman primates, and to determine if adequate measures are being taken to prevent exposure to persons and animals during importation.

The items of information collected from importers include the following:

- Names and contact information of importers, brokers, and transporters (42 C.F.R. 71.53 (g), 42 C.F.R. 71.53 (n))
- Standard operating procedures for handling nonhuman primates (42 C.F.R. 71.53 (g))
- Description of imported nonhuman primates (42 C.F.R. 71.53 (n))
- Statements indicating the purpose of importation (42 C.F.R. 71.53 (g))
- Health certificates, shipping documents, and nonhuman primate health records (42 C.F.R. 71.53(l)(3))
- Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m))
- Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m))

3. Use of Improved Information Technology and Burden Reduction

The application for registration can be submitted via email, regular mail, or expedited delivery, provided all necessary information is supplied (Attachment 7). The form for filovirus testing is submitted electronically (Attachment 8). Use of improved information technology would not further reduce the burden. Notification of imports and the request to release from quarantine may be sent by phone, SMS text, or email.

CDC also recently published in the Federal Register guidance for using the Document Image System (DIS) within the Automated Commercials Environment for importers of NHPs. This notice is available here: <https://www.federalregister.gov/documents/2016/12/30/2016-31750/electronic-filing-of-certain-import-data-into-the-document-image-system-through-the-automated>

The following collections may be submitted via DIS:

1) **Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form)**

In the event importers/filers choose to use ITDS/ACE to Brokers must document the importation of nonhuman primates or nonhuman primate products. The information requested of the brokers in DIS is the email notification message generated by CDC's Quarantine Activity Reporting System (QARS) when a registered importer notifies CDC of an incoming nonhuman primate shipment.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of or similar information exists. CDC DGMQ is currently the only regulatory agency authorized to collect this information for the purposes of protecting public health, which it accomplishes by preventing the importation of disease in nonhuman primates. Although CDC has information which was previously submitted by each registered importer as part of the application process, CDC does not have the specific information required to make current and critical health decisions. This information can only be collected from individual importers. CDC's Import Permit Program has responsibility for nonhuman primate products, and so that burden is not accounted for here.

5. Impact on Small Businesses or Other Small Entities

The burdens imposed have been reduced to the absolute minimum necessary for CDC to make informed decisions to protect the public and the health of those who may come in contact with imported non-human primates. Based on additional knowledge gained as a result of information collected, the burden has been reduced since the original submission. To aid small businesses, CDC is willing to discuss simplification of the submission with individual businesses.

6. Consequences of Collecting the Information Less Frequently

The frequency of data collection is determined by the number of times an importer wishes to import nonhuman primates. Monitored compliance with disease control requirements stipulated during the registration process now results in an extended 2-year registration, and thus, the frequency of data

collection has been significantly reduced. Rather than a complete submission for each shipment, only a specific itinerary and any changes requiring approval must be submitted during the two-year registration period. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information supports real-time monitoring and disease transmission activities required by regulation. Import brokers determine when they wish to ship non-human primates and submit information to CDC on a schedule that supports each broker's target shipping date(s) as well as public health goals. CDC has not established a fixed information collection schedule (annual, semi-annual, quarterly, monthly) as this would impede brokers' ability to set their own target dates for shipping.

CDC shares selected information from the import applications to facilitate scientific discussion about appropriate quarantine and disease prevention methodology. However, CDC does not share information identified as 'proprietary' by import brokers. CDC's procedures to protect confidential information fully comply with the regulation 5 CFR 1320.5

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60 day Federal Register Notice was published on December 6, 2019, Vol. 84, No. 235, page 66899. Six non-substantive public comments were received (Attachments 2B-2G). A standard response was sent.

B. There have been no other formal consultations since the public meeting on March 23, 1990. CDC does keep interested parties, including other Federal agencies, advised of new situations and requirements.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents. Respondents must comply with the permit requirements to import nonhuman primates into the United States or they are not permitted to import these animals.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The National Center for Emerging and Zoonotic Infectious Diseases has determined that the Privacy Act is applicable. The applicable System of Records Notice (SORN) is 09-20-0171 Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71. The information is stored in the Quarantine Activity Reporting System, and the Privacy Impact Assessment is included as an attachment to this supporting statement (Attachment 9).

The data will be used by CDC to assess efficacy of current regulations in preventing the introduction or spread of diseases communicable to humans into the United States via nonhuman primate. The

information collected from importers will not be shared unless in a manner specified in the SORN listed above.

Sensitive and identifiable information regarding the identity of nonhuman primate importers and their respective institutions, such as contact and business location information, is being collected and could affect a respondent's privacy if there were a breach of information security. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations. Procedural safeguards: Protections for computerized records include programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. Finally, CDC and contract employees who maintain records are instructed to check with the system manager prior to making disclosures of data.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment 10 CDC Nonresearch Determination Letter).

There are no questions of a sensitive nature in this data collection. Importers provide limited personal information, but rather provide information on the measures taken to prevent exposures of persons and animals during the importation and quarantine process for arriving non-human primates and the use of adequate disease control practices.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Respondents are registered importers (commercial or not-for-profit entities) of nonhuman primates who seek approval from CDC for importation. The burden imposed by the registration, permit application, notification, and documentation requirements is based on the estimated amount of time needed to perform the requirement, multiplied by the number of responses. The Requirements for Importers of Nonhuman Primates final rule requires importers to re-register every two years. This means that only

half of the 25 currently registered importers will need to respond to Registration and Documentation requirements in any one year. CDC estimates that one new importer will register with CDC per year. It is likely new importers will require additional time to develop the Documentation necessary to register with CDC, so additional burden hours are requested for New Importers.

CDC estimates the following number of respondents and the respective frequency with which they will need to send information to CDC. The below table reflects operational and programmatic updates and adjustments to increase clarity for respondents regarding specific information collections. The only information collections in the table below that include forms are CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (both new and re-registration) and 71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials. The other information collections refer to regulatory provisions within 42 CFR 71.53.

- CDC estimates one new applicant for CDC registration/year will need to make New Importer CDC registration (10 minutes).
- 24 CDC-registered importers will need to re-apply every two years for CDC registration (10 minutes each), or 12 importers per year. This estimate is derived from the current number of CDC-registered importers.
- CDC estimates one new applicant per year that will need to submit documentation to comply with the revised regulation. CDC estimates the burden of this requirement to be 10 hours.
- 25 CDC-registered importers will need to comply with the documentation requirements as requested by CDC. CDC estimates the burden to update existing documentation to be 30 minutes.
- 25 CDC-registered importers will need to notify CDC before each NHP shipment and once the shipments arrives at the quarantine facility. This occurs approximately 150 times per year and requires 15 minutes per set of notifications. The number of importers is derived from the current number of CDC-registered importers plus one to account for any new importers.
- 25 CDC-registered importers will need to submit statements to CDC regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m)). This occurs the same number of times importers need to notify CDC of a shipment arrival: 150 times per year at 15 minutes per response.
- 25 CDC-registered importers will need to submit statements to CDC, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m)). This occurs in a portion of the total imported shipments: 75 responses per year at 15 minutes each.
- 25 CDC-registered importers will need to request release of each NHP from CDC quarantine. This occurs approximately 150 times per year and requires 15 minutes per notification. The number of importers is derived from the current number of CDC-registered importers plus one to account for any new importers.
- CDC estimates that 10 CDC-registered importers will need to submit filovirus samples for testing. CDC estimates this requested filovirus testing will occur on average a total of 100 times per year, with each request for testing taking a respondent 20 minutes each time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name/CFR Reference	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Nonhuman Primate	CDC 75.10A Application for	1	1	10/60	1

Importer	Registration as an Importer of Nonhuman Primates (New Importer) (Attachment 7)				
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration) (Attachment 7)	12	1	10/60	2
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer) (Attachment 3)	1	1	10	10
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer) (Attachment 3)	12	1	30/60	6
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(k), (n) (no form) (Attachment 3)	25	6	15/60	38
Nonhuman Primate Importer	Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42	25	6	15/60	38

	CFR 71.53(m) (no form)				
Nonhuman Primate Importer	Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m) (no form))	25	3	15/60	19
Nonhuman Primate Importer	Quarantine release 71.53(l)(no form) (Attachment 3)	25	6	15/60	38
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (Attachment 8)	10	10	20/60	33
Total					185

B. Estimated Annualized Burden Costs

The estimated total cost to the public is \$8,844. These estimates are based on experience with the information requirements associated with existing application and review processes, increases in the number of importations, and knowledge of the professions involved in the importing process. The application process is a combined effort between veterinarians/facility directors (<http://www.bls.gov/oes/current/oes291131.htm>) and veterinary assistants/laboratory animal caretakers (<http://www.bls.gov/ooh/healthcare/veterinary-assistants-and-laboratory-animal-caretakers.htm>). CDC has therefore chosen to estimate the cost to the respondents in the following manner:

- The effort was apportioned by using the 75% percentile pay for vets (to account for the higher pay rate of the facilitate directors) with 75% of the respondent burden, and 25% of the response burden as being performed by animal caretakers with the mean wage assumed.
- The result of this estimate is \$47.50 per hour, which we have rounded to \$48 per hour in the table below.

All registered importers of non-human primates are required by 42 CFR Part 71.53 to maintain certain disease control procedures and keep certain records. Standard business practices indicated that importers already keep records on the origin, transportation, and disposition of animals. Thus, CDC asks for information which should already be maintained by the importers and need only be assembled and reported. The estimate of burden hours and costs reflects assembling and reporting only.

Estimated Annualized Burden Costs

Type of Respondent	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New Importer) (Attachment 7)	1	\$48	\$48
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration) (Attachment 7)	2	\$48	\$96
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer) (Attachment 3)	10	\$48	\$480
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer) (Attachment 3)	6	\$48	\$288
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(k), (n) (no form) (Attachment 3)	38	\$48	\$1,824
Nonhuman Primate Importer	Statements regarding the health of the nonhuman primates during	38	\$48	\$1,824

Type of Respondent	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	travel and CDC quarantine (42 CFR 71.53(m) (no form)			
Nonhuman Primate Importer	Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m)(no form)	19	\$48	\$912
Nonhuman Primate Importer	Quarantine release 71.53(l)(no form) (Attachment 3)	38	\$48	\$1,824
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (Attachment 8)	33	\$48	\$1,548
Total				\$8,844

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital and maintenance costs.

14. Annualized Cost to the Federal Government

The requirements for a permit to import nonhuman primates into the United States are administered by the CDC on an ongoing basis, as defined by CDC's regulatory authorities and responsibilities. The estimated average yearly cost to the Federal government is \$136,267. This estimate reflects CDC staff time for the review of documentation and notification, and includes costs for two site visits to the entity filing or renewing a permit, and an estimated time of 24 hours of paperwork and facility review to complete the registration process per site visit.

GS-13 @ 50% time	\$46,641
GS-13@ 80% time	\$74,626
Travel Costs	\$15,000
Total	\$136,267

15. Explanation for Program Changes or Adjustments

The Centers for Disease Control and Prevention (CDC) is requesting approval for a set of adjustments to the previously approved burden total for this information collection. These requested adjustments and changes result in a decrease of 737 hours. The revised total for this request is 185 hours. The adjustments are as follows:

Adjustments:

Based on the number of registered importers processed by CDC in the previous year, CDC is adjusting upward two of the information collections within this submission:

- Nonhuman Primate Importer Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(k), (n); increase of one respondent to 25 and two additional burden hours to 38.
- Nonhuman Primate Importer Quarantine release 71.53(l); increase of one respondent to 25 and two additional burden hours to 38.

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	Notification of shipment arrival 71.53(n)	Current Approval	24	36
		Revision Request	25	38
		Net Change	1	2

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	Nonhuman Primate Importer Quarantine release 71.53(l)	Current Approval	24	36
		Revision Request	25	38
		Net Change	1	2

Changes:

CDC is proposing some changes to CDC 75.10A Registration Form for NHP Importation to clarify for respondents the information that should be submitted and to make the form more concise and focused on the most important information for CDC's review. This results in no changes in respondent burden. The changes are as follows:

- The entire form has been reformatted for ease of use and questions have been narrowed to collect only the most relevant information about the importation program relevant to CDC's regulations.
- 3.b.2: Wording change to specify "exhaust air" filtration rather than just "incoming air"
- Section 4 has been included as a "Yes" or "No" option section so that importers can clearly mark the standard operating procedures that they have completed and should be available to CDC upon inspection.
- New question 5 (old 4): Clarified question to specify rooms with dedicated air-handling systems, rather than just being held separately in a different room or just separated.
- 5c: Delete reference to PPD from the form.

- o Justification: PPD is no longer considered an option for testing nonhuman primates (NHPs) for tuberculosis. The only acceptable antigen for testing NHPs is Mammalian Old Tuberculin (MOT or OT).
- Question 6: Change the “Are all animals that die during the initial period necropsied” and delete the next statement: “If yes, estimate percentage of animals necropsied”.
 - o Justification: All animals that die during CDC-mandated quarantine must be necropsied to determine the cause of death. The changes made will clarify our question.
- Section 9: This section has been trimmed to identify those occupational health issues most salient to work with NHPs. This limits questions to tuberculin skin tests, OSHA required respiratory control programs and annual fit testing (OSHA 29 CFR 1910.134), and the availability of an occupational health facility and program. The new form omits fields for on employment physicals and storage of worker serum samples for potential diagnostic purposes.

CDC is adding the following information collections to more clearly delineate between the information collections specified under the regulations at 24 CFR 71.53(m):

- Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m) (no form). Twenty-five CDC-registered importers will need to submit statements to CDC regarding the health of the nonhuman primates during travel and CDC quarantine. This occurs the same number of times importers need to notify CDC of a shipment arrival: 150 times per year (approximately six occurrences per importer) at 15 minutes per response. This is a total hourly burden of 38 hours per year.
- Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m). Twenty-five CDC-registered importers will need to submit statements to CDC, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. This occurs in a portion of the total imported shipments: 75 responses per year (approximately three occurrences per importer) at 15 minutes each. This results in a total burden of 19 hours per year.

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m) (no form)	Current Approval	-	-
		Revision Request	25	38
		Net Change	25	38

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m)	Current Approval	-	-
		Revision Request	25	19
		Net Change	25	19

CDC is removing information collections related to the PGA message set, because CDC is not using the PGA message set functionality within the Automated Commercial Environment. Additionally, CDC is removing the information collection pertaining to Documentation of Non-infectiousness because that burden is covered under OMB Control No. 0920-0199 in the CDC Division of Select Agents and Toxins Import Permit Program. The reductions are as follows:

- Removal of CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates, which results in a reduction of 38 burden hours
- Removal of CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products, which results in a reduction of 570 burden hours
- Removal of Documentation of Non-infectiousness 71.53(t), which results in a reduction of 190 burden hours.

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates	Current Approval	150	38
		Revision Request	0	0
		Net Change	-150	-38

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products	Current Approval	2280	570
		Revision Request	0	0
		Net Change	-2280	-570

Type of respondents	Form		Number of respondents	Total Response Burden (in hours)
NHP Importers	Documentation of Non-infectiousness 71.53(t)	Current Approval	2280	190
		Revision Request	0	0
		Net Change	-2280	-190

16. Plans for Tabulation and Publication and Project Time Schedule

These are recurring data collections, the time schedules for which are determined by importers' arrangements to import nonhuman primates. Data are not collected for statistical use. There are no current plans to publish any information received in the permit application process.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment 1: 42 USC 264: Regulations to Control Communicable Diseases

Attachment 2: 60 day Federal Register Notice

Attachment 2B: Public comment

Attachment 2C: Public comment

Attachment 2D: Public comment

Attachment 2E: Public comment

Attachment 2F: Public comment

Attachment 2G: Public comment

Attachment 3: 42 CFR 71.53 Foreign Quarantine

Attachment 4: 55 FR 15210: Special Permit Procedure

Attachment 5: Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples
Final Rule

Attachment 6: Requirements for Importers of Nonhuman Primates Final Rule

Attachment 7: CDC 75.10A Application for Registration as an Importer of Nonhuman Primates

Attachment 8: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials

Attachment 9: QARS Privacy Impact Assessment

Attachment 10: CDC Nonresearch Determination Letter