

**Foreign Quarantine Regulations (42 CFR 71)**  
**(OMB Control No. 0920-0134)**  
**Supporting Statement A**  
**Request for Revision of Currently Approved Data Collection**  
**Submitted 4/28/2016**

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**Foreign Quarantine Regulations (42 CFR 71)**  
**Statement in Support of Foreign Quarantine Regulations (42 CFR Part 71)**

- The goal of revision is to revise and clarify paperwork burden for the importation of dogs into the United States, specifically those requirements and burdens pertaining to rabies vaccination requirements, exemptions from rabies vaccination requirements, and to implement a new process for application and issuance of permits to import unvaccinated animals who do not meet the exemption requirements. CDC is also transitioning the Passenger Locator Form to another Information Collection Request, Airline and Maritime Conveyance and Traveler Information Collection, that will accompany a Notice of Proposed Rulemaking on 42 Code of Federal Regulations parts 70 and 71.
- The information will be used to assist CDC in meeting its statutory and regulatory responsibilities outlined in 42 Code of Federal Regulations (CFR) part 71, which are intended to prevent the introduction of disease into the United States.
- No statistical methods will be used. The information collection is solely intended to comply with statutory and regulatory responsibilities.
- There are no sub-populations to be analyzed. The universe of respondents is all individuals who seek to import dogs into the United States.
- Data will be analyzed to ensure compliance with CDC regulations.

This is a request for a revision of a currently approved information collection request (ICR) that expires September 30, 2017. CDC is requesting a 3 year OMB clearance for this information collection. The Centers for Disease Control and Prevention Division of Global Migration and Quarantine (DGMQ) is requesting approval for a set of program changes and an adjustment that pertain only to the paperwork and approval process for importing an unvaccinated dog, and provide greater clarity and a more accurate assessment of burden related to the requirements for vaccination certificates and the provision of permits to import unvaccinated dogs. The changes result in a net increase in both estimated respondents and burden hours. The additional number of respondents requested for this revision is 288,600, and the additional burden is 72,267 hours.

CDC is also transitioning the Passenger Locator Form to another Information Collection Request, Airline and Maritime Conveyance and Traveler Information Collection, that will accompany a Notice of Proposed Rulemaking on 42 Code of Federal Regulations parts 70 and 71. Due to this transition, CDC is removing 225,067 burden hours from OMB Control Number 0920-0134.

A. Justification

**1. Circumstances Making the Collection of Information Necessary**

Background

The purpose of this ICR is to request a revision of a currently approved data collection “Foreign Quarantine Regulations” that expires September 30, 2017. CDC is requesting a three year approval. This revision is an effort to provide greater clarity surrounding

paperwork requirements and focuses exclusively on certain ICs within OMB Control No. 0920-0134 pertaining to importation of dogs into the United States.

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment A1) 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. Legislation and the existing regulations governing quarantine activities (42 CFR 71) (Attachment A2) authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals and etiologic agents in order to protect the public's health. Other inspection agencies, such as Customs and Border Protection (CBP), assist quarantine officers in public health screening of persons, pets, and other importations of public health importance and make referrals to quarantine station staff when indicated. 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 procedures, as well as a minimum of interference with trade and travel.

Since 1956, Federal quarantine regulations have controlled the entry of dogs into the United States. *See* 21 FR 9870, Dec. 12, 1956 (Part 71 Quarantine Regulations, Attachment A3). Currently, HHS/CDC regulates imports of dogs into the United States under regulations found at 42 CFR 71.51. Among the principal concerns for regulating the import of dogs is to prevent introduction and spread of rabies.

Subsection 71.51(c)(2) indicates that “the [CDC] Director may authorize admission” of dogs that have not been adequately immunized against rabies provided that the dogs are confined under conditions that restrict their contact with humans and other animals until they have been immunized, aka confinement agreements. Generally, the use of the term “shall” in a regulation indicates a regulatory requirement, while the use of the term “may” indicates that the agency has discretion regarding the manner in which it chooses to enforce this particular aspect of its regulations. The intent of the confinement agreements between HHS/CDC and the importer is to ensure that inadequately immunized dogs will be confined in such a way as to minimize the risk of exposing persons and other animals especially dogs to rabies until the dogs are considered adequately immunized against rabies. HHS/CDC considers confinement agreements to constitute an exception to the general rule that, unless coming from a rabies-free country or intended for use in scientific research where rabies vaccination would interfere with that research, all imported dogs must be properly vaccinated against rabies.

Recently, CDC enacted a set of operational changes with regard to the processing of these confinement agreements due to the large increase in number, evidence that the agreements have been violated, and communication with state and local health departments concerning the burden caused by increase in volume. Additionally, violation of the confinement agreements presents a potential risk to public health. In order to more efficiently adjudicate these requests from the public, and adhere to the intent of the regulation, CDC is proposing a series of administrative changes that includes a revised permitting process. CDC is also taking this change to clarify current paperwork requirements pertaining to CDC's dog importation regulations.

## 2. Purpose and Use of Information Collection

As described above, CDC has regulatory authority over the importation of dogs in order to mitigate the risk of a zoonotic transmission of disease from dogs to people. In 2014, CDC issued guidance in the form of a Federal Register Notice (Attachment C) on the issuance and enforcement of CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement (Attachment D). This guidance was issued due to the substantial increase in recent years in the number of confinement agreements being requested by importers of dogs, which resulted in an increased burden to state and local health departments and CDC for supervision of confinement agreements. It was found that in many cases importers have violated their confinement agreements, these confinement agreements were issued to persons who import dogs for commercial purposes or for reasons other than as personal pets, which is contrary to the intent of the confinement agreement provisions.

The guidance states the factors CDC will consider when determining if a permit for importing an unvaccinated dog will be issued to ensure that the terms of the permit will not be violated or that an inadequately immunized dog does not pose a threat to public health. Because of the guidance, CDC believes that the number of confinement agreements issued will be fewer than previously requested in OMB Control No. 0920-0134.

In addition, during a review of public burden estimates under OMB Control No. 0920-0134, it became evident that the text of the burden tables in section A12 in previous Supporting Statements concerning the IC entitled “71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37)” was unclear regarding the intent of the information collection, underestimated the number of potential dogs entering the United States, and could lead to public confusion regarding the requirements and public burden associated with importing dogs into the United States.

In order to provide better clarity on the requirements and burdens on importers, CDC is requesting the removal of the IC entitled “71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37) from Tables 12.a and b of this Supporting Statement. In its place, CDC is proposing three new ICs that more accurately capture the anticipated public burden associated with each. Of particular note here is that CDC is providing two separate accounts of burden, one for the current confinement agreement ((CDC form 75.37, Attachment D) and one for the rabies vaccination certificate. CDC is not proposing to shift burden between the two requirements, only to provide a more accurate number of respondents for each, and to update the estimate of rabies vaccination certificates that are submitted by importers upon entry based on the number of dogs CDC believes are entering the United States.

CDC is also adding an IC for documentation submitted by importers who wish to receive a legitimate exemption from the requirement for a rabies vaccination per 42 CFR 71.51 (c)(i-iii). This was not included in previous versions of this Supporting Statement, but has been included now to clarify that CDC is accounting for importer burden if they believe

they have a legitimate reason to be exempt from rabies vaccination and want to submit that information to CDC.

Further, in order to make the dog importation process more uniform for both the respondent and the federal government, CDC is seeking approval to shift the routine disposition of information related to unvaccinated dogs and importation to CDC headquarters instead of the Quarantine Stations. This involves a transition of the routine use of CDC Form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement to be replaced with a new IC, the Application For Permission To Import A Dog Unimmunized Against Rabies (Attachment E). If the importer meets the criteria for importation of unimmunized dogs outlined in the 2014 Federal Register Notice, CDC will send the importer a Permit to Import a Dog Unimmunized against Rabies (Attachment F). This permit will be presented to CBP at the time when the dog enters the United States. Guidance for the importation of inadequately vaccinated dogs is available from CDC (Attachment G - Guidance Document for Completing the Application for Permission to Import a Dog Inadequately Immunized Against Rabies). For those cases when an individual arrives at a U.S.-port with an unimmunized or under-immunized dog, the CDC Form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement will be provided to the importer if CDC believes granting entry is appropriate.

A complete outline of the change in process and specific changes to particular information collections related to the importation of dogs is included in section A15 below.

The reporting, documentation and recordkeeping requirements contained in 42 CFR 71 regulations are used by CDC to carry out quarantine and public health responsibilities as required by law and regulation and have been part of current practice for several years. This information collection from individuals, air and maritime conveyance operators, and importers is critical to CDC in fulfilling regulatory requirements that aim to reduce the risk that an infectious disease is imported into the United States via contaminated or infected animals or other cargo, and for illness reporting on air and maritime conveyances under 42 CFR Part 71.

The burdens imposed have been reduced to the minimum considered necessary to permit CDC to carry out the purpose of the regulation, i.e., to prevent the introduction, transmission or spread of communicable diseases, be it in people or products, from foreign countries into the United States.

No changes to the following portions of the currently approved information collections are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21
  - o 42 CFR 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following depending on the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)

- Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 42 CFR 71.21(b)
    - Death/Illness reports from aircrafts (no form)
  - o 42 CFR 71.21(c)
    - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)\_
    - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

### **3. Use of Improved Information Technology and Burden Reduction**

With respect to this revision, rabies vaccination certificates and current CDC Form 75.37 are generally reviewed by CBP or CDC staff in hard copy at the port of entry. Electronic submission of the rabies vaccination certificates and new Permit to Import a Dog Unimmunized against Rabies - Single Entry is anticipated to be available using the Document Imaging System (DIS) associated with International Trade Data System/Automated Commercial Environment (ITDS/ACE) and will be accepted by CDC when the DIS becomes available. CDC will also reserve the right to inspect hard copies to ensure validation of the certificate.

In addition to conventional postage mail, email exchange may be used to send the Application For Permission To Import A Dog Unimmunized Against Rabies and any other information the importer believes is relevant to issuance of a CDC permit to import an unvaccinated dog.

No other changes are requested in this revision concerning the Use of Improved Information Technology and Burden Reduction. No changes to illness/death reporting, documentation submission or recordkeeping procedures concerning imports are requested as part of this revision. Current reporting and recordkeeping requirements imposed by the 42 CFR 71 (with regard to inspection and surveillance procedures at ports of entry) have been facilitated by the use of radio, email, or telephone notification of illness reports. Also, CDC will accept electronic submission of the PGA message sets via ITDS/ACE when it becomes available, and CDC will also accept the statements/documentation of non-infectiousness, permits for turtles, and death certificates via the DIS. As with the importation of dogs, CDC will reserve the right to see the hard copies if any discrepancies or conflicts in information arise.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

CDC is the only agency charged with enforcement of the dog importation regulations pertaining to human public health; therefore, no other agencies require the collection of this information for this purpose. However, all dogs that are imported into the United States for resale, research, or treatment, are generally required by the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS)/Animal Care to have a rabies vaccination certificate, with some exceptions. APHIS/Animal Care does not have a rabies vaccination requirement for the importation of dogs as personal pets. CDC's regulations will not contravene or supersede these regulations, and the information elements required by CDC and APHIS are aligned to reduce burden on the importers. The same rabies certificate that meets APHIS/Animal Care requirements will also meet CDC requirements.

Regarding the current hard copy collection of information on the other animal and animal products listed in Part 71, no changes are requested that are relevant to this section.

CDC has regulatory authority to collect information on certain regulated products and must have this information to perform its public health responsibilities. Concerning the voluntary electronic collection of information via ITDS/ACE, CDC will rely on CBP to administer the collection of information pertaining to imports. While CDC may request information in common with other agencies, the importer/filer only fills out a data field once, which may then be made available via memorandums of understanding or other data sharing agreements among multiple agencies, if needed. Importer/filer software may also pre-populate data fields for other agencies' Message Sets, so repeat entry may not be necessary. CBP is the sole authority to which import information must be submitted via ITDS/ACE, so it is very unlikely that any duplication will occur.

Concerning illness and death reporting, the existing regulations were widely reviewed by other federal inspection agencies, the World Health Organization (WHO), and the United States Army, Air Force, Navy, and Coast Guard. There is no duplication of data.

#### **5. Impact on Small Businesses or Other Small Entities**

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection



requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

## **6. Consequences of Collecting the Information Less Frequently**

Further reduction of required and requested recordkeeping or reporting would prevent CDC from meeting its legislative mandate and regulatory responsibilities, and could therefore endanger the public's health. There are no legal obstacles to reduce the burden.

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

Information regarding the potential presence of disease or the arrival of a potential vector of disease via animals, including dogs, or cargo must be reported on a real-time basis if it is to be used to prevent the importation and spread of disease into the United States

Information regarding the incidence of disease or death aboard maritime or air conveyances must also be reported on a real-time basis if it is to be used to prevent the importation and spread of disease into the United States. Depending on the situation, reporting may be verbal, written with no specific form specified, or written on the provided illness and death investigation forms with no extra copies required.

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

**A.** A notice to the public concerning CDC's revision of this ICR was published in the Federal Register on Wednesday, June 17, 2015 (Vol. 80, No. 116, PP 34645- 34647). (Attachment B). CDC received no comments from the public.

**B.** The regulatory requirements for the importation of dogs have been in place for several decades. While CDC generally does not request formal review of information collections from CBP, CDC is in constant communication with our federal partners concerning information requirements for imported dogs. CDC also has a memorandum of understanding (MOU) with the Department of Homeland Security (DHS) outlining that DHS will assist CDC in the enforcement of its quarantine rules and regulations (Attachment O). This MOU also states that CDC will provide training to DHS on CDC's regulations.

The primary partner for CDC at the ports of entry is CBP. Because CDC has staff at a limited number of ports of entry, CDC works closely with CBP to enhance the enforcement of CDC regulations on importations, including dogs. An integral element of this partnership is the training provided by CDC to CBP at the Federal Law Enforcement Training Center. Prior to CDC beginning the transition of the importation process, CDC anticipates the provision of training to CBP on how to administer the new permits. This training will include modules on the new permit as well as occasional just-in-time training when requested by CBP. CDC has been an active member of the Customs and Border Protection (CBP) Field Operations Academy (FOA) at the Federal Law Enforcement Training Center (FLETC) since 2006. The Academy's Officer Basic Training brings cohorts of 40+ new recruits through 89 days of intense training on nearly

every aspect of a primary CBP officer's job. The number of courses taught fluctuates, but averages around 30 sessions per year. CDC's role in the FOA Officer Basic Training has historically been to prepare CBP recruits to identify potential public health threats at ports of entry and provide an overview of CDC-regulated items.

This is accomplished for each Officer Basic Training session through a two-hour instructor-led course and that has reached over 14,000 CBP officers since its inception. The training introduces 1) the CBP/CDC partnership and also covers 2) the steps officers should take if they encounter ill travelers with specific symptoms, 3) what to look for while inspecting an applicant's medical examination documents, 4) the steps officers should take if they encounter CDC-regulated items, and 5) how to protect themselves from public health threats while they enforce our regulations. CDC has taught CBP trainees about their role as a public health partner at ports of entry in approximately 300 sessions at FOA.

CDC Quarantine and Border Health Services Branch leadership has visited CBP FOA leadership and other leadership at FLETC several times to maintain relationship with them, ensure that our partners' CDC Public Health training needs are being met and continue to maintain a strong partnership protecting our public from importations that may be a threat to their health. For example, after significant changes in branch leadership, Quarantine and Border Health Services Branch leadership and trainers traveled to CPB FOA and met with their leadership on December 16, 2015. In addition to formal introductions, discussions between CDC and CBP at this meeting included the relevance of the CDC Public Health curriculum and different methods that could be used to reinforce the content in the field. The main CBP point of contact for training is:

Luis R. Berenguer  
Supervisory Customs and Border Protection Officer, Course Developer/Instructor

CDC has also discussed the use of the permit in the DIS under ITDS. The main CBP point of contact for CDC's efforts to transition to the DIS under ITDS is:

Daniel Collier  
International Trade Specialist.

CDC anticipates that this change in process for the importation of dogs will result in less work for CBP, as the number of confinement letters processes at the ports will decline, and be replaced with the permits that only require a review. CDC endeavors to keep information requirements to the absolute minimum necessary to assess the risk for illness in dogs and prevent the introduction of disease into the United States. The requested changes to the information collections associated with importer dogs are in line with CDC attempts to make public burden estimates more transparent and attempts to streamline the transmission of information to CDC.

## **9. Explanations of Any Payment or Gift to Respondents**

No monetary incentives or gifts are provided to respondents.

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

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. CDC uses this notice for both people subject to the terms of the quarantine regulations, and includes importers complying with quarantine regulations in this population. The current verbiage of the does not explicitly include importers; however, CDC treats the PII of importers with the same security and privacy protection as if it did. CDC is currently awaiting clearance of an update to this SORN that explicitly includes importers as a category of individuals.

Concerning the current CDC form 75 37 NOTICE TO OWNERS AND IMPORTERS OF DOGS and new CDC Application For Permission To Import A Dog Unimmunized Against Rabies, full names and addresses of those completing the application are requested. The primary method of retrieval is name and individuals would be providing data primarily relating to their roles as an importer of dogs. Importers/filers will be providing personal information on themselves, and providing information on the measures taken to prevent exposure of persons and animals during the importation and the use of adequate disease control practices. Additionally, the Permit to Import a Dog Unimmunized against Rabies - Single Entry, while not completed by the importer, will contain the importers PII as well as potential contact information, and names will be searchable by that data category once stored in QARS. By choosing to import a dogs into the United States, an individual consents to the submission of the relevant, requirements documentation that enables CDC to determine if regulatory requirements have been met.

Personal identifiers (name, address, telephone number, cell number, etc.) will be collected and maintained under the Privacy Act system of records listed above. This information may be collected on importers/filers who are attempting to import certain animals and cargo into the United States and for individuals for whom an illness report is required according to 42 CFR 71.

When ITDS/ACE becomes available for use with CDC-regulated products, import related information collected from ITDS/ACE in the form of CDC PGA Message Sets and DIS scans, and illness and death reports from maritime and air conveyances, may be entered into a computer system, QARS, for analysis and later retrieved, if necessary. Currently, both import and illness/death information collected under this Control Number is entered into QARS by CDC staff during routine activities. Data containing personal identifiers and source documents, e.g. Notice to Importers of Dogs, will be retained until the event prompting the collection of data has concluded in accordance with DGMQ's records retention schedule. Data not containing personal identifiers will be retained indefinitely for statistical and historical documentation purposes. Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide "need to know" in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special "certified" process will be used to completely overwrite tapes on the mainframe or overwriting (not merely

deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

1. Overview of the data collection system: The data collection systems for this information collection request consist of electronic data transfers, and radio/phone communication, and hard copy document submission to CDC quarantine stations.

Currently, CDC has adopted a “preapproval” process for persons seeking to import inadequately immunized dogs into the United States. Importers are advised to contact CDC by electronic mail or postal mail to explain their need to import inadequately immunized dogs and request permission from CDC to import these dogs under the terms of a dog confinement agreement that would be issued at the port of entry. CDC reviews these requests and responds to importers either granting or denying their requests. Granted requests receive a signed letter from CDC to present to U.S. Customs and Border Protection (CBP) at the port of entry as proof that the importer may be issued a dog confinement agreement. CDC Form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement continues to be issued at the port of entry by CBP or CDC officers.

CDC is requesting to gradually change this process. This will involve a shift in the way that CDC allows the importation of unimmunized or under-immunized dogs. CDC Form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement will continue to be available for those individuals who present at the port of entry with an unimmunized or under-immunized dog without notifying CDC first. As the pre-approval process becomes the standard process, the Application For Permission To Import A Dog Unimmunized Against Rabies (Attachment E) will be the primary method for obtaining CDC permission to import unimmunized or under-immunized dogs. If the importer meets the criteria for importation of unimmunized dogs outlined in the 2014 Federal Register Notice, CDC will send the importer a Permit to Import a Dog Unimmunized against Rabies (Attachment F). This permit will be presented to CBP at the time when the dog enters the United States. For those cases when an individual arrives at a U.S.-port with an unimmunized or under-immunized dog, the CDC Form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement will be provided to the importer if CDC believes granting entry is appropriate.

No changes to the following portions of the currently approved information collections are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21
  - 42 CFR 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following depending on the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)

- o 42 CFR 71.21(b)
  - Death/Illness reports from aircrafts (no form)
- o 42 CFR 71.21(c)
  - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
  - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

2. A description of the information to be collected: This revision includes individually identifying information from individuals who are importing dogs, descriptions of animals for import, dates of vaccination for dogs, names of licensed veterinarians who vaccinated dogs, country of origin for imported dogs (and whether the countries is rabies free, information on whether the dog is intended for research, and descriptions of locations where dogs may be confined if they are allowed into the United States without a rabies vaccination.

The new Application For Permission To Import A Dog Unimmunized Against Rabies asks for the following information: PII of individual importing the animal, information concerning the shipper, a description of the dog, entry and final destination of the the dog in the United States, travel itinerary (air, land, or sea entry), purpose for importation of dog (e.g., commercial, personal, research), and the reason confinement is being requested, explanation why vaccination requirements cannot be met.

No changes to the Items of Information to be Collected for the following portions of the currently approved information collection request are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21
  - o 42 CFR 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following depending on

the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:

- Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
- Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
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- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
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  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

3. A description of how the information will be shared and for what purpose: Some information collected for the new Application For Permission To Import A Dog Unimmunized Against Rabies and Permit to Conditionally Import a Dog Inadequately Immunized against Rabies - Single Entry will be shared with state public health departments where the dog(s) is to be confined to ensure the terms of the agreement are met. Other information collected under this control number may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health concern; to private contractors assisting CDC in analyzing and reviewing records; to investigators under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice for litigation purposes; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request.

Except for these and other permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual's written consent.

No changes to how the information will be shared and for what purpose are requested for the following portions of the currently approved information collection:

- Air and maritime illness reporting under 42 CFR 71.21
  - o 42 CFR 71.21(a) Radio report of illness or death from ships. Maritime conveyance operators can report using any of the following depending on the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 42 CFR 71.21(b)
    - Death/Illness reports from aircrafts (no form)
  - o 42 CFR 71.21(c)
    - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
    - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

4. A statement detailing the impact the proposed collection will have on the respondent's privacy: Highly sensitive information is being collected and would affect the security of a respondent's personal identifying information if there were a breach of security. However, stringent safeguards are in place to ensure the security of a respondent's personal identifying information 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. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations which are located in a secure area of the airport. 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. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic medical records containing Privacy Act information. Finally, CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts and the CDC Project Director, contract officers and project officers oversees compliance with these requirements.

No changes to the statement detailing the impact the proposed collection will have on the respondent's privacy are requested for the following portions of the currently approved information collection:

No changes to the following portions of the currently approved information collections are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21
  - o 42 CFR 71.21(a) Radio report of illness or death from ships. Maritime conveyance operators can report using any of the following depending on the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 42 CFR 71.21(b)
    - Death/Illness reports from aircrafts (no form)
  - o 42 CFR 71.21(c)



- Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
  - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

5. Whether individuals are informed that providing the information is voluntary or mandatory: Respondents to this data collection will be informed whether or not providing the information described in this supporting statement is mandatory or voluntary. Concerning this revision, there have been regulations concerning requirements for the importation of dogs for several decades. These are long standing requirements and are communicated via CDC's website, to partners, and to importers on a routine basis.

No changes to whether individuals are informed that providing the information is voluntary or mandatory are requested for the following portions of the currently approved information collection:

No changes to the following portions of the currently approved information collections are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21
  - o 42 CFR 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following depending on the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 42 CFR 71.21(b)
    - Death/Illness reports from aircrafts (no form)

- o 42 CFR 71.21(c)
  - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
  - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

6. Opportunities for consent: No changes are requested to opportunities for consent to sharing of the information. Data from some imports and illness reports will become part of CDC Privacy Act System 09-20-0171, “Quarantine and Traveler-Related Activities, Including Records for Contact Tracing, Investigation, and Notification under 42 CFR Parts 70 and 71”, and may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health significance; to private contractors assisting CDC in analyzing and reviewing records; to investigators under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice for litigation purposes; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual’s written consent.

7. How the information will be secured: Information collected the new application and permit documents, and through electronic media (PGA Message Sets, statements of non-infectiousness, Maritime illness and death reports), and any information collected via hard copy under this control number will be entered into QARS and will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide “need to know” in order to carry out the duties of their positions or to accomplish the purposes for which the

data were collected. When information is deleted, a special “certified” process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

8. Whether a system of records is being created under the Privacy Act: No system of records is being created under this revision. Parts of this data collection are subject to the Privacy Act. The existing applicable Systems of Records Notice for this revision is 09-20-0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

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

### IRB Approval

NCEZID has reviewed the material for the Information Collection request and determined that it is Non-Research and IRB review is not required (Attachment P).

### Sensitive Questions

This information collection requests certain personally identifying information of both importers and travelers. The confinement process requires some PII in order to connect importers of dogs with the local and state health department to ensure confinement is taking place. Some personally identifying information is required in illness reports in order to identify ill travelers, and in import-related information to connect importers with their products. This information is necessary to engage in follow-up activities and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. As part of this information collection, CDC is not requiring or requesting the submission of any information related to criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and other matters that are commonly considered private.

Some questions relating to a travelers illness may be considered sensitive; however, no changes to the following portions of the currently approved information collection request are proposed as part of this revision:

- Air and maritime illness reporting under 42 CFR 71.21
  - o 42 CFR 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following depending on the illness or death report. The Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form is requested, not required:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 42 CFR 71.21(b)
    - Death/Illness reports from aircrafts (no form)

- o 42 CFR 71.21(c)
  - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
  - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form)
- 42 CFR 71.56(a)(iii) Appeal (no form)

## 12. Estimates of Annualized Burden Hours and Costs

The burden imposed by this revision is based upon the estimated amount of time needed to perform each particular information submission multiplied by the number of responses to CDC. Figures are based on estimates from Quarantine Staff activity at ports of entry. The requested burden includes those information requirements currently outlined in regulation and approved by OMB, as well as the corrected respondent burden for the required rabies vaccination certificate, and the decreased number of estimated annual confinement letters issued to importers of dogs. The number of respondents requested for this revision associated with the change in dog importation processes is 288,600, and the additional burden is 72,267 hours. The breakdown of additional hours is as follows:

- 42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates: 245,310 Respondents and 15 minutes per response. This equals 61,328 hours of burden.
- 42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate: 43,290 Respondents and 15 minutes per response, for a total of 10,823 hours
- 42 CFR 71.51(c)(2), (d) Application For Permission To Import A Dog Unimmunized Against Rabies: 1400 Respondents and 15 minutes per response, for a total of 350 hours. (This is half of the respondents previously associated with the CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement)

CDC is seeking an adjustment in the nature of a 50% reduction in burden associated with CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement. The new respondent number and hour burden is 1400 and 233, respectively.

CDC is removing the PLF from this information collection, and this results in a reduction of 2,700,800 respondents and 225,067 burden hours.

CDC is not requesting any changes to the following ICs in the burden tables:

- Air and maritime illness reporting under 42 CFR 71.21: 37700 respondents and 1824 burden hours
  - o 42 CFR 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 42 CFR 71.21(b)
    - Death/Illness reports from aircrafts (no form)
  - o 42 CFR 71.21(c)
    - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
    - 42 CFR 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance: 11 respondents and 1 burden hour.
- 42 CFR 71.35 Report of death/illness during stay in port (no form): 5 respondents and 3 burden hours
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review): 20 respondents and 5 burden hours
- 42 CFR 71.51 CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L): 30,000 respondents and 7,500 burden hours
- 42 CFR 71.52(d) Application for permits for importation of turtles: 5 respondents and 3 burden hours
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates: 5 respondents and 5 burden hours
- 42 CFR 71.56 (a)(2) Request for exemption: African rodents (no form): 20 respondents and 20 burden hours
- 42 CFR 71.56(a)(iii) Appeal (no form): 2 respondents and 2 burden hours
- 42 CFR 71.56 CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M): 60 respondents and 15 burden hours
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form): 2000 respondents and 167 burden hours
- 42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N): 2000 respondents and 500 burden hours.

- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form): 2000 respondents and 167 burden hours
- 42 CFR 71.56(a)(iii) Appeal (no form, written request only)

The total burden requested under this revision is 82,779 hours. There is no burden to respondents other than the time taken to complete the reports to CDC and to briefly maintain recordkeeping of illness aboard maritime conveyances and records of sickness or death in imported cats and dogs, as outlined in the table below.

#### 12 A. Estimates of Annualized Burden Hours

Type of Respondent	Regulatory Provision or Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Maritime conveyance operators	42 CFR 71.21(a) Radio report of illness of death from ships – Att H Maritime Conveyance Illness or Death Investigation Form/ Att I Cumulative Influenza/Influenza-Like Illness (ILI) Form/Radio report or transcribed email	2,000	1	2/60	67
Aircraft commander or operators	42 CFR 71.21 (b) Death/Illness reports from aircrafts	1,700	1	2/60	57
Maritime conveyance operators	Att J_42 CFR 71.21 (c ) (MIDRS) Gastrointestinal Illnesses reports (24 and 4 hours before arrival)	17,000	1	3/60	850
Maritime conveyance operators	42 CFR 71.21 (c) Recordkeeping - Medical logs	17,000	1	3/60	850
Isolated or Quarantined individuals	42 CFR 71.33 Report by persons in isolation or surveillance	11	1	3/60	1
Maritime conveyance	42 CFR 71.35 Report of	5	1	30/60	3

operators	death/illness during stay in port				
Importer	42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates	245,310	1	15/60	61,328
Importer	Att D_CDC Form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement	1,400	1	10/60	233
Importer	42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate	43,290	1	15/60	10,823
Importer	Att E 42 CFR 71.51(c)(2), (d) Application For Permission To Import A Dog Inadequately Against Rabies	1400	1	15/60	350
Importer	42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths	20	1	15/60	5
Importer/ Filer	Att K and Att L_42 CFR 71.51_CDC Requested Data on Regulated Imports: Domestic Dogs and Cats (PGA Message Set)	30,000	1	15/60	7,500
Importer	42 CFR 71.52(d) Turtle Importation Permits	5	1	30/60	3
Importers	42 CFR 71.55, 42 CFR 71.32 Dead Bodies - Death certificates	5	1	1	5
Importer	42 CFR 71.56 (a)(2) African Rodents - Request for	20	1	1	20

	exemption				
Importer	42 CFR 71.56(a)(iii) Appeal	2	1	1	2
Importer/ Filer	Att M_42 CFR 71.56 CDC Requested Data on Regulation Imports: Live African Rodents (PGA Message Set)	60	1	15/60	15
Filer/Importer	42 CFR 71.32 Statements or documentation of non-infectiousness	2000	1	5/60	167
Importer/ Filer	Att N 42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents; Products of all Family Viverridae (PGA Message Set)	2,000	1	15/60	500
Total					82,779

#### 12 B. Estimates of Annualized Cost

Respondents for this information collection include airline maritime conveyance operators, importers/filers, and the general public. Average wages for each category of respondent were calculated using occupation and wage statistics from the Bureau of Labor Statistics.

- For conveyance operators (air and maritime), an average of 53-2011 Airline Pilots, Copilots, and Flight Engineers and 53-5021 Captains, Mates, and Pilots of Water Vessels is used. This yields an average of \$50.60 per hour. (53-5021 Captains, Mates, and Pilots of Water Vessels: <http://www.bls.gov/oes/current/oes535021.htm>. 53-2011 Airline Pilots, Copilots, and Flight Engineers: <http://www.bls.gov/oes/current/oes532011.htm>)
- For the isolated or quarantined individuals, the general public occupational category is used. The hourly wage for this occupational category is \$22.71. (00-0000 All Occupations: [http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000))
- For importers and importers/filers, the general public occupational category is used as no BLS category was available for importers/filers or a similar occupation. The average wage is \$22.71 ( 00-0000 All Occupations: [http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000))



The additional cost associated with the new process for issuing dog importation permits, and the clarification and update of estimated burden for the rabies vaccination certificate, is \$1,641,183.

The reduction in cost associated with the removal of the PLF from this Information Collection Request is \$5,111,272 .

All other costs adjustments are associated with adjusting wages for the most current BLS data and reduction in estimated number of CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement issued to importers of dogs. The total respondent cost for this requested revision is \$1,930,867

Types of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Maritime conveyance operators	42 CFR 71.21(a) Radio report of illness or death from ships: Att H Maritime Conveyance Illness or Death Investigation Form/ Att I Cumulative Influenza/Influenza-Like Illness (ILI) Form/Radio report or transcribed email	67	\$50.60	\$3,390
Aircraft commander or operators	42 CFR 71.21 (b) Death/Illness reports from aircrafts	57	\$50.60	\$2,884
Maritime conveyance operators	Att J 42 CFR 71.21 (c ) (MIDRS) Gastrointestinal Illnesses reports 24 and 4 hours before arrival	850	\$50.60	\$43,010
Maritime conveyance operators	42 CFR 71.21 (c) Recordkeeping - Medical logs	850	\$50.60	\$43,010
Isolated or Quarantined individuals	42 CFR 71.33 Report by persons in isolation or surveillance	1	\$22.71	\$23
Maritime conveyance operators	42 CFR 71.35 Report of death/illness during stay in port	3	\$50.60	\$152
Importer	42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates	61,328	\$22.71	\$1,392,759
Importer	Att D CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog	233	\$22.71	\$5,291

Types of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	Confinement			
Importer	42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate	10823	\$22.71	\$245,790
Importer	Att E 42 CFR 71.51(c)(2), (d) Application For Permission To Import A Dog Unimmunized Against Rabies	350	\$22.71	\$7,949
Importer	42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths	5	\$22.71	\$114
Importer/ Filer	Att K and Att L_42 CFR 71.51_CDC Requested Data on Regulated Imports: Domestic Dogs and Cats (PGA Message Set)	7,500	\$22.71	\$170,325
Importer	42 CFR 71.52(d) Turtle Importation Permits	3	\$22.71	\$68
Importers	42 CFR 71.55, 42 CFR 71.32 Dead Bodies - Death certificates	5	\$22.71	\$114
Importer	42 CFR 71.56 (a)(2) African Rodents -Request for exemption	20	\$22.71	\$454
Importer	42 CFR 71.56(a)(iii) Appeal	2	22.71	\$45
Importer/ Filer	Att M_42 CFR 71.56 CDC Requested Data on Regulation Imports: Live African Rodents (PGA Message Set)	15	\$22.71	\$341
Importer/ Filer	42 CFR 71.32 Statements or documentation of non-infectiousness	167	\$22.71	\$3,793
Importer/ Filer	Att N 42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents; Products of all Family Viverridae (PGA Message Set)	500	\$22.71	\$11,355
<b>Total</b>				<b>\$1,930,867</b>

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

There are no other costs to respondents or record keepers. CDC does not include additional costs for vaccination or confinement, because it is anticipated the costs for these activities would be incurred routinely as a matter of pet ownership, either by the importer themselves or by the end owner of the dog, or the dogs may be exempt from these requirements as CDC's regulations. Foreign countries and many US states and local authorities maintain rabies vaccination requirements that are at least, or even more, stringent than CDC standards. For those dogs imported as cargo on a passenger air craft, these companies also have rabies vaccination requirements. It is unlikely that CDC rabies vaccination requirements are the only requirements encountered by the pet owner or importer.

Concerning confinement, an individual may choose to confine the animal in their house, as long as they are not in contact with other people or animals. We do not anticipate any additional cost for this process.

Examinations of pets is only required if the pet is ill on arrival or if it has died during transport. These exams are not routine. Depending on the time of arrival, the initial exam fee may be between \$100 and \$200. Rabies testing on a dog that dies may be between \$50 and \$100. The expected number of ill or dead dogs arriving into the United States for which CDC may require an examination is estimated at less than 30 per year.

### 14. Annualized Cost to the Government

CDC estimates the cost of reviewing hard copy information and PGA message sets or DIS entries on imports as a portion of annual time spent at work by individuals who specialize in CDC regulated imports. CDC uses this estimation method as not every import will come to the attention of CDC, only those which require review to determine if a public health risk exists. The personnel costs are as follows:

Staff GS Level	Average annual salary of staff reviewing data (Atlanta locality adjustment)	Percent of time spent on reviewing hard copies/CDC PGA Message Set Data	Total Cost
2 x GS-13	\$87,219	100%	\$174,438
1 x GS-9	\$50,578	50%	\$25,289
1 x GS-13	\$87,219	20%	\$17,444
1 x GS-14	\$103,065	20%	\$20,613
Total			\$237,784

For each report of illness in travelers covered by 42 CFR part 71, Quarantine staff collect and review the information to determine whether a public health response is necessary. Their actions are determined by the statutory and regulatory requirements for each report, and the time required to appropriately respond varies. The amount of time to respond depends on the specifics of the report, requiring action such as filing and/or data entry to conducting an investigation involving multiple staff.

The total staff hours is estimated by totaling the number of death or illness reports received by CDC and multiplying it by the average time it takes to receive and process the initial report. This is then multiplied by a GS12 level wage at the Atlanta locality.

	Time in hours required to review and collect initial incoming data	Average hourly wage of staff reviewing data (GS12 Atlanta locality adjustment)	Total Estimated Yearly Cost
Radio, hard copy, verbal reports	1827 reports x 84 minutes = 2558 hours	\$35.14	\$89,888

There are also system and personnel costs associated with the use, development, and maintenance of QARS, which is used for each of the information collections outlined in this information collection request. These costs include the IT costs and associated staffing costs.

These costs are as follows:

QARS System Costs	\$199,669
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	\$111,281
Total	\$310,950

The total estimated cost to the government for this ICR is \$638,622 per year.

## 15. Explanation for Program Changes or Adjustments

The changes proposed in this revision fall into two main categories associated with the importation of dogs, and the removal of the PLF from this Foreign Quarantine Regulations Information Collection:

1) The CDC and DGMQ is requesting approval for a set of program changes to the paperwork exchange and approval process for importing an unvaccinated or inadequately immunized dog. The current process is unnecessarily time consuming for the importer, CDC, and CBP and is not conducive to efficient exchange of information or the flow of goods into the United States. Below is a description of the current dog importation process and how it will change. The result of the program change is a net increase in burden hours, because the new application requires 5 minutes more per response than the current confinement agreement. The update to the dog importation process follows here:

Currently, CDC has adopted a “preapproval” process for persons seeking to import inadequately or unimmunized dogs into the United States. Importers are advised to contact CDC by electronic mail or postal mail to explain their need to import unvaccinated or inadequately immunized dogs and request permission from CDC to import these dogs under the terms of a dog confinement agreement that would be issued at the port of entry. CDC reviews these requests and responds to importers either granting or denying their requests based on the criteria published in the 2014 Federal Register Notice. Granted requests receive a signed letter from CDC to present to U.S. Customs and Border Protection (CBP) at the port of entry as proof that the importer may be issued a dog confinement agreement. CDC Form 75.37 NOTICE TO OWNERS AND

IMPORTERS OF DOGS: Requirement for Dog Confinement continues to be issued at the port of entry by CBP or CDC officials.

CDC is proposing to phase out the current, less structured pre-approval process and the routine use of the CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement and replace it with a new standardized Application For Permission To Import A Dog Unimmunized Against Rabies and Permit to Import a Dog Unimmunized against Rabies. At the end of the proposed transition, the process will require that the importer send an Application For Permission To Import A Dog Unimmunized Against Rabies to CDC. CDC will review the application and determine whether or not a permit is appropriate based on the same criteria outlined in the 2014 Federal Register Notice. If a permit is appropriate, CDC will send the signed permit to the importer who will be required to present the permit to CBP at the time of importation. CDC also anticipates that importers will be able to scan an official CDC permit into the DIS under ITDS.

Public burden attributed to the use of the proposed application and permit process is anticipated to increase by 5 minutes per response. CDC estimates that there will be approximately 1400 applications made to import unvaccinated or inadequately immunized dogs. This equals 117 additional hours above what would be required if the confinement letter were to be used for these 1400 importations.

CDC is expecting there to be a transition process between phase out of the routine use of the confinement letter to the new application and permit. Therefore, CDC is requesting to retain approval for the use of the confinement agreement for a potential 1400 importations. The anticipated burden for the use of the confinement agreement will remain at 10 minutes per response, for a total of 233 hours.

In the future, CDC may need to retain the confinement letter for some residual number of importations that do not notify CDC prior to arrival at the port of entry and who have a legitimate need for a confinement agreement.

2) CDC is also seeking to provide greater clarity in this revision around the documentation required to import a dog into the United States, and a more accurate assessment of the burden required to meet those requirements. Some of these changes are simple corrections to transcription errors that result in no additional burden, and others are based on enhanced assessments of the number of dogs coming into the United States. The changes are below:

First, CDC is requesting a correction to an accounting and transcription error in the burden tables in section A 12. Currently, the relevant row reads: 71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37). It should be: 71.51(c)(2) Dogs: Certification of Confinement, Vaccination (CDC form 75.37). This change results in no change to burden as it being removed from the Supporting Statement.

In addition to the change in this specific row in the table in A 12, the current statement of burden includes one information collection for both the confinement agreement and vaccine certification. To provide greater clarity on the anticipated burden posed by these

requirements, and a more accurate assessment of the number of potential respondents, CDC is requesting approval to remove the current information collection (IC) “71.51(c)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37)” and create 3 distinct information collections, each with its own account of burden in the tables in section A12:

- CDC will maintain the current CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement, with an adjustment of half of the original estimate for respondents and burden. This equals 1400 respondents and 233 burden hours, as described in the section above detailing how the importation process will change.
- CDC is adding “71.51(c)(2), (d) Application For Permission To Import A Dog Unimmunized Against Rabies”. This new form is being added to compliment modified guidance issued by CDC in 2014 concerning how eligibility for permits will be assessed under the regulations at 42 CFR 71.51. CDC estimates that there will be no more than 1400 applications sent to CDC per year under this new guidance, with an anticipated burden of 350 hours.
- CDC is including a separate IC pertaining to 71.51(c)(1), (d). The title for this IC is Valid Rabies Vaccination Certificate, which will include only the burden associated with rabies vaccination certificates. Based on estimates of the number of dogs that are imported into the United States<sup>1</sup>, CDC anticipates that there will be approximately 245,310 respondents to this information collection, with an estimated burden of 61,328 burden hours annually.

Second, CDC is also including an IC for 71.51(c)(i), (ii), and (iii) which provides exemption criteria for the importation of a dog without a rabies vaccination certificate. An importer may submit this information if they believe their dog(s) are exempt from the rabies vaccination requirement. This provision has been established in the regulation for several decades, but has not been previously submitted for approval through the Paperwork Reduction Act process, as it was overlooked as a separate IC.

- CDC estimates that this IC will apply to 15% of the 288,600 total dogs imported who are not-candidates for the new Permit to Import a Dog Unimmunized against Rabies. The estimated number of respondents to this IC is approximately 43,290, with an associated 10,823 burden hours

The number of respondents and burden associated with the change in the dog importation and confinement agreement process requested for this revision is 288,600, and the additional burden is 72,267 hours.

CDC is also transitioning the Passenger Locator Form to another Information Collection Request, Airline and Maritime Conveyance and Traveler Information Collection, that will accompany a Notice of Proposed Rulemaking on 42 Code of Federal Regulations parts

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<sup>1</sup> McQuiston, J. H., T. Wilson, S. Harris, R. M. Bacon, S. Shapiro, I. Trevino, J. Sinclair, G. Galland, and N. Marano, 2008: Importation of dogs into the United States: risks from rabies and other zoonotic diseases. *Zoonoses Public Health* 55, 421–426.

70 and 71. The reduction in the number of respondents and burden associated with the removal of the PLF is 2,700,800 respondents and 225,067 burden hours.

CDC is not proposing changes to any of the other information collections as part of this request.

- Air and maritime illness reporting under 42 CFR 71.21
  - o 71.21(a) Radio report of illness of death from ships. Maritime conveyance operators can report using any of the following:
    - Sections 1-3 of the Maritime Conveyance Illness and Death Investigation Form (Attachment H)
    - Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form Attachment (Attachment I)
    - Radio report or transcribed email (no form)
  - o 71.21(b)
    - Death/Illness reports from aircrafts (no form)
  - o 71.21(c)
    - Gastrointestinal Illnesses reports (24 and 4 hours before arrival) (MIDRS screenshot) (Attachment J)
    - 71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)
- 42 CFR 71.33 Report by persons in isolation or surveillance (no form)
- 42 CFR 71.35 Report of death/illness during stay in port (no form)
- 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)
- 42 CFR 71.52(d) Application for permits for importation of turtles (no form)
- Any ITDS Partner Government Agency (PGA) Message Sets approved in OMB Control No 0920-0134
  - o CDC Requested data on Regulated Imports: Domestic Dogs and Cats (Attachments K, L)
  - o CDC Requested Data on Regulated Imports: Live African Rodents (Attachment M)
  - o CDC Requested Data on Regulated Imports: Products of African Rodents, Products of all Family Viverridae (Attachment N)
- Statements or documentation of non-infectiousness currently authorized under 42 CFR 71.32 Persons, carriers, and things (no form)
- 42 CFR 71.55, 42 CFR 71.32 Dead Bodies – Death certificates (no form)
- 42 CFR 71.56 (a)(2) Record keeping - Request for exemption: African rodents
- 71.56(a)(iii) Appeal (no form)

## **16. Plans for Tabulation and Publication and Project Time Schedule**

Data are not collected for statistical purposes, but only to meet the regulatory mandate as implemented in the foreign quarantine regulations found at 42 CFR 71.

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

The display of the expiration data is not inappropriate. CDC requests no exemption.

## **18. Exceptions for Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.



## **List of Attachments**

Attachment A1 - Section 361 Public Health Service Act (42 USC 264)

Attachment A2 - 42 Code of Federal Regulations part 71

Attachment A3 - SAFE Port Act of 2006

Attachment A4 - 6 Code of Federal Regulations part 29.8(b)

Attachment A5 - 49 Code of Federal Regulations part 1520.11(b)

Attachment B - 60 Day Federal Register Notice

Attachment C – Federal Register Notice: Issuance and Enforcement Guidance for Dog Confinement Agreements

Attachment D - CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement

Attachment E - 42 CFR (71.51(c)(2), (d))Application For Permission To Import A Dog Unimmunized Against Rabies

Attachment F - Permit to Conditionally Import a Dog Inadequately Immunized against Rabies - Single Entry

Attachment G – Guidance Document for Completing the Application for Permission to Import a Dog Inadequately Immunized Against Rabies

Attachment H – 42 CFR 71.21(a) Maritime Conveyance Illness and Death Investigation Form (Sections 1-3)

Attachment I - 42 CFR 71.21(a) Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form

Attachment J - 71.21 (c ) (MIDRS) Gastrointestinal Illnesses reports 24 and 4 hours before arrival

Attachment K - 42 CFR 71.51 CDC Requested Data on Regulated Imports: Domestic Dogs (PGA Message Set)

Attachment L - 42 CFR 71.51\_CDC Requested Data on Regulated Imports: Domestic Cats (PGA Message Set)

Attachment M - 42 CFR 71.56 CDC Requested Data on Regulation Imports: Live African Rodents (PGA Message Set)

Attachment N - 42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents; Products of all Family Viverridae (PGA Message Set)

Attachment O - IRB Non-Research Determination

Attachment P – MOU HHS and DHS