Foreign Quarantine Regulations (42 CFR 71)
(OMB Control No. 0920-0134)

Supporting Statement A
Request for Revision of an Approved Information Collection

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Foreign Quarantine Regulations (42 CFR 71)
Statement in Support of Foreign Quarantine Regulations (42 CFR Part 71)
(OMB Control No. 0920-0134)

- The goal of this information collection is to facilitate a CDC public health mission as provided under the Public Health Service Act and Code of Federal Regulations. As part of this revision, CDC is making several administrative changes to make more transparent and to clarify CDC processes and responsibilities concerning illness reporting, and is removing burden associated with Partner Government Agency Message Sets under the International Trade Data System and Automated Commercial Environment. CDC is also updating certain information collection requirements and burden estimates pertaining to the importation of dogs.
- CDC uses this information to meet its statutory and regulatory responsibilities outlined in 42 CFR part 71, which are to prevent the introduction of communicable disease into the United States and its territories.
- No statistical methods are used. The information collection is intended solely 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 enter the United States, conveyance operators arriving to the United States, individuals who have been identified as ill during a flight or maritime voyage, and individuals seeking to import items defined under 42 CFR 71 subpart F Importations.
- Data is analyzed to ensure compliance with CDC regulations and to determine if program enhancements or refocus is needed to meet the needs of public health in the United States.

This is a request for a revision of a currently approved information collection request (ICR) that expires May 30, 2019. CDC is requesting a three-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 adjustments.

The changes are as follows, with detailed explanation in section A15:

1. Combining information collections included under 0920-0821 Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing with 0920-0134 Foreign Quarantine Regulations
    a. The information collections in 0920-0821 often occur as a direct result of the illness or death reports mandated of the air and maritime conveyances under the regulations at 42 CFR part 71 and approved under 0920-0134, and enable CDC to meet the same mission. Including the Airline, Maritime and Land Border Crossing Illness or Death Investigations forms within 0920-0134 will provide a clearer picture of how the illness report and investigation processes are related, and provide one control number wherein the public can review the estimated burden. OMB Control No. 0920-0821 would be discontinued following approval of this ICR.
2. CDC is disaggregating the information collection *42 CFR 71.21(a) report of illness or death from ships* so the influenza like illness (ILI) report, which is

voluntary, is separate from the routinely required report of ill person or death under section 71.21.

3. Removal of information collections pertaining to the Partner Government Agency (PGA) Message Sets
4. Removal of acute gastroenteritis reports from ships to the Maritime Illness and Death Reporting System, and removal of medical logs information collection

The adjustments are as follows, with a detailed explanation in section A15:

1. Revised estimates of the number of maritime reports of illness or death
2. Revised estimates of burden and respondents related to information requirements for the importation of dogs into the United States
3. Revised estimates under 42 CFR 71.55, 42 CFR 71.32 Dead Bodies - Death certificates
4. Revised estimate of the number of requests for exemptions for importation of African rodents

The total estimated burden under this revision is 268,493 burden hours (an increase of 185,714 hours) and 1,080,752 respondents.

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 information collection "Foreign Quarantine Regulations**"** that expires May 30, 2019. CDC is requesting a three-year approval. CDC is making several administrative changes to enhance transparency and to clarify CDC processes and agency responsibilities concerning illness reporting, and is removing burden associated with Partner Government Agency Message Sets under the International Trade Data System and Automated Commercial Environment. CDC does not anticipate using this particular functionality for its regulated imports. CDC is also updating certain information collection requirements pertaining to the importation of dogs as a result of a policy change concerning canine rabies risk assessments of countries of origin.

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. Statute and the existing regulations governing foreign 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 and within the United

States with a minimum of recordkeeping and reporting procedures, as well as a minimum of interference with trade and travel.

U.S. Quarantine Stations are located at 20 ports of entry and land-border crossings where international travelers arrive. The jurisdiction of each station includes air, maritime, and/or land-border ports of entry. Quarantine Station staff work in partnership with international, federal, state, and local agencies and organizations to fulfill their mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations. This work is performed to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or from one State or possession to another State or possession. When an illness suggestive of a communicable disease is reported by conveyance operators or port partners (e.g. Customs and Border Protection), Quarantine Officers respond to carry out an onsite public health assessment and collect data from the individual. This response may occur jointly with port partners. The collection of comprehensive, pertinent public health information during these responses enables Quarantine Officers to make an accurate public health assessment and identify appropriate next steps. For this reason, quarantine station staff need to systematically interview ill travelers and collect relevant health and epidemiologic information.

When Quarantine Officers are present at the port of entry, they may often respond in person to conduct assessment of an ill traveler. However, there are many instances in which a Quarantine Officer may not be able to meet a conveyance or border crosser in person, including (but not limited to) the following: the conveyance arrives at a port of entry that does not have a Quarantine Station on site; a maritime vessel is still out at sea when the report comes in; Quarantine Officers are already responding to another illness report; or the illness may be reported after hours and Quarantine Officers cannot arrive in time to meet the conveyance or border crosser without causing substantial delays to travel. If Quarantine Officers are unable to respond in-person, they provide phone consultation to port partners (e.g., Emergency Medical Services (EMS), DHS/CBP, and maritime partners such as ship medical personnel) on the scene, to determine the public health importance of the illness. In both circumstances, an interview of the ill person(s) is required to conduct the public health assessment, whether in-person, by phone, or through a trained responder (in consultation with the Quarantine Officer).

Data collected by DGMQ and the Quarantine staff during the initial report of illness or death, and during the follow-up using the illness or death response forms, is entered into the Quarantine Activity Reporting System (QARS). QARS is a secure internet database implemented in June 2005 to document and track the illnesses and deaths reported to Quarantine Stations that occurred on conveyances entering the United States and at land border crossings.

There have been no changes to the content of the currently approved Air Travel, Maritime Conveyance, or Land Travel Illness or Death Investigation forms (Attachments C, D, and E respectively) in the transition from OMB control number 0920-0821 to this information collection request.

On January 31, 2019 CDC published a Federal Register Notice informing the public about a policy change with regard to the definition of "rabies free" in the context of importing a dog into the United States. The revised guidance covering requirements for an application for a permit if an importer does not present the canine rabies certificate are described under 42 CFR 71.51 (available here: https://www.federalregister.gov/documents/2019/01/31/2019-00506/guidance-regarding-agency-interpretation-of-rabies-free-as-it-relates-to-the-importation-of-dogs).

Since 2007, federal importation regulations have been successful in eliminating the canine rabies virus variant (CRVV) in the United States, even though other rabies viruses still circulate among some wildlife species. The new policy focuses on the presence or absence of CRVV in the country the dog is coming from and the risk of reintroduction of CRVV into the United States. Requiring vaccination of dogs from countries with high risk of CRVV prevents CRVV from entering and spreading in the United States. In the Federal Register notice, CDC defines "high risk" to mean:

- High-risk means the country is at high risk for CRVV transmission as demonstrated by the presence and geographic distribution of the virus and by low quality of or low confidence in the country's surveillance systems and its dog vaccination programs.

CDC maintains a website that provides a list of these countries here: https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/rabies-vaccine.html. CDC routinely updates and creates new web content as needed to provide the public with relevant material concerning the importation of dogs as new information becomes available.

Going forward, CDC will only issue unimmunized dog permits for dogs imported for documented research purposes or veterinary treatment not available in the country of origin. Dogs from CRVV-free or low risk countries would not be required to present a rabies certificate. CDC does not anticipate a shifting of burden to state and local authorities because state and local jurisdictions already set rabies vaccination requirements regardless of the CDC requirement, and often they are more strict than the federal limits. Further, several variants of rabies circulate in the United States, many that don't in other countries. Requirements for vaccination once inside the US is more appropriate than requiring vaccination in countries that are rabies free. Finally, it is often the case that countries that have eliminated CRVV or are completely rabies free do not have access to the vaccine, as it is no longer required.

The burden and respondent estimates provided in section A12 reflect this potential change.

2. Purpose and Use of Information Collection

The reporting, documentation and recordkeeping requirements contained in 42 CFR 71 regulations, and the air, maritime, and land border crossing illness or death reporting forms, are used by CDC to carry out quarantine and public health responsibilities as required by regulation and have been part of current practice for decades. 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 enters the United States in ill travelers or via contaminated or infected animals or other cargo.

The initial reports of illness outlined in 42 CFR 71.21(a) and (b) simply require notification to CDC that an individual has died during travel to the United States or that an individual has met the definition of "ill person" while en route to the United States. This definition is as follows:

Ill person means an individual:
(i) Who if onboard an aircraft:

> **(A)** Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or
> **(B)** Has a fever that has persisted for more than 48 hours; or
> **(C)** Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the Federal Register.

(ii) Who if onboard a vessel:

> **(A)** Has a fever (a measured temperature of 100.4 °F [38 °C] or greater; or feels warm to the touch; or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing or suspected or confirmed pneumonia, persistent cough or cough with bloody sputum, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent vomiting (other than sea sickness), headache with stiff neck; or
> **(B)** Has a fever that has persisted for more than 48 hours; or
> **(C)** Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater); or
> **(D)** Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the Federal Register.

Additionally, during the H1N1 influenza pandemic of 2009, CDC implemented a voluntary information collection to capture influenza and influenza-like illnesses that occur on cruise ships, the Cumulative Influenza/Influenza-Like Illness (ILI) form (Attachment F). The data collected voluntarily from this form is used by CDC for a number of flu and ILI surveillance and response activities.

For routine response to illnesses associated with travel and reported to CDC, the purpose of the Air, Maritime, and Land Illness or Death Investigation forms is to systematically collect information, thereby enabling Quarantine Station staff to assess, detect, and respond rapidly, efficiently, and accurately to communicable disease threats of potential

public health importance at ports of entry. The information collected is also necessary for public health surveillance and follow-up purposes. The forms collect the following categories of information voluntarily: identifying and contact information, demographics, mode of transportation, pertinent clinical and medical history, epidemiologic history, other relevant facts (e.g., travel history, traveling companions, etc.), and information specific to the traveler's conveyance or mode of travel. This information is used by Quarantine Station staff to identify specific signs and symptoms common to the nine quarantinable diseases (Pandemic influenza; severe acute respiratory syndromes; Cholera; Plague; Diphtheria; Infectious Tuberculosis; Smallpox; Yellow fever; and Viral Hemorrhagic Fevers), as well as other communicable diseases or conditions of public health concern which may be transmissible in a conveyance setting.

Information collected on these forms are used by Quarantine Station staff to make decisions about a traveler's suspected illness as well as its communicability. This information enables Quarantine Station personnel to assist CBP in the public health management of ill persons at U.S. ports and plan the appropriate response. Quarantine staff enter this data into QARS for analysis and retention in the event public health follow up is needed.

CDC also has authority under 42 CFR part 71 subpart F to regulate the importation of certain animals that may pose a threat to human health. CDC currently has approval under OMB Control Number 0920-0134 to collect information pertaining to the following animals: dogs, cats, turtles, terrapins, tortoises, and African rodents. In addition to these animals, CDC has discretion under 42 CFR 71.32(b) to implement measures to prevent the introduction, transmission, or spread of communicable diseases whenever the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease. Under this authority, CDC requires that certain animal products be accompanied by a statement or documentation stating that the product has been rendered non-infectious.

The burdens imposed on respondents 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. CDC makes every attempt not to have duplicative information requirements. For example, the rabies vaccination certificate requirement is the same for both USDA and CDC, and is available in the Document Imagine System within ITDS. This is similar to requirements for nonhuman primate importation under 42 CFR 71.53 *Requirements for importers of nonhuman primates*.

3. Use of Improved Information Technology and Burden Reduction

Reports of illness or death occurring on an aircraft are made to CDC electronically, per CDC and International Civil Aviation Organization guidelines (*ICAO document 4444, Procedures for Air Navigation Services – Air Traffic Management, Ch.16, 16.6*). Reports can be made via Air Traffic Control and the Domestic Events Network to the CDC Emergency Operations Center (EOC), or via the airline's designated point of contact to the CDC Quarantine Station with jurisdiction for the arrival airport or CDC's EOC.

Reports of illness or death from maritime conveyances are made electronically to MaritimeAdmin@cdc.gov.

With respect to animal, animal product, and other cargo information collections under 42 CFR 71 subpart F, CDC makes as much use of electronic data submission as possible to reduce burden. Permits to import animals and items restricted under 42 CFR 71 subpart F, including the Application For a Permit To Import A Dog Unimmunized Against Rabies (Attachment G), are reviewed prior to attempted importation and are generally submitted to CDC electronically. Rabies vaccination certificates, the Permit To Import A Dog Unimmunized Against Rabies (Attachment H), and current CDC form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement (hereon CDC Form 75.37)(Attachment I) are generally reviewed by CBP or CDC staff in hard copy at the port of entry. However, electronic submission of the rabies vaccination certificates and Permits to Import a Dog Unimmunized against Rabies - Single Entry is available using the Document Imaging System (DIS) associated with International Trade Data System/Automated Commercial Environment (ITDS/ACE) and is accepted by CDC. Documentation through the DIS for dog imports is a less frequent method of submission, but is more common in the event that an importer does submit documentation under a commercial shipment. CBP may require formal entry criteria such as de Maximus values or those manifested as cargo and filing an informal entry, and these would be available via the DIS. CDC simply wants to make this option available, if needed by importers, to meet CBP requirements. CDC reserves the right to inspect hard copies to ensure validation of the certificate.

Submission of documentation stating that items have been rendered non-infectious may be submitted electronically via email, via the DIS at importation, or hard copy and the permits themselves can be submitted via the DIS or hard copy. Similarly, appeals for denial of permits may be made electronically or via hard copy mail to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is the only public health authority with regulatory responsibility for collecting information on the occurrence of death or illness onboard air and maritime conveyances traveling to the United States. There is no duplication of collection in that regard.

CDC has regulatory authority to collect information on certain regulated animals and products and must have this information to perform its public health responsibilities. The information required by CDC differs somewhat in that the information collected is only pertinent to human health, not animal health. When there is overlap, in the case of USDA, CDC works with USDA APHIS to ensure that requirements for the valid rabies vaccination certificate are similar so the one certificate meets the needs of both agencies. Similarly, with the use of the Document Imaging System, information submitted by the importer/filer is available for use by other agencies if needed for compliance with their rules.

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 are 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 it legislative mandate and regulatory responsibilities, and could therefore endanger the public's health.

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

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.

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

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 September 7, 2018 (Vol. 83, No. 174, PP 45449-45451). (Attachment B). CDC received no comments from the public.

B. The requirements for notifying CDC of illness or death aboard air and maritime conveyances have been in place for decades, and in 2017 the definition of "ill person" for the purposes of reporting was updated as part of notice and comment rulemaking. CDC formulated the definition of ill person specifically to assist in making a public health determination if further action is necessary, and endeavored to align the signs and symptoms with the ICAO guidelines for reporting. Similarly, the illness or death investigation forms have been in use for many years and only include that information needed to determine if further public health action is needed. CDC routinely communicates with CBP and local EMS for traveler evaluations referencing these forms.

The regulatory requirements for the importation of dogs have been in place for several decades, and while estimates of the number of dogs coming in have increased, the burden on individual importers has declined as requirements for rabies vaccination certificates apply to fewer dogs. 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. This MOU also states that CDC will provide training to DHS on CDC's regulations.

CDC anticipates that change under consideration for the importation of dogs would result in less work for CBP, as the number of dogs requiring review of CDC-required rabies related documentation will decline. CDC has also previewed this change with state public health veterinaries and other interested groups to ensure that the information requirements related to rabies are clearly understood.

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.

There is no guarantee of confidentiality provided to 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 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. No other system of records is being created as part of this request. A Privacy Impact Assessment of this system is attached (Attachment J)

Personal identifiers (name, address, telephone number, cell number, etc.) will be collected and maintained under the Privacy Act system of records listed above from importers 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.

Concerning the current CDC Form 75.37 and CDC Application For a Permit To Import A Dog Inadequately Immunized Against Rabies – Single Entry, 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 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 Application For a Permit To Import A Dog Inadequately Immunized 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 dog 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.

Import-related information collected from ITDS/ACE in the form of DIS scans and illness and death reports from maritime and air conveyances are 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. CDC Form 75.37, will be retained until the event prompting the collection of data has concluded in accordance with DGMQ's records retention schedule.

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.

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.

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.

Respondents to this data collection are generally aware that the information collected under this control number is required under regulation, and CDC publishes content on its website and in the Federal Register concerning these collections. Recent rulemaking in 2017 also included updates to the reporting requirements for ill persons and deaths that occur on conveyances traveling to the United States. For the information collected using the illness or death reporting forms, if an individual decides not to answer, the quarantine officer or partner cannot force them to answer. Only when a quarantine officer has a reasonable belief that a quarantinable communicable disease is present may an individual be detained to protect public health.

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 K).

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.

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 estimates for each information collection are as follows:

- 42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form sections 1-4
  - 500 respondents and five minutes per response for 42 total burden hours
- 42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form section 5
  - 100 respondents and 2 minutes per response for 3 burden hours
- Cumulative Influenza/Influenza-Like Illness (ILI) form
  - 3000 respondents and 2 minutes per response for 100 burden hours
- 42 CFR 71.21 (b) Death/Illness reports from aircrafts
  - 1700 respondents and 2 minutes per response for 57 burden hours
- Airline Travel Illness or Death Investigation Form
  - 1700 respondents and 5 minutes per response for 142 burden hours
- Land Travel Illness or Death Investigation Form
  - 100 respondents and 5 minutes per response for eight burden hours
- 42 CFR 71.33 Report by persons in isolation or surveillance
  - Eleven respondents and three minutes per response for one burden hour
- 42 CFR 71.35 Report of death/illness during stay in port
  - Five respondents and 30 minutes each for three burden hours
- 42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates
  - 113,500 respondents and 15 minutes per response for 28,375 burden hours
- CDC Form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement
  - 14 respondents and ten minutes per response for two burden hours
- 42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate
  - 958,000 respondents and 15 minutes per response for 239,500 burden hours
- 42 CFR 71.51(c)(2), (d) Application For Permission To Import A Dog Inadequately Against Rabies
  - 50 respondents and 45 minutes per response for 38 burden hours
- 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths
  - 20 respondents and 15 minutes per response for five burden hours
- 42 CFR 71.52(d) Turtle Importation Permits
  - 5 respondents and 30 minutes each for three burden hours

- 42 CFR 71.55 Dead Bodies, 42 CFR 71.32 - Death certificates
  - 20 respondents and one hour per response for 20 burden hours
- 42 CFR 71.56 (a)(2) African Rodents -Request for exemption
  - 25 respondents and one hour per response for 25 burden hours
- 42 CFR 71.56(a)(iii) Appeal
  - Two respondents and one hour per response for two burden hours
- 42 CFR 71.32 Statements or documentation of non-infectiousness
  - 2000 respondents and five minutes per response for 167 burden hours

The total burden requested under this revision is 268,493 hours. There is no burden to respondents other than the time taken to complete the reports to CDC and to maintain briefly recordkeeping of illness aboard maritime conveyances and records of sickness or death in imported cats and dogs, as outlined in the table below.

The forms migrating from 0920-0821 into this ICR include:

1. Airline Travel Illness or Death Investigation
2. Maritime Conveyance Illness or Death Investigation Form (sections 4-5)
3. Land Travel Illness or Death Investigation Form

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 Vessel Operator	42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form sections 1-4 (Attachment D)	500	1	5/60	42
Maritime Vessel Operator	42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form section 5 (Attachment D)	100	1	2/60	3
Maritime Vessel Operator	Cumulative Influenza/Influenza-Like Illness (ILI) (Attachment F)	3000	1	2/60	100

Pilot in command	42 CFR 71.21 (b) Death/Illness reports from aircrafts (No form)	1,700	1	2/60	57
Traveler	Airline Travel Illness or Death Investigation Form (Attachment C)	1,700	1	5/60	142
Traveler	Land Travel Illness or Death Investigation Form (Attachment E)	100	1	5/60	8
Isolated or Quarantined individuals	42 CFR 71.33 Report by persons in isolation or surveillance (No Form)	11	1	3/60	1
Maritime Vessel Operator	42 CFR 71.35 Report of death/illness during stay in port (No Form)	5	1	30/60	3
Importer	42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates (No Form)	113,500	1	15/60	28,375
Importer	CDC form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement (Attachment I)	14	1	10/60	2
Importer	42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate (No Form)	958,000	1	15/60	239,500
Importer	42 CFR 71.51(c)(2), (d) Application For a Permit To Import A Dog Unimmunized Against Rabies	50	1	45/60	38

	(Attachment G)				
Importer	42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (No Form)	20	1	15/60	5
Importer	42 CFR 71.52(d) Turtle Importation Permits (No Form)	5	1	30/60	3
Importers	42 CFR 71.55, 42 CFR 71.32 Dead Bodies - Death certificates (No Form)	20	1	1	20
Importer	42 CFR 71.56 (a)(2) African Rodents - Request for exemption (No Form)	25	1	1	25
Importer	42 CFR 71.56(a)(iii) Appeal (No Form)	2	1	1	2
Importer	42 CFR 71.32 Statements or documentation of non-infectiousness (No Form)	2000	1	5/60	167
Total					268,493

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 Maritime Vessel Operators 53-5021 Captains, Mates, and Pilots of Water Vessels is used. This yields an average of $38.93 per hour. (53-5021 Captains, Mates, and Pilots of Water Vessels: http://www.bls.gov/oes/current/oes535021.htm.)
- For pilots in command, 53-2011 Airline Pilots, Copilots, and Flight Engineers (http://www.bls.gov/oes/current/oes532011.htm) was used, with an average hourly wage of $77.54
- For the isolated or quarantined individuals, the general public occupational category is used. The hourly wage for this occupational category is $24.34. (00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)
- For importers, the general public occupational category is used as no BLS category was available for importers/filers or a similar occupation. The average wage is $24.34 (00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)

Types of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Maritime Vessel Operator	42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form sections 1-4 (Attachment D)	42	$38.93	$1,635.06
Maritime Vessel Operator	42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form section 5 (Attachment D)	3	$38.93	$116.79
Maritime Vessel Operator	Cumulative Influenza/Influenza-Like Illness (ILI) (Attachment F)	100	$38.93	$3,893.00
Pilot in Command	42 CFR 71.21 (b) Death/Illness reports from aircrafts (No form)	57	$77.54	$4,419.78
Traveler	Airline Travel Illness or Death Investigation Form (Attachment C)	142	$24.34	$3,456.28
Traveler	Land Travel Illness or Death Investigation Form (Attachment E)	8	$24.34	$194.72
Isolated or Quarantined individuals	42 CFR 71.33 Report by persons in isolation or surveillance (No Form)	1	$24.34	$24.34
Maritime Vessel Operator	42 CFR 71.35 Report of death/illness during stay in port (No Form)	3	$38.93	$116.79
Importer	42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates (No Form)	28,375	$24.34	$690,647.50
Importer	CDC form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement (Attachment I)	2	$24.34	$48.68
Importer	42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate (No Form)	239,500	$24.34	$5,829,430
Importer	42 CFR 71.51(c)(2), (d) Application For a Permit To Import A Dog Unimmunized	38	$24.34	$924.92

Types of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	Against Rabies (Attachment G)			
Importer	42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths (No Form)	5	$24.34	$121.70
Importer	42 CFR 71.52(d) Turtle Importation Permits (No Form)	3	$24.34	$73.02
Importers	42 CFR 71.55, 42 CFR 71.32 Dead Bodies - Death certificates (No Form)	20	$24.34	$486.80
Importer	42 CFR 71.56 (a)(2) African Rodents -Request for exemption (No Form)	25	$24.34	$608.50
Importer	42 CFR 71.56(a)(iii) Appeal (No Form)	2	$24.34	$48.68
Importer/ Filer	42 CFR 71.32 Statements or documentation of non-infectiousness (No Form)	167	$24.34	$4,064.78
Total				**$6,540,311.34**

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 of dogs, 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

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 time 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 90 minutes = 2558 hours	$35.14	$89,888

CDC estimates the cost of reviewing electronic applications or requests for permits, hard copy applications or requests for permits, DIS entries on imports as a portion of annual time spent at work by individuals who specialize in CDC regulated imports, both at headquarters and at the quarantine stations. 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:

HQ staff:

Staff GS Level	Average annual salary of staff reviewing data (Atlanta locality adjustment)	Percent of time spent on reviewing information submitted for imports	Total Cost
2.5 x GS-13	$229,078	100%	$229,078
1 x GS-14	$108, 281	20%	$21,656
Total			$250,734

At the quarantine stations, the costs for reviewing the import- related information is calculated by estimating the staff time needed per review and multiplying that by the wage of the individual performing the review. Only a small portion of the overall number of imports actually come to the attention of CDC, generally referred by DHS/CBP. Only those imports with problems or missing information require staff time to review. The following table describes the estimates field staff time spent on inspection services for items under Subpart F. Given the significant variability among station activities with regard to inspection, an average is given by staff time.

Field staff:

# of Staff	GS level (based on	% time	Total

	ATL adjustment)		
72 (4 per staffed station)	11 step 5 ($72,863)	20%	$1,049,227

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	$185,000
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	$116,911
Total	$301,911

The total estimated cost to the government for this ICR is $1,601,872 per year.

15. Explanation for Program Changes or Adjustments

The changes are as follows:

1. Combining information collections included under 0920-0821 Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing with 0920-0134 Foreign Quarantine Regulations
    a. The information collections in 0920-0821 often occur as a direct result of the illness or death reports mandated of the air and maritime conveyances under the regulations at 42 CFR part 71 and approved under 0920-0134, and enable CDC to meet the same mission. Including the Airline, Maritime and Land/Border Crossing Illness or Death Investigations forms within 0920-0134 will provide a clearer picture of how the illness report and investigation processes are related, and provide one control number wherein the public can review the estimated burden.
    b. The additional burden associated with inclusion of two of these three forms is as follows:
        i. Airline Illness or Death Investigations form: 1,700 respondents and 142 burden hours
        ii. Land/Border Crossing Illness or Death Investigations form: 100 respondents and 8 burden hours
        iii. Maritime is discussed in #2 below
    c. CDC will file an 83-D discontinuation of 0920-0821 if OMB approves this proposal.
2. CDC reorganizing how the illness and death reports from maritime vessels are accounted for in this information collection.
    a. CDC is disaggregating the information collection *42 CFR 71.21(a) report of illness or death from ships* so that the influenza like illness (ILI) report, which is voluntary, is separate from the required report of ill person or death under section 71.21.

b. CDC is also adding an information collection and burden from the Maritime Illness or Death Investigation Form formerly in OMB Control No 0920-0821 in the group of information collections
c. The burden from this reorganization is as follows:
    i. 42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form sections 1-4: 500 respondents and 42 burden hours
    ii. 42 CFR 71.21(a) report of illness or death from ships – Maritime Conveyance Illness or Death Investigation Form section 5: 100 respondents and three burden hours
    iii. Cumulative Influenza/Influenza-like Illness (ILI): 3000 respondents and 100 burden hours
    iv. The total additional burden associated with this change in maritime information collection is 78 hours and 1600 additional respondents

3. Removal of information collections pertaining to the Partner Government Agency (PGA) Message Sets
    a. CDC is not currently planning to collect information via the PGA message sets for any of the imports defined in 42 CFR part 71 subpart F Importations.
    b. The reduction in burden associated with this removal is 8,015 burden hours and 32,060 respondents.
4. Removal of acute gastroenteritis reports from ships to the Maritime Illness and Death Reporting System, and removal of medical logs information collection
    a. CDC's Vessel Sanitation Program is creating a separate information collection request for the reporting requirements under 42 CFR 71.21(c), currently titled 42 CFR 71.21 (c) (MIDRS) Gastrointestinal Illnesses reports (24 and 4 hours before arrival) and 42 CFR 71.21 (c) Recordkeeping -Medical logs.
    b. Removing these information collections from 0920-0134 will result in a decrease of 1,700 burden hours and 34,000 respondents.

The adjustments are as follows:

1. Revised estimates of burden and respondents related to importation of dogs into the United States
    a. CDC recently published a Federal Register Notice announcing a change in policy guidance affecting information collection requirements around canine rabies risk and country of origin.
    b. CDC is also providing an updated estimate of the number of dogs entering the United States that are affected by CDC's information collection requirements
        i. Under 42 CFR 71.51(c)(1), (d) – Valid Rabies Vaccination Certificates, CDC estimates that 113,500 respondents will need to provide a rabies vaccination certificate with an associated 28,375 burden hours, versus the previous estimate of 245,310 and 61,328 burden hours; a decrease of 131,810 respondents and 32,953 burden hours.

ii. Under CDC Form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement, CDC estimates that 14 individuals will need to complete this form with 2 hours of burden, versus the previous estimate of 1400 respondents and 233 burden hours; a decrease of 1,386 respondents and 231 burden hours. This is due to the large decline in dogs that will require a rabies vaccination certificate for entry.

iii. Under 42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate, CDC is increasing the number of importers with dogs that will meet this criteria. CDC estimates 958,000 respondents and 239,500 burden hours, versus a previous estimate of 43,290 respondents and 10,823 burden hours

iv. Under 42 CFR 71.51(c)(2), (d) Application For Permission To Import A Dog Inadequately Immunized Against Rabies CDC is increasing the amount of time estimated to complete the application from 15 minutes to 45 minutes, and is providing an updated estimate of applications. CDC estimates that 50 respondents will file an application with an associated burden of 38 hours, versus a previous estimate of 1400 respondents and 350 hours. This results in a decrease of 1350 respondents and 312 burden hours.

c. These adjustments result in an increase of 195,000 burden hours and 780,164 respondents

2. Revised estimates under 42 CFR 71.55, 42 CFR 71.32 Dead Bodies - Death certificates
    a. An increase of 15 respondents and 15 burden hours
3. Revised estimate of the number of requests for exemptions for importation of African rodents
    a. CDC is increasing the number of exemptions received from 20 to 25. This results in five additional hours of respondent burden.

The net result of these changes and adjustments requested for this revision is an additional 185,714 burden hours, with 268,493 total burden hours requested.

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 B - 60 Day Federal Register Notice

Attachment C – Air Travel Illness or Death Investigation Form

Attachment D – Maritime Conveyance Illness or Death Investigation Form

Attachment E – Land Travel Illness or Death Investigation Form

Attachment F - Maritime Conveyance Cumulative ILI Form

Attachment G - Application For a Permit To Import A Dog Inadequately Immunized Against Rabies

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

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

Attachment J - Privacy Impact Assessment

Attachment K - IRB Non-Research Determination