

Foreign Quarantine Regulations (42 CFR 71)
(OMB Control No. 0920-0134)
Supporting Statement A
Request for Revision of Currently Approved Data Collection
June 6, 2012

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List of Attachments

1. **Section 361 of the Public Health Service Act (42 U.S.C. 264)**
2. **42 CFR 70 and 71**
3. **60 day Federal Register Notice**
4. **Locator Form used in an outbreak of public health significance; and
Locator Form used for reporting of an ill passenger(s) (identical form)**
5. **Reportable Medical Conditions**
- 6a. **71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival
(Maritime Illness and Death Reporting System screenshot)**
- 6b. **71.21(a) Radio Report of death/illness - illness reports from ships (Maritime
Illness and Death Reporting System screenshot)**
7. **CDC form 75.37 NOTICE TO OWNERS AND IMPORTERS OF DOGS:
Requirement for Dog Confinement**
8. **CDC form 75.10A Application for Registration as an Importer of Nonhuman
Primates.**

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

This is a request for a revision of a currently approved data collection that expires June 30, 2012. CDC is requesting a three year approval to collect data. CDC is requesting approval for a set of adjustments and program changes to the previously approved burden total for this information collection. These requested adjustments and program changes are the result of revised estimates and improvements in program administration that increased the net estimated number of respondents and burden hours (see Section 12 A) in this information collection. The total number of additional hours requested for this information collection total 1569 hours. The adjustments and program changes are as follows:

Adjustments

Form Name: 71.21 Radio report of death or illness

- In 2009 CDC requested 317 burden hours from an estimated 9500 respondents under Form Name 71.21 Radio report of death or illness. For 2012, CDC has decided to break out each provision within 42 Code of Federal Regulations Part 71.21. The result is a burden table (Section 12 A) that includes those individual reporting requirements as described in 71.21 (a)(Attachment 6b), (b) and (c) (Attachment 6a).
- Revised estimates of the number of air and sea reports of illness include the effects of program improvements in collection and increased accuracy in estimating the number of reports of illnesses. These factors have resulted in a requested increase of 1507 burden hours and 28200 additional respondents.

Form Name 71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37)(Attachment 7)

- CDC is requesting an additional 33 hours as the result of an upward estimate of the number of “Dog Confinement Letters” issued to importers of dogs.

Form Name: 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)

- CDC is requesting an additional 4 hours in this information collection. This is the result of an upward revision of the number of respondents and additional estimated time per respondent.

Form Name: 71.52(d) Turtle Importation Permits (no form, just written request)

- CDC is requesting 2 fewer hours as a result of a downward estimate of the number of respondents to turtle importation requirements.

Program Changes

CDC is also requesting a set of changes to the data collection that includes modification to information collection instruments and additional data collections.

Form Name: Passenger Locator Form (Attachment 4)

- CDC is requesting a change in the format of the Passenger Locator Form to conform to the most up to date version of the scanning software used by CDC. No changes in the content of the form have been made.

Form Name 71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37) (Attachment 7)

- CDC is requesting a change in format and content for the “Dog Confinement Letter” to improve the clarity and ease of use by the public, as well as its utility for public health purposes. This improvement results in a form that requires 5 fewer minutes per respondent to complete. Given the revised estimate for the number of confinement letters issued (provided in Adjustments above), this form results in 167 fewer hours spent by the public in completing this form.

Form Name: 71.56 (a)(2) African Rodents -Request for exemption (no form, written request only)

- This is a new portion of this information collection. An estimated 20 hours are requested for this portion of the 0920-0134 information collection

While the information collections under 71.55 Dead Bodies Permits, and 71.56(a)(iii) Appeal are included in this 2012 submission, we do not estimate that they will affect more than 9 respondents per year.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The purpose of this submission is to request a revision of a currently approved data collection “**Foreign Quarantine Regulations**” that expires June 30, 2012. CDC is requesting a three year approval to collect data associated with reporting required by 42 CFR Part 71 and voluntary submission of reports to support preventing the introduction, transmission, or spread of communicable disease from foreign countries into the United States.

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment 1) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Legislation and the existing regulations governing quarantine activities (42 CFR 71) (Attachment 2) 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. Currently, with the exception of rodent inspection and the Vessel Sanitation Program (VSP), inspections are performed only on those vessels and aircraft that report illness prior to arrival or when illness is discovered upon arrival. The VSP requires reporting of gastrointestinal illness from cruise vessels that have 13 or more passengers, have an international itinerary, and call on a U.S. port. The reporting requirements are addressed in 42 CFR 71.21(c) (see Attachment 2). The authority to conduct the VSP has been delegated to the National Center for Environmental Health

(NCEH), Centers for Disease Control and Prevention (CDC). Other inspection agencies 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 as well as a minimum of interference with trade and travel.

The regulations found at 42 CFR 71 include the following reporting or recordkeeping requirements:

- 42 CFR 71.21 Reporting – radio report of death and illness
- 42 CFR 71.33(c) Reporting – report of persons held in isolation or surveillance
- 42 CFR 71.35 Reporting – report of death or illness on carrier during stay in port
- 42 CFR 71.51(b)(3) and (d) Reporting – requirement to admit dogs and cats
- 42 CFR 71.52(d) Reporting – application for permits to import turtles
- 42 CFR 71.53(d) and (e) Reporting and Recordkeeping – requirements for registered importers of nonhuman primates
- 42 CFR 71.55 Dead Bodies – Application for permit to import dead bodies
- 42 CFR 71.56 (a)(2) Record keeping - Request for exemption: African rodents
- 42 CFR 71.56(a)(iii) and (c) Appeal – Appeal the denial of permit for importation of regulated animals; and Appeal for order of quarantine, destruction or re-export of regulated animals.

In addition to these reporting and recordkeeping requirements, this information collection request also includes Passenger Locator Information Forms (PLF) used in an outbreak of public health concern and for reporting ill passenger(s) (Attachment 4) and certain voluntary reportable medical conditions (Attachment 5). A modification of format to the PLF is requested in this Supporting Statement to account for a change in the scanning software used for the PLF. No change in content is requested. The content will remain identical to the version approved by OMB on 10/28/11.

Adjustments to the data collection related to the confinement of dogs upon arrival to the United States are requested. The CDC form 75.37, “Notice of Importers of Dogs” will now be identified as CDC form 75.37 “NOTICE TO OWNERS AND IMPORTERS OF DOGS: Requirement for Dog Confinement (Attachment 7).” The form has been changed to enhance clarity around the purpose of the form, including: the type of data required, the regulatory requirements the form is meeting, the responsibilities of the importer, whether or not the animal has received a booster rabies vaccine, and the responsibility of the government agent in ensuring that the form is complete. A table of the proposed changes is included below.

Table of proposed changes to CDC form 75.37

<i>Revised CDC Form 75.37 "Dog Confinement Agreement"</i>	
<i>Revision</i>	<i>Justification</i>

<u>"Requirement for Dog Confinement" added to form's title</u>	<u>Clarifies form's purpose.</u>
<u>Data collection reformatted in table form with required fields noted with an asterisk</u>	<u>Highlights what data are absolutely necessary to collect and to improve ability to detect when data are missing.</u>
<u>Addition of data fields for "Agent"</u>	<u>Allow for follow-up with "Agent" if state unable to find dog(s) and in order to verify identity of "Agent".</u>
<u>Replaced "Representative" with "Agent"</u>	<u>Reflects regulatory wording.</u>
<u>Addition of data fields "email" and "Microchip/Tattoo"</u>	<u>Optional fields that can be completed if owner wishes to share the information for follow-up purposes. State agencies had requested inclusion of microchip data field.</u>
<u>Addition of check box option #4</u>	<u>Reflects current Rabies Compendium's guidelines.</u>
<u>Addition of "within 10 days of entry into the United States" to options #3 and #4</u>	<u>Reiterates regulatory requirements.</u>
<u>Reworded "The above restrictions are imposed under section 71.51, Title 42 Code of Federal Regulations, and compliance is necessary before the animal(s) is released from confinement."</u>	<u>Improves understanding of statement.</u>
<u>Updated statement "Notice to Owner or Agent".</u>	<u>Reflects current penalties.</u>
<u>Revised "Statement to U.S. Government Officer"</u>	<u>Reflects in more detail importer or agent responsibilities.</u>
<u>Moved government official's signature to the bottom of the form into a separate section entitled "Official Use Only".</u>	<u>Emphasizes that this signature line is for the government official reviewing the document and not for the owner or agent.</u>
<u>Inserted "I have verified that this document is legible and complete."</u>	<u>Clarifies that the government official is responsible for ensuring the legibility and completeness of the document.</u>

Privacy Impact Assessment

Overview of the Data Collection System: The data collection system for this information collection request consists of electronic data transfers, web-based reporting portals, personal interviews, and radio/phone reporting to CDC quarantine stations.

Items of Information to be Collected: This information collection involves information regarding signs and symptoms of ill travelers and any death onboard an aircraft or ship.

Once a report is made to CDC, public health officials conduct an assessment of the ill passenger using DGMQ's Illness Response and Investigation Forms approved by OMB (0920-0821).

This information collection also involves data related to the regulated animals included in Part 71. The information requested of the importers includes the number, description, intended use, identification of holding facilities, and measures taken to reduce the risk of zoonotic transmission of disease.

2. Purpose and Use of Information Collection

The reporting and recordkeeping requirements contained in these regulations are used by CDC to carry out quarantine responsibilities as required by law. The burdens imposed have been reduced to the minimum considered necessary to permit CDC to carry out the purpose of the legislation, i.e., to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Extending the data collection is warranted because of the public health benefits associated with preventing the introduction, transmission or spread of communicable diseases from foreign countries into the United States.

Modern quarantine is predicated on the need to aid persons who are infected with or exposed to infectious agents while protecting others from the dangers or inadvertent exposure. The challenges faced by the CDC Quarantine Stations were diverse and numerous during the 2003 SARS response. CDC Quarantine Station staff, augmented by other CDC staff, met nearly 12,000 flights from SARS areas and distributed health alert notices to 2.7 million arriving travelers over a three month period. In the final analysis, 98 percent of probable SARS cases in the United States were associated with international travel, and no secondary transmission occurred. During May and June 2003, the first cluster of human monkeypox cases in the United States was reported. Action was taken by CDC and the Food and Drug Administration (FDA) to prevent the spread of monkeypox by amending their respective regulation on the import, capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals.

Privacy Impact Assessment Information: This data is being collected to fulfill regulatory requirements under 42 CFR Part 71. The data is being collected to track individuals with communicable disease, and manage their exposure to others, so as to reduce death, illness, and economic loss from illness. The data will be used by CDC to prevent the spread of communicable disease during international travel and from travel from one State or possession to another State or possession.

On December 13, 2007, CDC published a notice of a new system of records under the Privacy Act of 1974 for its conduct of activities under 42 CFR 71 (72 FR 70867). The data will become part of CDC Privacy Act System of Records 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.

Highly sensitive information is being collected and would affect a respondent's privacy if there were a breach of confidentiality. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. 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 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.

3. Use of Improved Information Technology and Burden Reduction

Reporting and recordkeeping requirements imposed by the regulations (with regard to inspection and surveillance procedures at ports of entry) have been reduced and streamlined by the development of an improved early warning system that alerts CDC to

the occurrence of communicable disease, increased utilization of epidemiologic services, and development of modern concepts and operations to meet the rapidly changing conditions of international travel. These procedures many years ago replaced the much more disruptive and burdensome procedure of inspecting all ships and aircraft, including passengers and crew.

Reporting of death or illness onboard aircrafts can be reported via Air Traffic Control, who will notify CDC's Emergency Operations Center (EOC) through the Domestic Events Network; the EOC will notify the appropriate CDC Quarantine Station and the local health department of jurisdiction. Quarantine staff will communicate with the airline's designated point of contact to obtain necessary information about the death or ill traveler. Alternatively, the aircraft operator may communicate with the airline's land-based point of contact (e.g., Operations Center, Flight Control, airline station manager). The airline's point of contact will notify CDC by contacting the Quarantine Station with jurisdiction for the arrival airport or CDC Emergency Operations Center, who will notify the appropriate Quarantine Station.

Reporting of death or illnesses onboard ships, including gastrointestinal illnesses are reported to CDC's Vessel Sanitation Program is reported via a common Web-based application; Maritime Illness and Death Reporting System (MIDRS), <https://wwwn.cdc.gov/midrs/GILogin.aspx> (Attachment 6a: 71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival). While this is the preferred method of reporting illnesses and deaths to CDC, if MIDRS is not available, ships may contact the appropriate quarantine station directly by phone, fax, or e-mail. Other illnesses are reported through the same portal via a different data collection screen (Attachment 6b: 71.21(a) Radio Report of death/illness - illness reports from ships)

4. Efforts to Identify Duplication and Use of Similar Information

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. The Passenger Locator Form is universally accepted as a result of collaborations between CDC/DGMQ, WHO and the International Civil Aviation Organization (ICAO). Regarding the collection of information on the animals listed in Part 71, CDC has regulatory authority to collect this data and must have this information to perform its public health responsibilities.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the few such entities involved, such as importers of nonhuman primates, the burdens imposed have been reduced to the minimum necessary for CDC to meet its regulatory responsibilities.

6. Consequences of Collecting the Information Less Frequently

Further reduction of required recordkeeping or reporting would prevent CDC from meeting its legislative mandate 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 incidence of disease or the arrival of a potential vector of disease 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. Depending on the situation, reporting may be verbal, written with no specific form specified, or written on a simple form with no extra copies required. Records to be kept by importers of nonhuman primates are only provided to CDC in the event of a disease outbreak at the importer's facility or in connection with an onsite inspection of compliance. Proprietary information is only required from importers of nonhuman primates (e.g., design of facilities).

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

A. A notice to extend the current data collection package was published in the Federal Register on February 15, 2012, Volume 77, No. 31, pp. 8875-8877. (Attachment 3). No comments were received.

B. With respect to information required regarding arriving ill persons and arriving potential vectors of disease, consultation with the entity providing the information is less meaningful than periodic assessment of the need for collecting the information. This need is continually reassessed by disease control specialists based on disease prevalence patterns throughout the world and the relative risk of disease transmission and spread into the United States.

In developing the revised Passenger Locator Form, CDC consulted with several partners to ensure the new form would meet the needs of CDC and the international public health community, as well as air industry. These partners included the International Civil Aviation Organization and the International Air Transport Association. The individuals with whom we consulted are:

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9. Explanations of Any Payment or Gift to Respondents

No payments are made to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection request has been reviewed by the CDC Information Collection Review Office (ICRO). The ICRO has determined that the Privacy Act does apply to some aspects of this information collection request. The applicable System of Records Notice is 09-20-0171.

The Privacy Act is applicable to the information being collected for the “Passenger Locator Information Form.” (Attachment 4) 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 will be collected on an airline passenger locator card to obtain the necessary information needed to notify passengers who may have been exposed to a communicable disease during airline transit.

Information submitted will be entered into a computer system for analysis and later retrieved if necessary. Data containing personal identifiers and source documents 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.

The Privacy Act is not applicable to the information being collected for either CDC form 75.37, “Notice of Importers of Dogs” (Attachment 7) or CDC form 75.10 “Application for Registration as an Importer of Nonhuman Primates.” (Attachment 8) While full names and some limited information of those completing the information collection request documents are requested, the primary method of retrieval would not be performed by searching for address or passport number, and individuals would be providing data primarily relating to their roles as an importer of nonhuman primates or owner and importer of dogs. Importers will not be providing personal information on themselves but providing information on the measures taken to prevent exposure of persons and animals during the importation and quarantine process for arriving nonhuman primates

and the use of adequate disease control practices. Therefore, these forms do not meet the definition of a Privacy Act system of records.

10.1 Privacy Impact Assessment Information

Privacy Impact Assessment Information

1. Respondents to this data collection will be informed whether or not providing the data described in this supporting statement is mandatory or voluntary. The response to the data collection is mandatory if a traveler wishes to obtain a special permit to travel. The permit will not be issued without a completed locator form. The master of a vessel/conveyance is required by regulation to inform the local health authority. Importers will are only required to submit the forms.

2. Respondents indicate their consent by their signature on the locator form. Use of the information collection is described on the locator form. The data will be used to track disease patterns. Data 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.

3. 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.

4. 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.

11. Justification for Sensitive Questions

This data collection requests the traveler’s name and medical history. This information is necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.

12. Estimates of Annualized Burden Hours and Costs

The burdens imposed by these regulations are based on the estimated amount of time needed to perform each particular requirement multiplied by the number of responses. Figures are based on data accumulated over the past three years.

12 A. Estimates of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours
Maritime conveyance operators	71.21(a) Radio Report of death/illness - illness reports from ships (MIDRS)	2000	1	2/60	67
Aircraft commander or operators	71.21 (b) Death/Illness reports from aircrafts (verbal, no form)	1700	1	2/60	57
Maritime conveyance operators	71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS)	17000	1	3/60	850
Maritime conveyance operators	71.21 (c) Recordkeeping -Medical logs (no form, captains provide logs)	17000	1	3/60	850
Isolated or Quarantined individuals	71.33(c) Report by persons in isolation or	11	1	3/60	1

	surveillance (verbal, no form)				
Maritime conveyance operators	71.35 Report of death/illness during stay in port (verbal, no form)	5	1	30/60	3
Aircraft commander or operators	Locator Form used in an outbreak of public health significance	2,700,000	1	5/60	225,000
Aircraft commander or operators	Locator Form used for reporting of an ill passenger(s)	800	1	5/60	67
Importer	71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37)	2000	1	10/60	333
Importer	71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)	20	1	15/60	5
Importer	71.52(d) Turtle Importation Permits (no form, just written request)	5	1	30/60	3
Non-Human Primate Importer	71.53(d) Importer Registration – Nonhuman Primates	40	1	10/60	7

Non-Human Primate Importer	71.53(e) Recordkeeping (logs submitted, no form)	30	4	30/60	60
Importers	71.55 Dead bodies (death certificates submitted)	5	1	1	5
Importer	71.56 (a)(2) African Rodents - Request for exemption (no form, written request only)	20	1	1	20
Importer	71.56(a)(iii) Appeal (no form, written request only)	2	1	1	2
	Total	2,740,638			227,330

12 B. Estimates of Annualized Cost

Respondents for this data collection include airline and cruise ship captains, importers, non-human primate importers, public health professionals, 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 \$44.56 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 public health professionals, 19-1041 Epidemiologists is used. This is a likely category of public health professional to use the Passenger Locator Form. This hour wage is \$32.83. (19-1041 Epidemiologists: <http://www.bls.gov/oes/current/oes191041.htm>)
- For the general public, 00-0000 All Occupations, is used. The hourly wage for this occupational category is \$21.35. (00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)
- For importers, the general public occupational category is used. The average wage is \$21.35 (00-0000 All Occupations. 00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)
- Given the specific nature of nonhuman primate importers, CDC has determined a separate designation is needed, 19-1023 Zoologists and Wildlife Biologists. The occupational hourly rate is \$29.64. (19-1023 Zoologists and Wildlife Biologists: <http://www.bls.gov/oes/current/oes191023.htm>)

CDC is providing two estimates of the annualized cost of this information collection request. The first figure is the total estimated cost to respondents per year without the use of the Passenger Locator Form used in an outbreak of disease of public health significance. The second, larger figure includes the use of the Passenger Locator Form in an outbreak of disease of public health significance. It is more likely that the average annual cost for reporting and recordkeeping will be the first figure.

Types of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Maritime conveyance operators	71.21(a) Radio Report of death/illness - illness reports from ships	67	\$44.56	\$2,986
Aircraft commander or operators	71.21 (b) Death/Illness reports from aircrafts	57	\$44.56	\$2,540
Maritime conveyance operators	71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (VSP)	850	\$44.56	\$37,876
Maritime conveyance operators	71.21 (c) Recordkeeping - Medical logs	850	\$44.56	\$37,876
Isolated or Quarantined individuals	71.33(c) Report by persons in isolation or surveillance	1	\$21.35	\$21
Maritime conveyance operators	71.35 Report of death/illness during stay in port	3	\$44.56	\$134
Aircraft commander or operators	Locator Form used in an outbreak of public health significance	225,000	\$32.83	\$7,386,750
Aircraft commander or operators	Locator Form used for reporting of an ill passenger(s)	67	\$32.83	\$2,200
Importer	71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination	333	\$21.35	\$7,110
Importer	71.51(b) (3) Dogs/cats: Record of sickness or	5	\$21.35	\$107

Types of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	deaths			
Importer	71.52(d) Turtle Importation Permits	3	\$21.35	\$64
Non-Human Primate Importer	71.53(d) Importer Registration – Nonhuman Primates	7	\$29.64	\$208
	71.53(e) Recordkeeping	60	\$29.64	\$1,778
Importers	71.55 Dead bodies	5	\$21.35	\$107
Importer	71.56 (a)(2) African Rodents -Request for exemption	20	\$21.35	\$427
Importer	71.56(a)(iii) and (c) Appeal	2	\$21.35	\$43
	Total 1: without a disease outbreak, very limited use of PLF	2,330		\$93,477
	Total 2: with a disease outbreak, extensive use of PLF	227,330		\$7,480,227

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

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Government

Each report results in action being taken by Quarantine staff to respond to the report. Their action is determined by the statutory and regulatory requirements for each report. The action taken varies, depending on the specifics of the report, from filing and/or data entry to conducting an investigation involving multiple staff. CDC estimates the yearly cost for this information collection request as a function of the time required to review the collected data and the pay level of the average CDC staff member reviewing the data. The total hours used for the estimation correlate to the total hours requested from the public to respond to the data. The cost accounting is as follows.

Time required to review collected data in hours	Average hourly wage of staff reviewing data (GS12)	Total Estimated Yearly Cost
2330	\$28.88	\$65,753

As CDC anticipates the extensive use of the PLF to be a lower probability event, occurring less than once a year, the cost estimate above does not account for the additional 225,000 burden hours requested in the event of a public health event of international concern. Using the same methodology yields an estimated cost of \$6,498,000, but the costs could be greater depending on the staff or technology used to process the incoming data. The annualized cost to the Government is \$65,753.

15. Explanation for Program Changes or Adjustments

CDC is requesting approval for a set of adjustments and program changes to the previously approved burden total for this information collection. These requested adjustments and program changes are the result of revised estimates and changes to program administration that increased the net estimated number of respondents and burden hours (see Section 12 A) in this information collection. The total number of additional hours requested for this information collection total 1569 hours. The adjustments and program changes are as follows:

Adjustments

Form Name: 71.21 Radio report of death or illness

- In 2009 CDC requested 317 burden hours from an estimated 9500 respondents under Form Name 71.21 Radio report of death or illness. For 2012, CDC has decided to break out each provision within 42 Code of Federal Regulations Part 71.21. The result is a burden table (Section 12 A) that includes those individual reporting requirements as described in 71.21 (a)(Attachment 6b), (b) and (c) (Attachment 6a).
- Revised estimates of the number of air and sea reports of illness include the effects of program improvements in collection and increased accuracy in estimating the number of reports of illnesses. These factors have resulted in a requested increase of 1507 burden hours and 28200 additional respondents.

Form Name 71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37) (Attachment 7)

- CDC is requesting an additional 33 hours as the result of an upward estimate of the number of “Dog Confinement Letters” issued to importers of dogs.

Form Name: 71.51(b) (3) Dogs/cats: Record of sickness or deaths (no form, record review)

- CDC is requesting an additional 4 hours in this information collection. This is the result of an upward revision of the number of respondents and additional estimated time per respondent.

Form Name: 71.52(d) Turtle Importation Permits (no form, just written request)

- CDC is requesting 2 fewer hours as a result of a downward estimate of the number of respondents to turtle importation requirements.

Program Changes

CDC is also requesting a set of changes to the data collection that includes modification to information collection instruments and additional data collections.

Form Name: Passenger Locator Form (Attachment 4)

- CDC is requesting a change in the format of the Passenger Locator Form to conform to the most up to date version of the scanning software used by CDC. No changes in the content of the form have been made.

Form Name 71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (CDC form 75.37) (Attachment 7)

- CDC is requesting a change in format and content for the “Dog Confinement Letter” to improve the clarity and ease of use by the public, as well as its utility for public health purposes. This improvement results in a form that requires 5 fewer minutes per respondent to complete. Given the revised estimate for the number of confinement letters issued (provided in Adjustments above), this form results in 167 fewer hours spent by the public in completing this form.
- A full description of the changes appears in Section A 1 of this Supporting Statement.

Form Name: 71.56 (a)(2) African Rodents -Request for exemption (no form, written request only)

- This is a new portion of this information collection. An estimated 20 hours are requested for this portion of the 0920-0134 information collection

While the information collections under 71.55 Dead Bodies Permits, and 71.56(a)(iii) Appeal are included in this 2012 submission, we do not estimate that they will affect more than 9 respondents per year.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

In previous submissions, CDC had requested an exemption to the expiration date display on CDC forms 75.37 and 75.10A (Attachments 7 and 8). The information collected on these forms was routine and had not changed in over 12 years. The forms have been distributed to importers and others over the years, and the information reported has remained constant. Relatively minor changes in the type of data collected for CDC form 75.37 have been outlined in this Supporting Statement, and so CDC again requests an exemption to the expiration date for the reasons outlined above.

In addition, CDC had requested an exemption to the OMB control number and expiration date display on the Passenger Locator Form (Attachment 4). The display of the expiration date would be inappropriate on the Form as during a global disease outbreak, such as SARS, CDC would request the airlines from the affected areas distribute the form on CDC’s behalf prior to arrival at a U.S. port of entry. It is important to note that the PLF approved by OMB on 10/28/2011 will not be a CDC form. Rather, it will be a data collection instrument that is an amendment to ICAO Annex 9. The revised PLF has been

jointly developed and an agreement in principle reached on the new format by CDC and international partners, with the intent that any airline, regardless of arrival country, will be able to use the same form in the event of a communicable disease exposure. If there is a number/symbol that is of special relevance or importance to only one country, such as an OMB control number or an expiration date, the document will not be accepted by the ICAO Council. CDC is confident that ICAO, absent the OMB control number, will formally adopt the PLF as the international standard.

18. Exceptions for Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collections of Information Employing Statistical Methods

There are no statistical methods used in the collection of information.

1. Respondent universe and Sampling Methods

CDC requires certain signs and symptoms suggestive of communicable disease to be reported by air and sea conveyance operator before arriving in the United States (42 CFR 71.21). Therefore, the respondent universe is composed of airline or ship operators who are be required under regulations under 42 CFR Part 71 to report illness or death to the Centers for Disease Control. Other respondents include importers of the animals listed in Part 71, as well as any traveler who seeks to import human remains into the United States. In the event of an outbreak of a public health event of international concern, the respondent universe is expanded to include any traveler who enters the United States. No sampling is performed as this data collection outlines a data collection of illness or death aboard airplanes and ships required by regulation. 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.

2. Procedures for the Collection of Information

Reporting of death or illness onboard aircrafts can be reported via Air Traffic Control, who will notify CDC's Emergency Operations Center (EOC) through the Domestic Events Network; the EOC will notify the appropriate CDC Quarantine Station and the local health department of jurisdiction. Quarantine staff will communicate with the airline's designated point of contact to obtain necessary information about the death or ill traveler. Alternatively, the aircraft operator may communicate with the airline's land-based point of contact (e.g., Operations Center, Flight Control, airline station manager). The airline's point of contact will notify CDC by contacting the Quarantine Station with jurisdiction for the arrival airport or CDC Emergency Operations Center, who will notify the appropriate Quarantine Station.

Reports of death or illnesses onboard ships, including gastrointestinal illnesses, are made to CDC's Vessel Sanitation Program via a common Web-based application; Maritime Illness and Death Reporting System (MIDRS), <https://wwwn.cdc.gov/midrs/GILogin.aspx> (Attachments 6a and 6b). While this is the preferred method of reporting illnesses and deaths to CDC, if MIDRS is not available, ships may contact the appropriate quarantine station directly by phone, fax, or e-mail.

The data collection involving animals other than nonhuman primates is accomplished when individuals arrive at ports of entry. The data collected will be that required to ascertain that the type and number of animals are within the regulated animal categories, and that the animals are healthy upon visual inspection. Dogs not accompanied by proof of rabies vaccination, including those that are too young to be vaccinated (i.e. less than 3 months of age), may be admitted if the importer completes a confinement agreement (71.51(b)(2) Dogs/cats: Certification of Confinement, Vaccination (Attachment 7)) and confines the animal until it is considered adequately vaccinated against rabies.

The data collection involving nonhuman primates begins with an importer registering with the CDC, documenting that they have implemented disease control measures (Attachment 8). These requirements are defined in 42 CFR 71.53.

3. Methods to Maximize Response Rates and Deal with No Response

CDC requires certain signs and symptoms suggestive of communicable disease to be reported by air and sea conveyance operator before arriving in the United States (42 CFR 71.21). Not responding to this data collection is a violation of regulation. The requirements for the importation of animals and dead bodies are similarly codified in regulations. If individuals do not respond to the data collections, they are prohibited from importing animals or dead bodies.

4. Tests of Procedures or Methods to be Undertaken

CDC currently collects this data under a previously approved data collection. The electronic systems used for this data collection are continually updated and improved for quality of data collection and ease of use for both the public, industry and CDC program administrators

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data Not Applicable