

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

**Request for Extension
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This is a request for extension of a currently approved data collection that expires June 30, 2009. CDC is requesting a three year approval to collect data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 301 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

In addition to these reporting and recordkeeping requirements, this information collection request also includes Passenger Locator Information Forms used in an outbreak of public

health significance and for reporting ill passenger(s) (Attachment 3) and certain voluntary reportable medical conditions (Attachment 4).

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.

The final rule gives respondents options on how to submit data required by 71.13 – 71.14: airline and ship passenger and crew information. Any airline that submits information to Customs and Border Protection (CBP) through CBP’s Advance Passenger Information System (APIS), UN/EDIFACT submission process system, or Passenger Name Record must provide that information in the same form to CDC. If an airline does not use this system, the airline must solicit a list of data elements and transmit them to CDC through a CDC-approved system. The final rule requires the owner/operator of any ship carrying 13 or more passengers, and which is not a ferry as defined by the U.S. Coast Guard (USCG), that submits information through the CBP APIS submission process using the USCG’s Notice of Arrival and Departure system (e-NOAD) or any other CBP-approved system.

Items of Information to be Collected: This information collection involves information in identifiable form, including name, passport number, date of birth, mailing address, phone numbers and medical information.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age: There is no website for this information.

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 probably 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 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. For example, the Vessel Sanitation Program requires the reporting of gastrointestinal illness from cruise vessels that have 13 or more passengers, have an international itinerary, and call on a U.S. port. There are several ways to report the information: by telephone, fax, or two electronic methods.

Approximately 5 years ago, the Vessel Sanitation Program introduced an electronic method via an email using a specific template. The vessel obtains the template by sending an email to vsp-reports@cdc.gov and putting “new template” in the subject line. Vessels may also make reports via a web-based reporting system found at <http://www.cdc.gov/vsp/Report.aspx> (Attachment 5).

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 Information Form was reviewed with WHO and the International Civic Aviation Organization and they have proposed a similar one. However, their adaption is inadequate for CDC’s needs as it lacks fields for state names or zip codes which are essential to efforts to locate individuals in the U.S.

Most of the information required of international carriers, such as records of illnesses, is required by the carriers' insurance companies as well. Also, such carriers must report prior to arrival at U.S. ports, as required by U.S. Citizenship and Immigration Services (USCIS). The estimated amount of extra time required to add or maintain information necessary to meet the requirements of these regulations forms the basis for the burden and cost estimates.

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 March 11, 2009 (Vol. 74, No. 46; pp. 10592 (Attachment 6)). One non-substantive comment was received. An acknowledgment email was sent in response. (Attachment 9).

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.

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 3). 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 retrieval if necessary. Data containing personal identifiers and source documents will be retained until the event prompting the collection of data has concluded. 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.

Privacy Impact Assessment Information

A. This data collection is subject to the Privacy Act. The applicable Systems of Records Notice is 09-20-0171.

B. 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.

C. Respondents indicate their consent by their signature on the form. Use of the information collection is described on the 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.

D. The response to the data collection is mandatory if the traveler wishes to obtain a special permit to travel. The permit will not be issued without a completed form. The master of a vessel/conveyance is required by regulation to inform the local health authority.

11. Justification for Sensitive Questions

This data collection requests the traveler’s name, passport number, mailing address, phone numbers 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.

A. Estimates of Annualized Burden Hours

Citation	Number of Respondents	Number of Responses per Respondent	Average Burden per Respondent (in hours)	Total Burden
71.21 Radio Report of death/illness	9,500	1	2/60	317
71.33(c) Report by persons in isolation or surveillance	11	1	3/60	1
71.35 Report of death/illness in port	5	1	30/60	3
Locator Form used in an outbreak of public health significance	2,700,000	1	5/60	225,000
Locator Form used for reporting of an ill passenger(s)	800	1	5/60	67
71.51(b)(3) Admission of cats/dogs; death/illness	5	1	3/60	1
71.51(d) Dogs/cats: Certification of Confinement, Vaccination	1,200	1	15/60	300
71.52(d) Turtle Importation Permits	10	1	30/60	5
71.53(d) Importer Registration – Nonhuman Primates	40	1	10/60	7
71.53(e) Recordkeeping	30	4	30/60	60
Total	2,711,601			225,761

B. Estimates of Annualized Cost

Respondents for this data collection include airline and cruise ship captains, importers, and the general public. Average wages for each category of respondent were calculated using occupation and wage statistics from the Bureau of Labor Statistics.

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.

Citation/Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
71.21 Radio Report of death/illness Airplane and/or Ship's Captain	317	\$60.00	\$19,020.00
71.33(c) Report by persons in isolation or surveillance General public	1	\$13.83	\$13.83
71.35 Report of death/illness in port Airplane and/or Ship's Captain	3	\$60.00	\$180.00
Locator Form used in an outbreak of public health significance Flight Attendant	225,000	\$42.35	\$9,528,750.00
Locator Form used for reporting of an ill passenger(s) Flight Attendant	67	\$42.35	\$2,837.45
71.51(b)(3) Admission of cats/dogs; death/illness Pet owner or carrier responsible for care	1	\$13.83	\$13.83
71.51(d) Dogs/cats: Certification of Confinement, Vaccination Pet owner	300	\$13.83	\$549.00
71.52(d) Turtle Importation Permits Importer	5	\$21.02	\$105.10
71.53(d) Importer Registration – Nonhuman Primates Importer	7	\$21.02	\$147.14
71.53(e) Recordkeeping Importer	60	\$21.02	\$1,261.20
Total			\$24,127.55 \$9,552,877.50

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

None

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 to be \$100,000.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments. This is a request for extension without change.

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 this forms is routine and has not changed in over 12 years. The forms have been distributed to importers and other over the years, and the information reported has remained constant. In addition, CDC had requested an exemption to the expiration date display on the Passenger Locator Form. 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. As part of emergency preparedness efforts, CDC has already printed, distributed and stockpiled large quantities of the form. An exemption to the requirement to display the expiration date will enable CDC and the airlines to distribute the Form to airline passengers in a timely and cost effective manner.

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. The data collection procedures are as follows: For form CDC 75.37, information is hand entered at the port of entry. For form CDC 75.10A, information is entered by a potential importer of nonhuman primates and emailed or sent via facsimile to CDC. Information collected by the Vessel Sanitation Program is collected via telephone, facsimile, email using the VSP template or using the web-based reporting system. Other information is collected verbally, in person, or by telephone, with no form utilized by the respondent.

List of Attachments

- 1. Section 361 of the Public Health Service Act (42 U.S.C. 264)**
- 2. 42 CFR 71**
- 3. Passenger Locator Form**
- 4. Reportable Voluntary Medical Conditions**
- 5. VSP Web-based Reporting System**
- 6. 60 day Federal Register Notice**
- 7. CDC form 75.37**
- 8. CDC form 75.10A**
- 9. Public Comment and Response**