Quarantine Station Illness Response Forms:
Airline, Maritime, and Land/Border Crossing
(0920-0821, expires 04/30/2016)

Request for OMB Approval of a Revision for an Existing Information Collection Request

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Supporting Statement A

- The goal of this information collection is to ensure that CDC can capture sufficient health and epidemiologic information concerning a report of illness in a traveler, make an accurate public health assessment of the illness report, and identify appropriate next steps. CDC is also removing the United States Traveler Health Declaration and Ebola Risk Assessment tools and burden for those travelers coming from the formerly Ebola affected countries. Finally, CDC is removing the burden associated with the Interactive Voice Response (IVR) information collection tool. The risk assessment program for travelers coming to the United States from Ebola affected countries has ceased and these forms are no longer needed.
- The information will be used to determine if individuals meet risk thresholds for further medical evaluation or public health follow-up, according to guidance developed by the CDC.
- Depending on the report of illness, travelers will be interviewed by the CDC, Emergency Medical System, or DHS personnel using the illness or death investigation.
- The respondent universe for this information collection request is travelers coming to, or traveling within, the United States who are reported as having certain signs and symptoms of illness prior to or after arrival.
- No statistical methods will be used.

CDC is requesting a revision to a currently approved information collection, Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing (OMB Control No 0920-0821). CDC is seeking three year approval for this information collection.

No changes in data fields or collection processes are requested for the Air Travel, Maritime Conveyance, or Land Travel Illness or Death Investigation forms. Based on updated data, CDC is requesting adjustments in the number of respondents and burden hours associated with these forms. These adjustments are outlined in more detail in section A15.

CDC is requesting the removal of respondents and burden hours associated with the United States Traveler Health Declaration, Ebola Entry Risk Assessment Forms, the Ebola Entry Screening Risk Assessment (Ill Traveler Interview), and the IVR Active Monitoring Survey System. Travelers from the formerly Ebola affected countries are no longer being screened at United States ports of entry, nor are they undergoing public health follow-up, so these information collections have terminated. The reduction in burden is outlined in more detail in section A15.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 361 of the Public Health Service (PHS) Act (42 USC 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. Under its delegated authority, the Division of Global Migration and Quarantine (DGMQ) works to fulfill this responsibility through a variety of activities, including the operation of Quarantine Stations at ports of entry and administration of domestic and foreign quarantine regulations; 42 Code of Federal Regulation parts 70 and 71 (Attachment A2 and A3). These regulations authorize quarantine officers to inspect and undertake necessary control measures with respect to conveyances (e.g., airplanes, cruise and cargo ships), persons, and shipments of animals and etiologic agents in order to protect the public's health. This information collection concerns CDC's statutory and regulatory authority, and public health mission, of assessing individual travelers for public health risk following a report of illness from a conveyance or after 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, 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 and Border Protection Officers (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). More often than not, ship medical personnel will interview, or has already interviewed, the traveler for signs and symptoms of illness and provide information to CDC using the appropriate form.

Data collected by Quarantine Station staff using the illness or death investigation forms are 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.

Concerning the tools used in routine activities, there have been no changes to the currently approved Air Travel, Maritime Conveyance, or Land Travel Illness or Death Investigation forms (Attachments C, D, and E respectively). CDC is, however, updating the totals for respondents and burden hours based on updated data from QARS.

2. Purpose and Use of Information Collection

For routine response to illnesses associated with travel, 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: 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 conveyances and CBP in the public health management of ill persons at U.S. ports and plan the appropriate response. These data are then entered into QARS.

3. Use of Improved Information Technology and Burden Reduction

CDC is making use of information technology for several of the information collections described in this revision. The Air, Maritime, and Land Illness or Death investigation forms can be emailed to CDC if the documents are encrypted. Final forms can be printed and faxed securely to CDC if the respondent does not have access to email. The Maritime Illness or Death Investigation form is available as a fillable PDF to ship medical personnel.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has the regulatory authority for performing quarantine-related public health evaluation activities at U.S. ports of entry (42 Part 71). This includes responding to a report of an ill traveler or death of a traveler on a conveyance, or, when requested by DHS personnel at a land border crossing. As a result, CDC is the only agency collecting illness or death reports related to the introduction and transmission of communicable diseases at ports of entry. CDC works in collaboration with its international, federal, state, and local partners at ports of entry to ensure all illness responses are done in a coordinated manner.

5. Impact on Small Businesses or Other Small Entities

Some of the respondents may be considered small businesses. However, data collection variables are kept to the absolute minimum necessary in order to minimize burden on these entities while also determining if further public health action is needed.

6. Consequences of Collecting the Information Less Frequently

The frequency of information collection is determined by the frequency that illnesses or deaths on conveyances or at land borders are reported to Quarantine Stations at ports of entry. Control of communicable diseases or conditions of public health interest is dependent on rapid identification and immediate response when identified. If data are not collected immediately, there is a risk of introduction and spread of disease to the U.S. public.

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

Frequency of data collection is inconsistent with the guidelines, as discussed in Section A6. The frequency of data collection is determined by the frequency that illnesses or deaths on conveyances or at land borders are reported to Quarantine Stations at ports of entry; this could occur more often than quarterly.

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

A. A notice was published in the Federal Register on December 17, 2015 (Vol. 80, No. 242, pp. 78738-78740) (Attachment B) announcing the proposed data collection and requesting public comment. CDC received no public comment.

B. CDC is the primary authority with responsibility to prevent the introduction and spread of communicable disease in the U.S. through air, land, and sea ports of entry. No other entity collects the type and quantity of information from ill travelers. Because the respondents to this data collection are individual travelers and ship medical personnel, CDC does work with the cruise industries on the information collection process outlined in this Supporting Statement to ensure that these industries are able to operate with the

least interference possible, while also maintaining the ability to collect the information needed to protect public health.

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

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases and it has been 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, Quarantine- and Traveler-Related Activities, including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

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.

Several information collection tools in this request ask for personally identifiable information, occupation description, to include name, contact information, and travel related information, such as flight number, to ensure accurate identification of travelers. The presence of symptoms and history of exposures to disease is also collected to assist CDC in making a risk assessment and determine if further public health measures are needed.

Personal identifying information may be shared for the following purposes:

- Records may be disclosed to contractors to handle program work duties, performing many of the same functions as FTEs within DGMQ in situations where additional staff is required. Contractors are required to maintain Privacy Act safeguards with respect to such records.
- Records may be disclosed to state and local health departments and other cooperating medical and public health authorities and their counsel to more effectively deal with outbreaks and other significant public health conditions.
- Personal information from this system may be disclosed as a routine use to appropriate conveyance personnel, Federal agencies, state and local health

departments, Department of State and embassy personnel (U.S. and foreign), and health authorities in foreign countries for contact tracing investigations and notifications of possible exposures to serious communicable diseases in connection with travel.

- Records may be disclosed to the Department of Homeland Security to restrict travel of persons who pose a public health risk and in the instance of suspected domestic or international terrorism.
- Disclosure may be made to medical personnel providing evaluation and care for ill or exposed persons, including travelers.
- Records may be disclosed to the World Health Organization in accordance with U.S. responsibilities as a signatory to the International Health Regulations or other international agreements.
- Personal information may be disclosed to federal, state, and local authorities for taking necessary actions to place someone under quarantine or isolation, for enforcement of other quarantine regulations, or to protect the public's health and safety.
- Records may be disclosed to cooperating state and local legal departments enforcing concurrent legal authority related to quarantine or isolation activities.

Information is being collected that may have an impact on an individual if the information was disclosed. CDC will only share the information for the specific purposes, and with the specific agencies, outlined above.

Respondents to this data collection will be informed whether or not providing the data described in this supporting statement is mandatory or voluntary prior to providing the information to CDC. However, if an individual refuses to provide the requested information, or is not truthful about the information provided during screening or an illness investigation, CDC may, if it is reasonably believed that the individual is infected with or has been exposed to a quarantinable communicable disease, quarantine, isolate, or place the individual under surveillance under 42 CFR 71.32 and 71.33.

Several safeguards are in place to prevent unauthorized disclosure. 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 the Centers for Disease Control and Prevention (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.

Access to the CDC Clifton Road 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 keypad) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The local fire department is located directly next door to the Clifton Road facility. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) 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.

Protection for computerized records, both on the mainframe and the National Center Local Area Network (LAN), includes 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 media containing Privacy Act information. Additional safeguards may be built into the program by the system analyst, as warranted by the sensitivity of the data.

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 oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

Finally, no system of records is being created for this information collection. This information is collected under the Privacy Act system of records notice 09-20-0171, "Quarantine and Traveler Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71", published in the Federal Register, Vol. 72, No. 238, December 13, 2007, pp. 70867-70872.

Further information on the inclusion of PII in QARS is outlined in the Privacy Impact Assessment in Attachment F.

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

IRB Approval

CDC's National Center for Emerging and Zoonotic Infectious Diseases has determined that this project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment G).

Sensitive Questions

This information collection requests certain personally identifying information of both imports and travelers. Some personally identifying information will be collected during the proposed risk assessments in order to identify ill travelers. Some travelers might find these questions sensitive in nature, but 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

Below are the estimates of the Annualized Burden Hours and Costs that CDC is requesting for this revision to the OMB Control No. 0920-0821.

This estimate is based on the following assumptions and available data:

1) Based on data from QARS, CDC is updating its estimates of burden for the Air Travel, Maritime Conveyance, and Land Travel Illness or Death Investigation forms. The respondent burden for these forms is as follows
    a. CDC anticipates 1800 responses to the Air Travel Illness or Death Investigation form, with an associated burden of 150 hours
    b. CDC anticipates 750 responses to sections 3-5 of the Maritime Conveyance Illness or Death Investigation form, with 63 associated burden hours.
    c. CDC anticipates 100 responses to the Land Travel Illness or Death Investigation Form, with 8 hours of associated burden.

12 A. Estimates of Annualized Burden Hours

Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Traveler	Airline Travel Illness or Death Investigation Form	1,800	1	5/60	150
Ship Medical Personnel	Maritime Conveyance Illness or Death Investigation Form	750	1	5/60	63
Traveler	Land Travel Illness or Death Investigation Form	100	1	5/60	8
Total		**2650**			**221**

The total estimated cost of responding to these information collections tools is $7,092. Estimates of annualized cost are assessed using the following wages from the Bureau of Labor Statistics (BLS):

- Travelers, which are estimated using the BLS category 00-0000 “All Occupations” (http://www.bls.gov/oes/current/oes_nat.htm#00-0000).
- For Ship Medical Personnel or Equivalent, we developed a weighted average of 29-1171 Nurse Practitioners - $47.11 per hour (80%) and 29-1062 Family and General Practitioners - $89.58 per hour (20%). This equals $55.60 per hour.

12 B. Estimates of Annualized Cost

Respondent	Form	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Traveler	Airline Travel Illness or Death Investigation Form	150	$22.71	$3,407
Ship Medical Personnel	Maritime Conveyance Illness or Death Investigation Form	63	$55.60	$3,503
Traveler	Land Travel Illness or Death Investigation Form	8	$22.71	$182
Total		**221**		**$7,092**

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

There are no costs to respondents other than the time necessary to respond to the information collection

14. Annualized Cost to the Government

The total annual cost for this information collection is $467,353. As explained below, only the costs for illness and death investigations and the cost of the QARS IT system and administration are routine costs.

***All General Schedule wages are estimated using Atlanta locality adjustment.*

1) The routine costs for using the air, sea, and land illness or death investigation forms, the varicella email, and the ILI tool are as follows. This estimate represents the amount of time for the staff at the Quarantine Stations, to complete the forms and input them into QARS. The total staff costs are estimated from the amount of time required by CDC to receive, process, follow-up on, and compile the relevant information received from a respondent. Also included is the time for a Quarantine Medical Officer to review, provide any needed clinical consultation, and confirm the information received by CDC is complete. On average, CDC staff engaged in illness or death reporting spend approximately 90 minutes on each of the estimated 2,650 reports received, with Quarantine Public Health Officers accounting for 80% of the time, and Quarantine Medical Officers completing the additional 20%. This is for routine, annual costs for illness or death reports and investigations. The total number of hours spent is 3,975 (2650 reports x 90 minutes per report). A breakdown of cost by job class is in the table below.

Personnel	Time in hours required to review and collect illness or death investigation forms	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost

Quarantine Public Health Officer (GS12 Atlanta locality)	3975 x 80% = 3180	$35.58	$113,144
Quarantine Medical Officer (GS14 Atlanta locality)	3975 x 20% = 795	$50	$39,750
Total			**$152,894**

Additionally, there are systems and personnel costs associated with the development, use and maintenance of QARS, which will store information concerning travelers who are screened and who require public health follow up. These costs include the IT and associated staffing expenses. These costs are for the QARS system as a whole, which is also used for other activities, but whose costs cannot be divided according to function. The costs for the entire QARS system are as follows.

QARS System Costs	$201,793
Staff Costs (Atlanta locality adjustment): 1xGS-12 and 1xGS-9(75%)	$112,666
Total	**$314,459**

15. Explanation for Program Changes or Adjustments

CDC is requesting several adjustments and changes in this revision.
1) CDC is requesting an adjustment in the number of respondents and associated burden for the Air Travel, Maritime Conveyance, and Land Travel Illness or Death Investigation forms.

- CDC is requesting an increase in the number of respondents to the Air Travel Illness or Death Investigation form, from 1626 respondents to 1800. This results in an additional 14 hours of burden per year.
- CDC is requesting fewer respondents to the Maritime Conveyance Illness or Death Investigation Form, from 1873 to 750 reports. This results in a decrease of 93 hours.
- CDC is requesting a decrease in the number of respondents to the Land Travel Illness or Death Investigation form, from 259 respondents to 100. This results in a decrease of 14 hours.

2) CDC is deleting the entitled Ebola Entry Screening Risk Assessment (Ill Traveler Interview) (in English/French/Arabic) from the list of information collections and removing the associated burden. This results in 100 fewer respondents and 25 fewer burden hours.

3) CDC is requesting a change in the number of respondents and associated burden due to the removal of the United States Traveler Health Declaration and the Ebola Risk Assessment Form, as well as the IVR scripts, from this information collection request.

Travelers from the formerly Ebola affected countries are no longer being screening upon entry to the United States, so these particular tools are no longer necessary.

- CDC is requesting the removal of 49,238 respondents to the United States Travel Health Declaration (English: Hard Copy, fillable PDF, electronic portal), resulting in a decrease of 12,310 burden hours.
- CDC is requesting the removal of 1,586 respondents to the United States Travel Health Declaration (French translation guide), with a decrease 397 burden hours.
- CDC is requesting the removal of 176 respondents for the United States Travel Health Declaration (Arabic translation guide), with a decrease of 44 burden hours.

The changes for the Ebola Risk Assessment Form are as follows:

- CDC is requesting the removal of 3447 respondents to the Ebola Risk Assessment Form (English hard copy), and an associated decrease of 862 burden hours.
- CDC is requesting the removal of 111 respondents to the Ebola Risk Assessment French translation guide and a decrease of 28 burden hours.
- CDC is requesting the removal of 13 respondents to the Ebola Risk Assessment Arabic translation guide, and 3 fewer burden hours.

4) CDC is no longer requesting the use of this version of the IVR Active Monitoring Survey. Therefore, the following changes are requested:

- CDC is requesting the removal of 49,238 respondents to the IVR Active Monitoring Survey (English: Recorded), with 68,933 fewer burden hours.
- CDC is requesting the removal of 1,586 respondents to the IVR Active Monitoring Survey (French: Recorded) with a decrease of 2,220 hours of burden.
- CDC is requesting the removal of 176 respondents to the IVR Active Monitoring: Arabic translation assistance (no script), with a decrease of 246 burden hours.

The total reduction in burden associated with these adjustments and changes is 85,161 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC and CPB may report aggregate totals of number of people screened and number of positives publicly, as appropriate. Similarly, aggregate numbers of illness or death investigations may be reported.

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

Display of the expiration date is appropriate. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment A1 – Section 361 of the Public Health Service (PHS) Act (42 USC 264)
Attachment A2 – 42 Code of Federal Regulations part 70
Attachment A3 – 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 – Privacy Impact Assessment
Attachment G – Human Subjects Non-Research Determination