

# Maritime Illness Database and Reporting System (MIDRS)

OMB Control No. 0920-NEW

NEW

Formerly under *Foreign Quarantine Regulations* (OMB Control No. 0920-0134, expiration date 05/31/2019)

Supporting Statement Part A –

Justification

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**Goal of the study:** The Vessel Sanitation Program (VSP) is Congressionally mandated to prevent and control the introduction, transmission, or spread of acute gastroenteritis (AGE) into the United States (U.S.). They accomplish this by monitoring AGE illness on passenger ships (“cruise ships”), conducting sanitation inspections and epidemiologic investigations and providing public health guidance when outbreaks occur, and formulating public health recommendations to prevent future outbreaks. Cruise ships carrying 13 or more passengers and within 15 days of arriving in the U.S. from a foreign port are required to report the number of cases of AGE through CDC VSP’s Maritime Illness Database and Reporting System (MIDRS). The number of AGE cases is ascertained from a ship’s medical records, which include a line listing of AGE cases onboard (i.e., “AGE Log”) and a 72-hour food/activity history used to determine source of illness. MIDRS is currently approved under *Foreign Quarantine Regulations* (OMB Control No. 0920-0134, expiration date 05/31/2019), sponsored by the CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). The VSP is requesting a separate three-year PRA clearance for MIDRS and related medical records (AGE Log and 72 hour food/activity history), sponsored by the CDC National Center for Environmental Health (NCEH).

**Intended use of the resulting data:** VSP receives MIDRS reports at particular points during every voyage; these reports are used to monitor for AGE outbreaks and illness trends. When there is an increase in AGE cases, VSP guides the cruise line and cruise ship crew as they work to stop the outbreak from spreading, identify the source of exposure(s), and put prevention measures in place to prevent future outbreaks. When a VSP-led outbreak investigation is necessary, VSP reviews medical records including AGE Logs and 72-hour food/activity histories to determine the causative agent, likely source(s) of exposure, and route(s) of transmission to inform the development of prevention and response procedures for each outbreak event. VSP also uses this information to monitor AGE illness patterns over time, detect changes in circulating pathogens, and identify effective prevention and control strategies.

**Methods to be used to collect:** The MIDRS data collection system consists of a surveillance system that receives information electronically through a web-based reporting portal or by email; data can also be submitted by phone, email or fax and entered into MIDRS by VSP. AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active (symptomatic) AGE cases at any given port of call or at disembarkation. The AGE log and 72-hour food/activity history are completed and maintained on the ship as part of the case’s medical record owned by the cruise line; cruise lines decide how they are maintained onboard (e.g., electronic, paper). VSP reviews these records during operational inspections to confirm they are available if needed, and if there is an AGE outbreak or report of unusual AGE illness for a particular voyage.

**Subpopulation to be studied:** The respondents for the AGE Log and MIDRS reports are cruise ship medical staff or other designated personnel who report AGE cases among passengers or crew aboard cruise ships carrying 13 or more passengers and within 15 days of arriving in the U.S. from a foreign port. AGE cases provide information for the 72-hour food/activity histories.

**How data will be analyzed:** VSP will analyze data from MIDRS, AGE Logs, and 72-hour food/activity histories using descriptive methods to monitor for AGE outbreaks and identify trends. Results are used to determine exposures and causative agents of cruise ship AGE outbreaks, inform outbreak management plans, improve cruise industry infection control procedures, and create AGE outbreak prevention strategies.

## Part A. Justification

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### A.1. Circumstances Making the Collection of Information Necessary

#### *Mandatory Surveillance of Communicable Diseases from Foreign Countries at CDC*

The purpose of this new information collection request (ICR) is to request a three-year Paperwork Reduction Act (PRA) clearance to collect information about the number of passengers and crew members with acute gastroenteritis (AGE) on passenger vessels (“cruise ships”) carrying 13 or more passengers and within 15 days of arriving in the United States (U.S.) from a foreign port. This proposed information collection request (ICR) is titled “Maritime Illness Database and Reporting System (MIDRS).” MIDRS, an electronic surveillance system sponsored by CDC’s Vessel Sanitation Program (VSP), assists the cruise industry in meeting their mandatory reporting requirement of AGE. MIDRS collects basic voyage information and the aggregate numbers of passenger and crew AGE cases on the voyage. MIDRS is currently approved under *Foreign Quarantine Regulations (42 CFR 71)* (OMB Control No. 0920-0134, expiration date 05/31/2019), sponsored by the CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID).

The Centers for Disease Control and Prevention (CDC) is the lead agency for the United States Public Health Service (USPHS) on issues related to communicable disease control from international ports into the United States. Regulations require that carriers visiting a U.S. port from foreign ports report to CDC about any deaths and certain illnesses among arriving passengers and crew.

Under Section 361(a) of the Public Health Service Act (42 USC Section 264[a]) (Attachment 1a), the U.S. Secretary of Health and Human Services is authorized to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases into the U.S. from a foreign country. The authority for carrying out these functions on a daily basis has been delegated to CDC. VSP operates under the authority of the Public Health Service Act (42 U.S.C. Section 264 Quarantine and Inspection Regulations to Control Communicable Diseases) (Attachment 1a). In addition, Section 366(c) of the Public Health Service Act (42 USC Section 269[c]) (Attachment 1b) authorizes the promulgation of regulations applicable to vessels for preventing the introduction into the U.S. of “any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews.”

Currently, the two statutes are enacted under 42 CFR Part 71 *Foreign Quarantine Regulations* (Attachment 1c), from which CDC is authorized to detain, medically examine, and release persons arriving into the U.S. who are suspected of carrying these communicable diseases. As

part of its federal authority, CDC routinely monitors persons arriving at U.S. land border crossings and passengers and crew arriving at U.S. ports of entry for signs or symptoms of communicable diseases. When alerted about an ill passenger or crew member by the pilot of a plane or captain of a ship (under 42 CFR 71.35), CDC may detain passengers and crew as necessary to investigate whether the cause of the illness on board is a communicable disease.

CDC routinely monitors the number of cases of AGE onboard passenger vessels carrying 13 or more passengers and within 15 days of arriving in the U.S. from a foreign port (under 42 CFR 71.21[c]). The master of the ship or other designated personnel is required to report the aggregate number of cases no less than 24-hours prior to arriving in the U.S. from a foreign port; this information is submitted to VSP's MIDRS. MIDRS allows for rapid assessment and timely application of public health actions that are fundamental to the overall mission of VSP as mandated by the U.S. Congress.<sup>1</sup> VSP conducts outbreak investigations and special sanitary inspections under authorities 42 CFR 71.20 (a) and (b), 71.31 (a) and (b), and 71.48.

#### *History of the CDC Vessel Sanitation Program and Control of Acute Gastroenteritis (AGE)*

In the 1970s, the CDC established VSP as a cooperative activity with the cruise ship industry. Until 1986, the VSP conducted sanitation inspections of passenger cruise vessels to minimize health risks, especially those that might lead to diarrheal disease<sup>2</sup> outbreaks, through the Division of Quarantine, Center for Prevention Services (Attachment 3a), currently called the Division of Global Migration and Quarantine (DGMQ) at the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID).

On June 7, 1987, the VSP was transferred to the Center for Environmental Health (CEH), Office of the Director, Special Programs Group (Attachment 3b), currently the Division of Environmental Health Service and Practice (DEHSP), National Center for Environmental Health (NCEH). In 2000, VSP developed an electronic surveillance system called the Gastrointestinal Illness Surveillance System (GISS) to capture AGE<sup>3</sup> illness data. In 2007 VSP expanded GISS to collect non-AGE illness and deaths that are reported to DGMQ; the expanded system was called the Maritime Illness and Death Reporting System. In 2014 DGMQ and VSP separated their reporting methods because they found that their reports required different IT security

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<sup>1</sup> In order to complete the 1987 separation of shipboard quarantine and inspection functions across the two CDC national centers, the VSP will seek a separate PRA clearance for AGE-related surveillance on ships under MIDRS. DGMQ will continue to surveil non-AGE illnesses on cruise ships and all illnesses on other foreign to U.S. conveyances under *Foreign Quarantine Regulations* (OMB Control No. 0920-0134, expiration date 05/31/2019). As of June 10, 2014, DGMQ has changed its routing method for receiving reports from ships. It no longer accepts non-AGE-related death and illness reports via MIDRS.

<sup>2</sup> Diarrheal disease was defined as a person with 3 or more episodes of loose stool in a 24-hour period.

<sup>3</sup> 42 CFR §71.1(b) ii *Ill person* means an individual: (C) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever temperature of 100.4 °F [38 °C] or greater) (Attachment 4a); VSP 2018 Operations Manual (Attachment 4b).

requirements since DGMQ's reports include personally identifying information (PII) while VSP's reports do not. Therefore, DGMQ moved to an electronic form submitted by email directly to the appropriate Quarantine Station and VSP continued using the Maritime Illness and Death Reporting System. Since the Maritime Illness and Death Reporting System no longer collected information on deaths, VSP began referring to the system as the Maritime Illness Database and Reporting System, still known to the cruise industry as MIDRS. It is important to note that both the VSP and DGMQ continue to operate their respective programs under the regulation, 42 CFR Part 71 (Attachment 1c).

This new ICR was previously approved under *Foreign Quarantine Regulations (42 CFR 71)* (OMB Control No. 0920-0134; expiration date 5/31/2019). Operationally, CDC has divided the responsibilities for enforcing foreign quarantine regulations between the VSP and DGMQ. VSP takes the lead on overseeing AGE illness surveillance and outbreak investigation activities on passenger ships, as well as the routine sanitation inspections. When there are illnesses or outbreaks on ships for diseases of public health importance other than AGE illness, or a death due to any cause, then DGMQ takes the lead. The overarching goal of this ICR is to improve AGE illness reporting by the cruise industry while also improving the reporting systems in order to achieve a measurable health impact. The 60-day Federal Register Notice of the proposed information collection was published on 09/25/2018 and is further discussed in Section A.8 (Attachment 2).

## A.2. Purpose and Use of the Information Collection

The information collected will enable the accurate, reliable, uniform and timely submission to CDC of AGE illnesses, and consequently CDC's investigation or response to AGE outbreaks on passenger ships. Cruise ship personnel report basic voyage information and the aggregate number of passenger and crew member AGE illness cases to CDC's VSP via MIDRS, a common web-based application (<https://wwwn.cdc.gov/midrs/GILogin.aspx>) using a standardized template (Attachment 5a). While this is the preferred method of reporting AGE illnesses to CDC, if MIDRS is not available, ships may contact VSP by phone using a phone line monitored 24-hours per day, or by e-mail or fax. Information for MIDRS reports are derived from medical records collected, maintained, and owned by each ship, specifically the AGE Log (Attachment 5b; Attachment 4b, §4.1.2.1.3, p.62) and the 72-hour food/activity history (Attachment 5c, §4.1.2.2.1, p.64).

The information collected by the VSP is designed to align with and support the collaboration between the cruise ship industry and government to define and reduce health risks associated with vessels and to ensure a healthful and clean environment for vessels' passengers and crew. The industry's aggressive and ongoing efforts to achieve and maintain high standards of food and water safety, and environmental sanitation are critical to the success of protecting public health. Reporting and collection of AGE-related information will occur in an efficient,

standardized, and user-friendly manner that will generate a variety of routine and customizable reports.

Cruise ship medical staff are required to send a total number of AGE illness cases to VSP via MIDRS at the following designated times:

- 1) 24 to 36 hours before arriving to a U.S. port from a foreign port; this report is required even when there are no cases of AGE illness (“Routine 24-hr Report”; Attachment 4b, §4.2.1.1.1, p.66),
- 2) if the number of passenger or crew AGE reportable cases changes after the initial notification in the bullet above, but before the ship is 4 hours from arrival (“Routine 4-hr Report”; Attachment 4b, §4.2.1.1.2, p.66), and
- 3) when 2% or more of the passengers or crew are ill with AGE illness, and then again when 3% or more of the passengers or crew are ill with AGE illness (“Special 2% or 3% Report”; Attachment 4b, §4.2.2.1.1, p.67). This report must be sent at any time the vessel is in the U.S. or within 15 days of arriving to a U.S. port

With the information collected from AGE reports, CDC will have the capacity to:

- 1) determine if the number of reportable AGE cases is more than expected for the ship,
- 2) determine if unusual AGE cases have occurred,
- 3) provide support to the cruise line and cruise ship crew as they respond to an increase in AGE cases and work to prevent future outbreaks,
- 4) monitor AGE illness patterns over time, and
- 5) respond to inquiries from the public, the Department of Health and Human Services (HHS), U.S. Congress, and other stakeholders about AGE illness on cruise ships and its public health impact.

There are significant advantages to collecting information with this reporting tool:

- 1) The information being collected provides crucial information about AGE illnesses on passenger ships carrying 13 or more passengers and within 15 days of arriving in the U.S. from a foreign port; AGE illness can be caused by such pathogens as norovirus, *E. coli*, *Shigella*, *Salmonella*, and Hepatitis A.
- 2) Passenger ships have the capacity to submit AGE illness updates on an ongoing basis, facilitating real-time communication with and ongoing monitoring by CDC, resulting in more timely outbreak prevention and response. VSP’s ability to monitor AGE illnesses as they occur may also result in more complete enumeration of AGE outbreaks and the need for risk-based ship sanitation inspections and investigations.
- 3) Uniform data collection of the required information allows CDC to formulate ad hoc analyses and reports to inform AGE outbreak prevention and control on passenger ships.

CDC uses the information collected to monitor AGE illness on passenger ships, detect increases in AGE cases, and respond to and provide support for the cruise line public health response, thereby controlling the introduction, transmission, and spread of AGE illnesses into the U.S. from foreign ports. AGE illness monitoring allows CDC to determine whether the cruise industry is meeting the public health standards mutually agreed upon by VSP and the cruise industry that are intended to target AGE control and prevention efforts. These standards were developed during a collaborative process between cruise industry, food safety experts, water safety experts, and VSP, and were available for public comment by the general public through the Federal Register. VSP's operational standards can be found in the VSP 2018 Operations Manual (Attachment 4b). Finally, the information collected allows CDC to closely examine reported AGE illness levels and detect AGE illness elevations before they become full-blown outbreaks. The cruise lines with which VSP works report that outbreaks require costly, intense, and often lengthy responses, so preventing outbreaks enhances VSP's impact and reduces morbidity, mortality, and the burden of disease.

MIDRS is an electronic reporting and surveillance system that offers a variety of options for submitting reports, including online submission using a web portal, email, fax and phone. The Master of the vessel, the medical staff, or other designated staff receive reports of AGE illness from passengers and crew members onboard their ship, complete a medical assessment, and determines if that person meets the reportable case definition as outlined in 42 CFR 71.1 (b) ii (B) (Attachment 4a). If the ill person meets the AGE case definition, key data elements are recorded on a standardized AGE log (Attachment 5b; Attachment 4b, §4.1.2.1.3, p.62). AGE cases are asked about what they ate, drank, and did in the 72-hours prior to symptom onset ("72-hr. food/activity history) (Attachment 4b, §4.1.2.2.1, p.64) in order to identify a likely source of exposure and target response efforts.

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

Electronic submission is used to collect the majority of MIDRS data as opposed to the data being submitted by phone or fax; it is estimated that 95% of burden hours will be collected by electronic reporting. Also, on occasion VSP will review additional records owned and maintained onboard each vessel, such as AGE Logs, medical records, and 72-hour food/activity histories. AGE Logs use a standard form (Attachment 5b; Attachment 4b, §4.1.2.1.3, p.62); however, the documents below do not use a standard form:

- 72-hour food/activity histories (Attachment 4b, §4.1.2.2.1, p.64)
- Interviews with cabin mates and immediate contacts of crew members with AGE (initial, 24-, and 48-hour)
- Documentation of the 3-day assessment of crew members with AGE symptoms before joining the vessel

- Documentation of the date and time of last symptom and clearance to return to work for food and nonfood employees
- Documentation of the date and time of verbal interviews with asymptomatic cabin mates and immediate contacts of symptomatic crew.

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

The collection of this information is part of a Federal reporting requirement (42 Parts 71.21 (c) and 71.31 (a)) to monitor for communicable diseases, specifically for AGE. MIDRS consolidates information necessary for monitoring and the initiation of AGE outbreak investigations. AGE Logs, medical records, and 72-hour food/activity histories are collected, maintained and owned by the vessel and cruise line and are reviewed by VSP to assist in determining the cause of the outbreak and source(s) of exposure, which in turn allows VSP to provide guidance to the crew and cruise line on remediation efforts and recommendations to prevent future outbreaks. The information collected from the passenger ships is not available from other sources. There is no duplication of data.

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

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

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

Reports are collected in accordance with VSP guidance and federal requirements. Less frequent reporting would undermine AGE illness prevention and control efforts and negatively impact monitoring passenger vessel progress in these areas. Further reduction of required recordkeeping or reporting would prevent CDC from meeting its legislative mandate and could therefore endanger the public's health. The required reporting guidelines ensure that CDC's responses to inquiries from HHS, Congress, and other public or federal stakeholders are based on timely and up-to-date information. There are no legal obstacles to reduce the burden.

## A.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 in order to prevent the importation and spread of disease into the United States. This request fully complies with the regulation 5 CFR 1320.5.

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

### A. Federal Register Notice

A 60-day Federal Register Notice was published in the *Federal Register* on September 25, 2018, Vol. 83, No. 186, pp. 48425-48427 (Attachment 2). CDC/ATSDR did not receive public comments related to this notice.

### B. Other Consultations

The data collection instruments were designed collaboratively by CDC staff, the cruise industry, and subject matter experts in food/water safety, and epidemiology. Consultation will continue throughout the implementation process.

## A.9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments or gifts for providing information.

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

On March 23, 2018, the CDC Privacy Officer determined that the Privacy Act does not apply to the MIDRS (Attachment 10).

Respondents of MIDRS and AGE Logs are cruise ship medical staff or other designated personnel. Respondents of the 72-hour food/activity history are persons with reportable AGE on a passenger vessel in VSP's jurisdiction. The data collection does not involve research with human subjects. The information collection does not require consent from individuals or IRB approval.

### A. Overview of Data Collection System

MIDRS information is collected from cruise ship medical staff or other designated personnel via the MIDRS system. Respondents submit a report by completing the MIDRS template (Attachment 5a) in accordance with VSP guidance (Attachment 4b).

Data elements required for a MIDRS report include:

- submitter's email address
- vessel emergency contact name
- vessel emergency contact number
- ship name
- voyage number
- report type (24hr, 4hr, Special)
- cruise length
- embarkation port code
- embarkation date
- total number of passengers
- total number of crew
- number of passenger AGE cases
- number of crew AGE cases

Data placed in the system produces reports that VSP can use for further analysis. This procedure satisfies routine federal reporting requirements. Data entry occurs on a real-time basis. As a result, the reporting tools can be used for ongoing program management, and support more effective, data-driven technical assistance to the cruise ship industry. Activities do not involve the collection of information in identifiable form (IIF).

The required AGE Log contains the following data elements about the ship and voyage:

- vessel name
- voyage number
- date from
- date to
- total number of passengers
- reportable total number of passengers ill
- total number of crew
- reportable total number of crew ill

The AGE Log must also contain the following information for reportable AGE cases and people who have been dispensed anti-diarrheal medication from a crew member:

- patient ID
- date of the first medical visit or report to staff of illness
- time of the first medical visit or report to staff of illness
- person's last name
- person's first name
- person's age

- person's sex
- designation as passenger or crew member
- cabin number
- crew member position or job on the vessel if applicable
- date of illness onset
- time of illness onset
- illness symptoms including the presence or absence of the following selected signs and symptoms with a separate column for each of the following:
  - number of episodes of diarrhea in a 24-hour period
  - bloody stool (y/n)
  - number of episodes of vomiting in a 24-hour period
  - fever (y/n)
  - recorded temperature
  - abdominal cramps (y/n)
  - headaches (y/n)
  - myalgia (y/n)
  - date of last symptom
  - time of last symptom
  - entry (yes/no) for whether a specimen was requested
  - entry (yes/no) for whether a specimen was received
  - entry (yes/no) for antidiarrheal medication sold or dispensed by designated medical staff
  - entry (yes/no) for whether this was a reportable case
  - presence of underlying medical conditions that may affect the interpretation of AGE.

The 72-hour food/activity history for each reportable AGE case must contain at a minimum the following data elements:

- vessel name
- voyage number
- person's name
- person's age
- person's sex
- designation as a passenger or crew member
- cabin number
- total number of people in the cabin
- meal seating information (seating and table number)
- date and time of illness onset
- other people with the same symptoms
- travel and boarding information prior to joining the vessel
- tour group information if applicable
- ports visited prior to illness onset
- excursions attended

- food and beverage consumption while ashore including drinks with ice, meals and activities aboard the vessel for the 72 hours before illness onset (breakfast, lunch, dinner, snacks)
- activities attended onboard

Note that although the AGE log and the 72-hour food/activity history contain PII, VSP does not collect or receive this information in MIDRS. In the event of an outbreak, VSP will review the voyage’s AGE log and case’s 72-hour food/activity history, but does not own the information.

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

### IRB Approval

NCEH/ATSDR has reviewed this ICR and determined that this project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment 6).

### Sensitive Questions

Some information collected from passenger vessel personnel and travelers may be considered sensitive, such as questions related to a traveler’s illness (e.g., number of diarrhea episodes listed in AGE log, Attachment 5b). However, this information is necessary to engage in follow-up activities and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.

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

A. The burden 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. The estimated annual burden hours equals 1,537.

Table 1: Estimated Annualized Burden Hours

| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|--------------------|-----------|--------------------|---------------------------------|--|--------------------|
|                    |           |                    |                                 |  |                    |

|   |   |     |    |       |      |
|---|---|-----|----|-------|------|
| Cruise ship medical staff or other designated personnel | 71.21 (c) Gastrointestinal illnesses report 24 and 4 hours before arrival (MIDRS)   | 250 | 10 | 3/60  | 125  |
|   | 71.21 (c) Recordkeeping – Gastrointestinal Illnesses report 24 and 4 hours before arrival (MIDRS)   | 250 | 1  | 1/60  | 4    |
|   | 71.21 (c) AGE Logs  | 250 | 10 | 10/60 | 417  |
|   | 71.21 (c) Recordkeeping – medical records (AGE Logs)  | 250 | 1  | 1/60  | 4    |
|   | 71.21 (c) Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times                                   | 250 | 3  | 5/60  | 62.5 |
|   | 71.21 (c) Recordkeeping – medical records (Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times) | 250 | 1  | 1/60  | 4    |
|   | 71.21 (c) Documentation of 3-day pre-embarkation AGE illness assessment for all crew members  | 250 | 5  | 3/60  | 62.5 |
|   | 71.21 (c) Recordkeeping – medical records (Documentation of 3-day pre-embarkation AGE illness assessment for all crew members)  | 250 | 1  | 1/60  | 4    |
|   | 71.21(c) Documentation of   | 250 | 1  | 3/60  | 12.5 |

|                              |   |       |   |       |       |
|------------------------------|---|-------|---|-------|-------|
|                              | date/time of last symptom and clearance to return to work for food and nonfood employees  |       |   |       |       |
|                              | 71.21 (c) Recordkeeping - medical records (Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees) | 250   | 1 | 1/60  | 4     |
|                              | 71.21 (c) Recordkeeping - medical records (72 hour food/activity history)   | 250   | 1 | 1/60  | 4     |
| AGE passenger and crew cases | 71.21 (c) 72-hour food/activity history   | 5,000 | 1 | 10/60 | 833   |
| Total                        |   |       |   |       | 1,537 |

B. Respondents for this data collection include the master of the vessel, medical staff, or other designated personnel, and AGE passenger and crew cases. Average wages of each category of respondent were calculated using occupation and wage statistics from the Bureau of Labor Statistics.

- For conveyance operators (maritime), an average of 53-5021 Captains, Mates, and Pilots of Water Vessels is used. This yields an average of \$38.93 per hour. (53-5021 Captains, Mates, and Pilots of Water Vessels: <http://www.bls.gov/oes/current/oes535021.htm>).
- For AGE passenger and crew cases, an average of all occupations is used, which yields an average of \$24.34 per hour (00-0000 All Occupations: [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)).

Total respondent costs for this information collection is \$47,662.49.

Table 2: Estimated Annualized Burden Costs

| Type of Respondent           | Form Name  | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|------------------------------|--|--------------------|------------------|------------------------|
| Cruise ship medical staff or | 71.21 (c) Gastrointestinal Illnesses report 24 and 4 | 125                | \$38.93          | \$4,866.25             |

|                            |   |      |         |             |
|----------------------------|---|------|---------|-------------|
| other designated personnel | hours before arrival (MIDRS)  |      |         |             |
|                            | 71.21 (c) Recordkeeping – Gastrointestinal Illnesses report 24 and 4 hours before arrival (MIDRS)   | 4    | \$38.93 | \$155.72    |
|                            | 71.21 (c) AGE Logs  | 417  | \$38.93 | \$16,233.81 |
|                            | 71.21 (c) Recordkeeping – medical records (AGE Logs)  | 4    | \$38.93 | \$155.72    |
|                            | 71.21 (c) Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times                                   | 62.5 | \$38.93 | \$2433.13   |
|                            | 71.21 (c) Recordkeeping – medical records (Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times) | 4    | \$38.93 | \$155.72    |
|                            | 71.21 (c) Documentation of 3-day pre-embarkation AGE illness assessment for all crew members  | 62.5 | \$38.93 | \$2433.13   |
|                            | 71.21 (c) Recordkeeping – medical records (Documentation of 3-day pre-embarkation AGE illness assessment for all crew members)  | 4    | \$38.93 | \$155.72    |
|                            | 71.21 (c) Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees   | 12.5 | \$38.93 | \$486.63    |
|                            | 71.21 (c) Recordkeeping – medical records (Documentation of date/time of last symptom and clearance to return to  | 4    | \$38.93 | \$155.72    |

|                              |   |     |         |             |
|------------------------------|---|-----|---------|-------------|
|                              | work for food and nonfood employees)                                      |     |         |             |
|                              | 71.21 (c) Recordkeeping – medical records (72 hour food/activity history) | 4   | \$38.93 | \$155.72    |
| AGE passenger and crew cases | 71.21 (c) 72-hour food/activity history                                   | 833 | \$24.34 | \$20,275.22 |
| Total                        |   |     |         | \$47,662.49 |

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

Providing data to VSP through MIDRS requires one of the following modes:

- Web-based portal requiring a computer, internet access, and MIDRS account
- Email to MIDRS system requiring a computer and internet access
- Phone or fax requiring a phone and cell phone signal

Several of these IT equipment and service options are required for other international health and safety requirements such as the International Convention for the Safety of Life at Sea (SOLAS) (Attachment 9), so there are no additional costs to the respondents. There are no capital or maintenance costs incurred by the respondents above and beyond SOLAS requirements. There are no costs or burden to respondents for recordkeeping.

### A.14. Annualized Cost to the Federal Government

There is no cost to the federal government for this information collection. The Appropriations Act for the Departments of Labor, Health and Human Services, and Education, and related agencies, for the fiscal year ending September 30, 1987 (Pub. L. 99-591, sec. 101(i)) authorized CDC to collect fees for each passenger cruise ship sanitation inspection conducted by CDC’s VSP. The fees collected from sanitation inspections are used to fully fund all operational costs of VSP; no federal, taxpayer monies are received or used by VSP. Fees are determined each year based on VSP’s total annual operating costs divided by the estimated number of inspections, multiplied by a factor based on the ship size and estimated number of inspectors required to conduct the inspection. This calculation determines the per-ship inspection cost. Fees for each upcoming fiscal year are announced in the Federal Register approximately 3 months prior to initiation of each new fiscal year fee schedule.

## A.15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

## A.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 Public Health Service Act (42 U.S.C. Section 264, Quarantine and Inspection Regulations to Control Communicable Diseases, Attachment 1A). Three years are requested for continued data/information collection activities.

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

The display of the OMB expiration date is appropriate.

## A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

## List of Attachments

### Attachment 1. Authorizing Legislation

- 1a. 42 USC Section 264 – Quarantine and Inspection - Regulations to Control Communicable Diseases
- 1b. 42 USC Section 269 – Quarantine and Inspection – Bills of Health
- 1c. 42 CFR Part 71 – Foreign Quarantine Regulations

Attachment 2. 60-day Federal Register Notice

Attachment 3. Vessel Sanitation Program Delegation

3a. 1985 Federal Register Notice VSP in DGMQ

3b. 1987 Memo VSP from DGMQ to NCEH

Attachment 4. AGE Case Definition

4a. 42 CFR §71.1(b) ii

4b. VSP 2018 Operations Manual

Attachment 5. Medical Records

5a. MIDRS template

5b. AGE Log

5c. 72-hr Food/Activity history template

5d. Documentation of interviews to determine AGE illness status

5e. Documentation of 3-day pre-embarkation AGE illness assessment

5f. Documentation of Last Symptom and Clearance to Return to Work

Attachment 6. Research Determination Form

Attachment 7. 42 CFR 71.21 (c) Recordkeeping - Medical logs (not a standardized form, captains provide logs)

Attachment 8. 42 CFR 71.21(c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS screenshot)

Attachment 9. International Convention of Safety of Life at Sea

Attachment 10. Privacy Impact Assessment Form