

Maritime Illness Database and Reporting System (MIDRS)

OMB Control No. 0920-1260 (Expiration Date 04/30/2022)

Revision

Formerly under *Foreign Quarantine Regulations* (OMB Control No. 0920-0134)

Supporting Statement Part A –

Justification

Project Officer: Keisha Jenkins, DrPH, MPH,

LCDR U.S. Public Health Service

CDC Vessel Sanitation Program

Office: 770.488.3096

Email: KJenkins4@cdc.gov

Date: April 4, 2022

Table of Contents

Part A. Justification.....	4
A.1. Circumstances Making the Collection of Information Necessary.....	4
A.2. Purpose and Use of the Information Collection.....	6
A.3. Use of Improved Information Technology and Burden Reduction.....	9
A.4. Efforts to Identify Duplication and Use of Similar Information.....	9
A.5. Impact on Small Businesses or Other Small Entities.....	9
A.6. Consequences of Collecting the Information Less Frequently.....	9
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	10
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	11
A.9. Explanation of Any Payment or Gift to Respondents.....	11
A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	11
A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	14
A.12. Estimates of Annualized Burden Hours and Costs.....	14
A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	18
A.14. Annualized Cost to the Federal Government.....	18
A.15. Explanation for Program Changes or Adjustments.....	19
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	23
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	23
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	23

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.). It accomplishes 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.

Intended use of the resulting data: The 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 track and 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, who are crew and passenger respondents, provide information for the 72-hour food/activity histories. The crew also undergo additional assessments to monitor their fitness to work.

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

A.1. Circumstances Making the Collection of Information Necessary

The CDC's Vessel Sanitation Program (VSP) is requesting a 3-year Paperwork Reduction Act (PRA) clearance for this revision information collection request (ICR).

In the past three years, the VSP has received 13,352 AGE reports to through its "Maritime Illness Database and Reporting System (MIDRS)" (OMB Control No. 0920-1260; expiration date 04/30/2022). Since the first quarter of 2020, the COVID-19 pandemic disrupted the number of cruise ship voyages operating to U.S. ports of call. Between March 2020 and October 2021, cruise industry operations were suspended under a federally issued No Sail Order, and then subsequently under a Conditional Sailing Order to prevent the risk of introducing, transmitting, and spreading COVID-19 by cruise ship travelers. As a result, the number of AGE reports submitted to MIDRS in 2020 and 2021 were substantially lower (n=2,667 and n=1,717, respectively), compared to 2019 (n=8,968).

The cruise ship industry experience in 2020 and 2021 was not considered in this revision due to the disruption caused by the COVID-19 pandemic. Revised estimates were based largely on 2019 reporting, by assuming these numbers reflect a typical cruise season following the established industry practices outlined in the VSP Operations Manual (Attachment 4b). CDC has revised its burden estimates for an increase of 10,103,030 annual responses (n=10,116,780) compared to that approved in 2019 (n=13,750). CDC also estimates the total annualized time burden is 5,782,228 hours, which is an increase of 5,780,690 hours compared to the previously approved 1,538 hours. This increase in annual time burden is based largely on more accurate estimation of the number of respondents and the number of responses and adding the 12-month recordkeeping burden for both AGE surveillance records and for maintenance and sanitation records; this recordkeeping burden was not accurately accounted for in the prior ICR. Details about the proposed revisions are provided in Section A.15.

Mandatory Surveillance of Communicable Diseases from Foreign Countries at CDC

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. Through MIDRS, CDC's Vessel Sanitation Program (VSP) collects electronic 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. MIDRS 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.

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.¹ 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

¹ In order to complete the 1987 separation of shipboard quarantine and inspection functions across the two CDC national centers, the VSP obtained PRA clearance for AGE-related surveillance on ships under *MIDRS* (OMB Control No. 0920-1260) in 2019. DGMQ continues 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 03/31/2022).

health risks, especially those that might lead to diarrheal disease² 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, the VSP developed an electronic surveillance system called the Gastrointestinal Illness Surveillance System (GISS) to capture AGE³ illness data. In 2007, the 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 requirements. 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).

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 10/25/2022 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

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

³ 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).

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 for routine AGE surveillance (<https://www.cdc.gov/midrs/GILLogin.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 is 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 4b, §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 44% of MIDRS data and the remaining 56% is collected by phone, email, or fax.

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

The collection of this information is part of a Federal reporting requirement (42 CFR 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

The following special circumstances apply to this information collection. Cruise ship medical staff will report information to the VSP more often than quarterly. As shown in the time burden table in Section A.12,

- VSP estimates that approximately 300 cruise ships arrive in U.S. ports following repeat itineraries 30 times a year. Therefore, these 300 cruise ships are required to submit 24-hour AGE Illness Reports 30 times a year to VSP.
- An 80 percent subset of these same ships submit 4-hour AGE Illness Reports on the same 30 itineraries when the number of AGE cases changes.

The high frequency of AGE Illness Reports that a cruise ship must send is a result of industry operations. They must still report to VSP as the regulation requires.

The VSP must closely monitor these voyages in case an emergency investigation is warranted.

- In about 2 percent of these cruises (n=180), medical staff must send up to four special reports when the number of AGE cases exceed the 2-percent alert or the 3-percent outbreak thresholds.
- The medical staff of these 180 cruises must also send at least one daily report in the form of the AGE log but may need to send as many as 12 of these daily reports when the outbreak is severe and public health and safety is threatened.

The frequency of daily reports is necessary to control the spread of acute illness among crew and passengers alike.

Respondent Type	Form Name	Number of Respondents		Number of Responses per Respondent
Cruise ship medical staff or other designated personnel	AGE Illness Report 24 hours before arrival (web)	132	300*30=9,000	30
	AGE Illness Report 24 hours before arrival (phone/email/fax)	168		30
	AGE Illness Report 4 hours before arrival (web)	106	240*30=7,200	30
	AGE Illness Report 4 hours before arrival (phone/email/fax)	134		30
	Special Reports exceeding 2%-3% AGE Threshold (web/phone/email/fax)	180	9,000*0.02=180	4
	Daily Reports of AGE Logs	180		12

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 10/25/2021, Vol. 86, No. 203, pp. 58915 (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.

VSP holds regular training seminars based on public health practices that are based on the current VSP Operations Manual and important for protecting cruise ship passengers and crew from transmission and spread of gastrointestinal (GI) illnesses on cruise ships.

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 9).

Respondents of MIDRS and AGE Logs are cruise ship medical staff or other designated personnel. Respondents of the 72-hour food/activity history are crew and passengers with reportable AGE on a passenger vessel in VSP's jurisdiction.

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

- o fever (y/n)
- o recorded temperature
- o abdominal cramps (y/n)
- o headaches (y/n)
- o myalgia (y/n)
- o date of last symptom
- o time of last symptom
- o entry (yes/no) for whether a specimen was requested
- o entry (yes/no) for whether a specimen was received
- o entry (yes/no) for antidiarrheal medication sold or dispensed by designated medical staff
- o entry (yes/no) for whether this was a reportable case
- o 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.

In accordance with the Federal Records Management Act and the CDC Records Control Schedule (RCS), VSP keeps MIDRS records for at least six years, but no longer than ten years after the retirement of the system, as “minor research records.”

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

Research Determination

The NCEH/ATSDR Human Subjects Contact has reviewed this ICR and determined that this project does not meet the definition of research. It is classified as public health surveillance, as defined in 45 CFR 46.102(l)(2). IRB review is not required (Attachment 7).

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 MIDRS data collection system consists of an electronic surveillance system that receives information through a web-based reporting portal 24 hours and 4 hours prior to arrival at a U.S. port. This data can also be submitted by phone, email, or fax and entered into MIDRS by VSP. A MIDRS reference document is provided to assist cruise ship medical crew with submitting an electronic and email MIDRS report. AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active AGE cases at any given port of call or at disembarkation.

Based on the 2019 VSP experience, CDC estimates that approximately 300 ships arrive at U.S. ports 30 times per year (n=9,000 voyages). All arriving ships send 24-hour MIDRS reports (44 percent electronically [n=132]; 56 percent by phone, email, or fax [n=168]) to the VSP. A subset of approximately 80 percent of these ships may need to send 4-hour MIDRS reports either electronically (n=106) or by phone, email, or fax (n=134) if the number of cases changes after submission of the initial report. The number of voyages per year (n=30) for each ship is the number of responses each cruise ship may submit a report to MIDRS.

When AGE cases exceed the 2-percent alert threshold and the 3-percent outbreak threshold, special reports are sent to VSP. Based on its 2019 experience, VSP estimates that 2 percent of ships reporting to MIDRS ($n=300 \times 30 \times 0.02 = 180$) per year are required to send up to four special report updates until they are four hours from port. VSP also requires these ships to begin sending at least one and up to 12 daily reports in the form of AGE logs to monitor and assess whether a cruise ship outbreak investigation (CSOI) may be warranted. If so, VSP conducts CSOIs under OMB Control Number 0020-1255 (expiration date 03/30/2022).

The AGE log and the 72-hour food/activity history template are used to document AGE cases among crew ($n=575$ per cruise $\times 30$ cruises = 17,250 crew per year) and passengers ($n=2,795$ per cruise $\times 30$ cruises = 83,850 passengers per year).

The ship's crew undergo additional assessments. For example, all crew members undergo a three-day pre-embarkation AGE illness assessment (based on an average of 1,080 crew per ship in 2019: $n=1,080$ crew per voyage $\times 9,000$ voyages per year = 9,720,000 crew per year). Assuming 5 contacts and cabin mates per crew AGE cases ($n=575$ crew AGE cases $\times 5$ contacts per crew AGE case $\times 30$ voyages per year), approximately 86,250 crew contacts per year undergo additional screening and assessments such as initial, 24-hour, and 48-hour verbal interviews to assess AGE status. Crew AGE cases must also undergo a last symptom check to obtain a return-to-work clearance ($n=575$ crew AGE cases per voyage $\times 30$ voyages per year = 17,250). Documentation of these assessments and reports are maintained on the ship for at least 12 months (8,760 hours per year).

There are three types of respondents involved in AGE surveillance: cruise ship medical staff or other designated personnel who treat and report AGE cases to VSP, and the cruise ship crew and the cruise ship passengers who may become AGE cases. Of note, VSP does not receive any identifiable information from or about the AGE cases; this information is collected and owned by the cruise line and maintained on the ship as part of the AGE case's medical record.

A fourth type of respondent is the cruise ship engineering staff who perform shipboard engineering and sanitation system maintenance. Such records must be maintained for at least 12 months (8,760 hours). 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.

Table 1: Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Cruise ship medical staff or other designated personnel	AGE Illness Report 24 hours before arrival (web)	132	30	3/60	198
	AGE Illness Report 24 hours before arrival (phone/email/fax)	168	30	3/60	252
	AGE Illness Report 4 hours before arrival (web)	106	30	3/60	159

	AGE Illness Report 4 hours before arrival (phone/email/fax)	134	30	3/60	201
	Special Reports exceeding 2%-3% AGE Threshold (web/phone/email/fax)	180	4	3/60	36
	Daily Reports of AGE Logs	180	12	3/60	108
	Recordkeeping of AGE Surveillance Records	300	1	8,760	2,628,000
Cruise ship crew	72-hour Food/Activity History Template (AGE cases)	17,250	1	10/60	2,875
	Three-day Pre-embarkation AGE Illness Assessment (all crew members)	9,720,000	1	3/60	486,000
	Interviews to Determine AGE Status (initial, 24-hr, 48-hr)(asymptomatic cabin mates and immediate contacts of symptomatic crew)	86,250	3	5/60	21,562
	Last Symptom Check and Return to Work Clearance (food and nonfood employees)	17,250	1	3/60	862
Cruise ship passengers	72-hour Food/Activity History Template (AGE cases)	83,850	1	10/60	13,975
Cruise ship engineering staff or other designated personnel	Recordkeeping of Engineering and Sanitation Records	300	1	8,760	2,628,000
Total					5,782,228

B. Respondents for this data collection include the master of the vessel, medical staff, or other designated personnel, and cruise ship crew and passengers. The average hourly wage of each category of respondent was calculated using occupation and wage statistics from the Bureau of Labor Statistics May 2020 National Occupational Employment and Wage Estimates at https://www.bls.gov/oes/2020/may/oes_nat.htm.

For conveyance operators (maritime), Occupation Code 53-5021 (Captains, Mates, and Pilots of Water Vessels) is used. This yields an average of \$43.14 per hour.

For cruise ship crew, Occupation Code 53-5000 (Water Transportation Workers) is used. This yields an average of \$35.35 per hour.

For cruise ship passengers, Occupation Code (All Occupations) is used, which yields an average of \$27.07 per hour.

Table 2: Estimated Annualized Burden Costs

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Burden Costs
Cruise ship medical staff or other designated personnel	AGE Illness Report 24 hours before arrival (web)	132	30	3/60	\$43.14	\$8,541.72
	AGE Illness Report 24 hours before arrival (phone/email/fax)	168	30	3/60	\$43.14	\$10,871.28
	AGE Illness Report 4 hours before arrival (web)	106	30	3/60	\$43.14	\$6,859.26
	AGE Illness Report 4 hours before arrival (phone/email/fax)	134	30	3/60	\$43.14	\$8,671.14
	Special Reports exceeding 2%-3% AGE Threshold (web/phone/email/fax)	180	4	3/60	\$43.14	\$1,553.04
	Daily Reports of AGE Logs	180	12	3/60	\$43.14	\$4,659.12
	Recordkeeping of AGE Surveillance Records	300	1	8,760	\$43.14	\$113,371,920.00
Cruise ship crew	72-hour Food/Activity History Template (AGE cases)	17,250	1	10/60	\$35.35	\$101,631.25
	Three-day Pre-embarkation AGE Illness Assessment (all crew members)	197,640	30	3/60	\$35.35	\$10,479,861.00
	Interviews to Determine AGE Status (initial, 24-hr, 48-hr)(asymptomatic cabin mates and immediate contacts of symptomatic crew)	86,250	3	5/60	\$35.35	\$762,234.38
	Last Symptom Check and Return to Work Clearance (food and nonfood employees)	17,250	1	3/60	\$35.35	\$30,489.38
Cruise ship passengers	72-hour Food/Activity History Template (AGE cases)	83,850	1	10/60	\$27.07	\$378,303.25
Cruise ship engineering	Recordkeeping of Engineering and	300	1	8,760	\$35.35	\$92,899,800.00

staff or other designated personnel	Sanitation Records					
Total						\$218,065,394.81

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 8), 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.

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

The VSP made several changes to the time burden table after careful consideration of the VSP and cruise industry experience in 2019 as a typical year, and the standard practices outlined in

the VSP Operations Manual. The VSP did not consider their experience during 2020 and 2021 due to the COVID-19 pandemic impacts on the cruise industry.

Respondent Types

The same respondent types were identified in the burden table (i.e., cruise ship medical staff or other designated personnel; and AGE passenger and crew cases) in 2019 and are also shown in 2022; however, for this revision, the VSP changed the following:

- The aggregated estimates of all AGE cases (passenger and crew) were split into separate rows for cruise ship passengers and for cruise ship crew. This allowed:
 - A more accurate time and cost burden estimate for both types of respondents.
 - A more accurate alignment of several additional crew assessment forms away from the medical staff who administer them and to the crew who provide the responses.

In 2022, the VSP also added a fourth respondent type (i.e., cruise ship engineering staff or other designated personnel) to account for recordkeeping requirements for engineering and sanitation records. This respondent type was not previously accounted for in 2019.

Forms

The VSP renamed several forms to clarify their function, their mode of collection, and to re-assign them to the correct respondent type.

In addition, the 2019 table did not accurately present the 12-month recordkeeping burden required of the medical staff. In the previous ICR, the recordkeeping burden for each AGE surveillance form was underestimated as one minute per response. For 2022, VSP simplified its AGE surveillance recordkeeping estimation by combining the separate recordkeeping rows for each form into a single row for all forms and more accurately assigned the overall 12-month recordkeeping burden, converted to hours (n=12 months=8,760 hours).

The 2-percent and 3-percent alert threshold special reports from cruise ship medical staff, the 12-month engineering and sanitation recordkeeping burden and MIDRS quick reference guide were not accounted for in 2019 and were added to the table for 2022.

Table A.15.1. Respondent Type and Form Name Conversions from 2019 to 2022

2019 Type of Respondents	Original 2019 Form Name	Converted or New 2022 Form Name	2022 Type of Respondents
Cruise ship medical staff or other designated personnel	71.21 (c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival	AGE Illness Report 24 hours before arrival (web)	Cruise ship medical staff or other designated personnel (no change)

	(MIDRS)	AGE Illness Report 24 hours before arrival (phone/email/fax)	NOTE: Splitting the original form allowed more accurate estimates of numbers of reports by timeframe and by mode of delivery, as only a subset of cruise ships send 4-hour reports. The burden for this additional reporting was not accounted for in the prior ICR.
		AGE Illness Report 4 hours before arrival (web)	
		AGE Illness Report 4 hours before arrival (phone/email/fax)	
Cruise ship medical staff or other designated personnel	71.21 (c) Recordkeeping - Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS)	Recordkeeping of AGE Surveillance Records	Cruise ship medical staff or other designated personnel (no change) NOTE: In 2019, the recordkeeping burden for each form was underestimated as one minute per form per response. Merging the recordkeeping burden for all forms more accurately allowed VSP to account for the combined 12-month requirement on the cruise industry.
	71.21 (c) Recordkeeping - medical records (AGE Logs)		
	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)		
	71.21 (c) Recordkeeping - medical records (Documentation of 3-day pre-embarkation AGE illness assessment for all crew members)		
	71.21 (c) Recordkeeping - medical records (Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees)		
	71.21 (c) Recordkeeping - medical records (72-hour food/activity histories)		
Not accounted for in 2019	Not accounted for in 2019	Special Reports exceeding 2%-3% AGE Threshold (web/phone/email/fax) (new)	Cruise ship medical staff or other designated personnel (new) NOTE: Special reports were not previously added to the time burden estimates.

Not accounted for in 2019	Not accounted for in 2019	MIDRS quick reference guide	Cruise ship medical staff or other designated personnel (new)
Cruise ship medical staff or other designated personnel	71.21 (c) AGE Logs	Daily Reports of AGE Logs	Cruise ship medical staff or other designated personnel (no change) <i>NOTE: Renaming the form to clarify that daily reports are the AGE logs.</i>
Cruise ship medical staff or other designated personnel	71.21(c) Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times	Interviews to Determine AGE Status (initial, 24-hr, 48-hr) (asymptomatic cabin mates and immediate contacts of symptomatic crew)	(change to) Cruise ship crew <i>NOTE: Transferring the time burden to the crew who are the respondents.</i>
Cruise ship medical staff or other designated personnel	71.21(c) Documentation of 3-day pre-embarkation AGE illness assessment for all crew members	Three-day Pre-embarkation AGE Illness Assessment (all crew members)	(change to) Cruise ship crew <i>NOTE: Transferring the time burden to the crew who are the respondents.</i>
Cruise ship medical staff or other designated personnel	71.21(c) Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees	Last Symptom Check and Return to Work Clearance (food and nonfood employees)	(change to) Cruise ship crew <i>NOTE: Transferring the time burden to the crew who are the respondents.</i>
AGE passenger and crew cases	71.21 (c) 72-hour food/activity history	72-hour Food/Activity History Template (AGE cases)	Cruise ship crew <i>NOTE: Splitting the time burden between crew and passengers allows more accurate burden estimate for cruise ship crew when combined with additional worker assessments previously assigned to medical staff.</i>
		72-hour Food/Activity History Template (AGE cases)	Cruise ship passengers <i>NOTE: Splitting the time burden between crew and passengers allows more accurate burden estimate for cruise ship crew when combined with additional worker assessments previously assigned to medical staff.</i>

Not accounted for in 2019	Not accounted for in 2019	Recordkeeping of Engineering and Sanitation Records (new)	Cruise ship engineering staff or other designated personnel (new) <i>NOTE: Engineering and sanitation recordkeeping was not previously added to the time burden estimates.</i>
---------------------------	---------------------------	---	---

Number of Respondents and Number of Responses per Respondent

In 2019, VSP estimated that medical staff from 250 cruise ships per year report forms with varying frequency (ranging from 1 to 10 times per year). Based on numbers from its 2019 experience, VSP revises its estimate to approximately 9,000 MIDRS reports per year. VSP then extrapolates the 9,000 count to 300 ships that arrive 30 times at U.S. ports per year.

Previously, VSP did not separate the burden hours between 24- and 4-hour MIDRS reporting. Therefore, the time burden was underestimated because all arriving ships must send 24-hour MIDRS reports and a subset of approximately 80 percent of these ships may need to send additional 4-hour MIDRS reports if the number of cases changes after submission of the initial report. This additional burden is now reflected in the revised burden tables.

When AGE cases exceed the 2-percent alert threshold and the 3-percent outbreak threshold, special reports are sent to VSP. The addition of the special reports to the burden table increases the number of responses and the estimated time burden. Special reports were previously not accounted for.

VSP previously reported a yearly estimate of 5,000 AGE cases reporting once (combining crew and passenger). In total, MIDRS was approved for 13,750 responses per year.

The 72-hour food/activity history template are now used to separately document AGE cases among crew (n=575 per year) and passengers (n=2,795 per year) (total n=3,370). This is necessary because the ship’s crew, as a respondent type, undergo additional worker assessments. For example, all crew members undergo a three-day pre-embarkation AGE illness assessment (n=197,640 per year based on an average of 1,080 crew for 300 ships and 30 voyages). Assuming 5 contacts and cabin mates per crew AGE cases, approximately 2,875 crew per year undergo additional screening and assessments such as initial, 24-hour, and 48-hour verbal interviews to assess AGE status. This results in three assessments for 30 voyages, or 90 responses required for crew contacts and cabin mates. Crew AGE cases must also undergo a last symptom check to obtain a return-to-work clearance. Documentation of these assessments and reports are maintained on the ship for at least 12 months (8,760 hours per year).

Therefore, for 2022, CDC has revised its burden estimates for an increase of 10,103,030 annual responses (n=10,116,780) compared to that approved in 2019 (n=13,750). CDC also estimates the total annualized time burden is 5,782,228 hours, which is an increase of 5,780,690 hours compared to the previously approved 1,538 hours. This increase in annual time burden is based

largely on the 12-month recordkeeping burden for both AGE surveillance and for maintenance and sanitation records; this burden was previously unaccounted for in 2019.

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.