Emergency Cruise Ship Outbreak Investigations (CSOIs)

OMB Control No. 0920-1255 (Expiration Date 03/31/2025)

Revision

Supporting Statement Part A –

Justification

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Part A. Justification

Goal of the study: The goal of the emergency cruise ship outbreak investigations (CSOIs) is to rapidly determine unknown agents, source, risk factors, and/or mode of transmission for acute gastroenteritis (AGE) illness outbreaks on cruise ships in the U.S. jurisdiction.

Intended use of the resulting data: Data will be used to identify AGE outbreak cause and provide public health recommendations for prevention and control.

Methods to be used to collect: Methods used include retrospective cohort or case control design, health questionnaire, and personal interview.

Subpopulation to be studied: The respondents include passengers and/or crew members on cruise ships experiencing AGE outbreaks in the U.S. jurisdiction.

How data will be analyzed: VSP will analyze data using frequencies, proportions, measures of association (e.g., chi-square), odds ratios, and relative risk ratios.

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program (VSP), in the National Center for Environmental Health (NCEH), is requesting a three-year Paperwork Reduction Act (PRA) clearance for a revision of the generic clearance information collection request (Generic ICR), titled *Emergency Cruise Ship Outbreak Investigations (CSOIs)* (OMB Control No. 0920-1255, expiration date 03/31/2025). CSOIs are conducted in response to acute gastroenteritis (AGE) outbreaks on cruise ships within VSP's jurisdiction.

VSP conducted the following number of environmental health and epidemiologic consultations for outbreaks, greater than or equal to 3 percent of reportable AGE cases, by reviewing existing MIDRS records: four in 2022, 13 in 2023, 15 in 2024. No new information was collected. Additionally, VSP conducted no CSOIs in the past three years.[1]

VSP still proposes up to 10 CSOIs may be conducted annually in response to cruise ship AGE outbreaks. However, the refinement in estimates of AGE cases and responses results in a revised total of 13,000 responses for 10 CSOIs per year; this is a decrease of 39,234 responses over the previously approved 52,234. The total annualized time burden has decreased to 4,063 hours; this is a decrease of 8,997 hours compared to the previously approved 13,060 annual

[1] VSP posts information on its consultations and CSOIs annually at https://www.cdc.gov/vessel-sanitation/cruise-ship-outbreaks/earlier-outbreaks.html

hours. Details on the proposed changes are provided in Section A.15.

Mandatory Surveillance of Communicable Diseases from Foreign Countries at Two CDC National Centers

Under Section 361(a) of the Public Health Service Act (42 USC Section 264[a]) (Attachment A1), 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 USC Section 264, Quarantine and Inspection Regulations to Control Communicable Diseases) (Attachment A1). In addition, Section 366(c) of the Public Health Service Act (42 USC Section 269[c]) (Attachment A2) 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 A3), from which CDC is authorized to detain, medically examine, and release persons arriving in the United States 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 crewmember by the pilot of a plane or captain of a ship (under 42 CFR Part 71.35), CDC may detain passengers and crew as necessary to investigate whether the cause of the illness on board is a communicable disease. VSP conducts outbreak investigations under authorities 42 CFR 71.31 (a) and (b) and 71.48.

For many years, CDC conducted sanitation inspections of passenger cruise vessels to minimize health risks, especially those that might lead to gastrointestinal disease outbreaks, through the Division of Quarantine, Center for Prevention Services (Attachment C1), currently the Division of Global Migration and Health (DGMH) at the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). On June 7, 1987, VSP was transferred to the Center for Environmental Health (CEH), Office of the Director, Special Programs Group (Attachment C2), currently the Division of Environmental Health Safety and Practice (DEHSP), NCEH. It is important to note, however, that both VSP and DGMH continue to operate their respective programs under the regulation, 42 CFR Part 71 (Attachment A3).

When an outbreak of AGE is detected by VSP's syndromic surveillance system, the Maritime Illness Database and Reporting System (MIDRS) (OMB Control No. 0920-1260, expiration date

3/31/2026), rapid assessment and timely application of public health actions are fundamental to the overall mission of VSP as mandated by the U.S. Congress.

Vessel Sanitation Program Investigations

Using alerts through MIDRS to quickly initiate epidemiologic investigations of enteric diseases on passenger cruise ships is an important way that CDC's VSP protects the health of the public. This Generic ICR is specifically designed to support VSP's mission-critical function;[2] it allows CDC to process individual collection requests with 24-hour approval and ensures the timely information collection required by an emergency cruise ship outbreak investigation. Participation in CSOIs is voluntary among cruise ship passengers and crew. The 60-day Federal Register Notice was published on 11/25/2024 and is further discussed in Section A.8 (Attachment B).

A.2. Purpose and Use of the Information Collection

The purpose of this ICR is to allow CDC to conduct CSOIs of AGE outbreaks or when unusual AGE illness clusters occur. VSP deploys to the field and conducts CSOIs to assist cruise industry partners as they respond to AGE outbreaks or events on their vessels. Data collection instruments and methods must be rapidly created and implemented to direct appropriate public health action. Under this Generic ICR, CDC will seek emergency PRA clearance for each CSOI within 24-hours of submission to OMB. The data collection period for each CSOI will not exceed 30 days.

Scope of CSOIs

CSOIs covered by this Generic ICR are characterized by undetermined agents (e.g., a microorganism, toxin, or chemical substance), undetermined sources (e.g., person, food, water, or substance), undetermined modes of transmission (e.g., direct contact, vehicle), or undetermined risk factors (e.g., behavior, environmental exposure) which result in AGE. For the purposes of this Generic ICR, the following definitions[3] will apply:

- Agent: the entity (such as a microorganism, toxin, or chemical substance) whose presence is the cause of AGE.
- Source: the person, food, water, or substance from which an agent is transmitted to a host.

[2] CSOIs were previously conducted under *Emergency Epidemic Investigations* (OMB Control No. 0920-0008, discontinued). The replacement Generic ICR, *Emergency Epidemic Investigation Data Collections* (OMB Control No. 0920-1011, expiration date 01/31/2020), is designed to aid requesting entities. It no longer meets VSP needs since VSP outbreak responses are CDC-initiated.

[3] Definitions adapted from *Principles of Epidemiology in Public Health* Practice, 3rd Edition. Developed by: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office of Workforce and Career Development, Career Development Division, Atlanta, GA 30333. Available: https://stacks.cdc.gov/view/cdc/6914.

- Mode of transmission: the way an agent is transmitted from its source to a susceptible host.
- Risk factor: an aspect of personal behavior or lifestyle, or an environmental exposure that is associated with an increase in the occurrence of AGE.

Depending on the population onboard the cruise ship experiencing the illness or event, VSP may need to gather information from passengers and/or crewmembers. Causative agent, sources of exposure, modes of transmission, and risk factors can be ascertained by gathering the following types of information from both the affected and (seemingly) unaffected populations:

- Demographic information;
- Pre-embarkation travel information;
- Symptoms, including type, onset, duration;
- Contact with people who were sick or with their body fluids;
- Participation in ship and shore activities;
- Locations of eating and drinking; and
- Foods and beverages consumed both on the ship and on shore.

Rapid and flexible data collection is imperative given the mobile environment, the remaining duration of the voyage left for investigation, and the loss to follow-up if the investigation is delayed and passengers disembark and leave the ship, as some may return to locations outside of the U.S. Ultimately, the overarching goal when providing environmental health and epidemiologic support is to implement prevention and control measures based on the findings from the investigation to minimize adverse health consequences including the spread of illness to subsequent voyages.

This Generic ICR will cover investigations that meet ***all*** of the following criteria:

- The AGE outbreak or event occurs in people on a cruise ship in U.S. jurisdiction.
- The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce morbidity or mortality).
- The investigation is characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors.
- One or more CDC staff (including trainees and fellows) will be deployed to the field.
- Data collection is anticipated to be completed in 30 days or less.

This Generic ICR ***excludes*** each of the following:

- Investigations not related to cruise travel.
- Investigations related to non-urgent outbreaks or events.

- Investigations conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (e.g., research to contribute to generalizable knowledge).
- Investigations with data collection expected for greater than 30 days.

The timeline and procedures for seeking an approval under this Generic ICR are detailed in Section A.7 "Special Circumstances Relating to the Guidelines of 5 CFR 1320.5."

Triggering Event for a CSOI

Case definitions are used for identifying and classifying cases, both of which are done for mandatory reporting purposes via MIDRS, and not for clinical intervention or public health action (Attachment D). A reportable case of AGE is only a case reported to the master of the vessel, the medical staff, or other designated staff by a passenger or a crewmember and meets the definition below:

- Diarrhea (three or more episodes of loose stools in a 24-hour period or what is above normal for the individual; or
- Vomiting and one additional symptom including one or more episodes of loose stools in a 24-hour period, or abdominal cramps, or headache, or muscle aches, or fever (temperature of ≥38°C [100.4°F]).

Nausea, although a common symptom of AGE, is specifically excluded from this definition to avoid misclassifying seasickness (nausea and vomiting) as AGE. The reportable cases must include crewmembers with a symptom onset time of up to 3 days before boarding the vessel.

When the levels of illness meet VSP's alert threshold (i.e., 2% in either the passenger or crew populations), a special report is made to VSP via MIDRS (OMB Control No. 0920-1260, expiration date 03/31/2026) and remote environmental health and epidemiologic assistance is provided to the reporting cruise ship by VSP.

An additional report is required when the illness levels reach 3% in either the passenger or crew populations, which VSP considers an outbreak. When assistance is needed due to AGE outbreaks on cruise ships, this often requires VSP to deploy a response team to meet the ship in port within 24 hours of reaching the outbreak threshold. In situations where logistically possible, VSP deploys the response team to board the ship before its U.S. arrival and sail back to the U.S. port of disembarkation to conduct a more detailed and comprehensive epidemiologic evaluation of the outbreak to contain the illnesses onboard the vessel and prevent or limit the spread of illness to U.S port cities. When existing data sources fail to provide enough information for the implementation of effective prevention and control measures, new data must be collected.

The primary objective of each CSOI is to collect sufficient information to develop and implement effective prevention and control strategies to minimize adverse health consequences. To accomplish this objective, data on the conditions surrounding and preceding the onset of an outbreak or event must be collected rapidly. Data are collected by VSP in collaboration with VSP's cruise industry partners.

The negative consequences of not having the information are increased or sustained morbidity and mortality associated with the outbreak or event and the likely spread of illness to U.S. port cities. Another negative consequence of not having the information is the failure to implement prevention and control measures in future situations that lead to additional outbreaks or events and their associated morbidity and mortality.

The following are examples of past emergency cruise ship investigations that would meet the criteria for this Generic ICR. Example data collection instruments are provided in the attachments (Attachment E1-2).

Undetermined Agent: On October 29, 2016, VSP was contacted by a cruise line epidemiologist for assistance with an investigation of an outbreak of AGE among passengers on board a ship. A total of 184 passengers presented to the medical center with AGE symptoms, of which 69% of the cases reported diarrhea with the absence of vomiting. The recovery time for ill passengers was much slower than what is observed for viral etiology. Also, several cases had to be re-isolated after developing further symptoms upon being released from isolation. VSP investigation team traveled to Norfolk, Virginia to assist the cruise line with their epidemiologic investigation of the AGE outbreak to identify the source of exposure and to implement sanitation procedures to prevent further illnesses on board the ship. VSP investigation team activities included:

Hypothesis generation: AGE surveillance log, AGE 72-hour questionnaire, voyage itinerary, public vomiting/diarrhea logs, potable water bunkering, production, and distribution logs, potable water bacteriological testing records, potable water maintenance records, recreational water logs, including information about fecal and vomit accidents, vessel map of cabins with AGE cases, all dining menus, cooling logs for potentially hazardous food, and manifests for all groups of ≥15 people (groups traveling together). Data from these documents suggested the possibility of a food source exposing passengers to gastrointestinal illness.

Hypothesis testing: Case-control study to identify common food exposure source

Laboratory analysis: Clinical specimen and food samples sent to CDC for testing

In this investigation, the team was faced with an outbreak suspected to be caused by a bacterial agent that was laboratory confirmed as Clostridium perfringens (C. perfringens). To identify the source of this, the team developed a data collection instrument to complete a case-control study. The source was identified as contaminated papaya from Mexico, which was involved in a multistate outbreak of Salmonella. It was confirmed that the recalled papaya, sourced in Mexico, was provisioned on the ship. The data collection instrument used for this investigation is presented in attachment E1.

Undetermined Source: On January 23, 2014, a cruise line notified VSP by phone that one of its vessels had experienced a sudden surge of patients, both passengers and crew, experiencing AGE during the first 72 hours of a new voyage (embarkation date was January 21st). A sudden spike in cases often indicates a point-source exposure, so VSP decided to send an investigative

team to the ship to determine the exposure source and provide public health recommendations to both stop the outbreak and prevent it from spreading to the next voyage. Two VSP epidemiologists sailed with the ship from St. Thomas, US Virgin Islands, to Bayonne, New Jersey, to conduct an epidemiologic investigation from both retrospective cohort exposure history questionnaires and interviews with selected passengers and crew members. On January 29th, the voyage ended with 634 of 3,071 (20.64%) passengers and 54 of 1,166 (4.63%) crew members meeting VSP's AGE case definition. The ship's medical crew collected 10 clinical specimens, tested them onboard with a rapid norovirus detection kit, and learned that the specimens were positive for norovirus. More sensitive testing at CDC later confirmed that the specimens were positive for GII.4 Sydney, the most commonly circulating strain of norovirus for the two years preceding the outbreak. VSP investigative team activities included:

Hypothesis generation: AGE surveillance log, AGE 72-hour questionnaire, voyage itinerary, public vomiting/diarrhea logs, potable water bunkering, production, and distribution logs, potable water bacteriological testing records, potable water maintenance records, recreational water logs, including information about fecal and vomit accidents, vessel map of cabins with AGE cases, all dining menus, cooling logs for potentially hazardous food, and manifests for all groups of ≥15 people (groups traveling together). Data from these documents suggested the possibility of a food source exposing passengers to gastrointestinal illness.

Hypothesis testing: Retrospective cohort study to identify common exposure

Laboratory analysis: Clinical specimen tested onboard with rapid testing and sent to CDC for confirmatory and whole genome sequence testing.

A total of 3,050 passenger health questionnaires were distributed by the ship's crew. Of those, 2,410 questionnaires were returned (80.6% response rate). Exposure data analysis revealed that people who ate at the buffet and consumed unbottled water in the first 72 hours of the voyage were 45% more likely to have been ill than those who did not eat at the buffet and consume unbottled water.

While the ship was sailing to New Jersey, VSP investigative team conducted voluntary formal and informal interviews with selected passengers and crew members. Passengers relayed problems they noticed with the potable water on the ship, especially on the first day. Several passengers shared information about brown water with a foul odor coming from water faucets in their staterooms and in some public toilet rooms. After the voyage and during the sanitation barrier, VSP field team also noticed brown discolored water coming from the faucet at the handwashing sinks in a public toilet room on a lower level of the ship.

According to data analysis, the most likely source of exposure was unbottled water, with a 45% increased risk of illness after consuming unbottled water in the buffet within the first 72 hours of the voyage. The problems observed with the potable water by VSP team may have been a replication of the problems noted by passengers during interviews and described by the Chief Engineer as a common practice on the first day of a new voyage. Both the information gained

through interviews and through the health questionnaire were key to determining the likely source of exposure, which then dictated the best recommendations for remediation. There were no outbreaks on subsequent voyages following this investigation. The data collection instrument used for this investigation is presented in attachment E1.

Undetermined Transmission or Undetermined Risk Factor: During the outbreak, VSP investigative team was also able to identify that secondary transmission likely occurred through person-to-person spread and often through being present when someone experienced diarrhea or vomiting. Four hundred fifty-five respondents (23.9%) reportedly witnessed a vomiting or diarrhea event in a public area of the ship. Locations of those events included the following:

- In a public area of the ship not specified in the question (n=237; 128 later became ill).
- In a food outlet/restaurant on the ship (n=168; 59 later became ill).
- In a public toilet room on the ship (n=100; 47 later became ill).
- On an embarkation terminal shuttle (n=10; 5 later became ill).
- The embarkation terminal (n=9; 5 later became ill).
- In a lounge area on the ship (n=19; 9 later became ill).

Twenty-seven respondents indicated that they came into contact with the diarrhea or vomit (9 later became ill) and 52 said they did not know (24 later became ill). The information gleaned from the health questionnaires during this outbreak revealed a likely mode of transmission for secondary exposures and gave evidence to support the need for public health messaging about public vomiting events, how to care for sick friends and relatives, and the importance of proper hand hygiene to control the spread of pathogens that can cause illness.

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

Because the events necessitating the collection of information are of an emergency nature, most data are collected by interviews or self-administered paper-and-pencil questionnaires, which include embedded skip patterns. During CSOIs, there often is not sufficient time to develop, test, and launch electronic systems for collection of data. Electronic systems may introduce a new mode of disease transmission through the shared use of contaminated data collection devices, and not all potential respondents will have reliable internet access to use their own electronic device when the cruise ship is at sea.

Examples of CSOI data collection modes include face-to-face interview, and self-administered paper-and-pencil questionnaire. Often, multiple data collection modes are employed in a single CSOI. For example, each CSOI involves the identification of likely sources of transmission. To identify the sources, initial hypothesis-generating pencil-and-paper questionnaires may be

conducted. The initial data collected may be used to develop hypothesis-testing face-to-face interviews with selected passengers or crew (further described in Part B.1).

Data collection protocols are designed to be as unobtrusive as possible, and only the minimal information necessary is collected to reduce burden to the respondent. In all CSOIs, the number of questions posed will be held to a minimum needed given the event. The specific data collection protocol is tailored to meet the immediate needs of the cruise line and cruise ship experiencing and responding to the public health problem and will be used to identify the likely source of exposure and allow shipboard crewmembers to focus their response efforts. The choice of data collection methodology and mode may be influenced by:

- the population onboard the ship that is affected by the illnesses or event (passengers vs. crewmembers);
- what is already known about the problem when the team arrives in the field; and/or
- the severity of the event and the need for immediate actionable data that can be used to guide control efforts.

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

Literature searches and discussions with external partners initially are conducted to determine the extent of existing information. If found, previous information is used whenever appropriate to contribute to an investigation. However, an emergency generally requires the collection of data specific to the particular outbreak or event, because each situation is unique in many aspects (e.g. agents, locations, affected populations, sources exposure, modes of transmission, risk factors, and environmental factors).

While data collected are not generalizable, each investigation contributes to the general knowledge about a particular type of outbreak or event, and data collections are designed to incorporate knowledge gained from similar situations in the past. This knowledge can be used to anticipate the design of the initial surveys submitted for CSOI approval (Attachments E1-E2). Once in the field, a customized final survey will be designed to collect information specific to the situation.

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

Every effort will be made to minimize the burden on small businesses. In some emergency CSOIs, information may be collected from persons in small explorer ship or ferry businesses. It is estimated that 10% of responses will involve small businesses. Every effort is made to minimize the burden on all respondents during the collection of information during outbreaks

or events. Information collected is held to the absolute minimum required to inform effective prevention and control measures.

A.6. Consequences of Collecting the Information Less Frequently

CSOIs will involve one-time, rapid data collection efforts related to a specific outbreak or event. Not collecting this information impedes VSP from carrying out its congressionally mandated mission critical function of taking measures necessary to prevent the introduction, transmission, or spread of communicable diseases into the U.S. from a foreign country.

While most CSOIs involve 2 to 5 days of data collection, investigations conducted under this Generic ICR will not exceed 30 days. If data collection is required for a longer period of time due to unforeseen circumstances, a new request will be submitted to OMB explaining the circumstances for the unanticipated data collection and providing the forms that will be used for that collection (by this point, the content and scope of the inquiry should be clearer).

Furthermore, if the investigation expands outside the scope of the initial generic information collection (GenIC) (i.e., an outbreak occurs on a different cruise ship or the scope of the investigation is expanded), VSP will submit a new GenIC that covers the change.

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

As discussed in Section A.1, this Generic ICR covers CSOIs conducted in response to an AGE outbreak or event on a cruise ship that is characterized by undetermined agents, sources, modes of transmission, or risk factors initiated in response to a need for assistance from external cruise industry partners. This Generic ICR does not cover investigations conducted for the purposes of program evaluation, surveillance, needs assessment or research conducted primarily to contribute to generalizable knowledge.

CSOI data collection often needs to be initiated within hours of the request. Given the need for rapid data collection to minimize threats to public health and the short period of time available to collect date prior to the end of a cruise ship voyage, respondents are asked to respond to requests for data within 24 to 48 hours. This allows VSP to analyze the data and determine if additional information is required to support the emergency public health response.

To comply with the regulation 5 CFR 1320.5 and at the same time ensure that data are collected in a timely manner as necessary to protect the health of the public, CSOIs covered by this Generic ICR will adhere to the following timeline and processes (Attachment F):

1. Upon notification of an AGE outbreak or event by a cruise ship, VSP decides to organize and deploy a team to provide epidemiological and environmental health assistance to our partners while sailing with the ship to U.S. port of disembarkation. Boarding occurs during a port of call mid-voyage.
2. The CDC Information Collection Review Office (ICRO), U.S. Department of Health and Human Services (HHS), the OMB-OIRA Desk Officer, and his/her designated back up are immediately notified of the impending CSOI via an advance email notification (Attachment G) from VSP's Epidemiologist through the NCEH Information Collection Request Liaison (ICRL). This email will provide OMB with as much advance notice as possible that the request is being prepared.
3. VSP's Epidemiologist prepares and formally submits the CSOI packet including the "Request for Emergency Cruise Ship Outbreak Investigation (CSOI)" (Attachment H) describing the event and planned response, and the initial data collection forms (similar to Attachments E1-E2) through the NCEH ICRL to ICRO, HHS, and OMB-OIRA. If the time duration for collecting data using a survey is expected to exceed 30 minutes, a justification for the burden will be provided in Attachment I.
4. VSP staff may deploy and begin planning the investigation once the request is submitted to OMB.
5. Data collection cannot begin until OMB has approved the information collection or until 24 hours after OMB was notified of the investigation.
6. The OMB-OIRA Desk Officer responds with approval or comments on the proposed CSOI within 24 hours of receipt of the request.
7. Once approved, data collection for the CSOI will be conducted by customizing a standing set of surveys (Attachments E1-E2) given the suspected exposures.[4]
8. Prior to data collection, investigators must inform respondents that participation is voluntary, that respondents will not be personally identified in any published reports of the study, and that their privacy will be protected to the extent allowed under federal law.
9. Within seven business days of the completion of the CSOI, VSP will submit the final data collection instrument(s) and associated burden using the "Burden Memo" form

[4] VSP maintains a library of data collection instruments that includes all final data collection instruments conducted under this Generic ICR. A VSP staff person serves in the role of CSOI Information Collection Contact (ICC). The ICC oversees the notification and data retention process for individual GenICs. The ICC maintains a library of data collection forms that may be accessed by VSP when initiating new investigations. Upon the completion of an investigation, the ICC places the data collection instruments into the library. Information collected as part of a CSOI includes that necessary to identify the agents, sources, modes of transmission, or risk factors associated with an outbreak or public health event.

(Attachment I) to the NCEH ICRL, which are submitted to OMB quarterly as a non-substantive change to the Generic ICR.

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

A 60-day Federal Register Notice was published on 11/25/2024, Vol. 89, No. 227, page 92937 (Attachment B). CDC did not receive public comments related to this notice.

VSP was established in 1975 as a cooperative activity with the cruise ship industry. Due to the extensive and unique experience of VSP, there were no consultations outside of CDC.

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

Respondents receive no gift or payment for their participation in any information collections.

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

This Generic ICR has been reviewed by the NCEH/ATSDR Information Systems Security Officer (ISSO) who determined that the Privacy Act does not apply to this information collection (Attachment M). VSP does not collect information in identifiable form (IIF). Social security numbers are not collected.

Description of the information to be collected

The information collected varies by CSOI depending on the nature of the outbreak or event. Data to be collected align with the objectives of the investigation to identify and understand 1) the patterns of disease or injury occurrence, 2) prevalence of risk factors, 3) the etiologic agents or sources, or 4) the modes of transmission. Data collection may include both quantitative and qualitative data elements. Examples of information to be collected include descriptive information to characterize person, place, and time; symptomology information (e.g., to characterize illness, diagnoses); laboratory samples; medical conditions or symptoms of illness; medical information and notes; environmental factors; risk behaviors; patterns of behavior, potential exposures, and biological specimens. Social security numbers are not collected.

In summary, the potential data collection topics may include information on:

- Total number of people in respondent's cabin
- Person type (passenger, non-revenue passenger [e.g., guest chef], crewmember)

- Health status, including description and timing of any AGE symptoms
- Allergies or special diets followed
- Pre-embarkation activities during the incubation time period, including restaurants visited, foods/beverages consumed,
- Exposures on and off the ship, including public vomiting/diarrhea events, activities, food and beverage outlets, and food and beverage history

Questions that may be asked of key crewmembers for a given CSOI:

- Length of employment with the cruise line or in the cruise industry
- Total number of people in the respondent's cabin
- Crew type (i.e., food handler, non-food handler)
- Work location, generally and during the time preceding the outbreak
- Job duties, generally and during the time preceding the outbreak
- Health status, including description and timing of any AGE symptoms
- Timing of report of AGE illness, if applicable
- Exposures on and off the ship, including public vomiting/diarrhea events, activities, food and beverage outlets, and food and beverage history

Information is collected in collaboration with the external partners receiving epidemiological support. When external partners are the lead on the investigation, the information is collected under their authority and shared with VSP. Cruise industry partner policies and procedures for data storage and security are followed during each field investigation.

Data protection and storage

Data collected during a CSOI are considered private. CSOIs are not research and are not subject to the requirements for written, verbal, or waiver of consent under human subjects protections. Nevertheless, during CSOIs, CDC always places importance on providing consent information to fully inform the respondents about the investigation, their rights, and their decision to take part or not (Attachment J). VSP does not collect IIF or signatures from respondents.

In some investigations, clinical specimens (e.g., stool, emesis, blood), or environmental samples (e.g., water, food, surface swabs) may be collected by the appropriate shipboard personnel (e.g., the ship's physicians or nurses will collect clinical specimens, the ship's engineering department will collect water samples) to determine the causative agent for the outbreak. Specimens and samples are sent directly from the ship to the CDC or state department of health laboratory. All IIF are removed prior to submission and replaced with unique identifiers known only by the cruise line; VSP does not take custody of the specimens or samples to ensure a traceable chain of custody. Laboratory results are provided to the cruise line using their unique identifier.

Though the type of access control(s) implemented vary according to cruise line policies and procedures, examples include technical controls (e.g., password protection, storage on Virtual Private Network), physical controls (e.g., storage in locked cabinets or rooms), and administrative controls (e.g., daily offsite file back-ups, signed confidentiality agreements by staff who have access to files). Information collection is conducted according to a security plan developed in consultation with health authorities.

VSP maintains privacy by using unique, study identification numbers on all data collection forms. VSP does not maintain the link to the respondent's identity and the study. All personal identifiers are stripped from the data prior to establishing a final data analysis file. Results are only published in aggregate form.

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

The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events are directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

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

The Federal Regulations for Protection of Human Subjects (45 CFR 46) state that "research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Although CSOIs use systematic methods, they will not be designed to develop or contribute to generalizable knowledge and will not be research investigations.

As defined under 45 CFR 46.102(l)(2),[5] CDC uses its public health authority to undertake CSOIs as public health surveillance activities. Such activities are limited to those necessary to allow CDC to identify, monitor, assess, or investigate onsets of disease outbreaks. CSOIs provide timely situational awareness and priority setting during an outbreak that threatens public health. CDC uses the knowledge gained to directly benefit the affected cruise ship community and port cities visited by the ship.

[5] See eCFR :: 45 CFR 46.102 -- Definitions for purposes of this policy.

Human subjects review by an Institutional Review Board (IRB) is not required for CSOIs. The NCEH/ATSDR research determination for the Generic ICR is attached (Attachment L).

Sensitive Questions: Questions that might be considered sensitive (e.g., regarding risk behaviors, attitudes, or medical condition, symptoms, or diagnoses) are included only when necessary for the public health response. Before administering data collections, investigators inform respondents (either verbally or in writing) that participation is voluntary, and that respondents are not personally identified in any published reports of the study. Participants also are informed the data are being collected in response to an outbreak or event with adverse health consequences, and that the information they provide may help to identify effective prevention and control strategies.

A.12. Estimates of Annualized Burden Hours and Costs

Based on VSP experience, typically 20 to 30 AGE outbreaks are reported annually through MIDRS. In unusual years when a new strain of norovirus appears, VSP may observes double the number of outbreaks (e.g., 40 to 60).

VSP is still requesting a maximum of 10 CSOIs in response to cruise ship AGE outbreaks annually. Burden hours decreased from the previous collection as most cruise ship AGE outbreaks are caused by person-to-person transmission of norovirus and do not need further questionnaires administered. Therefore, the estimated 10 CSOIs are a subset of the total number of outbreaks reported to CDC per year.

The number of responses per year for 10 CSOIs is 13,000.

- The average number of respondents is 1,300 AGE cases (300 crew and 1,000 passenger) per CSOI.
- VSP has revised the respondent burden to more accurately reflect CSOI methods, as follows:
    - Each AGE case takes the self-administered questionnaire.
    - Next, VSP typically interviews a 15-percent subset of AGE cases who already responded to the questionnaire for additional information about their illness.
    - VSP is adding burden for a 10-percent subset of AGE cases who provide biospecimens for laboratory confirmation of the causative agent.

The total annual time burden requested is 4,063 hours. These estimates are based on the average reported burden for CSOIs characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors. The actual

number of respondents in each information collection and the number of responses per respondent varies depending on the purpose of each individual GenIC.

Table A-12.1. 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 crew	Self-administered Questionnaire	3,000	1	15/60	750
	Interview	450	1	15/60	113
	Biospecimen Collection	300	1	15/60	75
Cruise ship passengers	Self-administered Questionnaire	10,000	1	15/60	2,500
	Interview	1,500	1	15/60	375
	Biospecimen Collection	1,000	1	15/60	250
Total					4,063

A. Respondents for this data collection include 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 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 A-12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Costs
Cruise ship crew	Self-administered Questionnaire	3,000	1	15/60	$35.35	$26,512.50

	Interview	450	1	15/60	$35.35	$3,976.88
	Biospecimen Collection	300	1	15/60	$35.35	$2,651.25
Cruise ship passengers	Self-administered Questionnaire	10,000	1	15/60	$27.07	$67,675.00
	Interview	1,500	1	15/60	$27.07	$10,151.25
	Biospecimen Collection	1,000	1	15/60	$27.07	$6,767.50
Total						$117,734.38

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

There is no other total annual cost burden to respondents or record keepers.

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

Under the most recent MIDRS revision ICR (OMB Control No. 0920-1260, expiration date 03/31/2026), cruise ships report an estimated 1,300 AGE cases (300 crew and 1,000 passenger) per voyage, which is a decrease is the previous average.

In the previous PRA clearance approved in 2021, each AGE case was requested to complete a self-administered questionnaire, and a 15-percent subset of these AGE cases may be interviewed for additional information about their illness.

Furthermore, a 10-percent subset of AGE cases may be asked for biospecimens for laboratory confirmation of the causative agent. VSP uses existing laboratory biospecimen collection forms approved under other CDC ICRs (Attachment K under OMB Control No. 0920-0004, exp. date

04/30/2026 and *National Disease Surveillance Program II - Disease Summaries*; OMB Control No. 0920-0004; expiration date 10/31/2020; Form 50.34[6]).

VSP still proposes up to 10 CSOIs may be conducted annually in response to cruise ship AGE outbreaks. However, due to the refinement in estimates described above, this results in a revised total of 13,000 responses for 10 CSOIs per year; this is a decrease of 39,234 responses over the previously approved 52,234. The total annualized time burden has decreased to 4,063 hours; this is a decrease of 8,997 hours compared to the previously approved 13,060 annual hours.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The epidemiologic data collected in each CSOI provides information necessary for an effective public health response to an AGE outbreak or event with adverse health consequences and with undetermined agents, sources, modes of transmission, and risk factors. Therefore, collecting data as soon as possible after the onset of the outbreak or event is critical to the epidemiologic analysis. The duration of the data collection varies by CSOI but does not exceed 30 days. If it is determined an investigation will extend beyond 30 days, the lead investigator will submit a new GenIC.

For each CSOI, the lead investigator is responsible for developing an analysis plan and conducting the data analysis. Findings of an investigation may be presented or published (e.g., scientific journal article or report). Any publication of data derived from a CSOI is subject to review by relevant industry partners, CDC, or collaborating federal agencies.

Requests to release the information that is not available on VSP's web site (e.g., congressional inquiry, Freedom of Information Act requests) will be addressed on a case-by-case basis.

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

[6] Electronic version only at: https://www.cdc.gov/infectious-diseases-labs/php/submission-form/index.html.

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.