Emergency Cruise Ship Outbreak Investigations (CSOIs)

OMB Control No. 0920- NEW

Existing Collection in Use without an OMB Control Number

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 an existing generic clearance information collection in use without an OMB control number, titled *Emergency Cruise Ship Outbreak Investigations (CSOIs)*, which are conducted in response to acute gastroenteritis (AGE) outbreaks on cruise ships within the VSP's jurisdiction.

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 into 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 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 C2), currently the Division of Environmental Health Safety and Practice (DEHSP), NCEH. It is important to note, however, that both the VSP and DGMQ 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 - currently approved under DGMQ's PRA clearance titled Foreign Quarantine Regulations [OMB Control No. 0920-0134, expiration date 05/31/2019]), 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 clearance is specifically designed to support VSP's mission-critical function. CSOIs were previously conducted under *Emergency Epidemic Investigations* (OMB Control No. 0920-0008, expiration date 07/31/2014). The new generic clearance, *Emergency Epidemic Investigation Data Collections* (OMB Control No. 0920-1011, expiration date 01/31/2020) no longer meets VSP needs since VSP outbreak responses are CDC-initiated. A new generic

clearance mechanism for processing individual collection requests with 24-hour approval is requested to ensure the timely information collection required by an emergency cruise ship outbreak investigation is achieved. Participation in CSOIs is voluntary among cruise ship passengers and crew. The 60-day Federal Register Notice was published on 11/27/2018 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. The 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 clearance, 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 clearance 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 clearance, the following definitions[1] 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.
- Mode of transmission: the manner in which 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, the 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

[1] 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: http://www.cdc.gov/ophss/csels/dsepd/SS1978/SS1978.pdf.

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 clearance 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 clearance ***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 clearance 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 (*Foreign Quarantine Regulations* [OMB Control No. 0920-0134, expiration date 05/31/2019]) 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 clearance. Example data collection instruments are provided in the attachments (Attachment E3-E4).

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. The 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. The 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 E3.

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. The 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 also 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, the 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, the 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 the VSP team may have been 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 E4.

Undetermined Transmission or Undetermined Risk Factor: During the aforementioned outbreak, the 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. In order 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 situation 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 new generic clearance 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), the 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 clearance 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 clearance 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 clearance 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. The 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.[2]

[2] VSP maintains a library of data collection instruments that includes all final data collection instruments conducted under this generic clearance. 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.

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, the VSP will submit the final data collection instrument(s) and associated burden using the "Burden Memo" form (Attachment I) to the NCEH ICRL, which are submitted to OMB quarterly as a non-substantive change to the generic clearance.

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 11/27/2018, Vol. 83., No. 228, pages 60868-70 (Attachment B). CDC did not receive public comments related to this notice.

The VSP was established in 1975 as a cooperative activity with the cruise ship industry. Due to the extensive and unique experience of the 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 clearance ICR has been reviewed by the NCEH/ATSDR Information Systems Security Officer (ISSO) who determined that the Privacy Act applies to this information collection (Attachment M). The applicable System of Records Notice (SORN) is:

- SORN 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" (retrievable by name and ID number) http://www.cdc.gov/SORNnotice/09-20-0136.htm

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; environmental factors; risk behaviors; patterns of behavior, and potential exposures.

Examples of information in identifiable form (IIF) categories for which data may be collected include: passenger or crew name, medical information and notes, and biological specimens. Social security numbers are not collected.

In summary, the potential data collection topics in addition to IIF, 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

IIF is only collected when essential to the objective of the CSOI. Data collected in the course of a CSOI are considered private. Inadvertent release of this information may constitute an invasion of the subject's privacy. IIF are not included in any report from the CSOI. 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).

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 laboratory and 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. Results become part of the respondent's medical file owned and maintained by the cruise line.

The laboratory testing may be performed at a private or state facility, a federal agency laboratory (e.g., U.S. Food and Drug Administration Gulf Coast Seafood Laboratory), or at a CDC laboratory (e.g., National Calicivirus Laboratory, Foodborne and Diarrheal Diseases Epidemic Investigations Laboratory, National Center for Environmental Health Laboratory). If clinical specimens or environmental samples are collected and the causative agent is suspected to be norovirus, the National Calicivirus Laboratory form will be used (Attachment K1, *National Disease Surveillance Program II - Disease Summaries*; OMB Control No. 0920-0004; expiration date 10/31/2020). For clinical specimens or environmental samples suspected of any other causative agent, the general laboratory form will be used during this process (Attachment K2, *National Disease Surveillance Program II - Disease Summaries*; OMB Control No. 0920-0004; expiration date 10/31/2020; Form 50.34).

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.

IIF transmitted to VSP are treated in a private manner, unless otherwise compelled by law. VSP maintains privacy by using unique, study identification numbers on all data collection forms. Personal identifiers and the linkage to the study identification number are maintained separately in locked file cabinets or in encrypted computer files. All personal identifiers are

stripped from the data prior to establishing a final data analysis file. Results are only published in aggregate form.

Data are federal records and are maintained in accordance with the CDC/ATSDR Records Control Schedule. 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."

CSOIs will be undertaken to identify, characterize, and solve an immediate public health problem and the knowledge gained will directly benefit the affected cruise ship community and port cities visited by the ship. Although CSOIs will use systematic methods, they will not be designed to develop or contribute to generalizable knowledge and will not be research investigations. Human subjects review by an Institutional Review Board (IRB) will not be required. The NCEH/ATSDR research determination for the generic clearance 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, the VSP observes double the number of outbreaks (e.g., 40 to 60). Therefore, VSP estimates conducting a maximum of 10 CSOIs in response to cruise ship AGE outbreaks annually. Typically, CSOIs are possible when AGE outbreaks coincide with ship itineraries that allow the affected ships to be boarded for investigation and inspection. Unless the timing is right, a CSOI cannot be conducted. Therefore, the estimated 10 CSOIs are a subset of the total number of outbreaks reported to CDC per year.

The projected average number of respondents is 2,500 per CSOI, for a total of 25,000 respondents (24,750 questionnaire respondents and 250 interview respondents).

Due to the acute nature of the response, except in rare circumstances, each data collection instrument is administered to each respondent only once. VSP estimates the average burden per response is 15 minutes for each respondent per investigation. The actual burden for a specific investigation might be greater than 15 minutes per response for some investigations and less than 15 minutes per response in other investigations.

Therefore, the total estimated annual burden in hours is 6,250. 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 conducted in the previous five CSOIs. 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 Passengers or Crew	Questionnaire	24,750	1	15/60	6,188
	Interview	250	1	15/60	62
Total					6,250

The U.S. median national wage for all occupations in 2017 based on data from the Bureau of Labor Statistics (available at http://www.bls.gov/oes/current/oes_nat.htm) is $18.12. This wage is assumed for all CSOI participants because of the variety of types of participants expected. With a maximum annual respondent burden of 6,250 hours, the overall annual cost of respondents' time for the proposed collection is estimated to be a maximum of $113,250.00 (6,250 burden hours x $18.12).

Table A-12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cruise Ship Passenger or Crew	Questionnaire	6,188	$18.12	$112,126.56
	Interview	62	$18.12	$1,123.44
Total				$113,250.00

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

This is a new data collection to bring an existing collection in use without an OMB control number into compliance.

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

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

List of Attachments

A. Authorizing Legislation

A1. 42 USC Section 264 – Quarantine and Inspection - Regulations to Control Communicable Diseases

A2. 42 USC Section 269 – Quarantine and Inspection – Bills of Health

A3. 42 CFR Part 71 – Foreign Quarantine

B. 60-Day Federal Register Notice

C. Vessel Sanitation Program Delegation

C1. 1985 Federal Register Notice VSP in DGMQ

C2. 1987 CDC Memo VSP from DGMQ to NCEH

D. VSP 2018 Operations Manual

E. Example Questionnaires

E1. Acute Gastroenteritis (AGE) Example Questionnaire (Passenger or Crew)

E2. Semi-structured Interview Guide Example (Passenger or Crew)

E3. Example Questionnaire for Undetermined Agent

E4. Example Questionnaire for Undetermined Exposure and Undetermined Risk Factor

F. Steps for Conducting a CSOI

G. CSOI Advance Notification Email

H. Request for Emergency CSOI

I. CSOI Burden Memo

J. Consent Forms (sample)

K. CDC Laboratory Forms (approved under OMB Control No. 0920-0004)

K1. National Calicivirus Laboratory Form

K2. CDC Specimen Submission Form: Specimens of Human Origin (CDC Form No. 50.34)

L. CSOI Research Determination

M. Privacy Impact Assessment