

years old (76 hours); and 10 minutes for 191 children aged 12–17 years old who assent for themselves (32 hours).

Exposure Assessment Questionnaires for Biological and Environmental Testing for Adults, Parents, or Children: ATSDR/NCEH will administer an exposure questionnaire to all consented respondents that includes questions associated with potential exposure to PFAS both inside and outside the home (e.g., work or school). The adult questionnaire also includes several questions associated with water use and flooring type while the child questionnaire includes questions regarding playing in soil; these questions are intended to evaluate potential exposure and to support the environmental testing. The time associated with administering the questionnaire and completing the biological sampling is approximately 30

minutes for 1,440 adults (720 hours); 15 minutes for 264 parents responding for their children, 3–11 years old (66 hours); and 15 minutes for 191 children, 12–17 years old, who respond for themselves (48 hours).

Household Recruitment Script for Environmental Sampling: The households providing environmental samples (tap water and indoor dust) will be a random 10 percent subset of households that report using tap water for drinking water. Assuming a 65 percent response rate, ATSDR/NCEH will administer a five-minute recruitment script to 23 heads-of-households who are eligible to take part in each EA (152/10 * 100/65). This will result in annual recruitment from 117 heads-of-households and 10 hours for five EAs.

Consent for Environmental Testing: ATSDR/NCEH will consent a 10 percent

subset of households deemed eligible for the EA for testing of tap water and indoor dust samples; therefore, the desired number of households is 15 per EA, or 76 per year (152 * 10/100 * 5). The time associated with consenting to the environmental sampling is 10 minutes, resulting in a burden of 13 hours annually for five EAs.

Environmental Sample Collection Form: ATSDR will collect samples from approximately 15 households per EA or 76 households annually (152*10/100*5) and fill out a sample collection form. The average time burden is estimated as 15 minutes per response for the sample collection forms (19 hours annually).

ATSDR estimates the total annualized time burden is 1,390 hours.

Participation is voluntary, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
EA Community Members	Community Event Evaluation Survey	815	1	5/60
EA Adults	Household Eligibility Screener	1,170	1	5/60
	Consent	1,440	1	10/60
	Exposure Questionnaire (Adult)for Biological and Environmental Testing.	1,440	1	30/60
EA Parents	Parental Permission	455	1	10/60
	Exposure Questionnaire (Child)for Biological Testing (Parent Proxy).	264	1	15/60
EA Children	Assent	191	1	10/60
	Exposure Questionnaire (Child)for Biological Testing (Child completed).	191	1	15/60
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling ..	117	1	5/60
	Environmental Sampling Consent Form	76	1	10/60
	Environmental Sample Collection Form	76	1	15/60

Jeffrey M. Zirger,

Acting Team Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19BN; Docket No. CDC–2018–0104]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “Emergency Cruise Ship Outbreak Investigations (CSOIs)”. The purpose of this study is to allow the CDC Vessel Sanitation Program (VSP) to prevent the introduction, transmission, or spread of acute gastroenteritis (AGE) via cruise ships entering the United States from foreign countries.

DATES: CDC must receive written comments on or before January 28, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0104 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
 2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
 3. Enhance the quality, utility, and clarity of the information to be collected; and
 4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Emergency Cruise Ship Outbreak Investigations (COIs)—Existing Collection in Use without an OMB Control Number—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Established in 1975 as a cooperative activity with the cruise ship industry, the Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program (VSP) develops and implements comprehensive sanitation programs to minimize the risk of gastrointestinal diseases, by coordinating and conducting operational inspections, ongoing surveillance of gastrointestinal illness, and outbreak investigations on vessels.

Under the authority of the Public Health Service Act (42 U.S.C. Sections 264 and 269), the VSP is requesting a three-year approval for a new generic clearance information collection request (ICR). This ICR will provide the quick turn-around necessary to conduct emergency cruise ship outbreak investigations (CSOIs) in response to acute gastroenteritis (AGE) outbreaks. CSOIs are used to determine the causative agents and their sources, modes of transmission, or risk factors. The VSP's jurisdiction includes passenger vessels carrying 13 or more people sailing from foreign ports and within 15 days of arriving at a U.S. port.

VSP uses its syndromic surveillance system called the Maritime Illness and Death Reporting System (MIDRS) (approved under "Foreign Quarantine Regulations" [OMB Control No. 0920-0134, expiration date 05/31/2019]) to collect aggregate data about the number of people onboard ships in VSP's jurisdiction who are experiencing AGE symptoms. When the levels of illness meet VSP's alert threshold (*i.e.*, at least 2% in either the passenger or crew populations), a special report is made to VSP via MIDRS and remote environmental health and epidemiologic assistance is provided. VSP considers an outbreak to be $\geq 3\%$ of reportable AGE cases in either guest or crew populations. 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, and in some cases deploying 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 and environmental health evaluation of the outbreak.

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 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 delays allow passengers to disembark and leave the ship, including those returning to locations outside of the U.S.

This new generic clearance will cover investigations that meet all of the following criteria:

- 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.
 - Most CSOIs involve two to five days of data collection; data collection is completed in 30 days or less.
- This new generic clearance excludes each of the following:
- Investigations related to non-urgent outbreaks or events.
 - Investigations conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (*e.g.*, to contribute to generalizable knowledge).
 - Investigations with data collection expected for greater than 30 days.

The VSP estimates 10 CSOIs annually in response to cruise ship AGE outbreaks. The estimated number of respondents is 2,500 per CSOI, for a total of 25,000 respondents per year. The average time burden is 15 minutes for each respondent. Therefore, the total estimated annual burden in hours is 6,250. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Cruise Ship Passengers or Crew	Questionnaire	24,750	1	15/60	6,188
Cruise Ship Passengers or Crew	Interview	250	1	15/60	62
Total	6,250

Jeffrey M. Zirger,
Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0134]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Foreign Quarantine Regulations (42 CFR 71) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on September 7, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Foreign Quarantine Regulations (42 CFR 71) (OMB Control No. 0920-0134) (Exp 5/31/2019)—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Statute and the existing regulations governing foreign quarantine activities (42 CFR 71) authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals and etiologic agents in order to protect the public’s health. Other inspection agencies, such as Customs and Border Protection (CBP), assist quarantine officers in public health screening of persons, pets, and other importations of public health importance and make referrals to quarantine station staff when indicated.

These practices and procedures ensure protection against the introduction and spread of communicable diseases into and within the United States with a minimum of recordkeeping and reporting procedures, as well as a minimum of interference with trade and travel.

U.S. Quarantine Stations are located at 20 ports of entry and land-border crossings where international travelers arrive. The jurisdiction of each station includes air, maritime, and/or land-border ports of entry. Quarantine Station staff work in partnership with international, federal, state, and local agencies and organizations to fulfill their mission to reduce morbidity and mortality among globally mobile populations. This work is performed to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or from one State or possession to another State or possession. When an illness suggestive of a communicable disease is reported by conveyance operators or port partners (e.g. Customs and Border Protection), Quarantine Officers respond to carry out an onsite public health assessment and collect data from the individual. This response may occur jointly with port partners. The collection of comprehensive, pertinent public health information during these responses enables Quarantine Officers to make an accurate public health assessment and identify appropriate next steps. For this reason, quarantine station staff need to systematically interview ill travelers and collect relevant health and epidemiologic information.

CDC is making a number of changes and adjustments to this information collection. The changes are as follows:

- CDC is merging this information collection with another, 0920-0821 Illness Response Forms: Airline, Maritime, and Land/Border Crossing.
- CDC is disaggregating the information collection 42 CFR 71.21(a) report of illness or death from ships so that the influenza like illness (ILI) report, which is voluntary, is separate