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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-1255; Docket No. CDC-2024-
0096]

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 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 Vessel Sanitation Program
(VSP) conducts CSOIs in response to
acute gastroenteritis (AGE) outbreaks on
cruise ships within the VSP's
jurisdiction.

DATES: CDC must receive written
comments on or before January 24,
2025.

ADDRESSES: You may submit comments,
identified by Docket No. CDC-2024-
0096 by either of the following methods:

- *Federal eRulemaking Portal:*
www.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 H21-8, Atlanta,
Georgia 30329.

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

Please note: Submit all comments
through the Federal eRulemaking portal
(www.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
H21-8, Atlanta, Georgia 30329;
telephone: 404-639-7570; email: [omb@
cdc.gov](mailto: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;
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; and
5. Assess information collection costs.

Proposed Project

Emergency Cruise Ship Outbreak
Investigations (CSOIs (OMB Control No.
0920-1255, Exp. 3/31/2025)—
Extension—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 operational
public health programs to minimize the
risk of gastrointestinal illness. VSP
coordinates and conducts public health
inspections, ongoing surveillance of
gastrointestinal illness, and outbreak
investigations on cruise ships.

Under the authority of the Public
Health Service Act (42 U.S.C. 264 and
269), VSP is requesting a three-year
Extension Information Collection
Request (ICR) for an existing Generic
Clearance. This ICR will provide for the
quick turnaround necessary to conduct
emergency Cruise Ship Outbreak
Investigations (CSOIs) in response to
acute gastroenteritis (AGE) outbreaks.
CSOIs are used to determine causative
agents and their sources, modes of
transmission, or risk factors. 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) (OMB
Control No. 0920-1260, expiration date
03/31/2026) 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 VSP provides
environmental health and
epidemiologic assistance. VSP considers
an outbreak to be $\geq 3\%$ of reportable
AGE cases in either passenger or crew
populations.

When a cruise ship has an AGE
outbreak, VSP often must deploy a
response team to meet the ship in port
within 24 hours of reaching the
outbreak threshold. In some cases, the
response team must 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.

VSP can ascertain a causative agent,
sources of exposure, modes of
transmission, and risk factors 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 onshore 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 United States.

This Generic Clearance will cover investigations that meet all 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.

- Data collection is completed in 30 days or less (most CSOIs involve two to five days of data collection).

This 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.

VSP estimates 10 CSOIs annually in response to cruise ship AGE outbreaks. The estimated number of respondents is 1,300 per CSOI, for a total of 13,000 respondents per year. The average time burden is 15 minutes for each respondent. Therefore, the total estimated annual burden in hours is 4,063. 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 crew	Self-administered questionnaire	3,000	1	15/60	750
Cruise ship crew	Interview	450	1	15/60	113
Cruise ship crew	Biospecimen collection	300	1	15/60	75
Cruise ship passenger	Self-administered questionnaire	10,000	1	15/60	2,500
Cruise ship passenger	Interview	1,500	1	15/60	375
Cruise ship passenger	Biospecimen collection	1,000	1	15/60	250
Total					4,063

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-25-0792]

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 “Environmental Health Specialists Network (EHS-Net) Program” 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 August 9, 2024, to obtain comments from the public and affected agencies. CDC received three 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.

Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. 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

Environmental Health Specialists (EHS-Net) Program (OMB Control Number 0920-0792, Exp. 1/31/2025)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting a three-year Paperwork Reduction Act (PRA) approval for a Revision of this Generic