

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued  
 [Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	Key Question 2 ..... • Studies of adults ○ Parallel or cross-over RCTs ▪ n ≥25/group * ○ Nonrandomized comparative studies ▪ Must account for potential confounders. ▪ Dietary intake must be defined or described prospectively. ▪ We will aim for a minimum of about 10 observational studies for each specific intervention—CV event pair (e.g., reduced saturated fat and stroke). We will thus select the largest observational studies within each category.†. ▪ n ≥100/group.	
Timing .....	Key Question 1 ..... • Minimum intervention length: 4 weeks ..... • In cross-over studies, any change in outcome measure must exclude data from the first week after end of any prior treatments Key Question 2 ..... • Minimum follow-up ○ If population has no CV risk factors: 10 years. ○ If population has one or more CV risk factors (or unselected general population): 5 years.	None.
Setting .....	• General community settings, including nursing homes, assisted living facilities, etc.	• Hospital or other acute care settings. • Institutionalized, confined settings (e.g., prisons)
Publication .....	• English language • Published in peer-reviewed journals.	

\* Minimum sample size may be altered depending on the number of eligible studies found.

† Applying this approach for the 2016 AHRQ report n-3 fatty acids and cardiovascular disease (<https://doi.org/10.23970/AHRQEPERTA223>), we included: for cardiac event outcomes, observational studies with at least 10,000 participants; for stroke outcomes, at least 3000 participants; for arrhythmia outcomes, at least 2000 participants; congestive heart failure outcomes, at least 700 participants; and for peripheral vascular disease events and MACE outcomes, at least 500 participants. In all instances, if a study meets eligibility criteria for any outcome, we will extract all outcomes of interest from that study; therefore, there will be multiple instances of studies being included for an outcome even though the study might not have met study size criteria for that specific outcome.

CV = cardiovascular; CVD = cardiovascular disease; MUFA = mono-unsaturated fatty acids; PUFA = polyunsaturated fatty acids; c = cholesterol; LDL = low-density lipoprotein; IDL = intermediate-density lipoprotein; HDL high-density lipoprotein; TC—total cholesterol; Tg = Triglycerides/ Triacylglycerols; apoA = apolipoprotein; MAC[C]E = Major adverse cardiac (or cerebro) events; BMI = body mass index; KQ = key question; N = number of participants.

Dated: November 19, 2024.

**Marquita Cullom,**

*Associate Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Toxic Substances and Disease Registry**

[30Day-25-0047]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry

(ATSDR) has submitted the information collection request titled “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on August 16, 2024, to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR 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](http://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**

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control No. 0923-0047, Expiration Date 2/28/2025)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR).

*Background and Brief Description*

The information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Federal government’s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention

on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the ATSDR and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency’s services will be unavailable.

ATSDR will only submit a collection for approval under this Generic Clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are noncontroversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, the agency must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially

informing influential policy decisions; and

- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this Generic Clearance provides useful information, but it does not yield data that can be generalized to the overall population.

This type of Generic Clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: (1) the target population to which generalizations will be made; (2) the sampling frame; (3) the sample design (including stratification and clustering); (4) the precision requirements or power calculations that justify the proposed sample size; (5) the expected response rate; (6) the methods for assessing potential nonresponse bias; (7) the protocols for data collection; and (8) any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

This is an Extension of the previously approved collection. The respondents are Individuals and Households; Businesses and Organizations; and State, Local, or Tribal Government. ATSDR requests OMB approval for an estimated 7,075 annualized burden hours. There is no cost to respondents other than their time.

*Estimated Annualized Burden Hours*

Type of collection	Number of respondents	Annual frequency per response	Hours per response
Small discussion groups .....	300	1	90/60
Request for customer comment cards/complaint forms/post-conference or training surveys ....	1,500	1	15/60
Focus groups of customers, potential customers, delivery partners, or other stakeholders .....	2,000	1	2
Qualitative customer satisfaction surveys or interviews .....	3,000	1	30/60
Usability testing/in-person observation testing .....	1,500	1	30/60

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office,  
Office of Public Health Ethics and  
Regulations, 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-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](http://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](http://www.regulations.gov).

*Please note:* Submit all comments  
through the Federal eRulemaking portal  
([www.regulations.gov](http://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,