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/AHRQEPCERTA223*), 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.

[FR Doc. 2024–27488 Filed 11–22–24; 8:45 am]

BILLING CODE 4160–90–P

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*. 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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BILLING CODE 4163–18–P

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.*

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 ≥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,