an electronic version of the draft policy statement, go to *http://www.regulations.gov.* Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION:

A. Legal Authority

HHS/CDC is issuing this draft policy under the authority of sections 201–204 and 221 of Title II of Public Law 107–188, (42 U.S.C. 262a).

B. Background

For entities that possess select agents and toxins, the HHS select agent and toxin regulations (42 CFR part 73) require that ''biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.,* physical structure and features of the entity, and operational and procedural safeguards)'' (42 CFR 73.12(b)). BSL–4 and ABSL–4 laboratory facility specifications and operational procedures are used for work with dangerous and exotic biological agents that could easily be aerosol transmitted within the laboratory, cause severe to fatal disease in humans, and typically do not have available vaccines or treatments. Therefore, these laboratories must implement and maintain the highest level of biosafety precautions for containment.

HHS/CDC reviews how entities that maintain BSL–4 and/or ABSL–4 laboratories have verified that the design and operational parameters, including HVAC, are functioning properly when determining if entities have met the sufficiency requirement in section 12(b) of the HHS select agent and toxin regulations. In developing a biosafety plan, an individual or entity should consider requirements found in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (42 CFR 73.12(c)). HHS/CDC has developed a draft policy statement for BSL–4 and ABSL–4 laboratory verification based on the standards found in the 6th edition of the BMBL:

- *BSL–4 D16(a):* The ventilation system is designed to maintain the laboratory at negative pressure to surrounding areas and to provide differential pressure or directional airflow as appropriate between adjacent areas within the laboratory.
- *ABSL–4 D16(a):* The supply and exhaust components of the ventilation system are designed to maintain the ABSL–4 facility at negative pressure to surrounding areas and to provide differential pressure or directional airflow as appropriate between adjacent areas within the facility.
- *BSL–4 D20:* The facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.
- *ABSL–4 D21:* The ABSL–4 facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.

HHS/CDC is requesting public comment on a draft policy statement on BSL–4/ABSL–4 laboratory verifications standards, including HVAC, to aid individuals and entities in verifying that these laboratories are properly functioning. We are making this policy document available to the public in the Supplementary Materials tab of the docket at *www.regulations.gov* for review and comment. All comments, such as items related to the appropriate acceptance criteria used to ensure systems are functioning as intended and documentation to demonstrate the sufficiency requirement has been met, that we receive on or before March 21, 2022 will be carefully reviewed and considered.

Dated: January 13, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–00928 Filed 1–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–1255]

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 ''Emergency Cruise Ship Outbreak Investigations (CSOIs)'' 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 10/13/2021 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. 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

Emergency Cruise Ship Outbreak Investigations (CSOIs) (OMB Control No. 0920–1255, Exp. 03/30/2022)—Revision—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 Paperwork Reduction Act (PRA) clearance for a revision of an existing generic clearance information collection request (Generic ICR), titled ''Emergency Cruise Ship Outbreak Investigations (CSOIs)'' (OMB Control Number 0020–1255, expiration date 03/30/2022). This Generic ICR provides the quick turn-around necessary to conduct emergency 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)'' (OMB Control No. 0920–1260, expiration date 04/30/2022) 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 greater than or equal to 3% of reportable AGE cases in either guest or crew populations. When outbreaks occur, cruise ships submit daily reports of cases in the form of AGE logs to VSP. 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 Generic ICR 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 2 to 5 days of data collection; data collection is completed in 30 days or less.

This Generic ICR excludes each of the following:

- Investigations related to non-urgent outbreaks or events.
- Investigations conducted for the primary purpose of program evaluation, needs assessment, or research (*e.g.,* to contribute to generalizable knowledge).
- Investigations with data collection expected for greater than 30 days.

The cruise ship industry experience in 2020 and 2021 was largely not considered in this revision due to the disruption caused by the COVID–19 pandemic. Since the first quarter of 2020, the COVID–19 pandemic disrupted the number of cruise ship voyages operating to U.S. ports of call. Between March 2020 and October 2021, cruise industry operations were suspended under a federally issued No Sail Order, and then subsequently under a Conditional Sailing Order to prevent the risk of introducing, transmitting, and spreading COVID–19 by cruise ship travelers. The VSP conducted the following number of remote environmental health and epidemiologic consultations for outbreaks, greater than or equal to 3% of reportable AGE cases, by reviewing existing MIDRS records: 10 in 2019, none in 2020, and one in 2021. No new information was collected. Additionally, the VSP conducted no CSOIs in the past three years.

Under the most recent MIDRS revision, cruise ships report an estimated 3,370 AGE cases (575 crew and 2,795 passenger) per voyage; therefore, VSP uses this same increase of 870 over the previously approved 2,500 AGE cases per voyage for each CSOI. Previously, respondents were counted as either taking the self-administered questionnaire or the interview. Currently, all AGE cases are requested to complete a self-administered questionnaire. Then a 15% subset of these AGE cases may be interviewed for additional information about their illness. Furthermore, a 40% subset of AGE cases may be asked for biospecimens for laboratory confirmation of the causative agent. The VSP uses existing laboratory biospecimen collection forms approved under other CDC ICRs (OMB Control No. 0920–0004, exp. date 10/31/2020; OMB Control No. 0920–1309, exp. date 11/30/2023).

As previously approved, up to 10 CSOIs may be conducted annually in response to cruise ship AGE outbreaks. This results in a revised total of 52,234 responses for 10 CSOIs per year; this is an increase of 27,232 responses over the previously approved 25,000. The total annualized time burden has increased to 13,060 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Cruise ship crew	Self-administered Questionnaire	5,750	1	15/60
	Interview	862	1	15/60
	Biospecimen Collection	2,300	1	15/60
Cruise ship passengers	Self-administered Questionnaire	27,950	1	15/60
	Interview	4,192	1	15/60
	Biospecimen Collection	11,180	1	15/60

Jeffrey M. Zirger,

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–22–0607]

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 ''The National Violent Death Reporting System (NVDRS)'' 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 6, 2021, to obtain comments from the public and affected agencies. CDC received one non-substantive comment 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

The National Violent Death Reporting System (NVDRS) (OMB Control No. 0920–0607, Exp. 7/31/2023)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Violence is a public health problem. The World Health Organization has estimated that 804,000 suicides and 475,000 homicides occurred in the year 2012 worldwide. Violence in the United States is a particular problem for the young; suicide and homicide were among the top four leading causes of death for Americans 10–34 and 1–34 years of age in 2015, respectively. In 2002 Congress approved the first appropriation to start the National Violent Death Reporting System (NVDRS). NVDRS is coordinated and funded at the federal level but is dependent on separate data collection efforts managed by the state health department (or their bona fide agent) in each state.

NVDRS, implemented by the Centers for Disease Control and Prevention (CDC), is a state-based surveillance system developed to monitor the occurrence of violent deaths (*i.e.,* homicide, suicide, undetermined deaths, and unintentional firearm deaths) in the United States (U.S.) by collecting comprehensive, detailed, useful, and timely data from multiple sources (*e.g.,* death certificates, coroner/medical examiner reports, law enforcement reports) into a useable, anonymous database. NVDRS is an ongoing surveillance system that captures annual violent death counts and circumstances that precipitate each violent incident. Violent deaths are defined as any death resulting from the intentional use of physical force or power (*e.g.,* threats or intimidation) against oneself, another person, or against a group or community. CDC aggregates de-identified data from each state into one large national database that is analyzed and released in annual reports and publications. Descriptive analyses such as frequencies and rates are employed. A restricted access database is available for researchers to request access to NVDRS data for analysis and a web-based query system is open for public use that allows for electronic querying of data. NVDRS generates public health surveillance information at the national, state, and local levels that is more detailed, useful, and timely. Government, state and local communities have used NVDRS data to develop and evaluate prevention programs and strategies. NVDRS is also used to understand magnitude, trends, and characteristics of violent death and what factors protect people or put them at risk for experiencing violence.

CDC has received OMB approval for NVDRS since 2004. In this revision request CDC describes plans to (1) implement updates to the web-based system to improve performance, functionality, and accessibility, (2) add