

CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters

Request for OMB Approval of an Existing Information Collection

February 9, 2022

Supporting Statement A

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- **Goal of the study:** As part of its COVID-19 Program for Cruise Ships Operating in U.S. Waters, CDC will collect information from cruise ships operating or intending to operate in U.S. waters that choose to participate in the program. This program includes reporting of COVID-19 and COVID-19-like illnesses as well as a number of information collections designed to ensure cruise ships can prevent, detect, and respond to outbreaks of COVID-19.
- **Intended use of the resulting data:** CDC will use collected data to monitor the prevalence of COVID-19 on cruise ships and evaluate the effectiveness of its COVID-19 Program for Cruise Ships.
- **Methods to be used to collect:** Surveillance reporting will be collected using REDCap (a CDC-approved secure web application). CDC will accept electronic copies via email of all data collection components.
- **The subpopulation to be studied:** Respondents include all persons operating or intending to operate commercial, non-cargo, passenger-carrying vessels in international, interstate, or intrastate waterways subject to the jurisdiction of the United States with the capacity to carry 250 or more passengers and crew with an itinerary anticipating an overnight stay on board or a twenty-four hour stay on board for either passengers or crew (cruise ships) that choose to participate in CDC's COVID-19 Program for Cruise Ships Operating in U.S Waters.
- **How data will be analyzed:** There are no statistical methods. CDC will analyze data collected using descriptive methods to monitor COVID-19 prevalence, identify trends, and detect outbreaks.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) is requesting approval for three years for an existing information collection titled Phased Approach to the Resumption of Cruise Ship Passenger Operations, and retitled CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters. This collection is necessary to align with CDC's transition to a voluntary program, in coordination with interested cruise ship operators and other stakeholders, to assist the cruise ship industry to detect, mitigate, and control the spread of COVID-19 onboard cruise ships.

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world. As of February 8, 2022, a cumulative estimated total of over 396 million cases and over 5.7 million confirmed deaths have now been reported worldwide.¹ Even in countries that have managed to slow the rate of transmission, the risks for COVID-19 resurgence remains. In the United States, as of February 8, 2022, there have been over 76 million cases and over 900,000 confirmed deaths.² COVID-19 vaccines are now widely available in the United States, and vaccination is recommended for all people 5 years of age and older. As of February 8, 2022, more than 213 million people in the United States (68.2% of the population 5 years of age or older) have been fully vaccinated and more than 251 million people in the

¹ <https://covid19.who.int/>

² https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

United States (80.5% of the population 5 years of age or older) have received at least one dose.³ Additionally, COVID-19 vaccine booster shots have been recommended for everyone 12 years of age and older. In the United States, over 90 million people (43.7% of the population 12 years of age or older) have received a booster dose as of February 8, 2022.⁴

Cruise ship travel has the potential to exacerbate and amplify the spread of SARS-CoV-2, the virus that causes COVID-19. Scientific evidence suggests cruise ships pose a greater risk of COVID-19 transmission than other settings due to the high population density on board ships, which are typically more densely populated than cities or most other living situations.⁵ Additionally, CDC's cruise ship COVID-19 surveillance data showed that drastically decreasing population on board, absent other interventions, is not enough to extinguish transmission. Other factors likely contributing to onboard transmission are crews' living and working in close quarters—in a partially enclosed environment—where physical distancing remains challenging even with a limited number of people onboard.

While cruising will never be a zero-risk activity for spread of COVID-19, CDC has successfully worked with cruise ship operators and state, territorial, and local health authorities to manage this risk and allow cruise ship operators to resume passenger operations in a way that mitigates the risk to crew members, passengers, port personnel, and communities.

On October 30, 2020, CDC announced a Framework for Conditional Sailing Order (CSO) (Attachment C) for cruise ships through November 1, 2021, to prevent the further spread of COVID-19 from cruise ships into communities and protect public health and safety. The CSO provided a pathway to safer sailing, both to prevent COVID-19 outbreaks on ships and to prevent passengers and crew from seeding outbreaks at ports and in the communities where they live.

The CSO resumed cruise ship passenger operations through a four-phased approach:

- Mass crew testing and acquiring onboard laboratory testing equipment (Phase 1),
- Preparing for simulated and revenue voyages (e.g., identifying locations through port agreements to provide for the quarantine or isolation, respectively, of exposed and ill passengers) (Phase 2A) and simulated voyages to test onboard health and safety protocols (Phase 2B),
- Applying for a COVID-19 Conditional Sailing Certificate (Phase 3); and
- Restricted passenger revenue voyages with public health precautions (Phase 4).

The requirements in the CSO highlighted the need for further action before cruise ships could safely resume passenger operations in the United States.⁶ On October 25, 2021, CDC temporarily extended the

³ https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

⁴ https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

⁵ <https://academic.oup.com/jtm/article/27/3/taaa030/5766334>

⁶ As of July 23, 2021, the CSO and accompanying measures, such as technical instructions, were nonbinding recommendations for cruise ships arriving in, located within, or departing from a port in Florida. CDC continued to operate the CSO as a voluntary program in Florida for such ships that chose to follow the CSO's measures voluntarily.

Framework for Conditional Sailing Order until January 15, 2022, with minor modifications (Attachment D).

CDC remains committed to working with the cruise industry, state, territorial, and local health authorities, and seaport partners to continue cruise ship passenger operations in a way that protects passengers, crew, port communities, and the communities to which travelers will return. For this reason, after the expiration of the Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO) on January 15, 2022, CDC will implement a COVID-19 risk mitigation program for foreign-flagged cruise ships operating in U.S. waters.⁷ Cruise lines choosing to opt into this program will be required to follow these recommendations and guidance as a condition of participation in the program. These recommendations are aimed at further reducing the introduction and spread of SARS-CoV-2 on board cruise ships and are aligned with previous health and safety protocols under the CSO.

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A1) 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 U.S. This information collection concerns CDC's statutory and regulatory authority related to preventing the spread of communicable disease from maritime vessels into the U.S. The additional relevant legal authorities for this collection are found at section 365 of the Public Health Service Act (Attachment A1) and 42 C.F.R. §§ 70.2, 71.31(b), and 71.32(b) (Attachments A2 and A3).

2. Purpose and Use of Information Collection

CDC will implement its COVID-19 Program for Cruise Ships Operating in U.S. Waters after the expiration of the Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO)—published in the *Federal Register* on October 28, 2021 (Attachment D)— on January 15, 2022.

Cruise ships operating in U.S. waters choosing to participate in the program agree to follow all recommendations and guidance issued by CDC as part of this program. These recommendations are aimed at further reducing the introduction and spread of SARS-CoV-2 onboard cruise ships so that voyages may continue operating in a way that provides a safer and healthier environment for crew, passengers, and communities. CDC will work closely with cruise ships opting into the program and continue to monitor compliance with COVID-19 preventive measures and cases onboard these cruise ships through daily enhanced data collection and inspections.

The guidance and recommendations included in CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters are aligned with previous health and safety protocols under the CSO. As such, cruise ship operators who have resumed operations under the CSO will already be familiar with the components of the program, and operators who choose to participate in the program will be able to continue sailing with passengers without interruption.

⁷ U.S.-flagged cruise ships may follow CDC's COVID-19 Program for Cruise Ships at the cruise ship operator's discretion.

This information collection request outlines the reporting and document retention requirements that are part of CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters. Note, many of the data collection elements included in CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters are currently approved under this information collection, under *Phased Approach to the Resumption of Cruise Ship Passenger Operations*, OMB Control 0920-1335.

CDC will provide cruise lines operating cruise ships with information about the COVID-19 program and how to contact CDC to opt in or opt out of the COVID-19 Program for Cruise Ships.

Opting into the COVID-19 Program for Cruise Ships

Cruise lines operating cruise ships in U.S. waters choosing to participate in this program (“opting in”) are requested to notify the CDC in writing of their decision to opt in by February 18, 2022 (Attachment E).

Cruise lines choosing to participate in this program will be required to follow all recommendations and guidance as a condition of their participation—i.e., they will not be able to pick and choose which recommendations they follow. Those opting in will continue to receive a color status for cruise ships operating in U.S. waters on CDC’s Cruise Ship Color Status webpage.⁸

Cruise lines with ships not currently in U.S. waters—but that are expecting to return to U.S. waters after February 18, 2022—are requested to contact CDC via email at least 28 days prior to their ships’ arrival. Instructions on how to participate in the program will be provided.

Cruise lines that initially decide to participate in the program but then later decide not to participate should contact CDC via email for instructions.

Opting Out of the COVID-19 Program

Cruise lines operating in U.S. waters choosing not to participate in the program (“opting out”) are requested to notify CDC in writing by February 18, 2022 (Attachment E).

Cruise lines that do not notify CDC by 5:00 pm ET on February 18, 2022, will be considered to have opted out of this program. Cruise lines that decide to opt out will have any cruise ships operating in U.S. waters listed as “Gray” ships⁹ on CDC’s Cruise Ship Color Status webpage.¹⁰ This designation means that CDC has neither reviewed nor confirmed the cruise ship operator’s health and safety protocols. Additionally, these ships will be subject to other CDC orders and regulations to the same extent as other ships and conveyances subject to the jurisdiction of the United States.

⁸ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html>

⁹ U.S.-flagged cruise ships may follow CDC’s COVID-19 Program for cruise ships at the cruise ship operator’s discretion and receive a color status CDC’s Cruise Ship Color Status webpage. However, U.S.-flagged ships not following this program will *not* be listed as “gray” on CDC’s Color-Coding Status webpage.

¹⁰ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html>

Cruise lines that initially decide to opt out but later decide to opt into the program should contact CDC via email at least 28 days prior to the day they intend to join the program. Instructions on how to participate in the program will be provided.

Cruise Ship Vaccination Status Classification

Cruise lines that choose to participate in CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters must advise CDC of the vaccination status classification for each participating ship (Attachment F). This information will be included on CDC’s Cruise Ship Color Status webpage.

As part of CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters, cruise ship vaccination status classifications are defined as:

- **Not Highly Vaccinated:** ships with less than 95% passengers and 95% crew who are fully vaccinated.¹¹
 - o Cruise ship operators that select this vaccination status classification will be required to enforce mask use and physical distancing onboard according to CDC guidance.¹²
- **Highly Vaccinated:** ships with at least 95% passengers and 95% crew who are fully vaccinated, but less than 95% of passengers and 95% of crew are up to date with their COVID-19 vaccines.
 - o Cruise ship operators that select this vaccination status classification will be required to enforce mask use—but not physical distancing—onboard according to CDC guidance. These cruise ship operators may implement physical distancing policies at their discretion.
- **Vaccination Standard of Excellence:** ships with at least 95% passengers (including children) and 95% crew who are up to date with their COVID-19 vaccines.¹³
 - o Cruise ship operators that select this vaccination status classification will not be required to enforce mask use or physical distancing onboard. These cruise ship operators may implement mask use and physical distancing policies at their discretion.

Ships adhering to the “Highly Vaccinated” or “Vaccination Standard of Excellence” classifications must maintain these thresholds for each voyage.

COVID-19 Response Plans

¹¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>

¹² <https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html>

¹³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>

Cruise ship operators choosing to participate in CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters must have a COVID-19 response plan (Attachment G) that includes the following components:¹⁴

- Terminology and use of definitions that align with how CDC uses and defines the following terms: “confirmed COVID-19,” “COVID-19-like illness,” “close contact,” “fully vaccinated for COVID-19,” and “isolation” and “quarantine” (including timeframes for isolation and quarantine).
- Protocols for on board surveillance of passengers and crew with COVID-19 and COVID-19-like-illness.
- Protocols for training all crew on COVID-19 prevention, mitigation, and response activities.
- Protocols for on board isolation and quarantine, including how to increase capacity in case of an outbreak.
- Protocols for COVID-19 testing that aligns with CDC technical instructions.
- Protocols for onboard medical staffing—including number and type of staff—and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, face masks, personal protective equipment) for the infected without the immediate need to rely on shoreside hospitalization.
- Procedures for disembarkation of passengers who test positive for COVID-19.
- Statement that the cruise ship operator has observed and will continue to observe all elements of its COVID-19 response plan including following the most current CDC recommendations and guidance for any public health actions related to COVID-19.

Surveillance and Reporting

For cruise ships that have chosen to participate in the program, CDC requires daily submission of the “Enhanced Data Collection (EDC) During COVID-19 Pandemic Form” (Attachment H), in lieu of submitting the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form (approved under OMB Control 0920-0134 and in Attachment I for reference) for COVID-19-like illness and the Maritime Conveyance Illness or the Death Investigation Form (approved under OMB Control 0920-0134 and in Attachment J for reference) for individual cases of COVID-19. This EDC Form will be used to conduct surveillance for COVID-19 on board cruise ships using cumulative reports of confirmed COVID-19¹⁵ and COVID-19-like illness¹⁶, which includes acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) clinical criteria. Data points for this form include number of travelers (passengers and crew) currently onboard; case counts and

¹⁴ Cruise line brands may submit this information for all ships in their fleet.

¹⁵ Confirmed COVID-19 means laboratory confirmation for SARS-CoV-2, the virus that causes COVID-19, by viral test.

¹⁶ COVID-19-like illness clinical criteria include the following:

- Persons with at least one or more of the following symptoms: fever, cough, difficulty breathing, shortness of breath, new olfactory disorder, or new taste disorder; OR
- Persons with at least two or more of the following symptoms: sore throat, nasal congestion, runny nose (rhinorrhea), chills, rigors, muscle or body aches (myalgias), headache, fatigue, vomiting, or diarrhea ...in the absence of a non-infectious diagnosis as determined by the ship’s physician (e.g., allergies); OR
- Persons with severe respiratory illness with at least one of the following:
 - Clinical or radiographic evidence of pneumonia,
 - Acute respiratory distress syndrome (ARDS).

diagnostic testing data for COVID-19 and COVID-19-like Illness (CLI); screening testing of asymptomatic travelers, isolation practices, and the percentage of travelers who are fully vaccinated.

Access to the online EDC form has been provided to cruise lines by the Cruise Lines International Association (CLIA) and/or CDC. Cruise lines that do not have access should contact CLIA or CDC.

To address industry concerns about the burden of daily EDC submission, CDC will add an option in the online form (i.e., a check box) to streamline reporting if no cases were identified or no testing was conducted for that day. Additionally, to reduce reporting burden for cruise ships, CDC will continue to submit aggregate data to seaport authorities, state, local, and territorial health departments that oversee seaports, federal partners, and international maritime public health agencies.

The data collected in the EDC form are used to inform CDC's COVID-19 Color-Coding System for Cruise Ships.¹⁷ These data will greatly increase the transparency of the overall health of the crew members and passengers, and better allow the CDC to manage potential outbreaks and offer recommendations to the ship and port partners.

The color-coding system is only applicable to cruise ships that meet one of the following criteria:

1. Foreign-flagged cruise ships currently operating in U.S. waters; or
2. Foreign-flagged cruise ships currently operating outside of U.S. waters but planning to return to operation in international, interstate, or intrastate waterways subject to the jurisdiction of the United States; or
3. U.S.-flagged cruise ships choosing to participate in CDC's COVID-19 Program for Cruise Ships.¹⁸

Status of ships is contingent upon daily submission of the EDC form. When a cruise ship notifies CDC of suspected or confirmed cases of COVID-19 on board, CDC determines whether an investigation is needed based on a predetermined threshold.¹⁹ If an investigation is deemed necessary, CDC will solicit extra information from the cruise ship operator (Attachments K and L, Cruise COVID-19 Case Investigation Worksheet and Cruise COVID-19 Contact Investigation Worksheet, respectively) to determine what public health interventions may be necessary. This investigation gives CDC and the cruise industry the ability to work closely together to protect the health and safety of those on board and in communities.

COVID-19 Testing Capabilities

¹⁷ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html>

¹⁸ U.S.-flagged cruise ships may follow CDC's COVID-19 Program for Cruise Ships at the cruise ship operator's discretion. However, U.S.-flagged ships not following this program will not be listed as "gray" because they report cases to state and local jurisdictions as they do not fall under CDC's reporting jurisdiction

¹⁹ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html#faq-1>

As part of CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters, the purpose of testing is to quickly identify cases of COVID-19—and test and quarantine their close contacts who are not fully vaccinated—to prevent ongoing transmission between voyages. Cruise ship operators participating in the program must have onboard testing capabilities to test all symptomatic crew and passengers for COVID-19 and their close contacts. This includes having onboard rapid nucleic acid amplification test (NAAT) and antigen point-of-care equipment that meets the requirements specified by CDC in technical instructions²⁰ (e.g., authorized by FDA for use in a CLIA-waived setting); however, CDC will no longer need to pre-approve these tests. Instead, CDC will verify the cruise ship operator’s COVID-19 testing capabilities during routine cruise ship inspections.

For the program’s mass crew (and passenger, if applicable) testing requirement, cruise ship operators may use an onboard viral test (NAAT or antigen test) or arrange shoreside testing at a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory so long as it meets the requirements specified by CDC in its technical instructions. Additionally, cruise ship operators must have onboard viral tests for routine crew screening testing. Note, CDC will no longer need to pre-approve these tests. Cruise ship operators may contact CDC to request a list of acceptable NAAT and antigen tests.

Port Agreements

A cruise ship operator that chooses to participate in CDC’s COVID-19 Program for Cruise Ships in U.S. Waters must document the approval of all U.S. port and local health authorities where their ships intend to dock or make port during one or more passenger voyages. The agreement must include a port operations component (Attachment M, Agreement with Port of Entry), a medical care plan component (Attachment N, Agreement with Health Care Organization), and a housing component (Attachment O, Agreement with Housing Facility) meeting the requirements of CDC’s technical instructions.²¹ Note, cruise ship operators will not need to produce signed contracts between medical and housing facilities when submitting their port agreements. Cruise lines/brands may submit these agreements for all the ships in their fleet.

In lieu of documenting the approval of all local health authorities of jurisdiction, the cruise ship operator may instead submit to CDC a signed statement from a local health authority, on the health authority’s official letterhead, indicating that the health authority has declined to participate in deliberations and/or sign the port agreement, i.e., a “Statement of Non-Participation.” The cruise ship operator can submit to CDC documentation of attempted communication with the local health authority regarding the port agreement if a response is not received or if the local health authority declines to provide a signed statement. Additionally, the cruise ship operator may enter into a multi-port agreement (as opposed to a single port agreement) provided that all relevant port and local health authorities (including the state health authorities) are signatories to the agreement.

²⁰ <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html>

²¹ <https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html>

During discussions with cruise ship operators, port authorities, and state and local health authorities, all parties requested CDC assistance with the required agreements. In response to these requests, CDC has created specific guidance for additional reference (Attachment P, Checklist for Port and Local Health Authorities: Cruise Ship Operator Agreements).

Inspections

Cruise ships participating in CDC’s program are subject to in-person inspections by CDC inspectors (Attachment Q, Inspections). The cruise ship operator’s properties and records must be made available for inspection to allow CDC to ascertain compliance with its requirements. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, laboratory test results, and employee and passenger health records. CDC has issued additional technical guidance²² outlining the specific areas that may be inspected and corresponding recommendations.

CDC has provided, and will continue to provide as necessary, the technical instructions for the COVID-19 Program for Cruise Ships. CDC will work closely with cruise industry, state, territorial, and local health authorities, and seaport partners to evaluate the program components no later than March 18, 2022, and update them as needed. The evaluation will include a review of all public health recommendations and guidance issued as part of the program based on public health conditions and available scientific evidence.

Under CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters, the following data collection elements will occur:

Data Collection Elements
CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters
COVID-19 Program for Cruise Ships Notice of Participation/Nonparticipation <ul style="list-style-type: none"> • Submitted to CDC via email • May be submitted by cruise line brand
Cruise Ship Vaccination Status Classification <ul style="list-style-type: none"> • Submitted to CDC via email • May be submitted by cruise line brand
COVID-19 Response Plans <ul style="list-style-type: none"> • Submitted to CDC via email • May be submitted by cruise line holding company/ cruise line brand
Enhanced Data Collection (EDC) During COVID-19 Pandemic Form-Daily <ul style="list-style-type: none"> • Submitted to CDC via REDCap (https://www.project-redcap.org/)
Cruise COVID-19 Case Investigation Worksheet (if necessary) <ul style="list-style-type: none"> • Submitted to CDC via email
Cruise COVID-19 Contact Investigation Worksheet (if necessary) <ul style="list-style-type: none"> • Submitted to CDC via email
Cruise Ship Operator’s Agreements with U.S. Port Authorities and Local Health Authorities <ul style="list-style-type: none"> • Agreement with Ports of Entry (POE)

²² <https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html>

- Agreement with Health Care Organization(s)
- Agreement with Housing Facility
- Available to all parties: *Technical Instructions for a Foreign-Flagged Cruise Ship Operator’s Agreement with Port and Local Health Authorities under CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters*
- Submitted to CDC via email
- May be submitted by cruise line holding company/ cruise line brand

Inspections

Note: Above data collection elements are per ship unless otherwise indicated.

3. Use of Improved Information Technology and Burden Reduction

CDC will accept electronic copies of all reporting requirements outlined in this information collection. The CDC EDC form is electronically submitted using REDCap.²³ To address industry concerns about the burden of daily EDC submission, CDC will add an option in the online form (i.e., a check box) to streamline reporting if no cases were identified or no testing was conducted for that day. All documents associated with the COVID-19 Program for Cruise Ships Operating in U.S. Waters can be sent to CDC via email to reduce burden associated with mailing and receipt of hard copies.

Additionally, to reduce burden on cruise ship operators, several documents such as the COVID-19 response plan and the port agreements, may be submitted on behalf of multiple ships as long as every ship within each document is individually covered by the terms of the documents and agreements.

CDC has also made a number of resources available in an attempt to assist the cruise industry and other public health partners. For the testing requirements, while CDC does not recommend specific viral tests, a list of viral tests meeting CDC’s specifications can be provided to cruise ship operators upon request. CDC has also provided guidance and checklists for the port agreements so that all parties are aware of CDC’s expectations.

Cruise ship operators not operating under the program will have to submit the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form (approved under OMB Control 0920-0134) for COVID-19-like illness and the Maritime Conveyance Illness or the Death Investigation Form (approved under OMB Control 0920-0134) for each individual case of COVID-19 or COVID-19-like illness onboard their ships per 42 C.F.R. § 71.21. However, in lieu of this requirement, cruise ship operators that choose to participate in CDC’s program must submit cumulative case counts to CDC once per day electronically via the EDC form. This requirement significantly reduces the burden associated with case reporting for both cruise ship operators and CDC.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has the primary role in preventing the importation and spread of communicable disease into and within the U.S. The Director finds that cruise ship travel may exacerbate the global spread of COVID-19

²³ <https://www.project-redcap.org/>

and the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature and cannot be controlled sufficiently by the cruise ship industry or individual state or local health authorities.

Accordingly, under 42 C.F.R. § 70.2, the Director determines that measures taken or likely to be taken by state and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.²⁴

CDC is not aware of any duplication of information collection by other federal governmental authorities. CDC is working collaboratively with the U.S. Coast Guard and state, territorial, and local public health partners to coordinate the information collection and prevent unnecessary burden on respondents. Specifically, CDC sends twice weekly data reports to these stakeholders so that they do not have to collect any information directly from cruise ship operators. Requirements for the reporting of acute gastroenteritis under CDC's Vessel Sanitation Program (VSP) may overlap with CDC's EDC reporting form, but only in rare circumstances. If acute gastroenteritis is combined with other symptoms suggesting a CLI, then the ship must report via VSP's Maritime Illness Database and Reporting System and the EDC form.

5. Impact on Small Businesses or Other Small Entities

Some of the respondents at or near the 250-person capacity may be considered small businesses and CDC understands that the requirements of the COVID-19 Program for Cruise Ships Operating in U.S. Waters may represent a higher burden on the smaller cruise operators than on the larger operators. Smaller operators may not have the opportunity to work with an industry organization and may have fewer resources within their organizations to focus on adherence to requirements. However, operators can collaborate on the development of response plans and port agreements, so smaller operators may choose to work together to try to reduce the burden on any one operator.

It remains important to note that there is still a risk of COVID-19 outbreaks on smaller vessels, as has occurred on smaller river cruises.²⁵ The submission of a plan to prevent the spread of COVID-19, regardless of designation as a small business or small entity, is a critical public health tool to limit strain on U.S. domestic resources needed to address the spread of COVID-19 in the U.S. caused by individuals being debarked from maritime vessels.

6. Consequences of Collecting the Information Less Frequently

²⁴ These jurisdictions include the following U.S. states: Alabama, Alaska, California, Delaware, Florida, Georgia, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, and Washington State. These jurisdictions also include the following U.S. territories: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands

²⁵ Unpublished Maritime Unit data from daily EDC reporting and after travel reports from state and local health departments.

Daily EDC reporting is necessary to continue safe passenger operations under the COVID-19 Program for Cruise Ships Operating in U.S. Waters. Because COVID-19 can spread very rapidly onboard cruise ships, daily updates regarding COVID-19 cases onboard are critical to prevent additional spread among passengers and crew.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the Federal Register on April 30, 2021, 86 FR 22964, p. 22964-22967 (Attachment B). Twenty comments from the general public were received and CDC has provided responses to each. These comments and CDC's responses were included in CDC's October 2021 emergency extension request.

B. CDC communicates frequently with cruise lines, interagency partners, state and local health departments, and port officials concerning the latest efforts to address the COVID-19 risk onboard cruise ships. In this case, CDC is aware of several states that have requested federal public health actions to mitigate the risk of COVID-19 transmission in their communities as a result of cruise travel. To attempt to streamline the process and work with cruise lines' policies and procedures, CDC routinely obliges cruise lines' requests concerning these collections. Additionally, CDC is aware that most cruise lines have already incorporated COVID-19 mitigation measures in their business processes, and so this may not represent a significant additional burden in those cases.

Since late November 2020, CDC has engaged in biweekly phone calls with the cruise industry to ensure questions concerning public health measures onboard cruise ships are answered in a timely fashion and to solicit feedback from the cruise industry regarding the effectiveness of CDC's health and safety protocols. Additionally, CDC holds ad hoc meetings with cruise line representatives at their request. These phone calls and meetings will continue under CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters.

CDC has also received feedback from state and local health departments who frequently engage with the travel industry regarding the port agreements. Before signing these agreements, state and local partners were interested in receiving more specific instructions from CDC regarding the terms of these agreements. CDC responded by creating a checklist of items for consideration when collaborating with the cruise lines on the agreements required under the program (Attachment P).

Prior to implementing the COVID-19 Program for Cruise Ships Operating in U.S. Waters, CDC sent a survey (Attachment R) to cruise industry, interagency, state and local health department, and seaport partners to assess CDC's past maritime COVID-19 prevention and response activities and chart the way

forward to continuing healthy and safe cruising during the current pandemic and in the future. This survey was administered under the Public Health Emergency (PHE) PRA Waiver and was deemed non-research because it was an internal evaluation of a CDC program.

9. Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. No PII will be stored in a method that is searchable by that PII. All PII will be stored securely on CDC systems and only those staff/contractors with a need to know will have access to this data.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects (Attachment S). IRB approval is not required.

Justification for Sensitive Questions

There are no planned sensitive questions.

12. Estimates of Annual Burden Hours and Costs

A. Estimated Annual Burden Hours

CDC is assuming that among the 20 relevant cruise line brands, a maximum of 130 ships will decide to participate in CDC's COVID-19 Program for Cruise Ships. Because these estimates represent almost all of the brands and ships that CDC has record of ever operating in U.S. waters, the total estimated burden presented here is likely an overestimate. The total estimated annual burden is 17,531.5 hours per year.

Information Requirements Associated CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters

- COVID-19 Program for Cruise Ships Notice of Participation/Nonparticipation

- o Cruise lines operating cruise ships in U.S. waters are requested to notify the CDC in writing of their decision to participate (or not participate) in the program by February 18, 2022.
- o CDC is accepting this information on a per-line/brand, basis.
- o Each notification is estimated to require 5 hours of staff time to review the program components, develop a response, and submit to CDC.
- o Maximum annual hourly burden estimates are calculated as 20 cruise line brands x 5 hours= 100 hours/year.
- Cruise Ship Vaccination Status Classification
 - o Cruise lines that choose to participate in CDC's COVID-19 Program for Cruise Ships must advise CDC of the vaccination status classification for each participating ship. CDC recognizes that a cruise line brand may choose to respond on behalf of all its ships rather than on a ship-by-ship basis, reducing the burden. However, for the purposes of completeness, and so as not to presume behavior, the full estimate is provided below.
 - o Each notification is estimated to require 5 minutes of staff time to develop and submit.
 - o Maximum annual hourly burden estimates are calculated as 130 cruise ships x 5 minutes = 10.83 hours/year.
- COVID-19 Response Plan
 - o Most cruise line brands that will choose to participate in the program have already developed response plans that cover all of the vessels in their fleet (i.e., across all the brands they control). There are a limited number of lines that have not done so yet. CDC estimates there are at most three cruise ship operators that have not developed a response plan and would need to do so prior to entering U.S. waters if they choose to participate in CDC's program.
 - o Each plan is estimated to require a full 40-hours of staff time to develop and submit.
 - o Maximum annual hourly burden estimates are calculated as 3 cruise line brands x 40 hours =120 hours/year.
- Daily reporting to CDC using the Enhanced Data Collection during COVID-19 Pandemic (EDC) form
 - o Maximum annual hourly burden estimates are calculated as 130 ships x 20 minutes/report x 365 days/year= 15,816.67 hours/year
- Cruise COVID-19 Case Investigation Worksheet (if necessary)
 - o Only cruise ships that meet a predetermined investigation threshold²⁶ will receive a Cruise COVID-19 Case Investigation Worksheet.
 - o Approximately two ships per week receive this worksheet which takes 30 minutes to complete.
 - o Maximum annual hourly burden estimates are calculated as 2 ships/week x 30 minutes x 52 weeks/year= 52 hours/year.
- Cruise COVID-19 Contact Investigation Worksheet (if necessary)

²⁶ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html#faq-1>

- o Only cruise ships that meet a predetermined investigation threshold²⁷ will receive a Cruise COVID-19 Case Investigation Worksheet.
 - o Approximately two ships per month receive this worksheet which takes 30 minutes to complete.²⁸
 - o Maximum annual hourly burden estimates are calculated as 2 ships/month x 30 minutes x 12 months/year= 12 hours/year.
- Agreement with Health Care Organization with signoff from Local Health Authorities
 - o As part of the COVID-19 Program for Cruise ships, the cruise ship must document an agreement with a shoreside medical facility or healthcare system or multiple shoreside medical facilities or healthcare systems with redundant capacities to ensure that travelers receive appropriate medical care when needed. This will be required for each ship that chooses to participate in the program, but CDC recognizes that a cruise line may enter into an agreement with a medical facility for all its ships, reducing the burden. For the purposes of completeness, and so as not to presume behavior, the full estimate is provided below.
 - o CDC has created a check list to assist state and local health authorities with this agreement.
 - o Should the cruise lines need to make any changes or update the agreement, those changes can be sent to CDC.
 - o Approximately 100 ships have already completed this agreement.
 - o For the remaining 30 ships, CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 300 burden hours/year.
 - Agreement with Port of Entry with signoff from Local Health Authority
 - o As part of the COVID-19 Program for Cruise ships, the cruise ship must document an agreement with a Port of Entry that will accept the ship. This will be required for each ship that chooses to participate in the program, but CDC recognizes that a cruise line may enter into an agreement with a port for all its ships, reducing the burden. For the purposes of completeness, and so as not to presume behavior, the full estimate is provided below.
 - o CDC has created a check list to assist state and local health authorities with this agreement.
 - o Should the cruise lines need to make any changes or update the agreement, those changes can be sent to CDC.
 - o Approximately 100 ships have already completed this agreement.
 - o For the remaining 30 ships, CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 300 burden hours/year.
 - Agreement with Housing Facility with signoff from Local Health Authority

²⁷ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html#faq-1>

²⁸ This form is used less frequently than the Cruise COVID-19 Case Investigation Worksheet because, in the event of an outbreak, it is more important for CDC to focus on confirmed COVID-19 cases than COVID-19 close contacts (which are managed by the cruise ship operator). Additionally, while COVID-19 cases can still occur on highly vaccinated and Vaccination Standard of Excellence ships (requiring public health interventions), interventions for fully vaccinated close contacts on these ships are limited.

- o As part of the COVID-19 Program for Cruise ships, the cruise ship must document an agreement with a shoreside housing facility that will accept travelers from a ship with COVID-19 cases. This will be required for each ship that chooses to participate in the program, but CDC recognizes that a cruise line may enter into an agreement with a housing facility for all its ships, reducing the burden. It may also be the case that the cruise line has its own housing facility, reducing burden. For the purposes of completeness, and so as not to presume behavior, the full estimate is provided below.
- o CDC has created a check list to assist state and local health authorities with this agreement.
- o Should the cruise lines need to make any changes or update the agreement, those changes can be sent to CDC.
- o Approximately 100 ships have already completed this agreement.
- o For the remaining 30 ships, CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 300 burden hours/year.
- Inspections
 - o Under CDC’s COVID-19 Program for Cruise Ships, the cruise ship operator’s properties and records must be available for inspection to allow CDC to ascertain compliance with its recommendations and guidance. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, laboratory test results, and employee and passenger health records. These recommendations and guidance are outlined in the *Technical Instructions for CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters*.
 - o CDC anticipates a maximum of two routine inspections per ship. Additional inspections may be needed if there is a COVID-19 outbreak on board the ship. CDC predicts that cruise ship operators will spend two hours preparing for the inspection. With the estimated 130 vessels that may operate under the COVID-19 Program for Cruise Ships, and a maximum of two inspections, this equals 520 hours/year.

Type of Respondent	Form or Information Collection Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Cruise ship brand/operator	COVID-19 Program for Cruise Ships Notice of Participation/Nonparticipation (Attachment E- Instruction)	20	1	300/60	100
Cruise ship brand/operator	Cruise Ship Vaccination Status Classification (Attachment F- Instruction)	130	1	5/60	10.83
Cruise ship parent company	COVID-19 Response Plan (Attachment G-Instruction)	3	1	2400/60	120
Cruise ship	Enhanced Data Collection	130	365	20/60	15,816.67

physician	(EDC) During COVID-19 Pandemic Form (Daily) (Attachment H-Form)				
Cruise ship physician	Cruise COVID-19 Case Investigation Worksheet (if necessary) (Attachment K-Form)	104	1	30/60	52
Cruise ship physician	Cruise COVID-19 Contact Investigation Worksheet (if necessary) (Attachment L-Form)	24	1	30/60	12
Cruise ship brand/ operator	Agreement with Health Care Organization with signoff from Local Health Authorities (Attachment N- Instruction)	30	1	600/60	300
Cruise ship brand/ operator	Agreement with Port of Entry with signoff from Local Health Authority (Attachment M-Instruction)	30	1	600/60	300
Cruise ship brand/ operator	Agreement with Housing Facility with signoff from Local Health Authority (Attachment O-Instruction)	30	1	600/60	300
Cruise ship operator	Inspections (Attachment Q-Instruction)	130	2	120/60	520
Total					17,531.5

B. Estimated Annual Burden Costs

Estimates of the time burden associated with participating the COVID-19 Program for Cruise Ships Operating in U.S. Waters are included in the table below. Non-wage benefit adjustments provided below were sourced from BLS Employer Costs for Employee Compensation for civilian workers by occupational and industry group, available here: <https://www.bls.gov/news.release/ecec.t02.htm>

Hourly mean wages for Cruise Ship Operators were gathered from BLS category 11-3071 Transportation, Storage, and Distribution Managers (<https://www.bls.gov/oes/current/oes113071.htm>): \$59.44 CDC is adjusting this wage by 1.31 to account for non-wage benefits. The adjusted wage is \$77.87.

The estimated total cost is \$2,136,090.90.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
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Cruise ship brand/operator	COVID-19 Program for Cruise Ships Notice of Participation/Nonparticipation	100	\$77.87	\$778,700.00
Cruise ship brand/operator	Cruise Ship Vaccination Status Classification	10.83	\$77.87	\$843.33
Cruise ship parent company	COVID-19 Response Plan	120	\$77.87	\$9,344.40
Cruise ship physician	Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (Daily)	15,816.67	\$77.87	\$1,231,644.09
Cruise ship physician	Cruise COVID-19 Case Investigation Worksheet (if necessary)	52	\$77.87	\$4,049.24
Cruise ship physician	Cruise COVID-19 Contact Investigation Worksheet (if necessary)	12	\$77.87	\$934.44
Cruise ship brand/operator	Agreement with Health Care Organization with signoff from Local Health Authorities	300	\$77.87	\$23,361.00
Cruise ship brand/operator	Agreement with Port of Entry with signoff from Local Health Authority	300	\$77.87	\$23,361.00
Cruise ship brand/operator	Agreement with Housing Facility with signoff from Local Health Authority	300	\$77.87	\$23,361.00
Cruise ship operator	Inspections	520	\$77.87	\$40,492.40
Total				\$2,136,090.90

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

Other costs of participating in CDC’s COVID-19 Program for Cruise Ships Operating in U.S. Waters, beyond the information collections outline above, are primarily associated with the testing required. CDC estimates a cost for cruise line operators of \$9,309,100. This estimate includes the cost of mass crew testing and lab equipment on the ship.

- For costs associated with mass crew and passenger testing, CDC estimates the costs as follows:
 - o The cost of each test is estimated based on the reimbursement rates provided by the Centers for Medicare & Medicaid Services (CMS) for October 2021 which range from \$25-\$75. CDC is choosing a mid-point of \$50 for each test.
 - o CDC estimates that 30 ships have not yet completed the one-time mass crew (and passenger, if applicable) testing requirement. For the purposes of completeness, and so as not to presume behavior, the estimate includes both crew and passengers. Using an average of 1500 crew members and 3000 passengers that must be tested per ship, CDC

estimates an average annual cost of \$50 x 30 ships x (1500 crew + 3000 passengers) totaling \$6,750,000.00 per year.

- For costs associated with onboard testing capacity, CDC estimates:
 - o The cost of the onboard instrument used to test symptomatic cases and their contacts ranges from \$9,920- \$72,350 per ship. Roughly 30 ships still need to purchase this equipment. Using a midpoint cost of \$41,135, CDC estimates a total cost of \$1,234,050.00 per year.
 - o With regard to onboard testing supplies, CDC estimates a cost of \$14.90-\$20 per cartridge, and a mid-point estimate of \$17.45 per cartridge. CDC is estimating there will be approximately 10 symptomatic individuals and their contacts who need to be tested on a weekly basis on each of the maximum 130 ships. On an annual basis, this cost is estimated to equal \$1,179,620.00.
- The maintenance contracts for an onboard testing instrument are estimated to cost between \$1,896-\$7,800 yearly per ship. About 100 ships have already paid this cost, leaving 30 ships that have not. The total cost per year is estimated to be \$145,440.00 based on a midpoint estimate of \$4,848 per contract.

CDC assumes that some portion of the testing costs and acquisition of capital required to conduct testing for passengers will be passed on to passengers, however, CDC is unable to quantify this potential outcome and thus is not including any additional costs here.

We also note that the onboard testing materials can be used to test for other diseases, and so some of the capital expenditure will be useful for the cruise lines beyond the COVID-19 pandemic.

14. Annual Cost to the Government

The annual cost to the government is estimated by multiplying the average time to review materials submitted to CDC and conduct cruise ship inspections by the average wage of the individuals performing the reviews and inspections. The total estimated costs are \$1,477,542.

CDC estimates it will take six employees working full time to review the plans and agreements and conduct inspections. CDC assumes an average wage equivalent to GS 13s and GS 14s on an annual basis.²⁹ CDC is multiplying each wage by 2 to account for non-wage benefits.

Personnel Category	Annual Wage	Adjustment	Total Cost
3 x GS 14	\$133,383.00	x2	\$800,298.00
3 x GS 13	\$112,874.00	x2	\$677,244.00
Total Cost			\$1,477,542.00

15. Explanation for Program Changes or Adjustments

²⁹ <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/ATL.pdf>

After the expiration of the Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO) on January 15, 2022, CDC will implement a COVID-19 risk mitigation program for foreign-flagged cruise ships operating in U.S. waters. This new program changes this information collection from a requirement for foreign-flagged cruise ships to be able to sail in U.S. waters, to a program that they may choose to follow, but are not required to follow, to be able to sail in U.S. waters.

This information collection request does not contain all of the information collection tools included in the emergency extension submitted October 2021. CDC has discontinued the use of ten of the collection tools included in the October 2021 emergency extension. This information collection request also adds the COVID-19 Program for Cruise Ships Notice of Participation/Nonparticipation instruction and the Cruise Ship Vaccination Status Classification instruction.

Overall, the burden associated with this collection has decreased from 24,289.3 hours per year in October 2021 to 17,531.5 hours per year in this submission. This decrease in burden can be attributed to the reduced number of information collection tools required by CDC and the increased number of cruise ships that have already completed the information collections described above (from roughly 70 in October 2021 to about 100 at the time of this submission).

16. Plans for Tabulation and Publication and Project Time Schedule

CDC has no current plans to publish data associated with this specific data collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

A1: Public Health Service (PHS) Act (42 USC 264)
A2: 42 CFR 70
A3: 42 CFR 71
B: 60-Day Federal Register Notice
C: Framework for Conditional Sailing Order
D: Temporary Extension & Modification of Framework for Conditional Sailing Order
E: COVID-19 Program for Cruise Ships Notice of Participation/Non-Participation
F: Cruise Ship Vaccination Status Classification
G: COVID-19 Response Plan
H: Enhanced Data Collection (EDC) During COVID-19 Pandemic Form
I: Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form
J: Maritime Conveyance Illness or the Death Investigation Form
K: Cruise COVID-19 Case Investigation Worksheet
L: Cruise COVID-19 Contact Investigation Worksheet
M: Agreement with Port of Entry
N: Agreement with Health Care Organization
O: Agreement with Housing Facility
P: Checklist for Port and Local Health Authorities: Cruise Ship Operator Agreements
Q: Remote and In-person Inspections
R: CSO Partner Survey
S: Not Research Determination