

Phased Approach to the Resumption of Cruise Ship Passenger Operations

Request for OMB approval of an Emergency Information Collection
Extension

October 27, 2021

Supporting Statement A

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- **Goal of the study:** As part of its Phased Approach to the Resumption of Passenger Operations, CDC will collect information from cruise ships operating or intending to operate in U.S. waters. This phased approach includes increased 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 phased resumption of passenger operations.
- **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 via the eocevent349@cdc.gov address.
- **The subpopulation to be studied:** Respondents include all persons operating or intending to operate commercial, non-cargo, foreign-flagged, 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 individuals (passengers and crew).
- **How data will be analyzed:** There are no statistical methods.

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) requests an emergency 6-month extension for an Existing Information Collection titled Phased Approach to the Resumption of Cruise Ship Passenger Operations. This emergency extension is necessary because changes in CDC's Order titled Temporary Extension and Modification of Framework for Conditional Sailing Order (Attachment E) requires the use of this information collection by November 1, 2021. A full extension will be submitted following the expiration of the emergency.

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world. As of October 18, 2021, a cumulative estimated total of over 240 million cases and over 4.8 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 October 17, 2021, there have been over 44 million cases and more than 700,000 confirmed deaths.² COVID-19 vaccines are now widely available in the United States, and vaccination is recommended for all people 12 years of age and older. As of October 17, 2021, over 189 million people in the United States (66.7% of the population 12 years or older) have been fully vaccinated and over 218 million people in the United States (77.1% of the population 12 years or older) have received at least one dose.³

¹ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

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

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

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.⁴

On January 20, 2020, the Diamond Princess cruise ship departed Yokohama, Japan. On January 25, 2020, a symptomatic passenger departed the ship in Hong Kong, where he was later confirmed to have COVID-19. Upon the ship's return to Yokohama, Japanese authorities quarantined all passengers and crew on board the ship. Among the 3,711 Diamond Princess passengers and crew, 712 (19.2%) were subsequently confirmed to have COVID-19, 37 required intensive care, and nine died. Following this outbreak, two voyages of the Grand Princess cruise ship were ultimately associated with 159 confirmed COVID-19 cases, including eight deaths.

Because of these events, and the increased risk of COVID-19 transmission on cruise ships, on March 14, 2020, the CDC Director issued a No Sail Order and Other Measures Related to Operations (NSO) directing cruise ships not voluntarily suspending operations to comply with certain measures (85 FR 16628). To continue to protect public health and safety, and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, on April 9, 2020, the CDC Director issued No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations, modifying and extending the previous March 14, 2020 Order, which became effective on April 15, 2020 (85 FR 21004). Prior to the expiration of the April 9, 2020, Order, the CDC Director signed a Second Modification and Extension of No Sail Order and Other Measures Related to Operations on July 16, 2020, (85 FR 44085) which extended the No Sail Order until September 30, 2020. Finally, a Third Modification and Extension of No Sail Order and Other Measures Related to Operations was issued on September 30, 2020, (85 FR 62732). This Third Modification of the NSO, among other things, suspended passenger operations on board cruise ships and remained in effect through October 31, 2020.

While population density is a leading cause of increased COVID-19 transmission on cruise ships, CDC's surveillance data collected during the period of the NSO 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.

Additionally, as most individuals who are fully vaccinated for COVID-19 have only mild to no symptoms with breakthrough infections, the virus can quickly spread without detection among crew.⁵ Thus, asymptomatic spread of the virus among crew may perpetuate the transmission of COVID-19 on future voyages. This again stresses the need for interventions, including routine laboratory testing of crew, prior to restarting passenger operations.

⁴ <https://academic.oup.com/jtm/article/27/3/taaa030/5766334>

⁵ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6923e4.htm>

On October 30, 2020, CDC announced a Framework for Conditional Sailing Order (CSO) 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 provides 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 requirements in the CSO highlight the need for further action before cruise ships can safely resume passenger operations in the United States. This Order applies to all cruise ships operating in U.S. waters with the capacity to carry 250 or more individuals (passengers and crew), and with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.⁶ This Order additionally applies to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to U.S. waters during the period that the Order is in effect.

The CSO is a phased approach to resuming passenger operations. During the initial phases, cruise ship operators must demonstrate adherence to testing, quarantine and isolation practices, and physical distancing requirements to protect crew members while they build the laboratory capacity needed to test future passengers. Subsequent phases include simulated voyages to test cruise ship operators' ability to mitigate COVID-19 risk, certification for conditional sailing for ships that meet specific requirements, and return to passenger voyages in a manner that mitigates COVID-19 risk among passengers, crew members, and communities.

Despite the best efforts of cruise ship operators to provide a safer and healthier environment for crew and passengers, including operating highly vaccinated ships, outbreaks of COVID-19—including COVID-19 infections among the fully vaccinated—have continued to occur. Between June 26–September 17, 2021, 921 laboratory confirmed cases of COVID-19 were reported to CDC by cruise ships following the CSO.⁷ Several large outbreaks on cruise ships are highlighted below:

- On July 24, 2021, one symptomatic passenger who tested positive for COVID-19 on a cruise ship (Cruise Ship A) was epidemiologically linked to 20 additional lab-confirmed cases of COVID-19 over two voyages, including 2 passengers and 18 crew. The COVID-19 vaccination rate on this ship ranged between 99.8–100% for crew and 96.4–97.5% for passengers.
- Between July 24–August 28, a cruise ship (Cruise Ship B) reported 58 lab-confirmed COVID-19 cases among passengers and crew. The COVID-19 vaccination rate on this ship ranged between 96.8–97.7% for passengers and averaged 100% for crew.
- Between July 29–31, 2021, three symptomatic passengers tested positive for COVID-19 on a cruise ship (Cruise Ship C). Contact tracing and testing identified an additional 12 lab-confirmed cases of COVID-19, including 10 passengers and 2 crew. This was a highly vaccinated ship with 100% of crew and an average of 97% of passenger fully vaccinated.

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

⁷ This number does not include newly embarking crew who tested positive for SARS-CoV-2 prior to or during their embarkation quarantine period, or passengers who tested positive for SARS-CoV-2 at embarkation and did not board the ship.

- Between July 26–August 6, a cruise ship (Cruise Ship D) reported 7 lab-confirmed COVID-19 cases among passengers and crew. The COVID-19 vaccination rate on this ship ranged between 100% for crew and 96.8–97.7% for passengers.
- Between August 19–September 7, a cruise ship (Cruise Ship E) reported 105 lab-confirmed COVID-19 cases among passengers and crew on a total of four consecutive voyages. This was a highly vaccinated ship with 100% of crew and an average of 97% of passenger fully vaccinated at the time on the voyage(s).
- Between August 21–September 7, a cruise ship (Cruise Ship F) reported a total of 112 lab-confirmed COVID-19 cases among passengers and crew on four consecutive voyages despite the ships' 100% vaccination rate for everyone onboard.

Because the resumption of passenger voyages in the U.S. has facilitated the introduction and sustained transmission of COVID-19 among cruise ships, despite high vaccination rates among both crew and passengers, CDC will extend the Framework for Conditional Sailing Order until January 15, 2022. This action is effective November 1, 2021, at 12:01 A.M. (EDT) upon the expiration of the current Order.

This Temporary Extension & Modification of Framework for Conditional Sailing Order (CSO Extension) will apply to foreign-flagged cruise ships operating in U.S. waters with the capacity to carry at least 250 individuals and with an itinerary anticipating an overnight stay onboard or a twenty-four hour stay onboard for either passengers or crew.⁸ The Temporary Extension makes only minor modifications to the October 30, 2020, Framework for Conditional Sailing Order. After the expiration of this temporary extension, CDC intends to transition to a voluntary program, in coordination with 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.

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

The CSO Extension published in the *Federal Register* on **October XX**, 2021 (Attachment E) extends The Framework for Conditional Sailing Order published in the *Federal Register* on November 4, 2020 (Attachment F), and continues to prohibit a cruise ship operator from commencing or continuing any

⁸ As per the Preliminary Injunction Order, entered by the U.S. District Court for the Middle District of Florida on June 18, 2021, as of July 23, 2021, the CSO and accompanying measures, such as technical instructions, are nonbinding recommendations for cruise ships arriving in, located within, or departing from a port in Florida. Accordingly, the extended Order shall not apply to this subset of ships while this Preliminary Injunction Order remains in effect (or in the event the Preliminary Injunction becomes permanent). However, CDC will continue to operate the extended Order as a voluntary program in Florida for ships that choose to follow its measures on a voluntary basis.

regular passenger operations without a COVID-19 Conditional Sailing Certificate issued by HHS/CDC. This information collection request outlines the reporting and document retention requirements that are part of a phased approach to resuming passenger operations.

The CSO Extension builds upon the phased-in approach to resume cruise ship passenger operations introduced by the CSO. Cruise ship operators who have already completed the process under the CSO will not have to resubmit any information under the CSO Extension and can continue sailing with passengers without interruption. As many cruise ship operators are now familiar with the CSO and its requirements, many aspects of the phased-in approach can be completed concurrently under the CSO Extension.

Phase 1:

Per CDC’s CSO Extension, cruise ships operating or intending to operate in U.S. waters must acknowledge that a complete and accurate COVID-19 response plan (formerly referred to as “No Sail Order (NSO) response plan”) (Attachment G) is observed.⁹

The COVID-19 response plan, which can be submitted by a cruise ship holding company and apply to *all* cruise ships operated by the holding company’s brands, must include: (1) 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); (2) protocols for on board surveillance of passengers and crew with COVID-19 and COVID-19-like-illness; (3) protocols for training all crew on COVID-19 prevention, mitigation, and response activities; (4) protocols for on board isolation and quarantine, including how to increase capacity in case of an outbreak; (5) protocols for COVID-19 testing that aligns with CDC technical instructions; (6) 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; and (7) procedures for disembarkation of passengers who test positive for COVID-19.

Phase 1 also includes requirements for COVID-19 testing capabilities and reporting for cruise ship operators operating or intending to operate cruise ships in U.S. waters. Cruise ship operators 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) point-of-care equipment that meets the requirements specified by CDC in technical instructions or orders and have received CDC approval (Attachment H, Approval of Onboard COVID-19 Testing Instrument).¹⁰ For Phase 1’s mass crew 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)-

⁹ COVID-19 response plans were formerly referred to as “No Sail Order” response plans. Cruise ship operators that previously submitted a signed “Acknowledgment of No Sail Order Response Plan Completeness and Accuracy” to CDC have fulfilled the requirements of this section and do not need to re-submit a COVID-19 response plan.

¹⁰ Cruise line brands may submit this information for all ships in their fleet.

certified laboratory so long as it meets the requirements specified by CDC in technical instructions or orders and have received CDC approval (Attachment I, Mass Crew Testing).¹¹

Finally, Phase 1 also includes reporting requirements using the CDC Enhanced Data Collection during COVID-19 Pandemic (EDC) form (Attachment J). In lieu of submitting the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form (Attachment K) for COVID-19-like illness and the Maritime Conveyance Illness or the Death Investigation Form (Attachment L) for individual specific cases of COVID-19, the CDC will require daily submission of the EDC form during the period of the CSO Extension.¹² Data points for this form include number of travelers (passengers and crew) currently onboard; case counts and 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. The data collected in the EDC form are used to inform CDC's COVID-19 Color-Coding System for Cruise Ships.¹³ This 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 operating or planning to operate in U.S. waters. 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.¹⁴ If an investigation is deemed necessary, CDC will solicit extra information from the cruise ship operator (Attachments M and N, Cruise COVID-19 Case Investigation Worksheet and Cruise COVID-19 Contact Investigation Worksheet, respectively) to determine what 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.

Phase 2A:

The next phase, Phase 2A, focuses on preparation for simulated and restricted voyages. As required under the CSO Extension, a cruise ship operator's agreement with U.S. port authorities and local health authorities must include the following elements: (1) a port agreement between the cruise ship operator and port authority that takes into consideration the public health response resources of the jurisdiction in the event of a COVID-19 outbreak, a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations, and vaccination strategies to maximally protect passengers and crew from introduction, amplification, and spread of COVID-19 in the maritime environment and in land-based communities (Attachment O, Agreement with Port of Entry); (2) medical care agreements between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical

¹¹ Cruise line brands may submit this information for all ships in their fleet.

¹² Cruise ship operators with ships that have not been in U.S. waters during the period of the CSO and who wish to operate those ships in U.S. waters during the period that the CSO Extension remains in effect, must additionally submit the EDC form during (at a minimum) the 14 days preceding those ships' expected arrival in U.S. waters and continue to submit the EDC form after the ships' entering U.S. waters or, alternatively, arrange for such appropriate shoreside or ship-based testing of passenger and crew as directed by CDC with subsequent submission of the EDC form after the ships' arrival.

¹³ <https://www.cdc.gov/quarantine/cruise/cruise-ship-color-status.html>

¹⁴ <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html#green-ship>

instructions and orders (Attachment P, Agreement with Health Care Organization); and (3) housing agreements between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and their close contacts, identified from the day of embarkation through disembarkation for each voyage (Attachment Q, Agreement with Housing Facility). Cruise lines/brands may submit these agreements for all the ships in their fleet. Note, these agreements can remain in place for restricted voyages, as long as the agreements remain valid.¹⁵

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." 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.

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 posted specific guidance online and has provided a checklist (Attachment R, Checklist for Phase 2A Agreements) for additional reference.

Phase 2B:

Phase 2B of the CSO Extension establishes the requirements for simulated voyages where volunteers play the role of passengers to test cruise ship operators' ability to mitigate COVID-19 onboard. Passengers on simulated voyages must be at least 12 years old,¹⁶ provide their informed consent,¹⁷ and submit a medical certification to the cruise ship operator prior to embarkation (Attachment S, Informed Consent and Medical Certification for Simulated Voyage).

Before conducting a simulated voyage, a cruise ship operator must submit a Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate (Attachment T) at least 5 business days prior to the voyage. A cruise ship operator shall not apply for approval to conduct a simulated voyage until all of CDC's requirements relating to onboard laboratory capacity and screening testing of crew in U.S. waters have been satisfied.

A simulated voyage must include the following simulated activities: (i) embarkation and disembarkation procedures, including terminal check-in, (ii) on board activities, including at dining and entertainment venues, (iii) private island shore excursions, if any are planned during restricted passenger voyages, (iv) evacuation procedures, (v) transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms, (vi) quarantine of all remaining passengers and non-essential crew, and (vii) other activities as may be listed in CDC technical instructions and orders. Additionally, the cruise ship operator must (i) meet standards for hand hygiene, facemasks, and physical distancing for passengers and crew, as well as ship sanitation, as may be required by CDC technical

¹⁵ Cruise ship operators that previously submitted these agreements under the CSO will not have to re-submit the agreements, provided they remain valid for the period of the CSO Extension.

¹⁶ All persons younger than eighteen years old must be fully vaccinated against COVID-19 as a condition of participation on a simulated voyage.

¹⁷ If any minors are to participate in the simulation then the informed consent of a parent or guardian, and the written assent of the minor must also be documented in writing.

instructions or orders, (ii) conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation as required by CDC technical instructions or orders, and (iii) immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID-19 during the simulated voyage with rapid point-of-care results as required by CDC technical instructions or orders. Note, CDC may require the cruise ship operator to immediately end the simulated voyage and take other action to protect the health and safety of volunteer passengers and crew if during the simulation a threshold of COVID-19 cases, as determined by CDC in technical instructions, is met or exceeded.¹⁸

During simulated voyages, cruise ships are subject to virtual and in-person inspections by CDC (Attachment U, Remote and In-person 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 guidance outlining the specific areas that may be inspected and corresponding recommendations.

Following each simulated voyage, the cruise ship operator must document any deficiencies in its health and safety protocols through a Simulated Voyage After Action Report (Attachment V) and address how the cruise ship operator intends to address those deficiencies. This after-action report must also include COVID-19 test results for any volunteer passengers or crew on the simulated voyage. The after-action report must be submitted to CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate.

In lieu of conducting a simulated voyage, a cruise ship operator's responsible officials, at their discretion, may sign and submit to CDC an acknowledgement (Attachment W, Acknowledgment by a Cruise Ship Operator In Lieu of a Simulated Voyage) that 95 percent of crew (excluding any newly embarking crew in quarantine) are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

Furthermore, cruise ships that have been operating restricted passenger voyages under an Acknowledgment by a Cruise Ship Operator In Lieu of a Simulated Voyage may, at their discretion, transition to operating restricted passenger voyages with less than 95% of passengers fully vaccinated without first conducting a simulated voyage if the following are met: (1) The ship must maintain a percentage of fully vaccinated crew that is greater than or equal to 95%. 2) The ship must have operated on restricted passenger voyages under an acknowledgement by the cruise ship operator's responsible officials that they will only operate with 95% of crew (excluding any newly embarking crew in

¹⁸ During simulated passenger voyages, this threshold is currently met when 1.5% of COVID-19 cases is detected in passengers or 1.0% of COVID-19 cases is detected in crew. This threshold may be modified based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors. If a simulated voyage is ended early to protect health and safety, CDC will consult with the cruise ship operator regarding any deficiencies to be noted in the operator's action-action report and how such deficiencies are to be corrected prior to approving an application for a COVID-19 Conditional Sailing Certificate.

quarantine) and 95% of passengers who are fully vaccinated for at least 60 days. 3) At least 14 days prior to the transition to voyages with less than 95% of passengers fully vaccinated, the cruise ship operator must submit the following to CDC: (i) Protocols for how dining and entertainment venues, and recreational activities including buffets, seated dining, bars (including between bartenders and patrons), theaters, other performance venues, casinos, arcade room, spa services, fitness classes/gymnasiums, muster drills, and other areas where passengers congregate will be modified to incorporate mask use, physical distancing, and other public health measures as outlined in CDC technical instructions. (ii) Plans for training crew on new procedures for mask use, physical distancing, and other public health measures as outlined in CDC technical instructions. (iii) Protocols for increasing the number of isolation and quarantine cabins and on-board support staff (e.g., administrative personnel, testing personnel, contact tracers, medical personnel) as determined by the cruise ship operator and as needed in the event of an outbreak. (iv) Procedures for how crew will identify and distinguish between passengers who are fully vaccinated and passengers who are not fully vaccinated. (v) Procedures for notifying passengers who booked a 95% passenger vaccinated cruise that their cruise will no longer operate as a 95% passenger vaccinated cruise. (vi) The cruise ship operator must submit photographs or videos, no later than 7 days after commencing the first voyage with less than 95% of passengers fully vaccinated, showing compliance with indoor mask use and physical distancing, such as signage in elevators, dining table arrangements, and blocking out seats/bar stools (Attachment X, Transition to Operating Restricted Passenger Voyages with Less than 95% of Passengers Fully Vaccinated).

Similarly, cruise ship operators that have been conducting passenger operations outside of U.S. waters and intend to operate cruise ships with less than 95% of passengers fully vaccinated after repositioning to U.S. waters may, at their discretion, follow the procedures in this paragraph for conducting a modified simulated voyage instead of conducting a full simulated voyage if the following are met: (1) The ship must maintain a percentage of fully vaccinated crew that is greater than or equal to 95%. (2) The ship must have operated with passengers outside of U.S. waters for at least 60 days before entering U.S. waters. (3) The cruise ship operator must conduct at least one simulation of embarkation screening and testing at the port terminal it intends to use in the U.S.—to include the number of passengers not fully vaccinated expected on the first voyage—unless the ship will be operating at the terminal already in use by the same cruise line/brand for passenger operations. (4) At least 14 days prior to entering U.S. waters, the cruise ship operator must submit the following to CDC: (i) Protocols for how dining and entertainment venues, and recreational activities, including buffets, seated dining, bars (including between bartenders and patrons), theaters, other performance venues, casinos, arcade room, spa services, fitness classes/gymnasiums, muster drills, and other areas where passengers congregate will incorporate mask use, physical distancing, and other public health measures as outlined in technical instructions. (ii) Plans for training crew on procedures for mask use, physical distancing, and other public health measures as outlined in CDC technical instructions. (iii) Protocols for increasing the number of isolation and quarantine cabins and on-board support staff (e.g., administrative personnel, testing personnel, contact tracers, medical personnel) as determined by the cruise ship operator and as needed in the event an outbreak. (iv) Procedures for how crew will identify and distinguish between passengers who are fully vaccinated and passengers who are not fully vaccinated. (v) Procedures for notifying passengers who booked a 95% vaccinated cruise that their cruise will no longer operate as a 95% vaccinated cruise, if applicable. (vi) An after-action report explaining lessons learned from sailing outside of U.S. waters

and from the simulated embarkation screening and testing (if such a simulation was conducted). (vii) The cruise ship operator must submit photographs or videos, no later than 7 days after commencing the first voyage with less than 95% of passengers fully vaccinated, showing compliance with indoor mask use and physical distancing, such as signage in elevators, dining table arrangements, and blocking out seats/bar stools. (Attachment Y, Cruise Ships with Less than 95% of Passengers Fully Vaccinated After Repositioning to U.S. Waters)

Phase 3:

As a condition of applying for a COVID-19 Conditional Sailing Certificate (Phase 3), a cruise ship operator must have successfully conducted a simulated voyage, submitted an Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage, or—if applicable— completed the specific modified simulated voyage procedures described above.^{19,20} The CDC COVID-19 Conditional Sailing Certificate Application (Attachment Z) must include: (1) A completed CDC registration/application form that includes the signatures of the cruise ship operator’s responsible officials; (2) the name, titles, and contact information for the cruise ship operator’s responsible officials; (3) a completed statement of intent stating the name, carrying capacity for passengers and crew, itinerary, ports of call, length of voyage, and expected onboard or shoreside activities, for the cruise ship that the cruise ship operator intends to have certified for restricted passenger operations; (4) a certification statement signed by the responsible officials attesting that the cruise ship operator has complied and remains in compliance with CDC’s requirements for a COVID-19 Response Plan and EDC reporting prior to applying for a COVID-19 Conditional Sailing Certificate; (5) a certification statement signed by the responsible officials attesting that the cruise ship operator has adopted health and safety protocols that meet CDC’s standards for mitigating the risk of COVID-19 among passengers and crew onboard the cruise ship that will be commencing restricted passenger operations and will modify these protocols as needed to protect the public’s health as required by CDC technical instructions or orders; (6) a certification statement signed by the responsible officials attesting that the cruise ship operator has sufficient medical and point of care laboratory capabilities and staff on board the cruise ship that will be commencing restricted passenger operations to manage severe COVID-19 cases and outbreaks in exigent circumstances as required by CDC technical instructions or orders; and (7) a certification statement signed by the responsible officials attesting that the cruise ship operator is in compliance with the other requirements contained in this framework for mitigating the risk of COVID-19 on board cruise ships and agrees to continue to comply with these requirements.

¹⁹ Cruise ship operators that choose to sail with 95% vaccinated crew and 95% vaccinated passengers do not have to conduct a simulated voyage prior to applying for a COVID-19 Conditional Sailing Certificate, provided they have submitted an Attestation by a Cruise Ship Operator In Lieu of a Simulated Voyage.

²⁰ Cruise ships that have been operating restricted passenger voyages with 95% vaccinated crew and 95% vaccinated passengers may transition to voyages with less than 95% vaccinated passengers by conducting modified simulated voyage procedures in lieu of a full simulated voyage. Similarly, cruise ships that have been conducting passenger operations in non-U.S. jurisdictions and intend to operate in U.S. waters with less than 95% vaccinated passengers after repositioning to the U.S. may apply for a COVID-19 Conditional Sailing Certificate after conducting modified simulated voyage procedures instead of a full simulated voyage.

These documents must be submitted at least 5 business days prior to any proposed restricted voyage. If the Certificate is denied, revoked or suspended, a cruise ship operator may submit a written appeal of a denial of its application for a COVID-19 Conditional Sailing Certificate or a revocation or suspension of its COVID-19 Conditional Sailing Certificate.

During restricted voyages, the cruise ships are subject to virtual and in-person inspections by CDC (Attachment U, Remote and In-person 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 guidance outlining the specific areas that may be inspected and corresponding recommendations.

CDC has provided, and will continue to provide, the technical instructions for each phase as they are released through a non-substantive change request. Under CDC’s Phased Approach to the Resumption of Cruise Ship Passenger Operations, the following data collection elements will occur:

Data Collection Elements
CSO Extension: Information requirements associated with Phase 1
COVID-19 Response Plans (per cruise line holding company) (formerly referred to as No Sail Order Response Plans) <ul style="list-style-type: none"> Submitted to CDC via email
Acknowledgement of COVID-19 Response Plan Completeness and Accuracy <ul style="list-style-type: none"> Submitted to CDC via email
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
Request for Approval of Onboard COVID-19 Testing Instrument (may be submitted by cruise line brand) <ul style="list-style-type: none"> Submitted to CDC via email
Request for Mass Crew Testing (may be submitted by cruise line brand) <ul style="list-style-type: none"> Submitted to CDC via email
CSO Extension: Information requirements associated with Phase 2A
Cruise Ship Operator’s Agreements with U.S. Port Authorities and Local Health Authorities (may be submitted by cruise line brand) <ul style="list-style-type: none"> Agreement with Ports of Entry (POE) Agreement with Health Care Organization(s) Agreement with Housing Facility Contact information and signatures of all parties Copy of all attachments, exhibits, and annexes provided to CDC Available to all parties: <i>Checklist for Port and Local Health Authorities: Cruise Ship Operator Agreements under CDC’s Framework for Conditional Sailing Order (CSO)</i> Submitted to CDC via email

CSO Extension: Information requirements associated with Phase 2B simulated voyages
Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate <ul style="list-style-type: none"> Specify the time, location, contact information for all individuals or parties involved, and protocols or practices to be simulated Informed consent of volunteer passengers (CDC will not collect) Written certification from healthcare providers that indicates no pre-existing medical conditions that put them at increased risk from COVID-19 infection (CDC does not collect) Submitted to CDC via email
Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage (if applicable) <ul style="list-style-type: none"> Submitted to CDC via email
Modified Simulated Voyage Procedures for Cruise Ships Currently Operating in U.S. Waters that Wish to Transition to Voyages with Less than 95% Vaccinated Passengers (if applicable) <ul style="list-style-type: none"> Submitted to CDC via email
Modified Simulated Voyage Procedures for Cruise Ships that have been Conducting Passenger Operations in non-U.S. Jurisdictions and Intend to Operate in U.S. Waters with less than 95% Vaccinated Passengers after Repositioning to the U.S. (if applicable) <ul style="list-style-type: none"> Submitted to CDC via email
Remote and In-person Inspections
Simulated Voyage After-Action Report <ul style="list-style-type: none"> Submitted to CDC via email
CSO: Information requirements associated in preparation for Phase 3 restricted voyages
Application for a CDC COVID-19 Conditional Sailing Certificate <ul style="list-style-type: none"> Statement of intent U.S. Coast Guard Certificate of Inspection Proof of inspections by other agencies or entity Submitted to CDC via email
Written Appeal of a Denial of its Application for a COVID-19 Conditional Sailing Certificate or a Revocation or Suspension of its COVID-19 Conditional Sailing Certificate (if necessary) <ul style="list-style-type: none"> Submitted to CDC via email
Remote and In-person 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.²¹ Documents associated with the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate and the CDC COVID-19 Conditional Sailing Certificate Application can be sent to eoevent349@cdc.gov to reduce burden associated with mailing and receipt of hard copies.

Additionally, to reduce burden on cruise ship operators, several documents associated with the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate and the CDC COVID-19 Conditional Sailing Certificate Application, such as the COVID-19

²¹ <https://www.project-redcap.org/>

response plan and the Phase 2A 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 laboratory requirements, CDC can, upon request, provide a list of CLIA-waived point-of-care instruments that have been previously approved by the Maritime Unit (for informational purposes only). In addition, CDC can provide a list of CLIA-approved laboratories located outside the U.S. CDC has also provided templates/checklists for the COVID-19 response plan and the Phase 2A agreements so that all parties are aware of CDC's expectations.

Moreover, cruise ship operators have to submit the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form (Attachment K) for COVID-19-like illness and the Maritime Conveyance Illness or the Death Investigation Form (Attachment L) 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, the CSO Extension requires cruise ship operators to submit cumulative case counts to CDC once per day 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 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.²²

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 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 and Death Reporting System and the EDC form.

5. Impact on Small Businesses or Other Small Entities

²² 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

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 Conditional Sailing Certificates 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 to facilitate their applications and may have fewer resources within their organizations to focus on application development and adherence to requirements. However, operators can collaborate on the development of applications, 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.²³ 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

Daily EDC reporting is necessary to continue safe passenger operations under the CSO Extension. 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.

CDC requires the most up to date information possible with regard to the documents and reporting requirements under the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate and COVID-19 Conditional Sailing Certificate. A cruise ship operator may seek to amend or modify a Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate and COVID-19 Conditional Sailing Certificate by submitting amendments or modifications to CDC via eocevent349@cdc.gov for review and a determination. CDC may also require any cruise ship operator to amend or modify a COVID-19 Conditional Sailing Certificate based on public health considerations specific to the cruise ship, cruise ship operator, or affecting the health or safety of cruise travel as a whole.

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 (Attachment C), and CDC has provided responses to each (Attachment D).

²³ Unpublished Maritime Unit data from daily EDC reporting and after travel reports from state and local health departments.

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 airlines' 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.

Beginning in late November 2020, CDC has also been engaging in biweekly phone calls with cruise lines to ensure questions concerning the terms of the CSO are answered in a timely fashion to facilitate compliance. Additionally, CDC has ad hoc meetings with cruise line representatives at their request.

CDC has also received feedback from state and local health departments who frequently engage with the travel industry regarding the Phase 2A 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 Phase 2 and Phase 3 processes (Attachment R).

Prior to issuing the Temporary Extension and Modification Framework for Conditional Sailing Order, CDC sent a survey (Attachment AA) 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 BB). 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 all of the relevant cruise lines, a maximum of 130 ships will need to respond to the requirements under the CSO Extension to apply for Conditional Sailing Certificates. Because this represents almost all of the ships that CDC has record of *ever* operating in U.S. waters, the total estimated burden presented here is likely an overestimate. Additionally, CDC estimates that 70 ships have already completed all the requirements necessary to obtain a Conditional Sailing Certificate. These ships will not need to re-complete the requirements under the CSO Extension. Cruise lines may choose to submit requests for Phase 1-2A requirements that cover multiple vessels, but each request and application must include the relevant information for each vessel. The total estimated annual burden is 24,289.3 hours.

Information Requirements Associated with Phase 1

- COVID-19 Response Plan (formerly referred to as “No Sail Order Response Plan”)
 - Most cruise line holding companies have already submitted 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 submitted a response plan and would need to do so prior to entering U.S. waters.
 - Each plan is estimated to require a full 40-hours of staff time to develop and submit.
 - Maximum annual hourly burden estimates are calculated as 3 cruise ship holding companies x 40 hours, for a total of 120 hours.
- Daily reporting to CDC using the Enhanced Data Collection during COVID-19 Pandemic (EDC) form
 - Maximum annual hourly burden estimates are calculated as 130 ships, 20 minutes per report, 365 days a year, for a total of 15,816.67 hours (rounded to 15,817 hours in the table below)
- Cruise COVID-19 Case Investigation Worksheet (if necessary)
 - Only cruise ships that meet a predetermined investigation threshold²⁴ will receive a Cruise COVID-19 Case Investigation Worksheet.
 - Approximately two ships per week receive this worksheet which takes 30 minutes to complete.
 - Maximum annual hourly burden estimates are calculated as 2 ships/week x 30 minutes x 52 weeks per year, for a total of 52 hours.
- Cruise COVID-19 Contact Investigation Worksheet (if necessary)

²⁴ <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html#green-ship>

- o Only cruise ships that meet a predetermined investigation threshold²⁵ will receive a Cruise COVID-19 Case Investigation Worksheet.
- o Approximately two ships per month receive this worksheet which takes 30 minutes to complete.²⁶
- o Maximum annual hourly burden estimates are calculated as 2 ships/month x 30 minutes x 12 months per year, for a total of 12 hours.
- Approval of Onboard COVID-19 Testing Instrument
 - o To ensure that each cruise line is using the highest quality onboard laboratory instruments to diagnose COVID-19 cases and the integrity of testing for symptomatic passengers and crew, CDC is requiring that cruise lines provide the type of onboard testing instruments for approval.
 - o CDC is accepting this information on a per-line/brand or per-ship, basis. However, for the purposes of completeness, and so not as to presume behavior, the full estimate is provided below
 - o CDC estimates that 70 out of the maximum 130 ships have already provided this information. For the 60 remaining ships, CDC estimates it will take 1 hour to send this information to CDC. This is a total of 60 hours.
- Phase 1 Mass Crew Testing Requirement
 - o To ensure that each cruise line is using the highest quality laboratory services to diagnose COVID-19 cases and the integrity of testing, CDC is requiring that cruise lines provide the location of the CLIA certified lab used for processing samples or the type onboard viral test (NAAT or antigen test) being used.
 - o CDC is accepting this information on a per-line or per-ship, basis. For the purposes of completeness, and so not as to presume behavior, the full estimate is provided below.
 - o CDC estimates that 70 out of the maximum 130 ships have already provided this information to CDC. For the 60 ships that have not submitted this information, it will take 5 minutes to send this information to CDC. This is a total of 5 hours.

Information Requirements Associated with Phase 2A of the CSO Extension

- Agreement with Health Care Organization with signoff from Local Health Authorities
 - o In order to Request approval for a simulated voyage, 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, 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 not as to presume behavior, the full estimate is provided below.

²⁵ <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html#green-ship>

²⁶ 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 ships (requiring public health interventions), interventions for fully vaccinated close contacts on highly vaccinated ships are limited.

- 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 using the eocevent349@cdc.gov address and CDC will review.
- o Approximately 70 ships have already completed this agreement.
- o For the remaining 60 ships, CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 600 burden hours
- Agreement with Port of Entry with signoff from Local Health Authority
 - o In order to Request approval for a simulated voyage, the cruise ship must document an agreement with a Port of Entry that will accept the ship. This will be required for each ship, 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 not as 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 using the eocevent349@cdc.gov address and CDC will review.
 - o Approximately 70 ships have already completed this agreement.
 - o For the remaining 60 ships, CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 600 burden hours
- Agreement with Housing Facility with signoff from Local Health Authority
 - o In order to Request approval for a simulated voyage, 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, 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 not as 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 using the eocevent349@cdc.gov address and CDC will review.
 - o Approximately 70 ships have already completed this agreement.
 - o For the remaining 60 ships, CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 600 burden hours

Information Requirements Associated with Phase 2B Simulated Voyages

- o Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate
 - o To engage in a simulated voyage under the CSO Extension, a ship must provide the completed Request for Approval to Conduct a Simulated Voyage Prior to Issuance of

- COVID-19 Conditional Sailing Certificate document to CDC. The Request includes several operational requirements that must be implemented prior to submission (e.g. testing capacity, notification to travelers about risks of simulated voyage and consent form those travelers, continuation of capabilities under their approved COVID-19 response plan, other public health requirements as outlined in the CDC Technical Instructions).
- o CDC estimates that there are approximately 30 ships that may decide to conduct a simulated voyage, and that each Request document takes approximately 10 hours to complete, not counting the burden associated with the COVID-19 response plan, Agreements list above, After Action Reports, 3rd Party notification of Informed Consent and Medical Certification, and CLIA Certified Laboratory Information requests.
 - o CDC estimates an annual burden of 300 hours to complete the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate
 - Third Party Notification of Informed Consent and Medical Certification
 - o In order to conduct a simulated voyage, the cruise lines must collect an informed consent and medical document from each volunteer passenger, which states that they have no pre-existing medical conditions that put them at increased risk from COVID-19 infection.
 - o CDC is considering this a third-party information collection and is including the burden here. CDC is not collecting any identifiable information through this collection. Additionally, CDC is not limiting any additional measures cruise ships may take concerning consent, testing, or other health screening prior to boarding. CDC is setting the minimum standard through the Order, Technical Instructions, and this information collection request.
 - o CDC estimates that each simulated voyage will have approximately 600 simulated passengers. The total burden estimated for the medical documents is 30 ships x 600 simulated passengers, and 15 minutes per health document; this total is 4,500 hours of burden.
 - Remote and In-person Inspections
 - o Under the CSO Extension, the cruise ship operator's properties and records must be 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. These requirements are outlined in the Technical Instructions for Mitigation of COVID-19 Among Cruise Ships Resuming Passenger Operations.
 - o CDC anticipates a maximum of one inspection per ship. CDC predicts that cruise ship operators will spend two hours preparing for the inspection.
 - o With the estimated 30 vessels that may conduct simulated voyages under the CSO, this equals 60 hours.
 - After Action Report

- o After the completion of a Simulated Voyage, each ship must send an After-Action Report to CDC documenting any deficiencies in its health and safety protocols and address how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. This after-action report will also include test results for any volunteer passengers or crew on the simulated voyage. The after-action report will be submitted to the CDC as soon as practical at the end of the simulation and as part of the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate. CDC is providing a template for voluntary use by the cruise lines.
- o CDC estimates each ship will require 10 hours to complete the After-Action Report and submit it to CDC, for 300 hours of annual burden associated with this requirement.
- Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage (if applicable)
 - o In lieu of conducting a simulated voyage, a cruise ship operator's responsible officials, at their discretion, may sign and submit to CDC an acknowledgement that 95 percent of crew (excluding any newly embarking crew in quarantine) are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.
 - o CDC estimates there are 40 ships that may decide to pursue this option. It will take a cruise ship operator 5 minutes to complete the attention and submit it to CDC.
 - o CDC estimates an annual burden total of 3 hour and 20 minutes.
- Modified Simulated Voyage Procedures for Cruise Ships Currently Operating in U.S. Waters that Wish to Transition to Voyages with Less than 95% Vaccinated Passengers (if applicable)
 - o Cruise ships that have been operating restricted passenger voyages with 95% vaccinated crew and 95% vaccinated passengers may transition to voyages with less than 95% vaccinated passengers by conducting modified simulated voyage procedures in lieu of a full simulated voyage.
 - o CDC estimates there are 15 ships that may decide to pursue this option. It will take a cruise ship operator 4 hours to complete the modified simulated voyage requirements associated with this option.
 - o CDC estimates the total annual burden to be 60 hours.
- Modified Simulated Voyage Procedures for Cruise Ships that have been Conducting Passenger Operations in non-U.S. Jurisdictions and Intend to Operate in U.S. Waters with less than 95% Vaccinated Passengers after Repositioning to the U.S. (if applicable)
 - o Cruise ships that have been conducting passenger operations in non-U.S. jurisdictions and intend to operate in U.S. waters with less than 95% vaccinated passengers after repositioning to the U.S. may apply for a COVID-19 Conditional Sailing Certificate after conducting modified simulated voyage procedures instead of a full simulated voyage.
 - o CDC estimates there are 10 ships that may decide to pursue this option. It will take a cruise ship operator at most 8 hours to complete the modified simulated voyage requirements associated with this option.
 - o CDC estimates the total annual burden to be 80 hours.

Information Requirements Associated in Preparation for Phase 3 Restricted Voyages

- COVID-19 Conditional Sailing Certificate Application
 - An estimated 70 ships have already completed the COVID-19 Conditional Sailing Certificate Application
 - The Conditional Sail Application must be completed one time per ship.
 - CDC estimates that completion of the application and the associated requirements will take 10 hours for each of the 60 remaining ships.
 - While the Conditional Sail Certificate Application also requires the three agreements listed above, it does not require new agreements. There is no additional burden associated with this part of the process.
 - CDC estimates 600 hours of burden for the Conditional Sail Certificate Application.
- Remote and In-person Inspections
 - Under the CSO, the cruise ship operator’s properties and records must be 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. These requirements are outlined in the Technical Instructions for Mitigation of COVID-19 Among Cruise Ships Resuming Passenger Operations
 - 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 CSO, and a maximum of two inspections, this equals 520 hours.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Cruise ship holding company	COVID-19 Response Plan (Attachment G-Instruction)	3	1	2400/60	120
Cruise ship physician	Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (Daily) (Attachment J-Form)	130	365	20/60	15,817
Cruise ship physician	Cruise COVID-19 Case Investigation Worksheet (if necessary) (Attachment M-Form)	104	1	30/60	52

Cruise ship physician	Cruise COVID-19 Contact Investigation Worksheet (if necessary) (Attachment N-Form)	24	1	30/60	12
Cruise ship brand/operator	Approval of Onboard COVID-19 Testing Instrument (Attachment H-Instruction)	60	1	60/60	60
Cruise ship brand/operator	Mass Crew Testing Requirement (Attachment I-Instruction)	60	1	5/60	5
Cruise ship brand/operator	Agreement with Health Care Organization with signoff from Local Health Authorities (Attachment P-Instruction)	60	1	600/60	600
Cruise ship brand/operator	Agreement with Port of Entry with signoff from Local Health Authority (Attachment O-Instruction)	60	1	600/60	600
Cruise ship brand/operator	Agreement with Housing Facility with signoff from Local Health Authority (Attachment Q-Instruction)	60	1	600/60	600
Cruise ship operator	Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate (Attachment T-Form)	30	1	600/60	300

Passenger (3 rd party disclosure)	Informed Consent and Medical Certification with no pre-existing conditions for Simulated Voyage (Attachment S-Instruction)	18,000	1	15/60	4,500
Cruise ship operator	Remote and In-person Inspections (Attachment U-Instruction)	30	1	120/60	60
Cruise ship operator	After Action Report, Simulated Voyage (Attachment V-Form)	30	1	600/60	300
Cruise ship operator	Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage (if applicable) (Attachment W-Form)	40	1	5/60	3
Cruise ship operator	Modified Simulated Voyage Procedures for Cruise Ships Currently Operating in U.S. Waters that Wish to Transition to Voyages with Less than 95% Vaccinated Passengers (if applicable) (Attachment X-Instruction)	15	1	240/60	60
Cruise ship operator	Modified Simulated Voyage Procedures for Cruise Ships that have been Conducting Passenger Operations in non-	10	1	480/60	80

	U.S. Jurisdictions and Intend to Operate in U.S. Waters with less than 95% Vaccinated Passengers after Repositioning to the U.S. (if applicable) (Attachment Y-Instruction)				
Cruise ship operator	COVID-19 Conditional Sailing Certificate Application (Attachment Z-Form)	60	1	600/60	600
Cruise ship operator	Remote and In-person Inspections (Attachment U-Instruction)	130	2	120/60	520
Total					24,289

B. Estimated Annual Burden Costs

Estimates of the time burden associated with completion of the COVID-19 Conditional Sailing Certificate Application and the COVID-19 response plans 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.

00-0000 All Occupations (https://www.bls.gov/oes/current/oes_nat.htm#00-0000) was used to account for international passenger time. The mean hourly wage for this category is \$27.07. CDC adjusted by the hourly wage by 1.31 to account for non-wage benefits to obtain a figure of \$35.47.

The estimated total cost is \$1,700,607.79.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cruise ship operator/ 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)	15,817	\$77.87	\$1,231,669.79
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 operator/ parent company	Approval of Onboard COVID-19 Testing Instrument	60	\$77.87	\$4,672.20
Cruise ship operator/ parent company	Mass Crew Testing Requirement	5	\$77.87	\$389.35
Cruise ship operator/ parent company	Agreement with Health Care Organization with signoff from Local Health Authorities	600	\$77.87	\$46,722.00
Cruise ship operator/ parent company	Agreement with Port of Entry with signoff from Local Health Authority	600	\$77.87	\$46,722.00
Cruise ship operator/ parent company	Agreement with Housing Facility with signoff from Local Health Authority	600	\$77.87	\$46,722.00
Cruise ship operator/ parent company	Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate	300	\$77.87	\$23,361.00
Passenger (3 rd party disclosure)	Informed Consent and Medical Certification with no pre-existing conditions for	4,500	\$35.47	\$159,615.00

	Simulated Voyage			
Cruise ship operator	Remote and In-person Inspections	60	\$77.87	\$4,672.20
Cruise ship operator	After Action Report, Simulated Voyage	300	\$77.87	\$23,361.00
Cruise ship operator	Acknowledgement by a Cruise Ship Operator In Lieu of a Simulated Voyage (if applicable)	3.3	\$77.87	\$256.97
Cruise ship operator	Modified Simulated Voyage Procedures for Cruise Ships Currently Operating in U.S. Waters that Wish to Transition to Voyages with Less than 95% Vaccinated Passengers (if applicable)	60	\$77.87	\$4,672.20
Cruise ship operator	Modified Simulated Voyage Procedures for Cruise Ships that have been Conducting Passenger Operations in non-U.S. Jurisdictions and Intend to Operate in U.S. Waters with less than 95% Vaccinated Passengers after Repositioning to the U.S. (if applicable)	80	\$77.87	\$6,229.60
Cruise ship operator	COVID-19 Conditional Sailing Certificate Application	600	\$77.87	\$46,722.00
Cruise ship	Remote and In-	520	\$77.87	\$40,492.40

operator	person Inspections			
Total				\$1,700,607.79

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

Compliance with the Framework for Conditional Sailing Order, beyond the information collections outline above, are primarily associated with the testing required. CDC estimates a cost for cruise line operators of \$8,438,600. This estimate includes the cost of mass crew testing and lab equipment on the ship.

- For costs associated with the mass crew testing requirement, CDC estimates the costs as follows:
 - 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.
 - CDC estimates that 60 ships have not yet completed the one-time mass crew testing requirement. Using an average of 1500 crew members that must be tested per ship, CDC estimates an average annual cost of \$50 x 60 ships x 1500 crew totaling \$4,500,000 per year.
- For costs associated with onboard testing capacity, CDC estimates:
 - The cost of the onboard instrument used to test symptomatic cases and their contacts ranges from \$9,920- \$72,350 per ship. Roughly 60 ships still need to purchase this equipment. Using a midpoint cost of \$41,135, CDC estimates a total cost of \$2,468,100 per year.
 - 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.
- The maintenance contracts for an onboard testing instrument are estimated to cost between \$1,896-\$7,800 yearly per ship. About 70 ships have already paid this cost, leaving 60 ships that have not. The total cost per year is estimated to be \$290,880 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 applications and COVID-19 response plans by the average wage of the individuals performing the review. The total

estimated costs are \$974,252.00.

CDC estimates it will take four employees working full time to review the plans and applications. CDC assumes an average wage equivalent to GS 13s and GS 14s on an annual basis.²⁷ CDC is multiplying each wage by 2 to account for non-wage benefits.

Personnel Category	Annual Wage	Adjustment	Total Cost
2 x GS 14	\$131,923	x2	\$527,692.00
2 x GS 13	\$111,640	x2	\$446,560.00
Total Cost			\$974,252.00

15. Explanation for Program Changes or Adjustments

This is an emergency 6-month extension of an Existing Information Collection Request. This emergency extension is necessary because changes in CDC’s Order titled Temporary Extension and Modification of Framework for Conditional Sailing Order (Attachment E) requires the use of this information collection by November 1, 2021. A full extension will be submitted following the expiration of the emergency.

The resumption of passenger voyages in the U.S. has facilitated the introduction and sustained transmission of COVID-19 among cruise ships, despite high vaccination rates among both crew and passengers, highlighting the continued need to temporarily extend CDC’s public health management to mitigate this risk.

The CSO Extension slightly modifies the phased-in approach to resume cruise ship passenger operations introduced by the CSO. Cruise ship operators who have already completed the process under the CSO will not have to resubmit any information under the CSO Extension and can continue sailing with passengers without interruption. As many cruise ship operators are now familiar with the CSO and its requirements, many aspects of the phased-in approach can be completed concurrently under the CSO Extension.

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)

²⁷ <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/ATL.pdf>

A2: 42 CFR 70
A3: 42 CFR 71
B: 30-Day Federal Register Notice
C: Public Comments on 60-day FRN
D: Response to Public Comment
E: Temporary Extension & Modification of Framework for Conditional Sailing Order
F: Framework for Conditional Sailing Order
G: COVID-19 Response Plan
H: Approval of Onboard COVID-19 Testing Instrument
I: Mass Crew Testing
J: Enhanced Data Collection during COVID-19 Pandemic (EDC)
K: Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form
L: Maritime Conveyance Illness or the Death Investigation Form
M: Cruise COVID-19 Case Investigation Worksheet
N: Cruise COVID-19 Contact Investigation Worksheet
O: Agreement with Port of Entry
P: Agreement with Health Care Organization
Q: Agreement with Housing Facility
R: Checklist for Phase 2A Agreements
S: Informed Consent and Medical Certification for Simulated Voyage
T: Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate
U: Remote and In-person Inspections
V: Simulated Voyage After Action Report
W: Acknowledgment by a Cruise Ship Operator In Lieu of a Simulated Voyage
X: Transition to Operating Restricted Passenger Voyages with Less than 95% of Passengers Fully Vaccinated
Y: Cruise Ships with Less than 95% of Passengers Fully Vaccinated After Repositioning to U.S. Waters
Z: COVID-19 Conditional Sailing Certificate Application
AA: CSO Partner Survey
BB: Not Research Determination