

Phased Approach to the Resumption of Cruise Ship Passenger Operations

Request for OMB approval of an Emergency Information Collection

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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 commercial, non-cargo, passenger-carrying vessels that seek to operate in international, interstate, or intrastate waterways and 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.

CDC acknowledges that certain elements of this collection are already underway under the Conditional Sail Framework, and respondent burden has accrued during the period between the expiration of the information collections associated with 0920-1292 and the No Sail Order requirements. While CDC does not estimate that there have been more than nine respondent entities, as the cruise industry concentrated among large firms, the following burden has accrued associated with the information collections listed here:

- There have been 62 responses to the CLIA Certified Laboratory Information – Onshore. This has resulted in a burden of 5.17 hours.
- There have been 62 responses to Approval of Onboard COVID-19 Testing Instrument. This has resulted in a burden of 5.17 hours.
- There have been 65 submissions of the Request for Embarkation of Essential Crew and Contractors. This has resulted in a burden of 10.83 hours.
- There have been 65 submissions of the Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC’s Framework for Conditional Sailing Order. This has resulted in a burden of 16.25 hours.

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 approval for a New Information Collection titled Phased Approach to the Resumption of Cruise Ship Passenger Operations.

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world. As of April 14, 2021 , a cumulative estimated total of over 130 million cases and over 2.9 million

confirmed deaths have now been reported worldwide. 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 April 14, 2021, there have been over 30 million cases and more than 550,000 confirmed deaths. As of April 14, 2021, the U.S Food and Drug Administration (FDA) has granted emergency use authorization for three vaccines, approximately 120 million individuals in the U.S have received the first dose of the vaccine.

Unrestricted cruise ship travel has the potential to exacerbate and amplify the spread of SARS coronavirus 2 (SARS-CoV-2) the virus that causes COVID-19. 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 transmission on cruise ships, on March 14, 2020, the CDC Director issued a No Sail Order and Other Measures Related to Operations directing cruise ships not voluntarily suspending operations to comply with certain measures (85 FR 16628). This followed a March 13, 2020, announcement by Cruise Line International Association, the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Health Notice warning all travelers to defer cruise travel worldwide based on widespread ongoing transmission of COVID-19. Despite the announcement by CLIA, the application of the March 14, 2020 Order, and the Level 3 Travel Health Notice, cruise ships continued to be associated with new COVID-19 outbreaks. Between March 14 and April 15, 2020, COVID-19 outbreaks were reported on several additional cruise ships with passengers (85 FR 21004).

Accordingly, to protect public health and safety and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, 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). Under the April 15, 2020 Extension, as a condition of obtaining controlled free pratique to continue to engage in cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operations were limited, and cruise lines were required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 on board to ensure a safe work environment and disembarkation for crew members. A cruise ship operator's No Sail Order response plan (OMB Control No. 0920-1292, exp. date 10/31/2020) had to minimize to the greatest extent possible any impact on U.S. Government operations or the operations of any State or local government, or the U.S. healthcare system. While working with cruise ship operators to ensure the completeness and accuracy of these response plans, CDC allowed crew members to disembark from cruise ships in U.S. waters and return home if cruise ship operators formally attested, in writing, to complying with requirements to disembark crew members in such a manner as to minimize the risk to other travelers and communities.

Following the April 15, 2020 Extension, CDC published its Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected SARS-CoV-2 infections and exposures among crew members. During this period, CDC also further assisted cruise ship operators with humanitarian medical evacuations for people in need of lifesaving support. Under the April 15, 2020 Extension, CDC established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships through a requirement for weekly submission of the “Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (OMB Control Number 0920-0134, exp. 03/31/2022)”. Since then, the EDC form has been used to conduct surveillance for COVID-19 among crew who remained on board cruise ships based on cumulative reports of acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and other clinical indicators of COVID-19 (85 FR 62732).

As of January 24, 2021, EDC reports have shown a total of 18,836 polymerase chain reaction (PCR) tests performed, 354 (2%) of which were positive; 27 hospitalizations; 2 instances of mechanical ventilation; and 18 medical evacuations for crew on ships within U.S. jurisdiction since April 15, 2020. CDC also recommended that ships’ surveillance include routine testing for SARS-CoV-2 infection, including intermittent testing of a random sample of symptomatic and asymptomatic crew members.

In addition to reviewing the No Sail Order response plans, CDC continued to update its Interim Guidance as new information became available; provided technical expertise to ships with ongoing outbreaks; created cruise ship-specific websites to inform crew members, the public, and partners; and reviewed hundreds of written attestations submitted by cruise operators for safe disembarkation and transfer of crew members.

CDC established a “COVID-19 Color Coding System” for ships applicable to cruise ship operators with an appropriate No Sail Order response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their No Sail Order response plans upon completion of CDC review of the plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form as well as recent embarkations or crew transfers. Additional details regarding the color-coding system and color coding status for individual ships (which is updated weekly) may be found at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>.

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, 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), and Third Modification and Extension of No Sail Order and Other Measures Related to Operations on September 30, 2020, (85 FR 62732). This last order, among other things, suspended passenger operations on board cruise ships and remained in effect through October 31, 2020.

Current scientific evidence suggests that, absent mitigation measures of the type needed to prevent further transmission, cruise ships would continue to pose a greater risk of COVID-19 transmission than other settings. A recent article published in the *Journal of Travel Medicine* by Rocklöv et al. demonstrated that the Diamond Princess cruise ship experienced an onboard R0 (basic reproduction

rate) for COVID-19 of 14.8 before ship-wide quarantine was enacted¹. This means that each case onboard the Diamond Princess transmitted COVID-19 to approximately 15 other people. This reproduction rate is approximately four times higher than the R0 of the original epicenter of the outbreak in Wuhan, China, which was 3.7, meaning that each person with COVID-19 in the early days of the outbreak in Wuhan transmitted the disease to approximately four other people. In late February/early March, 149 cases of PCR-confirmed COVID-19 (of 589 tour participants) were found among U.S. residents linked to Egyptian Nile Cruises. This heightened rate of transmission onboard cruise ships has also been documented in other academic publications. Absent appropriate interventions to mitigate the spread of COVID-19, cruise ship conditions have the potential to amplify the spread of an already highly transmissible disease.

Rocklöv et al. surmised that this heightened rate of transmission is due to the high population density on board ships, which are typically more densely populated than cities or most other living situations. While this is one contributing factor, CDC's surveillance data collected through the EDC form and acquired during the period of the No Sail Order show 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, and where social distancing may prove challenging even with a limited number of people onboard.

In addition, the recent investigation by Payne et al. of transmission onboard a U.S. Navy ship demonstrated high transmission rates and high rates of mild disease and asymptomatic infection among crew². These mild presentations and asymptomatic cases make case detection and isolation and quarantine practices based on clinical presentation alone challenging. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next. This again stresses the need for appropriate interventions, including routine laboratory testing of crew, prior to restarting passenger operations.

Cruise ship operators have taken steps to advance their public health response to COVID-19, improve safety, and achieve readiness to safely resume passenger operations. Under the co-chairmanship of former Health and Human Services Secretary, Michael O. Leavitt, and former FDA Commissioner, Dr. Scott Gottlieb, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a "Healthy Sail Panel" of subject-matter experts from a variety of disciplines. The World Travel & Tourism Council (WTTC) and Carnival Corporation also recently hosted a global science summit on COVID-19 designed, "to inform practical, adaptable and science-based solutions for mitigating and living with COVID-19." MSC Cruises further established its own industry-led panel with "competency to review policy initiatives, technical innovations, or operational measures related to COVID-19."

While the actions taken by cruise ship operators to advance their public health response to COVID-19 are encouraging, further public health oversight is needed to provide uniform standards for mitigating the communicable disease risk to crew and prospective passengers.

¹ <https://academic.oup.com/jtm/article/27/3/taaa030/5766334>

² <https://www.cdc.gov/mmwr/volumes/69/wr/mm6923e4.htm>

On October 30, 2020, CDC announced a Framework for Conditional Sailing Order 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 requirements in the Framework for Conditional Sailing Order highlight the need for further action before cruise ships can safely resume passenger operations in the United States. This order applies to passenger operations on cruise ships with the capacity to carry at least 250 passengers in waters subject to U.S. jurisdiction.

The Framework for Conditional Sailing Order 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.

CDC is implementing a phased approach to resuming passenger operations. During the initial phases, cruise ship operators must demonstrate adherence to testing, quarantine and isolation, and social 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.

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 US. 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 Framework for Conditional Sailing Order published in the *Federal Register* on November 4, 2020 (Attachment C) prohibits a cruise ship operator from commencing or continuing any 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.

Per CDC's Framework for Conditional Sailing Order, cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, must have a NSO response plan deemed complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy (Attachment D). In addition, cruise ship operators must continue to follow their cruise lines' complete, accurate, and acknowledged NSO response plans per the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (i.e., "No Sail Order response plan"), as modified and extended July 16, 2020

(published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)) (Attachment E).

The Framework for Conditional Sailing Order introduced a phased-in approach to the resumption of cruise ship passenger operations. This Framework Order details the requirements of the initial phase, which focuses on mass testing of crew and building the laboratory capacity needed to test both crew and future passengers. This includes requests and subsequent CDC approvals for Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory using nucleic acid amplification tests (NAAT) for shoreside laboratory testing, and rapid NAAT point-of-care equipment for onboard laboratory capabilities. During the first phases of the CSO, cruise ship operators are required to submit a signed Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC's Framework for Conditional Sailing Order (CSO) (Attachment F). This attestation is tied to the color-coding system and is valid until the ship's color status changes to "Red". Lastly, cruise ship operators must submit requests for embarkation of essential crew and contractors; these requests are minimal as there is seldom turnover of essential crew.

The next phase of the Framework Order, Phase 2A, focuses on preparation for simulated voyages. As required under the CSO, 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 to determine the number of cruise ships operating out of any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak; (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 instructions and orders; 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 close contacts, identified from the day of embarkation through disembarkation for each voyage.

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 is posting specific guidance online and is providing a checklist (Attachment G) for additional reference. After cruise ship operators submit these agreements to CDC, they are eligible to request for embarkation of non-essential crew.

Phase 2A also includes a shift in reporting requirements using the CDC (EDC) form (Attachment H) previously approved in OMB Control Number 0920-0134 Foreign Quarantine Regulations. Starting in this phase, the form will be required from cruise ships on a daily, rather than weekly, rhythm. CDC was already receiving unrequested email reports from the cruise lines regarding cases identified on a daily basis. As approved under OMB Control Number 0920-0134, in lieu of submitting the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form (Attachment I) for COVID-like illness and the Maritime Conveyance Illness or Death Investigation Form (Attachment J) for individual specific cases of COVID-19, the CDC will require submission of the EDC form during the period of the CSO. Data points for this form include number of crew members currently onboard; case counts and diagnostic testing data for COVID-like Illness (CLI), acute respiratory distress syndrome, and

pneumonia among crew; screening testing of asymptomatic travelers, and isolation practices. This data will greatly increase the transparency of the overall health of the crewmembers onboard, and eventually passengers, and better allow the CDC to manage potential outbreaks and offer recommendations to the ship and port partners.

Phase 2B of the Framework Order focuses on simulated voyages with volunteers playing the role of passengers to test cruise ship operators’ ability to mitigate COVID-19 risk. 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 K) to conduct a simulated voyage at least 30 calendar days prior to the voyage. The minimum standards for simulated voyages include the following: informed consent, written certification from a health provider, embarkation of essential crew, laboratory testing of volunteer passengers, specified simulated activities, modified meal service. During the simulated voyages, the cruise ships are subject to virtual and in-person inspections by CDC. The cruise ship operator’s properties and records 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 will issue 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 an “after-action” report (Attachment L) 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 must also include test results for any volunteer passengers or crew on the simulated voyage.

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 or series of simulated voyages demonstrating the cruise ship operator’s ability to mitigate the risks of COVID-19 onboard its cruise ship. The CDC COVID-19 Conditional Sailing Certificate Application (Attachment M) form includes certain minimum requirements that must be met prior to a restricted voyage and burden for these requirements is outlined in section 12 below. Additional data collection elements include the following: a statement of intent; a copy of the ship’s U.S. Coast Guard Certificate of Inspection; proof of inspections by other agencies or entity. These documents must be submitted 60 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.

CDC will 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 in chronological order:

Data Collection Elements
Ongoing
Enhanced Data Collection (EDC) During COVID-19 Pandemic Form-Updated Weekly 60-65 ships figure out the burden

No Sail Order
No Sail Order Response Plans (per cruise ship operator) <ul style="list-style-type: none"> • Template provided to cruise ship operators • Posted online: <i>Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew</i>
Request for Embarkation of Essential Crew and Contractors submitted to USCG
Attestation for Non-Commercial Travel of Disembarking Crew for Cruise Ship Operators During the No Sail Order (NSO)
Virtual Implementation Checks
Acknowledgement of No Sail Order Response Plan Completeness and Accuracy- 2 ships
Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the No Sail Order (Attachment N)
CSO: Information requirements associated with Phase 1 – in preparation for simulated voyages in chronological order (Phase 2A)
Enhanced Data Collection (EDC) During COVID-19 Pandemic Form-Daily
Request for Approval of Shoreside COVID-19 Laboratory <ul style="list-style-type: none"> • Mass screening testing of all crew • All embarking crew • Passengers
Request for Approval of Onboard COVID-19 Testing Instrument <ul style="list-style-type: none"> • Symptomatic travelers (crew and future passengers) • Close contacts • CDC provided list of previously approved instruments upon request
Request for Embarkation of Essential Crew and Contractors <ul style="list-style-type: none"> • Template provided to cruise ship operators
Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC’s Framework for Conditional Sailing Order (CSO)
CSO: Information requirements associated with Phase 2A– in preparation for simulated voyages in chronological order
Cruise Ship Operator’s Agreement with U.S. Port Authorities and Local Health Authorities <ul style="list-style-type: none"> • Agreement with housing facility • Agreement with medical care • Agreement with Ports of Entry (POE) • Contact information and signatures of all parties • Copy of all attachments, exhibits, and annexes provided to CDC • Posted online: <i>Technical Instructions for a Cruise Ship Operator’s Agreement with Port and Local Health Authorities under CDC’s Framework for Conditional Sailing Order</i> • 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> • These agreements can remain in place for the restricted voyages, as long as the agreements remain valid.
Request for Embarkation of Non-Essential Crew
CSO: Information requirements associated with simulated voyages in chronological order (Phase 2B)
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)

<ul style="list-style-type: none"> Written certification from healthcare providers that indicates no pre-existing medical conditions that put them at increased risk from COVID-19 infection (CDC will not collect)
Remote and In-person Inspections <ul style="list-style-type: none"> The cruise ship operator’s properties and records 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. Posted online : <i>COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order</i> <ul style="list-style-type: none"> Outlines what will be inspected Inspection Checklist for CDC staff (currently under development):
Simulated Voyage After-Action Report <ul style="list-style-type: none"> Document any deficiencies in health and safety protocols and how these will be addressed Test results for any volunteer passengers or crew
CSO: Information requirements associated in preparation for restricted voyages in chronological order (Phase 3)
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
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
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 the REDCap³. Documents associated with the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate form and the CDC COVID-19 Conditional Sailing Certificate Applications phases can be sent to eocevent349@cdc.gov to reduce burden associated with mailing and receipt of hard copies.

CDC remains willing to accept NSO response plans, previously approved under OMB Control Number 0920-1292 submitted by cruise industry organizations representing multiple operators, e.g., Cruise Lines International Association, the world’s largest cruise industry trade association that represents approximately 95% of global cruise ship passenger capacity. Cruise lines may also submit CLIA Certified Laboratory Information for all ships in their fleet or several ships, rather than on a per ship basis. This may also reduce burden.

Cruise lines may also submit documents associated with the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate form and the CDC COVID-19 Conditional Sailing Certificate Applications, such as the agreements, on behalf of multiple

³ <https://www.project-redcap.org/>

ships as long as every ship within each document is individually covered by the terms of the documents and agreements.

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 US. 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.

CDC does not envision a 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. 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. Additionally, this information collection request is not duplicative of the previous OMB package 0920-1292.

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 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.

For the laboratory requirements in the Framework Order, 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.

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, and 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

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. This may require changes an initial submission to ensure that cruise lines can address COVID-19 outbreaks onboard and prevent undue burden to healthcare and public health resources in the United States. 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.

With regard to the daily reporting requirement for the CDC EDC form, because COVID-19 can spread so rapidly and the CSO envisions a return to passenger operations, having knowledge of cases on a daily basis will be critical to preventing further spread.

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. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation such that the comments may inform future efforts (Attachment B).

B. To gather information regarding industry-led efforts to respond to COVID-19 and solicit public input, on July 21, 2020, CDC published a Request for Information (RFI) in the *Federal Register* related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083) (Attachment O). The document had a 60-day comment period that ended on September 21, 2020 and nearly 13,000 comments were received.

Respondents to the RFI included members of the public, the cruise industry, seaport authorities, and the travel and hospitality industries. A majority of respondents (approximately 75%) expressed support for the resumption of passenger cruising in the US. The vast majority of these commenters also expressed the need for increased public health measures, including health screening, testing, mask use, social distancing, travel insurance, refunds, and shipboard public health capacity as important steps to take before cruising resumes. Approximately 25% of respondents, including many previous cruise passengers, were in favor of delaying the resumption of passenger cruising because of the current state of the pandemic, and supported waiting until a vaccine is widely available. Comments received related to the reduction of number of passengers, the need for routine testing of passengers and crew, social distancing, coordination between CDC and the cruise industry, limiting ports of call to private islands,

agreements with local public health and medical facilities, and the economic benefits of cruising. CDC carefully considered these comments in drafting the Framework for Conditional Sailing Order and this ICR. CDC continues to consult with international maritime public health partners on ways to reduce COVID-19 transmission on ships and continue to monitor the global COVID-19 situation. CDC is also seeking comment on the estimates of burden presented in section 12.

Beginning in late November 2020, CDC has also been engaging in weekly phone calls with cruise lines to ensure questions concerning the terms of the CSO are answered in a timely fashion to facilitate compliance.

CDC has also heard from state and local health departments who frequently engage with the travel industry. We have 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.

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 P). IRB approval is not required.

Justification for Sensitive Questions

There are no planned sensitive questions.

12. Estimates of 6-month Burden Hours and Costs

A. Estimated 6-month 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 to perform simulated voyages and apply for conditional sailing certificates. Because this represents almost all of the ships that CDC has record of operating in U.S. waters, the total estimated burden presented here is likely an overestimate. Cruise lines may choose to submit requests for simulated voyages and applications for conditional sail certificates that cover multiple vessels, but each request and application must include the relevant information for each vessel. The total estimated annual burden is 69,532 hours.

Information collections under the No Sail Order framework (CDC notes that there are likely less than 10 ships that fall into this category of respondents, but CDC is providing for transparency.)

- No Sail Order Response Plan
 - Most cruise lines have submitted NSOs that cover their vessels. There are a limited number of lines that have not done so yet. Each plan is estimated to require a full 40-hours of staff time to develop and submit. As stated in Section 3 above, if cruise lines determine that one plan on behalf of an association is their preferred method of compliance, then CDC will consider that plan as meeting the requirements. For the purposes of completeness, and so not as to presume behavior, the full estimate is provided below. CDC estimates there are at most five lines or vessels that have not submitted an NSO and would need to do so prior to entering U.S. waters. The NSO template remains available to assist in plan development (Attachment Q). Use of the template is voluntary.
 - Maximum annual hourly burden estimates are calculated as 5 ships (or lines) x 40 hours, for a total of 200 hours.
- During the period of the NSO, ships are prohibited from embarking essential crew and contractors without prior notice to CDC.
 - CDC estimates approximately 5 ships or cruise lines will make these requests at 10 minutes per request. This represents a total of 50 minutes (rounded to 1 hour in the table below)
- During the period of the NSO, ships are prohibited from disembarking or transferring crew without prior notice to CDC. In order to do so, a cruise line must submit to CDC an Attestation for Non-Commercial Travel of Disembarking Crew for Cruise Ship Operators During the No Sail Order. This is not an information collection but does require time for the cruise line to submit the Attestation document to CDC and so that burden is noted here.
 - Maximum annual hourly burden estimates are calculated as 5 ships 15 minutes per disembarkation event (5 disembarkation per ship), for a total of 6.25 hours (rounded to 7 hours in the table below)
- During the period of the NSO, CDC may conduct Virtual Implementation Checks of cruise ships to ensure compliance with the terms of the order. CDC anticipates this may take place at most twice per vessel.
 - Maximum annual hourly burden estimates are calculated as 5 ships x 2 inspections x 75 minutes per inspection, for a total of 12.5 hours (rounded to 13 in the table below)
- During the period of the NSO, ships are prohibited from disembarking crew with an intent to use commercial travel to their destination without prior notice to CDC. Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the No Sail Order
 - Maximum annual hourly burden estimates are calculated as 5 ships 15 minutes per disembarkation event (5 disembarkation per ship), for a total of 6.25 hours (rounded to 7 hours in the table below)

Information Requirements Associated With Phase 1 – In Preparation For Simulated Voyages In Chronological Order (Phase 2A)

- The transition from the NSO to the CSO framework will involve moving from weekly to daily reporting to CDC using the EDC form.
 - Maximum annual hourly burden estimates are calculated as 130 ships, 15 minutes per report, 365 days a year, for a total of 11,862.5 hours (rounded to 11,863 hours in the table below)
- CLIA Certified Laboratory Information – Onshore
 - 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.
 - CDC is accepting this information on a per-line or per-ship, basis.
 - CDC anticipates 20 lines have provided this information for on average of 25 ships, and it takes 5 minutes to send this information to CDC. This is a total of 41.67 hours, which CDC is rounding up to 42 hours, in the table below.
- Approval of Onboard COVID-19 Testing Instrument
 - 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.
 - CDC is accepting this information on a per-line or per-ship, basis.
 - CDC anticipates 20 ships and lines will have provided this information for on average 25 ships, and it takes 10 hours to send this information to CDC. This is a total of This is a total of 41.67 hours, which CDC is rounding up to 42 hours, in the table below.
- Request for Embarkation of Essential Crew and Contractors
 - Prior to embarking additional essential crew and contactors, cruise lines must notify CDC of the intent to do so by sending an email to eocevent349@cdc.gov. The template (Attachment R) will be made available to the cruise lines directly and through the relevant cruise line associations.
 - CDC anticipates that a maximum of 130 requests to embark essential crew and contractors will be made, but there may be fewer if cruise lines submit requests for multiple vessels per request.
 - Burden is therefore calculated as 130 ships x 5 requests per ship x 10 minutes request, for a total of 108.00 hours (rounded up to 109 hours in the table below)
- During the initial period of the CSO, ships are prohibited from disembarking crew with an intent to use commercial travel to their destination without prior notice to CDC. Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC’s Framework for Conditional Sailing Order (CSO)
 - Maximum annual hourly burden estimates are calculated as 130 ships, 5 attestations per ship, and 15 minutes per disembarkation event (5 disembarkation per ship), for a total of 162.5 hours (rounded to 163 hours in the table below).
 -

Information Requirements Associated With Phase 2a of the CSO– In Preparation For Simulated Voyages, In Chronological Order

- Agreement with Health Care Organization with signoff from Local Health Authorities
 - In order to Request approval for a simulated voyage and to embark non-essential crew, 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. CDC is creating a check list to assist the Local Health Authorities with this agreement.
 - 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.
 - CDC estimates approximately 10 hours to complete an agreement with a healthcare organization, for a total of 1300 burden hours
- Agreement with Port of Entry with signoff from Local Health Authority
 - In order to Request approval for a simulated voyage and to embark non-essential crew, 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.
 - CDC estimates approximately 10 hours to complete an agreement with a Port of Entry, for a total of 1300 burden hours.
- Agreement with Housing Facility with signoff from Local Health Authority
 - In order to Request approval for a simulated voyage and to embark non-essential crew, 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.
 - 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.
 - CDC estimates approximately 10 hours to complete an agreement with a housing facility, for a total of 1300 burden hours.
- Request for Embarkation of Non-Essential Crew and contractors
 - Prior to embarking additional non-essential crew and contractors, cruise lines must notify CDC of the intent to do so by sending an email to eocevent349@cdc.gov. The template (Attachment S) will be made available to the cruise lines directly and through the relevant cruise line associations.
 - CDC anticipates that a maximum of 130 requests to embark non-essential crew and contractors will be made, but there may be fewer if cruise lines submit requests for multiple vessels per request.

- o Burden is therefore calculated as 130 ships x 1 request per ship x 10 minutes request, for a total of 21.7 hours (rounded up to 22 hours in the table below)

Information Requirements Associated With Simulated Voyages In Chronological Order (Phase 2b)

- 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 order, 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 NSO, other public health requirements as outlined in the CDC Technical Instructions).
 - o CDC estimates that there are approximately 130 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 NSO, Agreements list above, After Action Reports, 3rd Party notification of Informed Consent and Medical Certification, and CLIA Certified Laboratory Information requests.
 - o CDC estimates approximately 10 hours to complete the Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate
- 3rd 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. 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 300 simulated passengers. The total burden estimated for the medical documents is 130 ships x 300 simulated passengers, and 75 minutes per health document; this total is 48,750 hours of burden.
- Remote and In-person Inspections
 - o 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

- o CDC anticipates a maximum of one inspection per ship at 120 minutes each. With the estimated 130 vessels that may operated during the CSO, this equals 260 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 1300 hours of annual burden associated with this requirement.

Information Requirements Associated In Preparation For Restricted Voyages In Chronological Order (Phase 3)

- COVID-19 Conditional Sailing Certificate Application
 - o An estimated 130 ships will complete the COVID-19 Conditional Sailing Certificate application one time. CDC estimates that completion of the application and the associated requirements will take 10 hours.
 - o The application requires a statement of intent to enter into restricted voyages, a U.S. Coast Guard Certificate of Inspection, or proof of inspection from other agencies or groups contracted by the cruise line to perform these inspections.
 - o 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.
 - o CDC estimates 1300 hours of burden for the Conditional Sail Certificate Application.
- Inspection Checklist
 - o Each ship that receives a Conditional Sail Certificate will need to maintain certain items for potential inspection if CDC determine that an inspection is necessary to ensure the requirements of the Certificate are maintained. Most the of elements included in this check list are already part of the Vessel Sanitation Program inspections outlined in OMB Control Number 0920-1255 – Cruise Ship Outbreak Investigations. However, because not all are included, we are providing an additional 2 hours of burden to account for additional pieces of information that a ship would need to provide during the inspection.
 - o CDC is providing a burden estimate assuming that 130 ships will be inspected, with a total burden of 260 hours.

Type of Respondent	Form Name	No. of Respondents	No. Responses per	Avg. Burden per response	Total Burden (in hrs.)
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			Respondent	(in hrs.)	
Cruise ship operator	No Sail Order Response Plan	5	1	2400/60	200
Cruise ship operator	Request for Embarkation of Essential Crew and Contractors submitted to USCG	5	1	10/60	1
Cruise ship operator	CDC an Attestation for Non-Commercial Travel of Disembarking Crew for Cruise Ship Operators During the No Sail Order	5	5	15/60	7
Cruise ship operator	Virtual Implementation Checks	5	2	75/60	13
Cruise ship operator	Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (Daily)	130	365	15/60	11,863
Cruise ship operator	CLIA Certified Laboratory Information – Onshore	20	25	5/60	42
Cruise ship operator	Approval of Onboard COVID-19 Testing Instrument	20	25	5/60	42
Cruise ship operator	Request for Embarkation of Essential Crew and Contractors	130	5	10/60	109
Cruise ship operator	Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC's Framework for	130	5	15/60	163

	Conditional Sailing Order (CSO)				
Cruise ship operator	Agreement with Health Care Organization with signoff from Local Health Authorities	130	1	600/60	1300
Cruise ship operator	Agreement with Port of Entry with signoff from Local Health Authority	130	1	600/60	1300
Cruise ship operator	Agreement with Housing Facility with signoff from Local Health Authority	130	1	600/60	1300
Cruise ship operator	Request for Embarkation of Non-Essential Crew and contractors	130	1	10/60	22
Cruise ship operator	Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate	130	1	600/60	1300
Passenger (3 rd party disclosure)	Informed Consent and Medical Certification with no pre-existing conditions for Simulated Voyage	39000	1	75/60	48,750
Cruise ship operator	Remote and In-person Inspections	130	1	120/60	260
Cruise ship operator	After Action Report, Simulated Voyage	130	1	600/60	1300
Cruise ship operator	COVID-19 Conditional Sailing Certificate Application	130	1	600/60	1300
Cruise ship operator	Remote and In-person Inspections	130	1	120/60	260

Total					69,532

B. Estimated 6-month Burden Costs

Estimates of the time burden associated with completion of the COVID-19 Conditional Sailing Certificate application and the NSO 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>

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>): \$64.13. CDC is adjusting this wage by 1.31 to account for non-wage benefits. The adjusted wage is \$84.01.

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 \$24.98. CDC adjusted by the hourly wage by 1.31 to account for non-wage benefits to obtain a figure of \$32.72.

The estimated total cost is \$3,340,995.82

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cruise ship operator	No Sail Order Response Plan	200	\$84.01	\$16,802.00
Cruise ship operator	Request for Embarkation of Essential Crew and Contractors submitted to USCG	1	\$84.01	\$84.01
Cruise ship operator	CDC an Attestation for Non-Commercial Travel of Disembarking Crew for Cruise Ship Operators During the No Sail Order	7	\$84.01	\$588.07
Cruise ship operator	Virtual Implementation Checks	13	\$84.01	\$1,092.13
Cruise ship operator	Enhanced Data Collection (EDC) During COVID-19	11,863	\$84.01	\$996,610.63

	Pandemic Form (Daily)			
Cruise ship operator	CLIA Certified Laboratory Information – Onshore	42	\$84.01	\$3,528.42
Cruise ship operator	Approval of Onboard COVID-19 Testing Instrument	42	\$84.01	\$3,528.42
Cruise ship operator	Request for Embarkation of Essential Crew and Contractors	109	\$84.01	\$9,157.09
Cruise ship operator	Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC’s Framework for Conditional Sailing Order (CSO)	163	\$84.01	\$13,693.63
Cruise ship operator	Agreement with Health Care Organization with signoff from Local Health Authorities	1300	\$84.01	\$109,213.00
Cruise ship operator	Agreement with Port of Entry with signoff from Local Health Authority	1300	\$84.01	\$109,213.00
Cruise ship operator	Agreement with Housing Facility with signoff from Local Health Authority	1300	\$84.01	\$109,213.00
Cruise ship operator	Request for Embarkation of Non-Essential Crew and contractors	22	\$84.01	\$840.10
Cruise ship operator	Request for Approval to Conduct a	1300	\$84.01	\$109,213.00

	Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate			
Passenger (3 rd party disclosure)	Informed Consent and Medical Certification with no pre-existing conditions for Simulated Voyage	48,750	\$32.72	\$1,595,100.00
Cruise shop operator	Remote and In-person Inspections	260	\$84.01	\$21,842.60
Cruise shop operator	After Action Report, Simulated Voyage	1300	\$84.01	\$109,213.00
Cruise ship operator	COVID-19 Conditional Sailing Certificate Application	1300	\$84.01	\$109,213.00
Cruise ship operator	Remote and In-person Inspections	260	\$84.01	\$21,842.60
Total				\$3,340,995.82

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, both onshore and onboard. CDC estimates a cost for cruise line operators of \$300,300,000. This estimate includes the cost of onboard testing and lab equipment on the ship.

- For costs associated with shoreside testing capacity, CDC estimates the costs as follows:
 - The cost of each onshore test is estimated based on the reimbursement rates provided by CMS⁴, which range from \$50-\$100. CDC is choosing a mid-point of \$75 for each test.
 - Based on the number of reported tests provided to CDC under 0920-0134 using the Enhanced Data Collection form for COVID, and the weekly required tests for crew outlined in the CSO, CDC estimates approximately 70,000 tests will be performed for a total of \$5.25 million dollars a week. On an annual basis, this equals \$273 million.
- For costs associated with onboard testing capacity, CDC estimates the costs as follows:

⁴ <https://www.cms.gov/files/document/admin-info-20-06-clia.pdf>

- o Estimated onboard instrument cost to test symptomatic cases and their contacts: \$33,000 to \$58,000 per ship. Using a midpoint cost of \$45,500, CDC estimates a maximum of 130 ships, for a total of \$5,915,000 per year.
- o With regard to onboard testing supplies, CDC estimates a cost of \$40-\$85 dollars per cartridge, and a mid-point estimate of \$62.50 per cartridge. CDC is estimating there will be approximately 50 symptomatic individuals and their contacts who need to be tested on a weekly basis on each of the estimated 130 ships. On an annual basis, this equals \$21,125,000.
- Estimated Maintenance Contracts for Onboard Instrument are \$1,500 to 2,500 yearly per ship. This equals \$260,000 per year based on a midpoint estimate of \$2,000 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. 6-month Cost to the Government

The annual cost to the government is estimated by multiplying the average time to review applications and NSO response plans by the average wage of the individuals performing the review. The total estimated costs are \$1,162,112.

CDC estimates it will take eight employees working full time to review the plans and applications. CDC assumes an average wage equivalent to GS 13s and GS14s on an annual basis. CDC is multiplying each wage by 2 to account for non-wage benefits. As this emergency information collection request is for 6 months, the estimated burden will be approximately half of the total below.

Personnel Category	Annual Wage	Adjustment	Total Cost
2 x GS 14	\$113,581	x2	\$454,324
2 x GS 13	\$96,117	x2	\$384,468
2 x GS 12	\$80,830	x2	\$323,320
Total Cost			\$1,162,112

15. Explanation for Program Changes or Adjustments

This is a new Information Collection Request. The NSO Response Plan collection was previously included in OMB Control No. 0920-1292. The methods and tools associated with the NSO Response Plans are unchanged from their prior OMB clearance for those ships who have not already submitted their NSO response plan.

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 Sail Order FRN
- D - Acknowledgment of No Sail Order Response Plan Completeness and Accuracy
- E - No Sail Order FRN
- F - Attestation for Non-Commercial Travel of Disembarking Crew for Cruise Ship Operators During the No Sail Order (NSO)
- G - Local Health Authority and Port Agreement Checklist
- 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 Death Investigation Form
- K - Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate
- L - Simulated Voyage After-Action Report Template
- M - CDC COVID-19 Conditional Sailing Certificate Application
- N - Attestation for Commercial Transportation of Disembarking Crew for Cruise Ship Operators During the Initial Phases of CDC's Framework for Conditional Sailing Order (CSO)
- O - Federal Register Notice Request for Information
- P - Non-research determination
- Q - No Sail Order Plan Template
- R - Request for Embarkation of Essential Crew and Contractors
- S - Request for Embarkation of Non-Essential Crew