

# **Cruise Operator COVID-19 Response Plans**

Request for OMB approval of a New Information Collection

January 22, 2021

## **Supporting Statement A**

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## **Contents**

A. Justification.....	3
1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of Information Collection.....	5
3. Use of Improved Information Technology and Burden Reduction.....	5
4. Efforts to Identify Duplication and Use of Similar Information.....	5
5. Impact on Small Businesses or Other Small Entities.....	6
6. Consequences of Collecting the Information Less Frequently.....	6
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	6
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	6
9. Explanations of Any Payment or Gift to Respondents.....	7
10. Assurance of Confidentiality Provided to Respondents.....	7
11. Justification for Sensitive Questions.....	7
12. Estimates of Annualized Burden Hours and Costs.....	7
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	8
14. Annualized Cost to the Government.....	9
15. Explanation for Program Changes or Adjustments.....	9
16. Plans for Tabulation and Publication and Project Time Schedule.....	9
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	9
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	9
List of Attachments.....	10

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- **Goal of the study:** The goal of this information collection is to ensure that cruise ship operators have created appropriate, actionable, and robust plan to prevent, mitigate, and respond to the spread of COVID-19 on board cruise ships.
- **Intended use of the resulting data:** The information will be used to determine if cruise ship operators have developed sufficiently robust plans to prevent the spread of COVID-19 onboard.
- **Methods to be used to collect:** Cruise ship operators will submit the COVID response plans to CDC for review.
- **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) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew
- **How data will be analyzed:** No statistical methods will be used.

CDC is requesting an emergency clearance for this information collection for 180 days.

In order to provide timely guidance on the development of plans under this information collection and the April 9, 2020 No Sail Order, CDC distributed interim guidance and a Cruise Operator No Sail Order Response Plan Completion Template. CDC has received six COVID-19 response plans prior to the approval of this information collection by the Office of Management and Budget, representing approximately 240 hours of respondent burden incurred in violation of the Paperwork Reduction Act.

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

Recent CDC actions in response to COVID-19 onboard maritime vessels has shown that cruise ship travel markedly increases the risk and impact of the COVID-19 disease outbreak within the United States. If unrestricted cruise ship passenger operations were permitted to resume after the March 14, 2020 No Sail Order (Attachment D) expired infected and exposed cruise ship cases would continue to place healthcare workers at substantial increased risk. Specifically, these cases would divert medical resources away from persons with other medical problems and other COVID-19 cases, consuming precious diagnostics, therapeutics, and protective equipment that are already in short supply. Ongoing concerns with cruise ship transmission would further draw valuable resources away from the immense federal, state, and local effort to contain and mitigate the spread of COVID-19. Further, the current ongoing non-passenger operation of cruise

ships has not sufficiently abated the public health concern, as ship crews become sick and require medical care drawing on otherwise engaged federal, state, and local resources. As operators of non-U.S. flagged vessels sailing in international waters, it is imperative that the cruise ship industry and cruise lines develop and execute on plans for the care of their crew that do not rely on limited U.S. resources during a public health emergency.

Since the announcement by Cruise Lines International Association (“CLIA”), the leading industry trade group, that its members would voluntarily suspend commercial cruise ship operations, there have been a number COVID-19 clusters and outbreaks onboard cruise ships including the *Costa Magica*, *Costa Favolosa*, *Celebrity Eclipse*, *Disney Wonder*, *Holland America Zaandam*, and *Celebrity Coral Princess*. As of April 9, 2020, the *Costa Magica* and the *Costa Favolosa*, reported at least 88 ill crew members on board with respiratory symptoms of COVID-19. On March 26, 2020, in coordination with U.S. Coast Guard and public health personnel, four infected crew members were evacuated off the *Magica* and seven from the *Favolosa* for life-critical care at Jackson Memorial Hospital in Miami, Florida. The *Zaandam* cruise ship reported illness consistent with COVID-19 in at least 250 persons onboard – guests and crew members; 76 of these persons remain symptomatic. Four passengers onboard the *Zaandam* have died (one for non-COVID-19 related reasons).<sup>1</sup> As of April 17, 2020, 59 persons onboard the *Celebrity Eclipse* had tested positive for COVID-19. Several crew and passenger onboard the *Eclipse* required emergency medical evacuation and were hospitalized in San Diego, California after having tested positive for COVID-19. The *Disney Wonder* now has 65 COVID-19 cases linked to its last two voyages.

Most recently, the *Coral Princess* reported 23 persons (13 passengers and 10 crew members) who are confirmed positive for COVID-19 and an additional 45 suspected cases in crew onboard with influenza-like illness. As of April 17, 2020, four passengers died, 21 of 26 passengers and 5 of 10 crew that disembarked between 5-9 April remain hospitalized, of which, 6 are on supplemental oxygen.

As of April 17, 2020 most cruise ships have disembarked passengers, there are approximately 85 cruise ships which remain at sea off the coasts of the United States with an estimated 63,000 crew onboard; Some of these crew are not critical to maintain the seaworthiness or basic safe operation of the cruise ships; many are part of the hotel and hospitality crew; most of the ships (approx. 50) are off the coast of Florida. CDC is currently aware of 29 cruise ships at port or anchorage in the U.S. with known or suspected COVID-19 infection among the crew who remain onboard.

The intensive care requirements for infected crew in need of life-critical care greatly stresses an already overburdened healthcare system facing shortage of masks, test kits, beds, and ventilators needed to respond to COVID-19. The addition of further COVID-19 cases from cruise ships places healthcare workers at substantial increased risk. Moreover, safely evacuating, triaging, and repatriating cruise ship crew involves complex logistics, incurs financial costs at all levels of government, and diverts resources away from broader efforts to suppress or mitigate COVID-19.

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<sup>1</sup> “President of Holland America cruise line pleads for compassion while Florida debates allowing ships to dock,” Fox News, March 31, 2020, available at: <https://www.foxnews.com/travel/zaandam-holland-america-cruise-president-florida-debate>.

Accordingly, and consistent with 42 C.F.R. §§ 71.31(b) and 71.32(b), the Director of CDC (“Director”) finds evidence to support a reasonable belief that cruise ships continue to be or may become infected or contaminated with a quarantinable communicable disease.<sup>2</sup> This reasonable belief is based on information from epidemiologic and other data regarding the nature and transmission of COVID-19 on cruise ships, including the information described in the March 14, 2020 Order and evidence from onboard the *Costa Magica*, *Costa Favolosa*, *Zaandam*, and other cruise ships. As a result, persons onboard cruise ships may be infected with or exposed to COVID-19 by virtue of being onboard at a time when cases of COVID-19 are being reported in significant numbers globally and specifically on cruise ships, when testing is available.

CDC has issued an updated No Sail Order (Attachment E), which includes requiring cruise ships operators seeking to conduct operations within the jurisdiction of the United States (international, interstate, or intrastate waterways) to submit plans to prevent, mitigate, and respond to the spread of COVID-19 on board without requiring substantial assistance from the federal and local authorities. Within these plans are notification requirements that obligate cruise ship operators to provide CDC and local health departments in the follow circumstances:

- Disembarking U.S. residents who plan to leave the ships and travel by private transport
- Disembarking crew to the United States for repatriation via non-commercial travel to home countries
- Crew transfers for purposes such as maintaining Minimum Safe Manning standards

In addition, cruise ship operators can choose to submit an attestation statement to CDC attesting that their ship is free of COVID-19. If this is statement is accepted, cruise ship operators have the option to repatriate their crew via commercial travel.

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 information required under this emergency clearance will be reviewed by CDC to ensure that cruise ship operators have constructed appropriate, actionable, and robust plans to prevent, mitigate, and respond to the spread of COVID-19 on board cruise ships.

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<sup>2</sup> COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 C.F.R. §§ 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

CDC will review the cruise ship operators' plan and approve only those plans that demonstrate the following:

- a. Onboard surveillance of passengers and crew with acute respiratory illnesses, influenza-like illnesses, pneumonia, and COVID-19, including reporting to HHS/CDC on a weekly basis on overall case counts, methods of testing, and number of persons requiring hospitalization or medical evacuation;
- b. Reports on the number of persons onboard the cruise ship and any increase in the numbers of persons with COVID-19 made to HHS/CDC and USCG on a daily basis for as long as the cruise ship is within waters subject to the jurisdiction of the United States.
- c. Onboard monitoring of passengers and crew through temperature checks and medical screening, including addressing frequency of monitoring and screening;
- d. Training of all crew on COVID-19 prevention, mitigation, and response activities;
- e. Protocols for any COVID-19 testing, including details relating to the shore-side transport, administration, and operationalization of laboratory work if onboard laboratory work is not feasible;
- f. Onboard isolation, quarantine, and social distancing protocols to minimize the risk of transmission and spread of COVID-19;
- g. Onboard medical staffing, including number and type of staff, and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, facemasks, personal protective equipment) for the infected without the need for hospitalization onshore;
- h. An outbreak management and response plan to provision and assist an affected cruise ship that relies on industry resources, e.g., mobilization of additional cruise ships or other vessels to act as "hospital" ship for the infected, "quarantine" ship for the exposed, and "residential" ship for those providing care and treatment, including the ability to transport individuals between ships as needed;
- i. Categorization of affected individuals into risk categories with clear stepwise approaches for care and management of each category;
- j. A medical care plan addressing onboard care versus evacuation to on-shore hospitals for critically ill individuals, specifying how availability of beds for critically ill at local hospitals will be determined in advance and how the cruise ship operator will ensure acceptance at local medical facilities to treat the critically ill in a manner that limits the burden on federal, state, and local resources and avoids, to the greatest extent possible, medivac situations. If medical evacuation is necessary arrangements for evacuation must be made with commercial resources (e.g., ship tender, chartered standby vessel, chartered airlift) and arrangements made with a designated medical facility that has agreed to accept such evacuees. All medical evacuation plans must be coordinated with the U.S. Coast Guard;
- k. Detailed logistical planning for evacuating and repatriating, both U.S. citizens and foreign nationals, to their respective communities and home countries via foreign government or industry-chartered private transport

and flights, including the steps the cruise ship operator will take to ensure those involved in the transport are not exposed; (the use of commercial flights to evacuate or repatriate individuals, both within or from the United States, is prohibited);

- l. The projected logistical and resource impact on state and local government and public health authorities and steps taken to minimize the impact and engage with these authorities; all plans must provide for industry/cruise line management of suspected or confirmed cases of COVID-19 without resource burden on Federal, State, or local governments;
- m. Plan execution in all U.S. geographical areas – all plans must be capable of being executed anywhere in international, interstate, or intrastate waterways subject to the jurisdiction of the United States; and
- n. Cleaning and disinfection protocols for affected cruise ships.

The cruise ship operator must also ensure that the plan is consistent with the most current CDC recommendations and guidance for any public health actions related to COVID-19. Where appropriate, a cruise ship operator may coordinate the development, implementation, and operationalization of a plan with other cruise ship operators, including an industry trade group, e.g. CLIA.

As a condition of the granting of controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, the cruise ship operator (whether an individual cruise ship captain, a cruise line, or other) shall make the plan available to USCG and HHS/CDC personnel. This controlled free pratique does not include the boarding or disembarkation of commercial passengers, per the terms of the No Sail order, without consultation of HHS/CDC and U.S. Coast Guard.

The plans must describe in how the cruise operators will operationalize/are operationalizing each aspect of the requirements so that CDC can evaluate if the plans will provide sufficient measures to prevent, detect, and respond to COVID-19 onboard. The plans must establish mechanisms to ensure compliance with the NSO, and outline steps to minimize impact on Federal, State, local governments or the U.S. healthcare system. It is not sufficient for the plans to describe only how the operators intend to safely disembark individuals onboard, but must describe aspects of prevention, surveillance and monitoring for COVID-19, isolation and quarantine of cases and suspected cases, medical management of suspected cases, transfers of crew, and cleaning and disinfection processes.

CDC has posted [Interim Guidance for the Mitigation of COVID-19 Among Crew During the Period of the No Sail Order](https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html), available here:

<https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html>.

CDC provided this interim guidance and a Cruise Operator NSO Response Plan Completion Template (Attachment F) (use of the template is voluntary) to assist the industry with developing their plans. Plans should be emailed to [eocevent349@cdc.gov](mailto:eocevent349@cdc.gov) by April 23, 2020. CDC will accept a single plan submitted by CLIA on behalf of their member cruise lines, individual cruise line plans submitted on behalf of all ships within the cruise line's fleet, or individual ship plans.

Once a cruise operator's plan is approved, CDC's criteria are met and the requirements are agreed upon, the ships can engage in limited operations, including disembarkation of crew and travel by charter and additional sign off or plan review from CDC is not required.

### **3. Use of Improved Information Technology and Burden Reduction**

CDC will accept electronic copies of the cruise ship operator COVID-19 response plans sent to [eoevent349@cdc.gov](mailto:eoevent349@cdc.gov) to reduce burden associated with mailing and receipt of hard copies.

CDC is also willing to accept plans submitted by cruise industry organizations representing multiple operators, e.g. CLIA, the world's largest cruise industry trade association that represents approximately 95% of global cruise ship passenger capacity. If these organizations and their members develop a plan that applies to every one of the ships seeking to operate in within the jurisdiction of the United States, this will reduce burden on individual members and on the respondent universe as a whole.

### **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.

CDC does not envision a duplication of information collection by other 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.

### **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 No Sail Order 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 plan and may have fewer resources within their organizations to focus on plan development. However, in the No Sail Order CDC states that operators can collaborate on the development of a plan, 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, 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 evacuated from maritime vessels.

## **6. Consequences of Collecting the Information Less Frequently**

Failure to collect this information on an as needed basis would undermine the CDC's ability to determine whether cruise ship operators have plans to prevent the spread of COVID-19 on their vessels, potentially leading to additional cases onboard, as well as increased burden on U.S. communities who may have to care for evacuated passenger or crew.

Where appropriate, a cruise ship operator may coordinate the development, implementation, and operationalization of a plan with other cruise ship operators, including an industry trade group, e.g. CLIA. This would limit the response burden for any individual operator.

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

Frequency of data collection is inconsistent with the guidelines, as discussed in Section A6. The frequency of data collection is determined by the frequency that cruise ships want to operate with the jurisdiction of the U.S.

## **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 (Attachment B).

B. CDC is the primary authority with responsibility to prevent the introduction and spread of communicable disease in the U.S. through air, land and seaports of entry and interstate. CDC has consulted with the U.S. Coast Guard on this information collection.

To address the continued and significant risks and burdens posed by ongoing cruise ship operations, CDC and other Federal agencies engaged with CLIA representatives in early March. On March 13, 2020, CLIA and their associated members announced that all member cruise lines would voluntarily suspend cruise ship operations from U.S. ports of call for 30 days as public health officials and the Federal government continue to address COVID-19. A number of other cruise lines followed CLIA's example and similarly voluntarily suspended operations.

CLIA also drafted a response plan, "On Course: Cruise Industry COVID-19 Response and Protocols" that committed to responding to outbreaks of the disease without

burdening the U.S. government.” This included responsibility for transporting the [exposed or infected] individuals in appropriate buses, cars, or ambulances for care. The Plan also incorporated multiple redundancies in its response efforts. Specifically, CLIA committed to making five ships available for temporary housing purposes. They would be tasked with sailing to any affected ship and taking affected guests and crew aboard for the self-isolation period.

As the No Sail Order has been extended and applied to those operators who were previously volunteering to suspect operations, CDC continues to work with CLIA and cruise operators to clarify the intent of the Order and to prevent the importation and spread of COVID-19 associated with these types of vessels.

## **9. Explanations of Any Payment or Gift to Respondents**

No monetary incentives or gifts are provided to respondents.

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

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases and it has been determined that the Privacy Act does not apply to this information collection request. No personally identifiable information is being solicited as part of this collection.

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

### IRB Determination

CDC’s National Center for Emerging and Zoonotic Infectious Diseases has determined that this project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachments C).

### Justification for Sensitive Questions

No sensitive questions are being asked as part of this information collection.

## **12. Estimates of Annualized Burden Hours and Costs**

Below are the estimates of the Annualized Burden Hours that CDC is requesting for this emergency request.

The total burden requested for this revision is 100 respondents, i.e. cruise line operators, and 4,134 burden hours.

This estimate is based on the following assumptions:

100 cruise ship operators will comply with the requirement to submit a plan to operate in the U.S. Each plan is estimated to require a full 40-hours of staff time to develop and submit. This includes the 60 members of CLIA as well as 40 other smaller operators. As stated in Section 3 above, if CLIA’s membership determines that one plan on behalf of the association is their preferred method of compliance, then CDC will consider that plan as meeting the requirements. This would result in a substantial reduction in burden. However, CDC is not assuming this will happen, and so the full estimate is provided below. Additionally, CDC is making a template available to assist in plan development (Attachment F). Use of the template is voluntary.

As stated above, the plans must incorporate several reporting requirements. Cruise ship operators to provide CDC and/or local health departments in the follow circumstances:

- Disembarking U.S. residents who plan to leave the ships and travel by private transport
  - CDC estimates five notifications per cruise ship operator, at five minutes per response. The total is 42 respondent hours.
- Disembarking crew to the United States for repatriation to home countries
  - CDC estimates two notifications per cruise ship operator, at five minutes per response. The total is 17 respondent hours.
- Crew transfers for purposes such as maintaining Minimum Safe Manning standards
  - CDC estimates five notifications per cruise ship operator, at five minutes per response. The total is 42 respondent hours.

In addition, if there is an intent repatriate crew from the ship, cruise ship operators can choose to submit an attestation statement to CDC attesting that their ship is free of COVID-19 (Attachment G). CDC must review and accept the attestation for commercial travel to be an option.

- CDC estimates 1 notifications per cruise ship operator, at 20 minutes per response. The total is 33 respondent hours.

#### 12 A. Estimates of Annualized Burden Hours

Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Cruise ship operator	COVID-19 Response Plan (no form)	100	1	2400/60	4,000
Cruise ship operator	72-hour notification to CDC of disembarkation or	100	5	5/60	<b>42</b>

	U.S. residents for private travel				
Cruise ship operator	72-hour notification to state/local health department of disembarkation for crew repatriation	100	2	5/60	<b>17</b>
Cruise ship operator	72-hour notification for crew transfers	100	5	5/60	<b>42</b>
Cruise ship operator	Attestation statement of COVID-19 free ship (for repatriating crew via commercial travel)	100	1	20/60	<b>33</b>
<b>Total</b>					<b>4,134</b>

#### 12 B. Estimates of Annualized Cost

There will be no anticipated costs to respondents other than time. Estimates of respondent costs are provided for the six months of requested emergency approval. Wages for travelers were gathered from BLS category 11-3071 Transportation, Storage, and Distribution Managers” (<https://www.bls.gov/oes/current/oes113071.htm>). This wage is then adjusted 30% to account for non-wage benefits. The estimated total cost is **\$265,774.86**.

Respondent	Form	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cruise ship operator	COVID-19 Response Plan (no form)	4,000	\$64.29	\$257,160
Cruise ship operator	72-hour notification of disembarkation or U.S. residents for private travel	42	\$64.29	\$2,700.18
Cruise ship operator	72-hour notification of disembarkation for crew repatriation	17	\$64.29	\$1,092.93
Cruise ship operator	72-hour notification for crew transfers	42	\$64.29	\$2,700.18

Cruise Ship Operator	Attestation statement of COVID-19 free ship (for repatriating crew via commercial travel)	33	\$64.29	\$2,121.57
<b>Total</b>		<b>4,134</b>		<b>\$265,774.86</b>

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

There are no costs to respondents other than the time necessary to develop the plan and respond to the information collection

**14. Annualized Cost to the Government**

The annual cost to the government is estimated by multiplying the average time to review a plan by the average wage of the individual performing the review. The total estimated costs are \$25,468.56

CDC estimates it will take two employees 4 hours to review each plan. This would be multiplied by 100 plans for 800 hours. CDC assumes an average wage equivalent to a GS14. This wage is then doubled to account for non-wage benefits. The total cost is below.

Personnel	Wage + Non-Wage	Time (hours)	Total
GS14-1 (Adj x 2)	\$108.84	800	\$10,884

For the notifications and attestation review, CDC estimates an equivalent amount of time to review each submission as it requires of the respondent to submit: 134 hours. The annual costs associated with these notifications and attestations are as follows:

Personnel	Wage + Non-Wage	Time (hours)	Total
GS14-1 (Adj x 2)	\$108.84	134	\$14,584.56

**15. Explanation for Program Changes or Adjustments**

This is a new information collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

CDC does not plan to publish or conduct any analysis of the plans except to determine whether or not a cruise operator is eligible to conduct operations within the jurisdictions of the U.S.

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

Display of the expiration date is appropriate. No exemption is requested.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## **List of Attachments**

Attachment A1 - Section 361 and 365 of the Public Health Service (PHS) Act

Attachment A2 - 42 Code of Federal Regulations part 70

Attachment A3 – 42 Code of Federal Regulations part 71

Attachment B - 60-day Federal Register Notice

Attachment C – IRB Non-research Determination

Attachment D – March 14, 2020 No Sail Order

Attachment E – April 9, 2020 No Sail Order

Attachment F – Cruise Operator NSO Response Plan Completion Template

Attachment G – Attestation Commercial Travel