**Non-Substantive Change Request Memo**

Phased Approach to the Resumption of

Cruise Ship Passenger Operations

**(OMB Control No. 0920-1335)**

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The Centers for Disease Control and Prevention (CDC) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request: “Phased Approach to the Resumption of

Cruise Ship Passenger Operations”

This change request is to make the following changes to the Enhanced Data Collection Form and add two worksheets for facilitating COVIC-19 case and contact investigations.

Current 0920-1335 approval:

1. ***Update Enhanced Data Collection (EDC) Form*:**
2. Change: Added hyperlinks to “close contacts” and “fully vaccinated” and “CDC website

appendix”

Justification: Reduce burden on submitting clinicians; now they can click on hyperlink rather than scrolling to the footnotes.

1. Change: Addition of “During”

Justification: Clarify that individuals tested during quarantine should be included in this section (rather than the routine screening section) because the ship’s color status is adversely affected otherwise..

1. Change: Addition of the data variables: voyage number, voyage start and end dates

Justification: Allow CDC to determine the number of voyages each ship has conducted since resuming passenger operations. Also provide important context when evaluating whether a ship has a potential COVID-19 outbreak under control.

1. Change: Added example of latitude and longitude in decimal degrees.

Justification: Clinicians periodically submit latitude and longitude in the wrong format. This should increase clarity and reduce errors.

1. Change: Added “Other Respiratory Pathogens” given recent additions of diseases to this section.

Justification: To reference “Reporting Cruise Ship Fatalities or Other Illness of Public

Health Concern” section.

1. Change: Added guidance/reminder to clinicians to NOT report persistent positives to top of form (previously only at beginning of asymptomatic testing section).

Justification: Clarified that persistent positives should not be reported to EDC. This will reduce burden for submitting clinicians and reduce potential errors.

1. Change: Added non-COVID-19 febrile person guidance “a febrile person in the presence

of a more likely diagnosis (e.g., cellulitis, urinary tract infection, tooth abscess) does not represent CLI and should not be reported…”

Justification: Added based on feedback/questions from cruise clinicians to prevent unnecessary reporting/reduce burden on industry.

1. Change: Added “presumptive positive” to describe antigen-positive results among the

asymptomatic persons.

Justification: Clarified based on feedback/questions from cruise clinicians

1. Change: Moved “Prior receipt of a COVID-19 vaccine will not affect the results of

COVID-19 viral tests” on the form

Justification: Fixed location error (i.e., formatting correction)

1. Change: Addition of isolation guidance to a beginning section of EDC (previously on at

end of form).

Justification: Added based on feedback/questions from cruise clinicians.

1. Change: Revised isolation practices to add option for COVID-19 isolation removal for the

following symptomatic persons after repeat/sequential COVID-negative test results: persons with COVID-19-like illness (CLI) that initially test negative for COVID-19 and negative for all other respiratory pathogens

Justification: Added based on feedback from industry and consult with CDC subject-matter-experts.

1. Change: Removed questions related to pending tests; total of 30 rows deleted.

Justification: These questions proved confusing to cruise clinicians, and the extra data being collected by

distinguishing results from tests conducted today versus tests conducted yesterday were not being used by CDC.

1. Change: Addition of example “if a symptomatic person is NAAT-negative then tests NAAT-

positive on the next day, do not report the initial NAAT-negative result to EDC”

Justification: Added for clarity based on feedback from cruise clinicians.

1. Change: Addition of “…in the absence of a non-infectious diagnosis as determined by the

ship’s physician (e.g., heart failure).”.

Justification: Clarified COVID-19-like illness (CLI) definition/criteria so that non-infectious symptoms are not erroneously reported as CLI..

1. Change: Addition of the question “Of those persons with **CLI** that tested negative for

COVID-19 using a viral test, how many were newly embarking crew members in quarantine?”

Justification: This added question will reduce the frequency of errors in ship color status and thus the need for ship follow-ups. CLI cases testing negative who are embarking crew members in quarantine do not contribute to color status.

1. Change: Removed “not fully vaccinated”.

Justification: Updated CDC guidance states that even fully vaccinated individuals should be tested if they were exposed to COVID-19.

1. ***Add Cruise COVID-19 Case Investigation worksheet*:**

Change: For each lab-confirmed COVID-19 crew or passenger, this worksheet will collect data on demographics, COVID-19-related vaccination status, COVID-19-related test dates, symptoms, co-morbidities, potential exposures, and potential close contacts.

Justification: Any ship that meets [Yellow](https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html#green-ship)criteria, indicates the ship has met the COVID-19 case count threshold for a CDC investigation. In order for CDC to do the investigation, CDC needs more specific information about the COVID-19 cases to assist in determining whether a specific ship has an outbreak under control, or if there is a potential to overwhelm ship resources.

1. ***Add Cruise COVID-19 Contact Investigation worksheet*:**

Change: For each individual identified as a close contact of a lab-confirmed COVID-19 case, this worksheet will collect data on demographics, COVID-19-related vaccination status, COVID-19-related test dates, and quarantine history

Justification: It will be sent when ship outbreaks are uncontrolled with the need to monitor the ship’s contact tracing abilities. This new worksheet will provide CDC with information on the potential for COVID-19 to spread on a cruise ship and also to determine if ships followed appropriate procedures when quarantining contacts.

CDC considers these changes non-substantive since it is part of the CDC COVID-19 Cruise Ship investigation process already outlined to determine cruise ship voyage status. Additionally, cruise medical and public health staff collect this information already.

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.

Annual Burden

1. **EDC Form:** CDC estimates that there is no change in burden for these changes to the EDC Form since any increase in burden with the addition data variables is negated by the decrease in burden of filling out the pending test results and changes to reduce errors.
2. **Cruise COVID-19 Case Investigation worksheet:** CDC estimates that there will be approximately 6 ships that turn yellow each week per recent numbers. Therefore, there will be approximately 300 (6\*52 weeks) ships filling out these forms annually at a time burden of approximately 30 minutes per form, resulting in 150 burden hours.
3. **Cruise COVID-19 Contact Investigation worksheet:** CDC estimates that there will be approximately 3 ships that turn yellow and have uncontrolled outbreaks each week. Therefore, there will be approximately 150 (3\*52 weeks) ships filling out these forms annually at a time burden of approximately 30 minutes per form, resulting in 75 burden hours.

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| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (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 by A Cruise Ship OperatorIn Lieu Of A Simulated Voyage  | 130 | 5 | 15/60 | 163 |
| 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 (3rd party disclosure) | Informed Consent and Medical Certification with no pre-existing conditions for Simulated Voyage | 39000 | 1 | 75/60 | 48,750 |
| Cruise shop operator | Remote and In-person Inspections | 130 | 1 | 120/60 | 260 |
| Cruise shop 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 |
| Cruise Clinician or Public Health Staff | Cruise COVID-19 Case Investigation worksheet | 300 | 1 | 30/60 | 150 |
| Cruise Clinician or Public Health Staff | Cruise COVID-19 Contact Investigation worksheet | 150 | 1 | 30/60 | 75 |
| **Total** |  |  |  |  | 69,755 |

With these updates the annual estimated burden for this package would increase from 69,531 to 69,755.