

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 COVID-19 case and contact investigations.

Current 0920-1335 approval:

1. Update Enhanced Data Collection (EDC) Form:

- A. 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.

- B. 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..

- C. 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.

- D. 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.

- E. 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.

- F. 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.

- G. 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.

- H. Change: Added “presumptive positive” to describe antigen-positive results among the asymptomatic persons.
Justification: Clarified based on feedback/questions from cruise clinicians
- I. 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)
- J. 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.
- K. 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.
- L. 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.
- M. 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.
- N. 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..
- O. 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.
- P. 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.

2. *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](#) 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.

3. *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

- 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.
- 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.
- 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.

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 Operator In 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	130	1	600/60	1300

	from Local Health Authority				
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 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.