

Non-Substantive Change Request Memo

Phased Approach to the Resumption of
Cruise Ship Passenger Operations
(OMB Control No. 0920-1335)

Program Contact

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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 (EDC) Form to bring it in alignment with current CDC guidance found on CDC’s website.

Current 0920-1335 approval:

1. Update Enhanced Data Collection (EDC) Form:

- A. Change: Replaced email address.
Rationale: The email address listed is no longer in use.

- B. Change: Clarified form is no longer required and updated hyperlink to guidance
Rationale: CDC has updated its guidance for the mitigation and management of COVID-19 on board cruise ships. The language in this section of the EDC Form was amended to align with the new guidance that can be found on CDC’s website.

- C. Change: Removed symbol and replaced with a footnote.
Rationale: Changed for consistency and simplicity, footnotes may be easier to interpret than symbols.

- D. Change: Simplified “Important Reminders” section.
Rationale: Simplified form by removing language that is included in general CDC guidance.

- E. Change: Added “Individual cases of influenza or ILI should not be reported to CDC
quarantine stations using the Maritime Illness and Death Investigation
form. Both ILI and test-positive influenza cases are included in this EDC form
under Symptomatic Case Counts and Viral Testing”
Rationale: This change was made to clarify to cruise ship operators that, if they are reporting via EDC, it is not necessary to report individual seasonal influenza or ILI cases through other forms that are not the EDC. This reduces burden and eliminates redundancies.

- F. Change: Reworded the instructions for reporting symptomatic case counts with viral
testing and replaced a link to outdated CDC guidance with FDA’s current
guidance.
Rationale: The language in this section of the EDC Form was changed slightly to align with
CDC’s updated guidance for the mitigation and management of COVID-
19 on board cruise ships.

- G. Change: Added the word “definition”.
Rationale: The word definition was added to clarify that the clinical criteria for CLI and the
definition of CLI are one in the same.

- H. Change: Added a new question “Of those persons with **CLI** that tested negative for COVID-19 using a viral test AND the ship performs RSV testing, how many tested positive for respiratory syncytial virus [RSV]?”
 Rationale: This question was added because some ships are using a testing apparatus that tests for COVID-19, influenza A&B, and RSV via one specimen. Adding this question will reduce the burden on ships using this test by providing them a *mechanism* to report RSV-positive cases to CDC. Without this question, these cruise ships were making time-consuming attempts and labor-intensive efforts to contact CDC on how to report these RSV cases.
- I. Change: Added example language “(e.g., symptomatic persons testing positive for both COVID-19 *and* another respiratory pathogen [e.g., influenza, RSV])”.
 Rationale: This language was added to address a cruise line’s question about where to report a dual COVID-19 & influenza case.
- J. Change: Reorganized and reworded the instructions for the “Hospitalizations, Ventilator Use, And Medical Evacuations” section.
 Rationale: The instructions for this section were reorganized and reworded to provide greater clarity to cruise ship clinicians regarding which travelers should be reported in the section.
- K. Change: Removed instructions and guidance for reporting asymptomatic cases to CDC, and replaced the hyperlink to outdated CDC guidance with FDA’s current guidance regarding antigen testing.
 Rationale: The instructions that were removed from this this section are included in the “Important Reminders” section above. Additionally, the guidance that was removed from this section is included in CDC’s updated guidance for the mitigation and management of COVID-19 on board cruise ships.
 The language was redundant and thus removed to streamline the EDC form.
- L. Change: Removed the instructions for reporting identified close contact testing and replaced the hyperlink to outdated CDC guidance with FDA’s current guidance regarding antigen testing.
 Rationale: The instructions that were removed from this this section are included in the “Important Reminders” section above. The language was redundant and thus removed to streamline the EDC form.
- M. Change: Removed the instructions for reporting embarkation day screening testing and replaced the hyperlink to outdated CDC guidance with FDA’s current guidance regarding antigen testing.
 Rationale: The instructions that were removed from this this section are included in the “Important Reminders” section above. The language was redundant and thus removed to streamline the EDC form.
- N. Change: Removed the instructions for reporting during or end of quarantine screening testing of newly embarking crew and added a hyperlink FDA’s current guidance regarding antigen testing.

- Rationale: The instructions that were removed from this this section are included in the “Important Reminders” section above. The language was redundant and thus removed to streamline the EDC form.
- O. Change: Removed the instructions for reporting routine screening testing and replaced the hyperlink to outdated CDC guidance with FDA’s current guidance regarding antigen testing.
Rationale: The instructions that were removed from this this section are included in the “Important Reminders” section above. The language was redundant and thus removed to streamline the EDC form.
- P. Change: Removed the instructions for reporting disembarkation screening testing of travelers and replaced the hyperlink to outdated CDC guidance with FDA’s current guidance regarding antigen testing.
Rationale: The instructions that were removed from this this section are included in the “Important Reminders” section above. The language was redundant and thus removed to streamline the EDC form.
- Q. Change: Removed text related to isolation practices.
Rationale: This information is communicated in CDC guidance; it does not need to be included on the EDC Form.
- R. Change: Reorganized and reworded footnote text.
Rationale: The language in this section of the EDC Form was reorganized to provide clarity to cruise ship clinicians using the EDC form and reworded to align with CDC’s updated guidance for the mitigation and management of COVID-19 on board cruise ships.

Annual Burden

1. **EDC Form:** CDC estimates that there is no change in burden associated with the revisions made to the EDC Form. The EDC Form was simplified and amended to align with current CDC guidance by removing language that was redundant, outdated, or publicly available on CDC’s website. Furthermore, the revisions to the Form do not require any additional information to be collected by cruise ship operators. Given the nature of the revisions and the fact that most cruise ship clinicians have prior experience completing the EDC Form, the 20 minutes required to fill out the form may still be a slight overestimate.