

Non-Substantive Change Request Memo

Phased Approach to the Resumption of
Cruise Ship Passenger Operations
(OMB Control No. 0920-1335, exp. 1/31/2026)

October 23, 2023

Request for Urgent Review Justification: Minor edits to OBM-approved Acute Respiratory Infection Reporting (ARI) Form. We would like to rollout the new form with reduced reporting burden to capture ARI disease case trends on maritime vessels as respiratory virus season is underway.

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Effective Date of Proposed Changes: Immediately upon receipt of OMB approval

In June 2023, OMB approved a nonmaterial/non-substantive change submitted by the Centers for Disease Control and Prevention (CDC) regarding its COVID-19 surveillance reporting form for cruise ships under the Information Collection Request: “Phased Approach to the Resumption of Cruise Ship Passenger Operations,” OMB Control No. 0920-1335. This change aligned with the end of the COVID-19 Public Health Emergency (PHE) by reducing the reporting burden to cruise ships given the revised reporting form was shorter, allowed for consolidated reporting of multiple conditions, and renamed to reflect a change in focus from COVID-19 to Acute Respiratory Illness (ARI) more generally. In addition, the frequency of reporting was reduced from daily to once, at the end of each voyage.

CDC has been preparing to implement this reporting change pending development and clearance of associated guidance for preventing, detecting, and managing ARI cases on board cruise ships. However, upon further discussion with cruise lines, there is now a desire to request cruise ships report earlier if $\geq 3\%$ of passengers or crew are sick so that CDC can provide technical assistance in managing the outbreak, and then again at the end of the voyage to monitor progression of the outbreak. While this means a small number of ships may be requested to report twice, the burden of twice per voyage reporting is still significantly less than the previous daily reporting (15,817 hours in 2023 to 1,050 hours in this Change Request).

Hence, CDC is submitting this change request to modify changes made to the June 2023 change request. CDC considers these changes non-substantive since they are either updating hyperlinks, changing names or definitions, or other minor changes that still result in a burden that is significantly less than the current daily reporting. An itemized justification of each proposed change is provided below.

1. Update Cruise Ship Cumulative Acute Respiratory Illness (ARI) Reporting Form:

- A. Change: Updated to include criteria for when to report cases sooner than arrival in U.S., depending on percentage of people on board who have ARI.
FROM: “to be submitted electronically via REDCap once per voyage, within 24 hours before arrival in U.S., ^[1]”
TO: “to be submitted electronically via REDCap once per voyage, within 24 hours before arrival in U.S., ^[1] and also sooner if 3% or more of the voyage’s passengers or crew have ARI”

Rationale: Provides CDC opportunity to make public health interventions for significant outbreaks sooner (i.e., if a ship with a large outbreak only reports 24 hours before porting in the U.S., the voyage will end by the time CDC has an opportunity to assist this ship).

- B. Change: Updated future webpage title
FROM: “[Guidance for Cruise Ships on Acute Viral Respiratory Illness Management.](#)”
TO: “[Guidance for Cruise Ships on Management of Acute Respiratory Illness due to Viral Infection](#)”

- Rationale: Updated to align with latest title of new webpage
- C. Change: Updated terminology
FROM: “Maritime”
TO: “Cruise Ship”
Rationale: Updated to align with title of this document
- D. Change: Moved footnote
Rationale: Definitions added for confirmed influenza and RSV
- E. Change: Updated reporting section
Rationale: Clarified CDC’s regulatory requirements (under 42 CFR part 71) for diseases other than ARI and added link to existing reporting guidance
- F. Change: Additions at the request of CDC subject-matter-experts
Rationale: For clarity vs. updated testing parameters
- G. Change: Removed “respiratory syncytial virus” name
Rationale: Virus acronym (RSV) defined earlier in document
- H. Change: Revisions at the request of CDC subject-matter expert
Rational: To align with language in future webpage guidance
- I. Change: Corrected a misplaced footnote.
Rationale: N/A
- J. Change: Removed previous Question #6, revised for free text option for ship clinicians, and moved to end of form (now Question #12)
Rationale: Updated due to cruise industry and CDC SME feedback

Annual Burden

Cruise Ship Cumulative Acute Respiratory Illness (ARI) Reporting Form: The ARI Reporting Form is an updated version of the prior ARI Form. CDC estimates that this modification of the new ARI Reporting form will result in a decrease in burden from 15,817 for the daily reporting to 1,051 hours annually. While this is an increase of 50 hours annually from the last non-sub change request that was 1,000 annual burden hours, because that form has not been officially implemented yet pending development and clearance of associated guidance, CDC still considers this a decrease in burden to the previous daily reporting.

FOR ALL CRUISE SHIPS: Submitting once per voyage within 24 hours before arrival in U.S.,

- The number of respondents remains unchanged at 100.
- The estimated number of times each respondent would need to respond decreases from 365 to 60 because CDC has yet to implement the previous non-substantive change of requesting one report per voyage, a decrease in frequency compared to the one report each day. CDC used 2019 data from cumulative influenza-like illness reports to estimate the number of times a cruise ship may report per year.
- The number of questions remains at twelve. Hence, CDC continues to estimate it will take respondents 10 minutes to fill this out.

- Thus, the total estimated annualized burden for the once-per-voyage reporting of the revised form will remain unchanged at 1,000 hours.

FOR CRUISE SHIPS WITH >3% OF PASSENGERS WITH ARI: For cruise ships submitting a second report per voyage (i.e., sooner than 24 hours before arrival in U.S because 3% or more of the voyage’s passengers or crew have ARI),

- The number of respondents remains unchanged at 100.
- The estimated number of times each respondent would need to respond is estimated at 3; CDC used 2019 data from cumulative influenza-like illness reports meeting its pre-existing outbreak threshold (of 1,380 cases per 1,000 traveler days) to estimate the number of times a cruise ship may meet the new $\geq 3\%$ ARI threshold.
- The number of questions remains at twelve. Hence, CDC continues to estimate it will take respondents 10 minutes to fill this out.

The total estimated annualized burden for ships that have to submit an additional report due to $\geq 3\%$ of ARI cases is 50 hours.

Effects of changes requested in this Change Request (burden table excerpt):

Type of Respondent	Form or Information Collection Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Cruise ship physician	Cruise Ship Cumulative Acute Respiratory Illness (ARI) Reporting Form (submitted once per voyage, within 24 hours before arrival in U.S.)	100	60	10/60	1,000
Cruise ship physician	Cruise Ship Cumulative Acute Respiratory Illness (ARI) Reporting Form (submitted sooner than 24 hours before arrival in U.S because 3% or more of the voyage’s passengers or crew have ARI)	100	3	10/60	50

The total estimated annualized burden for the revised form is now increased slightly to 1,050. However this still represents a significant decrease from the previously implemented daily reporting program which had a burden of 15,817 hours.

The revised form is provided as Attachment H_10202023.