

**Request for Nonmaterial/Non-substantive change
Foreign Quarantine Regulations (42 CFR 71)
(OMB Control No. 0920-0134)
Expires 03/31/2022**

Program Contact

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Circumstances of Change Request for OMB 0920-0134

The Centers for Disease Control and Prevention (CDC), Division of Global Migration and Quarantine (DGMQ) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request: Foreign Quarantine Regulations (42 CFR 71), OMB Control No. 0920-0134, expiration date: 05/31/2022.

CDC continues to manage several outbreaks of COVID-like illness among cruise ship crew. CDC is requesting approval for a set of changes to the electronic reporting tool, the “Enhanced Data Collection During COVID-19 Pandemic” REDCap form (Attachment A1(changes), Attachment A2 (REDCap screenshot), to facilitate collection of the data from cruise ships under the extended No Sail Order of July 16, 2020. This method remains the most efficient mechanism for collecting information and allows for faster analysis in a secure environment (<https://www.project-redcap.org/>).

CDC is requesting approval for the following changes. These changes are informed by CDC experience with respiratory illness reporting from cruise ships over the last several months, and have benefitted from industry and subject matter expert input. CDC does not anticipate that these changes result in additional reporting burden.

Description of the changes

- Change #1: Expanded definition for the definition of acute respiratory illness (ARI) to include “*and in the absence of a non-infectious diagnosis as determined by the ship’s medical provider (e.g., allergies)*”
- Justification: Clarification in response to ship clinician complaints that the previous definition could apply to non-infectious conditions
- Change #2: Additional reporting requirement/surrogate marker for COVID-19-like illness
- Justification: The expanded reporting requirement is based on that latest epidemiologic evidence of the clinical manifestations of COVID-19 that has emerged in the scientific literature since the inception of EDC reporting. The additional symptoms/signs align with [CDC guidance](#) and [CSTE clinical definitions for COVID-19](#).
- Change #3: Additional lab reporting option of rapid antigen test for detecting SARS-CoV-2
- Justification: This rapid antigen is now commercially available and [recommended by CDC](#). FDA authorized PCR tests have become more common and standardized, so CDC no longer needs burden the cruise lines by providing the manufacturer of the test. However, non-molecular tests, such as antigen or serology, are still either new or with enough non-FDA authorized versions in use that CDC needs this information to ensure the quality of the data being provided.
- Change #4: Expanded options to account for when PCR test results are pending and for providing the PCR results in relation to a previous EDC-reporting week
- Justification: Added at the request of ship clinicians based on experienced inability to enter into EDC-reporting system as currently available

Change #5: Shore-side authority PCR vs. antigen testing (with explanations on timing of tests in relation to CDC reporting as cruise-associated cases)

Justification: Added at the request of ship clinicians based on experienced inability to enter into EDC-reporting system as currently available. With this reporting, there is no true subset of cases, but CDC divided the positives (antigen or PCR) into those performed on the ship versus those performed after disembarking the ship (primarily due to country of repatriation requirements). These specifics to the EDC were added at the request of the cruise lines.

Change #6: Additional COVID-19-like illness (CLI) inserted into isolation statement

Justification: Self-explanatory (and consistent with CDC recommendations).

The new, web-based version of the “Enhanced Data Collection During COVID-19 Pandemic” form solicits additional information from the cruise ships concerning acute respiratory illness, influenza-like-illness, and pneumonia. Similarly, it will also ask if any pre-existing or additional diagnostic testing has been done and whether the cruise ship has implemented isolation procedures according to CDC COVID-19 guidelines. It will also ask for the number of crew on board and the nearest U.S. port.

CDC will be providing guidance on the use of the form via multiple channels to ensure broad distribution to the cruise industry. Those channels include distribution via Cruise Lines International Association (CLIA), which is the world’s largest cruise industry trade association; email correspondence from CDC Maritime Activity to cruise line medical directors; and posting guidance to CDC’s maritime industry website, available here: <https://www.cdc.gov/quarantine/maritime/recommendations-for-ships.html>.

REDCap is a secure internet application for building and managing online surveys and databases. It can be used to collect virtually any type of data, including in environments compliant with electronic records legislation (21 Code of Federal Regulations Part 11), the Federal Information Security Management Act of 2002 (44 US Code §3541), and the Health Insurance Portability and Accountability Act of 1996 (Public Law 104– 191, 110 Stat 1936). The tool is specifically designed to support online or offline data capture for research studies and operations, and is accessible through computers, tablets, and smartphones. CDC believes this process will be easier to integrate into cruise ship operations than using a paper form.

Burden

This form would not constitute an additional burden to cruise ship operators, as they would have the option of using the paper or electronic version. CDC anticipates that the vast majority of cruise lines will use the electronic version. The current information collection is approved for 2,167 hours from 250 respondents. Based on data received from the EDC form, CDC is revising this estimate down to 50 respondents. This results in an estimates burden of 520 hours. The total burden under 0920-0134 will decrease to 269,014 hours.

Per the terms of the extended No Sail Order, CDC will require that the form be submitted once a week by any cruise ship originating from, stopping in, or anchored off of the U.S. Cruise ships should already have the information needed to complete the form in their medical logs; based on the pilot, the form should take around 10-12 minutes to complete. For the purposes of estimating burden hours, the upper limit of this range (i.e., 12 minutes) is used.

Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Cruise ship operator	Enhanced Data Collection During COVID-19 Pandemic	50	52	12/60	520
Total					520

Privacy

There is no PII collected as part of this information collection.

Attachments

Attachment A – Enhanced Data Collection During COVID-19 Pandemic (REDCap)