#### UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA

NORWEGIAN CRUISE LINE HOLDINGS LTD.; NCL (BAHAMAS) LTD., d/b/a NORWEGIAN CRUISE LINE; SEVEN SEAS CRUISES S. DE R.L., d/b/a REGENT SEVEN SEAS CRUISES; OCEANIA CRUISES S. DE R.L., d/b/a OCEANIA CRUISES;

Plaintiffs,

V.

SCOTT A. RIVKEES, M.D., State Surgeon General and Head of the Florida Department of Health, in his official capacity;

Defendant.

**Case No.** 1:21-cv-22492-KMW

#### **DECLARATION OF OLGA VIEIRA**

- I, Olga Vieira, do hereby depose and state:
- 1. I am of legal age and I make this declaration on the basis of my personal and professional knowledge and experience as well as publicly available information.
- 2. I am a partner at the law firm of Quinn Emanuel Urquhart & Sullivan LLP and counsel to Plaintiffs Norwegian Cruise Line Holdings Ltd., NCL (Bahamas) Ltd., Seven Seas Cruises S. de R.L., and Oceania Cruises S. de R.L. in the above-captioned matter.
- 3. Attached hereto as Exhibit 1 is a true and correct PDF copy of the Letter from CDC to Cruise Industry Colleagues dated April 28, 2021.
- 4. Attached hereto as Exhibit 2 is a true and correct PDF copy of CDC's Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC's Framework for Conditional Sailing Order dated May 14, 2021, available at https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html.
- 5. Attached hereto as Exhibit 3 is a true and correct PDF copy of CDC's COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order dated May 26, 2021, available at https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html.

6. Attached hereto as Exhibit 4 is a true and correct PDF copy of CDC's Conditional Sailing Certificate for the Norwegian Gem dated July 9, 2021.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2021

**OLGA VIEIRA** 

# Exhibit 1

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC) Atlanta GA 30329-4027

April 28, 2021

Dear Cruise Industry Colleagues,

Since April 12, 2021, senior leadership from the Centers for Disease Control and Prevention (CDC) and other relevant federal agencies have engaged in twice-weekly meetings with representatives from various cruise lines. The objective of these meetings has been to engage in dialogue and exchange information with individual cruise line representatives<sup>1</sup> regarding the impact of vaccines<sup>2</sup> and other scientific developments since the Framework for Conditional Sailing Order (CSO) was issued in October 2020. Participants had the opportunity to ask operational questions about the CSO and CDC's published technical instructions for cruise ships.

During these discussions, individual cruise line representatives were able to express their concerns as to the pace and phases of the CSO, ask questions related to the implementation of the CSO, and reiterate their desire to resume cruising as soon as possible. CDC subject matter experts discussed the public health challenges of cruising safely and responsibly during a global pandemic, particularly regarding the emergence of SARS-CoV-2 variants of concern. These challenges include ensuring cruise ship passenger operations are conducted in a way that protects crew, passengers, port personnel, and U.S. communities. CDC experts explained the rationale behind certain requirements of the CSO and similarities with other requirements and recommendations regarding maritime operations from international public health entities.

We acknowledge that cruising will never be a zero-risk activity and that the goal of the CSO's phased approach is to resume passenger operations in a way that mitigates the risk of COVID-19 transmission onboard cruise ships and across port communities. We remain committed to the resumption of passenger operations in the United States following the requirements in the CSO by mid-summer, which aligns with the goals announced by many major cruise lines. In furtherance of this mutual effort, we provide the following clarifications to its Phase 2A technical instructions issued on April 2, 2021.

We look forward to reviewing plans submitted by the cruise lines for Phase 2A and moving into the next phase of the CSO soon.

#### Clarifications

#### Timeline to resuming passenger operations under the phased approach

The 30 calendar day timeframe for the submission to CDC of a cruise ship operator's notice for conducting a simulated voyage and the 60 calendar day timeframe for submission to CDC of the

<sup>&</sup>lt;sup>1</sup> Cruise industry participants included American Queen Steamboat Company, Bahamas Paradise Cruise Line, Carnival Corporation, Cruise Line International Association, Disney Cruise Line, Norwegian Cruise Line Holdings, Royal Caribbean Group, and Viking Cruises.

<sup>&</sup>lt;sup>2</sup> As part of these discussions, CDC reviewed CLIA's vaccine position statement which CDC understands to be that trade group's current position regarding the role of vaccines in restarting cruising.

- cruise ship operator's COVID-19 Conditional Sailing Certificate application as set forth in the CSO are suggested as guidelines. CDC Maritime Unit will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.
- CDC encourages the finalization of the Phase 2A port agreements to allow cruise ships to embark non-essential crew for simulated and restricted voyages. Prior to finalization of the Phase 2A agreements with port and local health authorities, CDC will allow cruise ships to embark 50 percent of the non-essential crew expected to sail on the first restricted voyage. CDC expects that a full complement of crew will not be needed for a cruise ship operator to conduct a simulated voyage because such simulations may be conducted with a small percentage of passengers.

#### Phase 2A: Port agreements – General Components

In documenting the approval of all U.S. port and local health authorities where the ship intends to dock or make port during one or more simulated voyages or restricted passenger voyages, the cruise ship operator may enter into a multi-port agreement (as opposed to a single port agreement) provided that all relevant port and local health authorities (including the state health authorities) are signatories to the agreement. Such multi-port agreements may be particularly suitable if one port has limited medical or housing capacity and a nearby port is able to supplement these capacities.

#### Phase 2A: Port agreements – Vaccination Components

- In completing the vaccination component of a Phase 2A agreement, including a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations, cruise ship operators must disclose and document their current plans to vaccinate crew. This includes if a cruise ship operator only plans to encourage crew to be vaccinated on a voluntary basis once vaccines become more widely available.
- In completing the vaccination component of a Phase 2A agreement, including presentation of proposals regarding how the cruise ship operator intends to incorporate vaccination strategies to protect passengers, cruise ship operators must disclose and document their current strategy. This includes if a cruise ship operator only plans to encourage passengers to be vaccinated on a voluntary basis once vaccines become more widely available.

#### Phase 2A: Port agreements – Medical and Housing Components

- In determining the sufficiency of shoreside medical and housing facilities, port authorities and local health departments should consider the cruise ship operator's plan and timeline for vaccination of crew and presentation of proposals incorporating vaccination strategies to maximally protect passengers. Those cruise ship operators with a clear and specific vaccination plan and timeline may have only a limited need for shoreside medical and housing facilities compared to operators who only plan or propose to encourage vaccinations.

#### Phase 2A: Port agreements – Medical Components

- CDC acknowledges that shoreside medical facilities and healthcare systems cannot guarantee bed capacity. In documenting a cruise ship operator's contractual arrangement with such

facilities or systems, redundant contracts, or contracts allowing for preferential acceptance of patients on a space-available basis, will be considered acceptable.

#### Phase 2A: Port agreements – Housing Components

- In determining whether a cruise ship operator has contractual arrangements for shoreside housing facilities in sufficient quantities to meet the needs of travelers for isolation or quarantine, the parties to a Phase 2A agreement may consider the ability of travelers to use their own personal vehicles to return safely to their residences. The parties should consider the time needed for travelers to drive to their final destinations to avoid the need for overnight stays en route. At a minimum, the health department at the final destination must be notified and travelers must be advised to complete their isolation or quarantine at home. For more information, please visit CDC's <a href="Interim Guidance for Transporting or Arranging Transportation by Air into, from, or within the United States of People with COVID-19 or COVID-19 Exposure webpage.">Interim Guidance for Transporting or Arranging Transportation by Exposure</a>
- CDC routinely works with state and local health departments and the U.S. Department of Homeland Security to prevent travelers from boarding commercial airplanes if they:
  - o are known or suspected to have a contagious disease, or
  - o were exposed to a contagious disease that poses a threat to the public's health.
    - For more information see <u>Travel Restrictions to Prevent the Spread of Disease</u>.

Accordingly, the parties to a Phase 2A agreement should consider the housing needs of travelers who are unable to return to their residences by private vehicle as they will not be permitted to board commercial flights.

- In documenting that the parties to a Phase 2A agreement have deliberated and jointly considered the needs of travelers under quarantine or isolation, including needs relating to security and legal considerations to prevent travelers from violating any mandatory isolation or quarantine, it is assumed that a government entity may issue an order for mandatory isolation or quarantine, and that the cruise ship operator would cooperate with the government entity in addressing security needs.
- Referencing the requirement that shoreside housing provide separate ventilation systems for all travelers who are not part of the household, CDC notes that a standard hotel room with a thermostat on the wall or individual air handling unit is an example of housing that would meet this requirement.

We remain committed to providing any requested technical assistance with Phase 2A agreements and looks forward to receiving these port agreements from the industry. Any technical questions from the cruise ship operators or other relevant stakeholders regarding the Phase 2A port agreements should be addressed to eocevent349@cdc.gov.

We would like to take this opportunity to provide you with our current thinking regarding the following possible updates.

#### **Upcoming Updates**

#### **Color-coding update**

- Cruise ship operators may be allowed to use commercial travel to disembark crew regardless of the cruise ship's color status. Cruise ship operators will be restricted from using commercial travel for crew who have tested positive for SARS-COV-2, the virus that causes COVID-19 (unless they have documentation of recovery from a COVID-19 infection in the previous 90 days) and are within their isolation period and their close contacts (unless fully vaccinated) who are within their quarantine period.

#### Testing and quarantine updates during restricted voyages based on vaccination status

- CDC will update testing and quarantine requirements for passengers and crew to closely align with CDC's guidance for fully vaccinated and not fully vaccinated persons.

	Not Fully Vaccinated Crew	Fully Vaccinated Crew
<b>Embarkation Day Testing</b>	- NAAT	- Viral (NAAT or antigen)
Quarantine Testing	- NAAT	- Viral (NAAT or antigen)
[& Duration]	[end quarantine after day 10 if negative]	[end quarantine after day 7 if negative]
End of Quarantine Testing	- NAAT	<ul> <li>Viral (NAAT or antigen)</li> </ul>
Routine Screening Testing	- Viral (NAAT or antigen)	- Viral (NAAT or antigen)
Disembarkation Day Testing	- Viral (NAAT or antigen)	- Not applicable

#### Updates for fully vaccinated passengers and crew

In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 98 percent of crew are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

We appreciate your support, and that of our partners, as we work together to fight COVID-19.

Sincerely,

CAPT Aimee Treffiletti, USPHS

Maritime Unit

Global Migration Task Force

CC:

**Gary Rasicot** 

**Department of Homeland Security** 

Joel Szabat

Department of Transportation

# Exhibit 2



# Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC's Framework for Conditional Sailing Order

**Summary of Recent Changes** 

May 14, 2021

Clarified screening and laboratory testing requirements for passengers.

### **Audience**

This document is intended to assist cruise ship operators in preparing to conduct simulated ("trial") voyages in advance of restricted passenger voyages under a COVID-19 Conditional Sailing Certificate. This includes conducting simulated voyages insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship as per the terms of CDC's Framework for Conditional Sailing Order (CSO), developing an afteraction report, and addressing any identified deficiencies.

### Purpose

This document provides technical instructions for Phase 2B of CDC's CSO for cruise ship operations in U.S. waters to ensure health and safety protections for travelers (crew and future passengers) and port personnel prior to resuming passenger operations in a way that mitigates the risk of spreading COVID-19.

These instructions are not intended as, and do not constitute, a comprehensive statement regarding a cruise ship operator's duties and obligations under CDC's CSO. These instructions reflect CDC's reasoned judgement based on the best available current science regarding the subject areas covered in the document. Cruise ship operators should carefully consider and incorporate these instructions in developing their own health and safety protocols.

# Notifying and Requesting CDC Approval to Conduct a Simulated Voyage

A cruise ship operator should notify CDC and request CDC's approval to conduct a simulated voyage at least 30 calendar days[1] prior to the date on which the cruise ship operator proposes to conduct the simulation. Submit notifications and requests to CDC electronically through eocevent349@cdc.gov. Additionally, this notice and request for approval must:

- Specify the dates and location of the proposed simulation.
- Verify that the cruise ship operator is eligible to conduct a simulated voyage as per the terms of the CSO and these technical instructions.
- Submit documentation that the cruise ship operator has a written agreement (or a multi-port agreement) with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a simulated voyage. The written agreement must specifically include the name of the cruise ship that will be conducting the simulation and meet the standards of the CSO and CDC's technical instructions for Phase 2A of CDC's CSO.
- Provide a copy of the cruise ship operator's proposed written notification to volunteer passengers. This written notification must advise volunteer passengers that they are participating in health and safety protocols that are unproven and untested in the United States for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity. At the cruise ship operators' discretion, this written notification can occur through website posting, email, or written letter to the volunteer passengers.

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- Identify and provide one or more points of contact for persons who will be overseeing and implementing the proposed simulation for each cruise ship. This must include points of contact who will be physically present on the ship during the simulated voyage.
- Include the protocols or practices to be simulated, which must, at a minimum, incorporate the requirements for conducting simulated voyages under these technical instructions.
- Be signed by the cruise ship operator's responsible officials, meaning the Chief Executive Officer (or equivalent) of
  the operating cruise company and all parent companies, the Chief Compliance Officer (or equivalent) of the
  operating cruise company and all parent companies, and the highest-ranking Medical Officer of the operating cruise
  company and all parent companies.
- Certify under 18 U.S.C. § 1001 that all of CDC's requirements relating to the protection of crew onboard cruise ships in U.S. waters (i.e., Phase 1 of the CSO) have been satisfied and continue to be met.

CDC will respond to these requests in a timely manner. CDC may deny the request to conduct a simulated voyage if the cruise ship operator is not in compliance with any of CDC's requirements for the mitigation of COVID-19 onboard cruise ships, technical instructions, or orders, or if in CDC's determination the simulated voyage does not provide adequate safeguards to minimize the risk of COVID-19 for all participants. CDC may also oversee and inspect any aspect of the simulated voyage, including through in-person or remote means allowing for visual observation.

[1] The 30-calendar day timeframe is suggested as a guideline. CDC will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.

# Eligibility for Conducting a Simulated Voyage

As part of the cruise ship operator's notification and request to conduct a simulated voyage, a cruise ship operator must verify that it meets the following eligibility criteria:

- The cruise ship operator has received a determination by CDC that a plan submitted in response to the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (i.e., "No Sail Order response plan"), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)) is complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy.
- The cruise ship operator has continued to submit the Enhanced Data Collection (EDC) form as specified in CDC technical instructions or orders. If the cruise ship has been operating outside of U.S. waters, the cruise ship operator has submitted the EDC form during (at a minimum) the 28 days preceding the ship's expected arrival in U.S. waters and will continue to submit the EDC form after the ship enters U.S. waters.
- The cruise ship operator has observed and continues to observe all elements of its No Sail Order response plan including by following the most current CDC recommendations and guidance for any public health actions related to COVID-19, or if any deviations from the plan have occurred such deviations have been reported and corrective actions taken to the satisfaction of CDC.
- The cruise ship operator has arranged for and submitted and continues to arrange for and submit laboratory test results as required by CDC for every crew member on board ships operating in U.S. waters. If the cruise ship operator has ships operating outside of U.S. waters and intends for these ships to return to operating in U.S. waters while the CSO remains in effect, then the operator has arranged for and submitted laboratory test results as required by CDC for every crew member on board these ships.
- If the cruise ship received any ship-to-ship transfers in the last 14 days, crew must have come from a ship that was not Red.

Case <u>f.:124 cwise প্রথা এক প্রথা দিন্দ কি এব</u> দিন্দ কি এব embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.

- The cruise ship operator has a written agreement (or a multi-port agreement) with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a simulated voyage. The written agreement must specifically include the name of the cruise ship that will be conducting the simulation and meet the standards of the CSO and CDC's technical instructions for Phase 2A of CDC's CSO. The written agreement must include a:
  - port component (including a vaccination component) between the cruise ship operator and port authority to determine the number of cruise ships operating out of any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak;
  - medical care component between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical instructions and orders; and
  - housing component between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and close contacts, identified from the day of embarkation through disembarkation for each voyage.

# Requirements Relating to Volunteer Passengers

A simulated voyage must be designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard a cruise ship. This includes using volunteers simulating the role of passengers. A cruise ship operator must observe the following requirements relating to volunteer passengers:

- The minimum number of required volunteer passengers for each simulated voyage must be at least 10% of the maximum number of passengers permitted onboard for the first two restricted voyages as per the terms of the cruise ship operator's Phase 2A agreement with U.S. port and local health authorities.
- The cruise ship operator must advise volunteer passengers of CDC's Travel Health Notice for COVID-19 and Cruise Ship Travel for Travelers Who Are Not Fully Vaccinated prior to the simulated voyage. At the cruise ship operators' discretion, this information can be provided via linking to CDC's webpage, through email, or written letter to the volunteer passengers.
- All volunteer passengers must be informed in writing that they are participating in a simulation of health and safety protocols that are unproven and untested in the United States for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity. At the cruise ship operators' discretion, this written notification can occur through website posting, email, or written letter to the volunteer passengers. A copy of this written notification must also be provided to CDC as part of the cruise ship operator's notification and request to conduct a simulated voyage.
- All volunteer passengers must be at least eighteen years old or older on the day of the simulation and at the time that their consent to participate is obtained.
- The cruise ship operator must ensure **all** volunteer passengers have either:
  - Proof of being fully vaccinated against COVID-19 using an U.S. Food and Drug Administration (FDA)-authorized vaccine or a vaccine product that has received emergency use listing from the World Health Organization (WHO); or
  - If not fully vaccinated, written documentation from a healthcare provider or self-certified statement that the volunteer passenger has no medical conditions that would place the volunteer at high risk for severe COVID-19 as determined through CDC guidance.
- The simulation must be conducted with the signed informed consent of all participants and not as a condition of employment or in exchange for consideration or future reward. For the purpose of these technical instructions, passage on board the ship, accommodations, provision of food and beverages, participation in shore excursions and private island visits, and attendance at entertainment events while participating as part of a simulated voyage will not be deemed a form of consideration. The cruise ship operator must document this signed informed consent for each participant in writing, either on paper or electronically. The cruise ship operator must also preserve the paper or electronic consent forms and make them available to CDC upon request at any time while the CSO remains in effect.
- All volunteer passengers must be evaluated for signs and symptoms of COVID-19 prior to embarkation and disembarkation. Cruise ship operators must educate all volunteer passengers about the signs and symptoms of COVID-19 and the need to notify cruise ship medical staff immediately if symptoms develop.

# Case All 20 Lower 2452 1844 Mus Dargerine mitigs 20 pertities and long the collection of the simulated voyage, unless they are fully vaccinated or have documentation of recovery from COVID-19 in the past 90 days. Cruise ship operators are advised that as a condition of receiving a COVID-19 Conditional Sailing Certificate, at least 75% of all volunteer passengers who are not fully vaccinated and do not have documentation of recovery from COVID-19 must provide their post disembarkation specimen to the selected laboratory (see options for post-disembarkation testing below) for COVID-19 testing within the specified time frame. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based

To facilitate contact tracing, the cruise ship operator must advise all volunteer passengers to notify the cruise ship operator if they develop symptoms of COVID-19 or are diagnosed with COVID-19 with any SARS-CoV-2 viral test within 14 days after the voyage. Passengers who develop symptoms within 14 days should be advised to be tested. The cruise ship operator must in turn report aggregate results to CDC in the after-action report or through an amended after-action report.

# Requirements Relating to the General Components of a Simulation and Simulated Activities

on lessons learned from previous simulated voyages and other factors.

A simulated voyage must be designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 on board a cruise ship. This includes observing the general components of a simulation and simulating the following shipboard activities:

- At least one simulation must be conducted for each ship for which the cruise ship operator intends to commence restricted passenger voyages. The simulation(s) must occur prior to the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate under the CSO.
- The cruise ship's color-coding status must be Green or Orange at the time of the simulated voyage. If the cruise ship's color-coding status is Yellow or Red, then the simulation must be postponed until such time as the ship's status changes to Green or Orange. Cruise ship operators will not be required to submit a new request to conduct a simulated voyage in the event of postponement, but operators must notify CDC of the revised dates of the simulation.
- If the cruise ship operator has entered into a Phase 2A agreement with the port or local health authority of more than one port and the cruise ship operator intends for the ship to dock at more than one U.S. port during restricted passenger voyages, then the simulated voyage(s) must include each U.S. port.
- The cruise ship operator must maintain a list of all passengers, crew, port personnel, and other persons who participated in the simulated voyage. This list must be preserved and made available to CDC upon request at any time while the CSO remains in effect.
- Simulated voyages must be between 2-7 days in length with a least one overnight stay[2] to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard the cruise ship, including through embarkation, disembarkation, and post-disembarkation testing.
- Activities conducted on voyages that occurred outside of U.S. waters during the period of the No Sail Order (NSO) and the CSO that were not conducted as part of a CDC-approved simulated voyage, do not count towards the activities that must be simulated on a simulated voyage. However, cruise ship operators may incorporate best practices and lessons learned from these voyages as part of the simulation and in the after-action report submitted to CDC.
- The cruise ship operator must meet standards during the simulated voyage for hand hygiene, use of face masks, and social distancing for passengers and crew, as well as ship sanitation, as required by CDC technical instructions or orders.
- The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing during the simulated voyage.
- The following activities must be simulated onboard each ship for which the cruise ship operator intends to commence restricted passenger voyages before applying for a COVID-19 Conditional Sailing Certificate. However, at the cruise ship operator's discretion, these activities may be conducted as part of the same simulated voyage or as part of separate simulated voyages:
  - Embarkation and disembarkation procedures, as approved by U.S. port and local health authorities as part the cruise ship operator's Phase 2A agreements, including procedures for terminal check-in.
  - Onboard activities, including seating and meal service at dining and entertainment venues.

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- Transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms.
- Onboard and shoreside isolation and quarantine, as per the terms of the cruise ship operator's Phase 2A agreements, of at least 5% of all passengers and non-essential crew.
- Recreational activities that the cruise ship operator intends to offer as part of any restricted passenger voyages, e.g., casinos, spa services, fitness classes, gymnasiums.
- Private-island shore excursions if any are planned during restricted passenger voyages. The following measures must be observed on the private island:
  - Only one ship can port at the island at any one time.
  - A routine screening testing protocol must be implemented for island staff who are expected to interact
    with volunteer passengers or crew, unless they are fully vaccinated or have documentation of recovery
    from COVID-19 in the past 90 days.
  - Mask use and social distancing must be observed in indoor areas while on the island.
- Port of call shore excursions if any are planned during restricted passenger voyages. The following measures must be observed on port of call shore excursions:
  - Shore excursions must only include passengers and crew from the same ship.
  - Cruise ship operator must ensure all shore excursion tour companies facilitate social distancing, mask wearing, and other COVID-19 public health measures throughout the tour while in any indoor areas.
  - Cruise ship operators must have a protocol for managing persons with COVID-19 and close contacts at all foreign ports of call. At a minimum, the protocol must include the following:
    - Disembarkation and housing of persons with suspected or confirmed COVID-19 needing shore-based hospital care and their travel companion(s) for the duration of their isolation or quarantine period.
    - Commercial repatriation of U.S.-based persons with COVID-19 and close contacts only after meeting criteria to end isolation and quarantine per CDC guidance. For commercial repatriation of foreignbased persons with COVID-19 and close contacts, cruise ship operators must consult with all relevant public health authorities.

[2] To fully test all procedures during a simulated voyage, CDC recommends a minimum voyage length of 3 days with 2 overnight stays.

# Requirements Relating to Screening and Laboratory Testing

Cruise ship operators must screen passengers for signs or symptoms of COVID-19 and screen for a known close contact exposure to a person with COVID-19 within the past 14 days.

- Passengers with signs or symptoms of COVID-19
  - Deny boarding if not fully vaccinated and without documentation of recovery<sup>[1]</sup>.
  - May board at operator's discretion if fully vaccinated or with documentation of recovery and embarkation day test is negative by viral test (antigen-negative must be confirmed with NAAT. If an alternate infectious etiology (e.g., influenza, respiratory syncytial virus (RSV), Legionella, Streptococcal pharyngitis) is identified through laboratory testing, routine infection control precautions recommended for the diagnosis should be followed.
- Passengers who have a known close contact exposure in the past 14 days
  - Deny boarding if not fully vaccinated and without documentation of recovery [1]
  - May board at operator's discretion if:
    - fully vaccinated and asymptomatic
    - with documentation of recovery from COVID-19 and asymptomatic

A cruise ship operator must observe the following requirements relating to laboratory testing of <u>passengers and crew</u> who are not fully vaccinated or do not have documentation of recovery from COVID-19 [1] as part of a simulated voyage:

• Day of Embarkation Testing: testing must be performed by NAAT using one of the following testing instruments and processes with same day results:

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- Previously approved Phase 1 onboard point-of-care equipment, or
- Other testing instruments and processes approved by CDC
  - Prior to collecting specimens and conducting testing: Cruise ship operators must contact CDC at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens for approval. Include "Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]" in the subject line as part of your request for CDC approval.
  - CDC's response to the cruise ship operator's email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting specimens.
- Results must be available prior to boarding the cruise ship. Volunteer passengers who test positive for SARS-CoV-2 should be denied boarding, unless determined to be a persistent positive by cruise ship medical personnel.
- Day of Disembarkation Testing: testing must be performed by NAAT using one of the following testing instruments and process with same day results:
  - Previously approved Phase 1 shoreside laboratory, or
  - Previously approved Phase 1 onboard point-of-care equipment, or
  - Other testing instruments and processes approved by CDC
    - Prior to collecting specimens and conducting testing: Cruise ship operators must contact CDC
      at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens for approval. Include
      "Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]" in the subject line as
      part of your request for CDC approval.
    - CDC's response to the cruise ship operator's email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting specimens.
  - Results must be available before the passenger leaves the cruise ship, seaport, or offsite testing location, but specimen collection and testing can occur onboard or shoreside.
- Post Disembarkation Testing Options: To validate the efficacy of the cruise ship operator's ability to mitigate the risk
  of COVID-19 onboard the cruise ship, post disembarkation testing for volunteer passengers is required for simulated
  voyages.
  - As a condition of receiving a COVID-19 Conditional Sailing Certificate, cruise ship operators must have at least 75% of all passengers who are not fully vaccinated and do not have documentation of recovery from COVID-19 provide their post disembarkation specimen to the selected laboratory for COVID-19 testing 3 to 5 days after completion of the simulated voyage. Passengers who are fully vaccinated or who have documentation of recovery from COVID-19 [1] are exempt from post disembarkation testing. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
  - The cruise ship operator must in turn report aggregate results to CDC in the after-action report.
  - Cruise ship operators have the option of supplying all volunteer passengers with a self-collected nasal midturbinate nucleic acid amplification test (NAAT) specimen collection kit to be shipped directly to a laboratory.
    - All volunteer passengers must:
      - Receive education on self-collection technique.
      - Be instructed to collect the specimen 3 to 5 days after completion of the simulated voyage for testing.
      - Be instructed to store and ship the specimen directly to the laboratory within the specifications of the manufacturer.
    - The shoreside laboratory must use a NAAT that has been authorized for emergency use by FDA and that has been evaluated on the FDA reference panel for SARS-CoV-2 with a limit of detection (LOD) value ≤18,000 NDU/ml. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory. All additional requirements as listed for Shoreside COVID-19 Laboratory Screening Testing of All Crew, above, must also be followed.
  - Cruise ship operators can alternatively direct volunteer passengers to obtain a nasopharyngeal (NP) specimen
    at a shoreside laboratory for SARS-COV-2 testing 3 to 5 days after completion of the simulated voyage for
    testing.
    - The shoreside laboratory must use a NAAT that has been authorized for emergency use by FDA and that has been evaluated on the FDA reference panel for SARS-CoV-2 with a limit of detection (LOD) value

Case 1:21-cv-22492以外以 CDGOUSTAPPT(3/2015 Alf 34 additional requirements as listed for Shoreside COVID-19 Laboratory Screening Testing of All Crew, above, must also be followed.

- Cruise ship operators must conduct laboratory testing of any passengers or crew who report illness consistent with COVID-19 during the simulated voyage (as well as any identified close contacts) using point-of-care equipment and parameters approved by CDC as part of Phase 1 of the CSO. Refer to the Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew for requirements of onboard COVID-19 testing for symptomatic travelers and close contacts.
- Cruise ship operators must continue to conduct routine screening testing of crew according to the corresponding color-coding interval. Cruise ship operators at their discretion may stagger whole ship crew testing during the corresponding color-coding interval (e.g., weekly, every two weeks, every 28 days). For example, the cruise ship operator may choose to test the same percentage of crew on each day of the week if required to test weekly. To ensure consistency, screening testing must be completed within 4 consecutive days of each color-coding interval and the testing schedule for each crew member should remain the same across all color-coding intervals.

[1]Documentation of recovery from COVID-19 includes the following:

- Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
- A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

# Considerations Genetic Sequencing

If positive specimens are identified within 14 days after the voyage, it may be difficult to differentiate between exposures that occurred on board the ship and after disembarkation. In such situations the cruise ship operator may wish to request that a laboratory conduct genetic sequencing of SARS-CoV-2-positive specimens to determine the likelihood that the exposures occurred on board. If sequencing is being considered, please consult with CDC for additional information and instructions through eocevent349@cdc.gov. Results should also be made available to CDC as part of the after-action report. CDC will be available to assist cruise operators in interpreting results of any genetic sequencing.

- If sequencing will be performed: specimens can be stored at 2–8°C for no more than 72 hours from the time of collection. The 72-hour timeframe is a strict requirement for specimen quality. Specimens that require storage longer than 72 hours must be frozen at ≤ -70°C.
- If specimens are shipped: prior to shipping, specimens should be frozen at ≤ -70°C and shipped on dry ice. The quality of the specimen directly affects sequencing and virus culture success. Ideally, specimens should have a reverse transcription polymerase chain reaction (RT-PCR) cycle threshold (Ct) value of ≤28. If Ct values are not available, specimens that are positive/strong positive for SARS-CoV-2 may be sent (avoid weakly positive samples).

# Advisory Related to Terminating a Simulated Voyage to Protect Health and Safety

CDC advises cruise ship operators that it may require them to immediately end a simulated voyage and take other actions to protect the health and safety of volunteer passengers and crew if a threshold of COVID-19 cases is met or exceeded during the simulation. During simulated voyages, this threshold is met when 1.5% of COVID-19 cases is detected in passengers or 1.0% of COVID-19 cases is detected in crew. This threshold may be modified for future simulated voyages or restricted passenger voyages based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors. In the event that a simulated voyage is ended early to protect health and safety, CDC will consult with the cruise ship operator regarding any deficiencies to be noted in the operator's action-action report and how such deficiencies are to be corrected prior to approving any additional simulated voyages.

Cased it in the cruise ship operator will have to repeat the simulated voyage at a later date. If the threshold for the voyage is met or exceeded during the simulation, the cruise ship operator will also have to advise all travelers to avoid commercial air.

exceeded during the simulation, the cruise ship operator will also have to advise all travelers to avoid commercial air travel or ground transportation for 14-days post voyage, unless they have one of the following:

- Proof of being fully vaccinated against COVID-19 using an U.S. Food and Drug Administration (FDA)-authorized vaccine or a vaccine product that has received emergency use listing from the World Health Organization (WHO), or
- Documentation of recovery from COVID-19 in the past 90 days, which includes the following:
  - Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
  - A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

# Requirements Related to the Simulated Voyage After-Action Report (AAR)

A cruise ship operator must observe the following requirements relating to the post-simulation after-action report:

- The cruise ship operator must document in writing any deficiencies observed in its health and safety protocols and describe how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. A deficiency is any significant departure from the cruise ship operator's health and safety protocols or, if such health and safety protocols are followed, any documented transmission of COVID-19 that requires a change, modification, or adjustment of the operator's protocols to ensure safer and healthier sailing.
- The cruise ship operator must report all post-disembarkation test results in aggregate to CDC in the after-action report. To obtain a COVID-19 Conditional Sailing Certificate, cruise ship operators must have at least 75% of all passengers who are not fully vaccinated and do not have documentation of recovery from COVID-19 provide their post disembarkation specimen to the selected laboratory for COVID-19 testing. CDC may lower the 75% postdisembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
- The after-action report must include the cruise ship operator's assessments and conclusions regarding the efficacy of its health and safety protocols at mitigating the risk of COVID-19 onboard a cruise ship and whether any changes, modifications, or adjustments to these protocols will occur based on "lessons learned" from the simulated voyage.
- Where appropriate, the cruise ship operator may incorporate into the after-action report discussion of best practices and lessons learned from voyages that occurred outside of U.S. waters during the period of the NSO or CSO and were not a part of the simulation.
- Where appropriate, the cruise ship operator may incorporate into the after-action report photographic, video, testimonial, or other evidence documenting that the simulated voyage was conducted in accordance with the cruise ship operator's health and safety protocols and these technical instructions.
- The after-action report must be submitted to the CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate.
- CDC may conduct such oversight and inspection of simulated voyages as it deems necessary in its discretion, including through in-person or remote means allowing for visual observation. The findings and/or observations of these inspections will be shared with the cruise ship operator and must be incorporated into the operator's afteraction report.

CDC will provide the cruise ship operator with a template for completing the after-action report after approving the operator's request to conduct a simulated voyage.

# Role of Vaccinations During Simulated Voyages

• For purposes of CDC vaccination guidance, cruise ships are considered residential, non-healthcare, congregate settings representing a global population.

# Option in Lieu of a Simulated Voyage

In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 95 percent of crew (excluding any newly embarking crew in quarantine) are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

# Simulated Voyages and the Passenger Vessel Safety Act

Cruise ship operators are advised that CDC has no responsibility for enforcing requirements relating to the Passenger Vessel Safety Act and no authority to waive these statutory requirements.

### CDC's Mask Order

All persons, including port personnel, crew, and passengers (including those that are fully vaccinated) are advised that CDC's Order requires wearing of masks on conveyances entering, traveling within or leaving the United States, and in U.S. transportation hubs (see maritime-specific Frequently Asked Questions) remains in effect.

# Reporting to Federal Agencies During Simulated Voyages

CDC requires daily submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form" for passengers and crew. This EDC Form will be used to conduct surveillance for COVID-19 on board cruise ships using cumulative reports of COVID-19-like illness, which includes acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) clinical criteria.

Access to the online EDC form has been provided to cruise lines by the Cruise Lines International Association (CLIA) or CDC. Cruise lines that do not have access should contact CLIA or CDC (email eocevent349@cdc.gov).

In addition to this daily surveillance via the online EDC form, cruise ship operators must continue to report to USCG via Advance Notice of Vessel Arrival (ANOA) as required by regulation. Cruise ship operators are reminded that USCG considers COVID-19 illness on board a cruise ship a hazardous condition and must be immediately reported to the local Captain of the Port when the cruise ship is within waters subject to the jurisdiction of the United States.

Acute Gastroenteritis (AGE) cases must be reported to CDC's Vessel Sanitation Program (VSP) in accordance with VSP's 2018 Operations Manual.

Illnesses of public health concern that are neither COVID-19 nor AGE, and all deaths must be reported to the CDC Quarantine Station with jurisdiction for the port.

Page last reviewed: June 4, 2021

# Exhibit 3

# COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order

#### Summary of Recent Changes

#### May 26, 2021

Provided cruise ship operators with more discretion regarding fully vaccinated travelers. Provided additional discretionary considerations for ships with at least 95% of crew and 95% of passengers fully vaccinated.

#### May 18, 2021

Clarified disembarkation testing is only for cruises more than 4 nights.

#### May 14, 2021

Added sections for Screening of Embarking Passengers for Restricted Voyages, Testing of Embarking and Disembarking Passengers for Restricted Voyages, Test Selection and Specifications for Passenger Screening Testing on Restricted Voyages, and Onboard COVID-19 Testing for Symptomatic Passengers and their Close Contacts.

### **Audience**

This document is intended to assist cruise ship operators in ensuring health and safety protections during simulated and restricted passenger operations in a way that mitigates the risk of spreading COVID-19. This document is issued under CDC's Framework for Conditional Sailing Order (CSO) and its requirements must be observed in the same manner as other technical instructions issued under the CSO. This document also contains recommendations to further reduce the spread of SARS-CoV-2, the virus that causes COVID-19, that cruise ship operators should consider for incorporation into their health and safety protocols as best practices.

In addition, cruise ship operators must continue to adhere to requirements in CDC's Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew during passenger voyages.

CDC will update this information as needed and notify cruise ship operators of such updates.

# Purpose

CDC's oversight and inspection of cruise ships during simulated and restricted passenger voyages will be based on this Operations Manual. The findings and/or observations of these inspections will be shared with the cruise ship operator. Cruise ship operators are expected to align their health and safety protocols with any CDC findings and observations. Such findings and observations must also be incorporated into the cruise ship operator's simulated voyage after-action report or as a condition of applying for and retaining permission to conduct restricted passenger voyages. Based on these inspections, CDC may also issue additional recommendations to the cruise ship operator that the operator should consider for adoption into their health and safety protocols as best practices.

As per the terms of the CSO, cruise ship operators, upon request, must make their properties and records available for inspection to allow CDC to ascertain compliance. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health

Inspections of cruise ships during simulated and restricted passenger voyages:

- May be conducted by CDC with or without prior notification to the cruise ship operator;
- May be conducted by CDC through in-person or remote means;
- Will be conducted by CDC during a portion of the simulated voyage or restricted passenger voyage;
- May include CDC inspectors sailing on the simulated or restricted passenger voyage with prior notification to the cruise ship operator; and
- Will not have an associated fee[1] or inspection score.

Persons are prohibited from interfering with the ability of CDC inspectors to inspect and conduct oversight, including but not limited to interfering with CDC's ability to interview cruise ship crew and personnel or visually inspect and oversee collection of laboratory specimens and laboratory testing.

This manual is not intended as, and does not constitute, a comprehensive statement regarding a cruise ship operator's duties and obligations under CDC's CSO. These instructions reflect CDC's reasoned judgement based on the best available current science regarding the subject areas covered in the document. Cruise ship operators should carefully consider and incorporate these instructions in developing their own health and safety protocols.

[1] When not under the Conditional Sailing Order, cruise ship operators pay a fee based on the ship's size for operational inspections or reinspections conducted by CDC's Vessel Sanitation Program.

# Applicability of the VSP 2018 Operations Manual

Cruise ship operators must continue to follow the Vessel Sanitation Program (VSP) 2018 Operations Manual PDF – 291 pages]. In addition to ascertaining compliance in implementing and maintaining public health standards in accordance with the CSO's Technical Instructions, CDC inspectors will further evaluate adherence to environmental health and sanitation standards outlined in the current VSP 2018 Operations Manual.

All variances involving passenger interactive experiences previously approved by VSP are suspended until further notice.

CDC will recommend or direct the master of a vessel not to sail when an imminent health hazard is identified and cannot be immediately corrected, in accordance with VSP's 2018 Operations Manual.

### **Preventive Measures**

Cruise ships involve the movement of large numbers of people in settings where they are likely to have close contact with one another. Close-contact environments facilitate transmission of SARS-CoV-2 and other respiratory viruses from person to person through exposure to respiratory droplets, aerosols, or contact with contaminated surfaces. Cruise ships may also be a means by which infected persons travel between geographic locations.

#### Requirements

To further reduce the spread of SARS-CoV-2, cruise ship operators must:

- Inform passengers of any mandatory public health measures prior to boarding
- Place posters in high-traffic areas that encourage hand hygiene to help stop the spread
- Ensure handwashing facilities are well-stocked with soap and a method to dry hands, such as paper towels or air dryers, in accordance with the 2018 VSP Operations Manual

Cruise ship operators must continue to follow the preventative measures for crew outlined in CDC's Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew.

Recommendations 2/14

- Incorporate COVID-19 vaccination strategies to maximally protect passengers and crew in the maritime environment, seaports, and in land-based communities.
- Encourage passengers to avoid touching eyes, nose, and mouth with unwashed hands.
- Reduce face-to-face interactions between crew and passengers to the extent practicable.
- Discourage handshaking and encourage the use of non-contact methods of greeting.
- Promote respiratory and hand hygiene and cough etiquette.
- Inform passengers that use of cigarettes, e-cigarettes, pipes, or smokeless tobacco can lead to increased contact between potentially contaminated hands and their mouths.
- Place hand sanitizer (containing at least 60% alcohol) in multiple locations and in sufficient quantities to encourage hand hygiene

# Surveillance for COVID-19

Because of the close-contact environment on cruise ships and the potential for asymptomatic and pre-symptomatic transmission, it is important that close contacts of individuals with SARS-CoV-2 infection be quickly identified and tested.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Implement procedures for maintaining records associated with active COVID-19 surveillance and make these records available to CDC upon request for review. These records include:
  - Surveillance log for acute respiratory illness (ARI), influenza-like Illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) symptoms, positive antigen results, and positive nucleic acid amplification test (NAAT) results.
  - Medical documentation of prior positive SARS-CoV-2 viral test results for crew.
    - Because retesting for SARS-CoV-2 is not recommended during the 90 days post lab-confirmed diagnosis (unless symptomatic), records must be available to review the ship's tracking of the 90-day timeframe for crew who have tested positive prior to these crew resuming routine laboratory testing.
  - Records relating to the isolation of persons positive for SARS-CoV-2 and the quarantine of close contacts. These
    include dates of isolation and quarantine, originally assigned cabin numbers, cabin numbers for isolation and
    quarantine, medical records, and sign and symptom logs.
  - Records relating to the contact tracing of any identified close contacts.
  - All medical records must be maintained for at least 90-days and must be made available to CDC upon request for review.

#### Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as a best practice should:

• Consider the use of wearable recording technology, e.g. proximity bands, to rapidly identify close contacts if contact tracing is necessary.

### **Medical Centers**

Medical centers on cruise ships can vary widely depending on ship size, itinerary, length of cruise, and passenger demographics.

#### Requirements

#### 

- Healthcare personnel must adhere to Standard and Transmission-based Precautions when caring for patients with suspected or confirmed SARS-CoV-2 infection. Recommended PPE is described in the Infection Control Guidance.
- Maintain adequate supplies of antipyretics (e.g., acetaminophen and ibuprofen), antivirals and other therapeutics for COVID-19 🖸, if commercially available, other antimicrobial medications, oral and intravenous steroids, and supplemental oxygen. Information to estimate needed medical staffing and equipment can be found in the Federal Healthcare Resilience Task Force Alternate Care Site Toolkit 🔼 [PDF 227 pages] 🖸, Supplement 2.
- As treatment and testing become more available in the United States, cruise ships must align with the latest CDC recommendations.
- Healthcare personnel must stay up to date on COVID-19 training and Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19).

# Laboratory

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure that a CDC-approved onboard testing instrument is properly installed, and the CDC-approved assay is being used.
- Designate a laboratory point of contact (POC) responsible for managing quality assurance and quality control and decision-making.
- Ensure test results are traceable from specimen collection through reporting to the individual, including all supporting materials, records, and equipment.
- Follow assay storage and handling guidance found in the assay's FDA EUA Instructions for Use 🔼 (IFU) document.
- Develop and maintain a **testing manual** to be followed on each applicable ship for the testing instrument and assay. The testing manual must be made available to CDC inspectors upon request for review.
  - The testing manual must include the following content:
    - CDC's Nasopharyngeal Specimen Collection Infographic 🔼 [PDF 2 pages]
    - Specimen collection, storage, and handling procedures, including documentation and labeling of specimens
    - Instructions for Use (IFU) for the CDC-approved onboard testing instrument
    - Reporting procedures for results, including how results are reported and who receives test results
    - Equipment manual provided by the manufacturer
    - Procedure for daily documentation of testing location & reagent storage area temperatures
- Maintain the following records as part of the testing manual or in a separate document accessible to CDC inspectors:
  - o Personnel training records for specimen collection, labeling, storage, testing, and reporting
  - Documentation that all onboard medical personnel involved with specimen collection and laboratory testing have completed "Ready? Set? Test! Checklist 🔼 [PDF 4 pages]" (regulatory sections do not apply)
  - o Documentation that all onboard medical personnel involved with specimen collection and laboratory testing have completed competency testing ▶ [PDF 11 pages] ☑ .
  - Documentation that all onboard medical personnel have read and reviewed:
    - Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a
      Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and
      Recommendations for Promoting Quality Testing
    - "To Test or Not to Test? Considerations for Waived Testing" <a>▶</a> [PDF 60 pages]
    - 📱 "Ready? Set? Test! Patient Testing Is Important. Get the right results." 🔼 [PDF 56 pages]
  - Preventative equipment maintenance records as specified by the manufacturer and quality assurance as described in the "Ready? Set? Test! Checklist [PDF 4 pages]"
  - Daily documentation of the testing & reagent storage area temperatures

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- Documentation of corrective action if any quality assurance failures occur
- Documentation of testing, including equipment logs, maintenance records, quality control documents, and test results
- Display instructions, infographics, and similar material in close vicinity to where the CDC-approved onboard testing instrument is used and in clear view of the medical personnel using the instrument. The following posters must be displayed near the onboard testing instrument:
  - Specimen collection instructions <a> [PDF 2 pages]</a>
  - "Ready Set? Test!" Poster 📙 [PDF 1 page]

# Screening of Embarking Passengers for Restricted Voyages

- Cruise ship operators must screen passengers for signs or symptoms of COVID-19 and screen for a known close contact exposure to a person with COVID-19 within the past 14 days.
  - Passengers with signs or symptoms of COVID-19
    - Deny boarding if not fully vaccinated and without documentation of recovery<sup>2</sup>.
    - May board at operator's discretion if fully vaccinated or with documentation of recovery and embarkation day test is negative by viral test (antigen-negative must be confirmed with NAAT). If an alternate infectious etiology (e.g., influenza, respiratory syncytial virus (RSV), Legionella, Streptococcal pharyngitis) is identified through laboratory testing, routine infection control precautions recommended for the diagnosis should be followed.
  - Passengers who have a known close contact exposure in the past 14 days
    - Deny boarding if not fully vaccinated and without documentation of recovery<sup>2</sup>
    - May board at operator's discretion if:
      - fully vaccinated and asymptomatic
      - with documentation of recovery from COVID-19 and asymptomatic

#### [2] Documentation of recovery from COVID-19 includes the following:

- Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
- A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare
  provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel.
  A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The
  letter does not have to specifically mention travel.

# Testing of Embarking and Disembarking Passengers for Restricted Voyages

Screening Testing of All Embarking and Disembarking Passengers for Restricted Voyages

	Not Fully Vaccinated Passengers	Fully Vaccinated Passengers
Embarkation Day Testing	Viral (NAAT or antigen)	Not Applicable*
Disembarkation Testing ^	Viral (NAAT or antigen)	Not Applicable
Back-to-Back Sailing*Testing	Viral (NAAT or antigen)	Not Applicable

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^ Disembarkation testing is only required for voyages of more than 4 nights.

 ${}^{\mathbf{Y}}$ Back-to-back sailing refers to passengers who stay on board for two or more voyages.

- Cruise ship operators must collect specimens for SARS-CoV-2 viral testing<sup>3</sup> as follows, unless passengers are fully vaccinated or have documentation of recovery in the past 90 days:
  - All<sup>4</sup> newly embarking passengers on the day of embarkation.
  - All<sup>4</sup> disembarking passengers if the voyage is more than 4 nights. Specimens may be collected up to 24-hours prior to disembarkation but results must be available prior to disembarking.
  - All<sup>4</sup> passengers on back-to-back sailings prior to the ship sailing on the next voyage.
- CDC may oversee the collection of passenger specimens through remote means allowing for visual observation.
- Cruise ship operators must immediately transport the specimens to the testing equipment location. Locations may
  include a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, onboard laboratory, pier-side
  equipment, or an offsite area.
- Passengers who receive a positive viral test result for SARS-CoV-2 prior to embarkation, and any of their close
  contacts who are not fully vaccinated, must be denied boarding. Cruise ship operators may use confirmatory NAAT
  testing for a positive antigen screening test following CDC's Interim Guidance for Antigen Testing for SARS-CoV-2.
- Cruise ship operators must follow their Phase 2A port agreements to ensure all travelers identified through embarkation and disembarkation day testing as positive for SARS-CoV-2 are appropriately managed.
- Cruise ship operators must report all laboratory results in aggregate to CDC through the Enhanced Data Collection (EDC) form.
  - To ensure the integrity of testing, persons with positive NAAT results must not be retested, and the original positive results must be reported. Subsequent negative results do not negate an initial positive result.
  - Confirmatory testing for a positive antigen screening test should take place as soon as possible after the antigen test, and not longer than 48 hours after the initial antigen testing. If more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a NAAT should be considered a separate test not a confirmation of the earlier test.

[3] Viral tests for SARS-CoV-2 include nucleic acid amplification tests (NAAT) and antigen tests. Examples of NAAT include but are not restricted to reverse transcription polymerase chain reaction (RT-PCR), reverse transcription loop-mediated isothermal amplification (RT-LAMP), transcription-mediated amplification (TMA), nicking enzyme amplification reaction (NEAR), helicase-dependent amplification (HDA). Tests used must be cleared or authorized for emergency use by the U.S. Food and Drug Administration (FDA).

[4] CDC considers all positive viral test results as new cases, unless laboratory documentation of a previous SARS-CoV-2 by viral test result within the previous 90-days is provided, and the individual is asymptomatic. Cruise ship operators may use confirmatory NAAT testing for a positive antigen screening test following Interim Guidance for Antigen Testing for SARS-CoV-2. Cruise ship operators must have a protocol for evaluating documentation of recovery, including reviewing previous laboratory results.

- Medical personnel should document all positive SARS-COV-2 test results (pre-embarkation, throughout the
  passenger's voyage, and post-disembarkation) in the ships' medical records. These medical records must be made
  available for CDC inspection upon request.
- Passengers who test positive for SARS-COV-2 should not be re-tested (e.g., as part of a contact investigation) until 90-days post lab-confirmed diagnosis, unless they are symptomatic. Symptomatic passengers must be isolated and re-evaluated, including retesting for SARS-CoV-2. If an alternate infectious etiology (e.g., influenza, respiratory syncytial virus (RSV), Legionella, Streptococcal pharyngitis) is identified through laboratory testing, routine infection control precautions recommended for the diagnosis should be followed.

# CAFEST Selection Mand Specifications for Passenger Serening 25 of 34 Testing on Restricted Voyages

- When choosing a testing method, cruise ship operators should consider the differences in sensitivity between NAAT
  and antigen tests. At this time, CDC prefers NAAT for use on cruise ships because it is less likely to miss cases of
  SARS-CoV-2 infection (i.e., higher sensitivity) when compared to antigen testing.
- Cruise ship operators, at their discretion, may contact CDC at eocevent349@cdc.gov prior to procuring antigen test
  systems to ensure the selected test meets the specifications listed below. Include "Screening Testing for Passengers
   [SHIP NAME]" in the subject line.
- Tests must be performed as authorized under their Emergency Use Authorization (EUA) and described in the manufacturer's instructions for use (IFU). Any specimen type and source specified in the IFU may be used and must be collected by, or under the supervision of, a health care professional.
  - Refer to the U.S. Food and Drug Administration (FDA) website for a list of the SARS-CoV-2 point-of-care and rapid tests that have received Emergency Use Authorization (EUA) 🖸 .
    - Tests that have been authorized for use in a point-of-care setting will have a W, for Waived, in the Authorized Settings column of the FDA table.
    - The laboratory or testing site must use a test authorized for point-of-care use by the FDA and must follow the manufacturer's instructions for each test.
- Viral test (including NAAT and antigen tests) systems must be:
  - CLIA-waived by FDA;
  - Allow for specimen-to-test system transfer in a way that minimizes the risk of contamination.
- For antigen testing, cruise ship operators should follow CDC's Interim Guidance for Antigen Testing for SARS-CoV-2.
- Shoreside testing must be conducted by a CLIA-certified laboratory using a viral test (i.e., NAAT or antigen).
- For NAAT, the test must have been cleared or authorized for emergency use by FDA and evaluated on the FDA reference panel ☐ for SARS-CoV-2 with a limit of detection (LOD) value ≤18,000 NDU/ml.<sup>5</sup>
- Self-tests are not accepted at this time.
- Screening testing staff must be trained and competent in specimen collection, be able to properly use testing equipment, follow all manufacturer's instructions, and have access to and use recommended personal protective equipment (PPE) for specimen collection, handling, and testing.
  - CDC may ensure competency by conducting oversight of these practices through remote, visual observation.
  - Cruise ship operators must maintain onboard SARS-CoV-2 testing equipment to manufacturer's specifications.
- The SARS-CoV-2 virus has developed mutations with the potential to negatively impact the performance of tests for its detection.
  - The FDA webpage on Molecular Tests Impacted by SARS-CoV-2 Mutations provides information regarding the potential impact of viral mutations on COVID-19 tests.
  - CDC will continue to assess the information provided by the FDA, public health authorities, and the test manufacturer to determine which tests should remain in use or be approved for future use.

[5] NDU=RNA NAAT detectable unit; CDC's laboratory 2019-nCOV RT-PCR diagnostic panel was used to define the LOD cut-off value. A high LOD indicates that the assay has a lower sensitivity which may result in more false negative results, especially in asymptomatic infected people. A lower LOD represents an assay's ability to detect a smaller amount of viral material in a given sample, signaling a more sensitive test.

# Onboard COVID-19 Testing for Symptomatic Passengers and their Close Contacts

Cruise ship operators must follow requirements as outlined in CDC's https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html for onboard COVID-19 testing for symptomatic travelers (crew and passengers) and close contacts.

### Can fection Prevention in the country of the countr

Infection prevention and control (IPC) is key to reducing the spread of SARS-CoV-2. Procedures and records associated with IPC implementation will be evaluated during inspections. Each cruise ship must maintain a written **Infection Prevention and Control Plan (IPCP)** that details standard procedures and policies to specifically address infection control and cleaning/disinfection procedures to reduce the spread of COVID-19.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must include the following as part of a written IPCP:

- Duties and responsibilities of each department and their staff for all passenger and crew public areas.
- Steps in IPC management and control and the triggers required for action at each step. At a minimum, triggers must address a graduated approach to IPC management in response to increasing case counts.
- Disinfectant products or systems used, including the surfaces or items the disinfectants will be applied to, concentrations, and required contact times. Use disinfectant products or systems that are listed on the Environmental Protection Agency (EPA) List N: Disinfectants for Coronavirus (COVID-19)
- Procedures for informing passengers and crew members that a threshold of COVID-19 has been met or exceeded.
   This section must address the procedures for notification of passengers and crew currently onboard the ship and those embarking the vessel on the subsequent voyage.
- Graduated procedures for returning the vessel to normal operating conditions after a threshold of COVID-19 has been met or exceeded, including de-escalation of cleaning and disinfection protocols.
- Procedures to protect passengers and crew from exposure to disinfectants, if not already included in the ship's safety management system. At a minimum, this must include the following:
  - Safety data sheets (SDSs)
  - PPE per CDC guidance for crew
  - Health and safety procedures to minimize respiratory and dermal exposures to both passengers and crew
- Procedures to align with the preventive measures based on the color-coding status outlined in CSO Technical Instructions.

### Mask Use

At this time, all persons, including port personnel, crew, and passengers are advised that CDC's Mask Order remains in effect and requires the wearing of masks on conveyances entering, traveling within, or leaving the United States, and in U.S. transportation hubs. (see Maritime-specific Frequently Asked Questions).

- While the Order permits temporarily removing a mask for brief periods of time while eating or drinking, removal of the mask for extended meal service or beverage consumption would constitute a violation of this Order.
- Cruise ship operators, at their discretion, may advise all passengers and crew that they do not have to wear a mask if outdoors. CDC still recommends that people wear a mask if they are not fully vaccinated and in a crowded area.
- Masks do not have to be worn while inside one's own cabin.
- Travelers should not wear a mask when doing activities that may get the mask wet, like swimming at the beach or in recreational water facilities. A wet mask can make it difficult to breathe and may not work as well when wet. This means it is particularly important for bathers to maintain physical distancing of at least 6 feet (2 meters) when in the water with others who are not traveling companions or part of the same family.

#### **Fully Vaccinated Travelers**

- Cruise ship operators, at their discretion, may advise passengers and crew that—if they are fully vaccinated—they
  may gather or conduct activities outdoors, including engaging in extended meal service or beverage consumption,
  without wearing a mask.
- Cruise ship operators, at their discretion, may advise crew who are fully vaccinated that they do not have to wear a mask or maintain physical distance in areas of the ship that are inaccessible to passengers.

- Case 红虫e wip 224 92 KMWeir Discretine may desi 配 The person 中心 34 crew where masks and physical distancing are not required (e.g., casinos; bars; spas; entertainment venues; and dining areas, including self-serve buffets).
  - For ships with at least 95% of crew and 95% of passengers fully vaccinated, cruise ship operators, at their discretion, may advise passengers and crew that they do not have to wear a mask or maintain physical distance in any areas.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Provide passengers and crew with information on how to properly wear, take off, and clean (if reusable) masks.
- Remind passengers and crew not to touch their masks when wearing them.
- Position posters educating passengers on how to properly wear masks in high traffic areas throughout the ship.

# Physical Distancing

Strict adherence to passenger and crew testing protocols will aid in identifying potential cases of COVID-19 on board a cruise ship, however, continued prevention efforts are necessary to reduce the possibility of transmission to others if a case occurs on board the ship.

Cruise ship operators, at their discretion, may designate areas only accessible to fully vaccinated passengers and crew where masks and physical distancing are not required (e.g., casinos; bars; spas; entertainment venues; and dining areas, including self-serve buffets).

For ships with at least 95% of crew and 95% of passengers fully vaccinated, the following requirements are recommendations only.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Implement physical distancing protocols to provide at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and crowd reduction measures in all congregate and high traffic areas of the vessel.
  - Dining (also see Food Services section below)
    - Change restaurant and bar layouts to ensure that all parties remain at least 6 feet (2 meters) apart (e.g., removing tables/stools/chairs, marking tables/stools/chairs that are not for use)
  - Elevators and Stairwells
    - Limit capacity, provide floor markings, and provide marked queuing areas to eliminate congregation
    - Use floor markings in elevator lobbies and near the entrance to escalators to reinforce physical distancing of at least 6 feet (2 meters). Place decals inside the elevator to identify where passengers should stand, if needed.
    - Post signs reminding occupants to minimize surface touching. They should use an object (such as a pen cap) or their knuckle to push elevator buttons.

#### Entertainment Venues and Activities

- Limit capacity in areas with performances, dancing, acting, and singing, and similar activities.
- Provide physical distancing between seating areas, such as by blocking out seats to allow individuals to remain at least 6 feet (2 meters) apart.
- Limit capacity in areas with activities such as rock-climbing walls, zip-lines, mini golf, sports courts, jogging, skating, arcade rooms, and similar activities.

#### Casinos

- Block out seats and gaming equipment to allow individuals to remain at least 6 feet (2 meters) apart
- Limit customers' sharing of objects (e.g., items used in table games, dice) when possible, and clean and disinfect these objects between uses as much as possible
- Set up physical barriers where it is difficult for individuals to remain at least 6 feet (2 meters) apart

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 Provide physical distancing of at least 6 feet (2 meters) between equipment, such as by blocking out or removing equipment

#### Public Toilet Rooms

- Ensure handwashing facilities are well-stocked with soap and a method to dry hands, such as paper towels or air dryers, in accordance with the 2018 VSP Operations Manual.
- Add physical barriers, such as plastic flexible screens, between toilet room sinks, stalls, and urinals, especially when they cannot be at least 6 feet (2 meters) apart.
- Ensure that people standing in line can maintain a 6-foot (2-meter) distance from one another. Post signs or markers to help attendees maintain the appropriate physical distance of at least 6 feet (2 meters).
- Clean public toilet rooms regularly using products from the EPA List N: Disinfectants for Coronavirus (COVID-19) 

  , at least twice per day (e.g., in the morning and evening or after times of heavy use).
- Provide information on how to wash hands properly. Hang signs <a>[PDF 1 page]</a> in toilet rooms.

#### Gangways

Provide physical guides, such as floor markings and signage, to instruct passengers to maintain a 6-foot (2-meter) distance from one another

#### Recreational Water Facilities (RWFs)

- Reduce the bather load for each facility to meet physical distancing. When physical distancing of at least 6 feet (2 meters) between bathers is not possible, such as in small whirlpool spas, RWFs should be used by the same family or traveling companions only. This can be accomplished by close monitoring. Exceptions to physical distancing are permitted when necessary to:
  - Rescue a distressed swimmer, perform cardiopulmonary resuscitation (CPR), or provide first aid; or
  - Evacuate the water or pool deck due to an emergency.
- Place seating area items located in or around RWFs, such as tables, chairs, loungers, sun beds, and poufs, 6 feet (2 meters) apart from each other to adhere to physical distancing. These items can be grouped together for families and traveling companions.
- Follow the physical distancing protocols of 6 feet (2 meters) for lines to use slides and other interactive RWF areas.
- Access Points (such as dining room entrances, guest services, disembarkation points)
  - Ensure that crew and passengers maintain 6 feet (2 meters) of physical distance while waiting for access.

#### Signs and Messages

Post signs, in highly visible locations (such as at entrances and in toilet rooms), to promote steps that
prevent the spread of the virus (such as practicing physical distancing of at least 6 feet (2 meters), and
properly wearing a cloth mask).

#### Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider the use of wearable proximity alerting technology, e.g. proximity bands, to alert the wearer of physical distancing infractions to assist with maintaining physical distancing protocols.
- Implement additional physical distancing protocols to provide at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and crowd reduction measures.
  - Elevators and Stairwells
    - Encourage occupants to take stairs when possible, especially when elevator lobbies are crowded or when only going a few flights.
    - Where feasible, designate certain stairwells or sides of stairwells as "up" and "down" to better promote physical distancing of at least 6 feet (2 meters).
    - Use stanchions (for lobbies only; not inside elevators) or other ways to mark pathways to help people travel in one direction and stay 6 feet (2 meters)
    - Consider limiting the number of people in an elevator.
    - Encourage escalator and elevator passengers to wash their hands and avoid touching their face after holding on to handrails or touching buttons.
    - Consider adding supplemental air ventilation or local air treatment devices in frequently used elevator cars.

- Limit to reservation only time slots or limit capacity.
- Public Hand Washing Facilities
  - Make sure waste receptacles are emptied regularly.
- Muster Drills
  - Conducted virtually or in a staggered manner to allow physical distancing of at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family.
- Signs and Messages
  - Provide announcements on preventing the spread of the virus in manner that is accessible to all passengers.

## **HVAC Systems**

When indoors, ventilation mitigation strategies can help reduce viral particle concentration. The lower the concentration, the less likely viral particles can be inhaled into the lungs (potentially lowering the inhaled dose); contact eyes, nose, and mouth; or fall out of the air to accumulate on surfaces. Protective ventilation practices and interventions can reduce the airborne concentrations and reduce the overall viral dose to occupants.

Heating, Ventilation, and Air Conditioning (HVAC) preventive measures should be implemented to minimize the possibility of dispersing the COVID-19 virus through the air. A layered approach should be applied using more than one preventive measure.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure ventilation systems operate properly for the occupancy level for each space.
  - Make sure air filters are properly sized and within their recommended service life.
  - Inspect filter housing and racks to ensure appropriate filter fit and minimize air that flows around, instead of through, the filter.
- Ensure toilet room exhaust fans are functional and operating at full capacity.
- Ensure sufficient negative air pressure in medical centers, and predetermined isolation and quarantine cabins.

#### Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider closing exclusively indoor RWFs, due to ventilation concerns.
- Increase the introduction of outdoor air:
  - o Open outdoor air dampers beyond minimum settings to reduce or eliminate HVAC air recirculation.
  - Open windows and doors, when weather conditions allow, to increase outdoor air flow. Do not open windows and doors if doing so poses a safety or health risk.
- Use fans to increase the effectiveness of open windows:
  - Avoid placing fans in a way that could potentially cause contaminated air to flow directly from one person to another.
- Rebalance or adjust HVAC systems to increase total airflow to occupied spaces when possible.
- Turn off any demand-controlled ventilation (DCV) controls that reduce air supply based on occupancy or temperature during occupied hours.
- Improve central air filtration:
  - Increase air filtration 🖸 to as high as possible without significantly reducing design airflow. Increased filtration efficiency is especially helpful when enhanced outdoor air delivery options are limited.
    - Filters with a higher number of Minimum Efficiency Reporting Value (MERV) have higher efficiency and ability to capture particles from the air. High-Efficiency Particulate Air (HEPA) filters can achieve at least 99.97% removal of viral particles in the air.

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Consider using ultraviolet germicidal irradiation (UVGI) as a supplemental treatment to inactivate SARS-CoV-2, especially if options for increasing room ventilation and filtration are limited. Upper-room UVGI systems
 [PDF – 87 pages] can be used to provide air cleaning within occupied spaces, and in-duct UVGI systems can help enhance air cleaning of recirculated air inside central ventilation systems.

### **Food Services**

Passenger interactive experiences include, but are not limited, to interactive cooking, culinary workshops and demonstrations, mixology/blending classes, and galley and other "behind the scene" tours.

Cruise ship operators, at their discretion, may designate areas as only accessible to fully vaccinated passengers and crew where masks and physical distancing are not required (e.g., casinos; bars; spas; entertainment venues; and dining areas, including self-serve buffets).

For ships with at least 95% of crew and 95% of passengers fully vaccinated, the following requirements are recommendations <u>only</u>,

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Change restaurant and bar layouts to ensure that all customer parties remain at least 6 feet (2 meters) apart (such as removing tables, stools, and chairs or marking any that are not for use).
- Limit seating capacity to allow for physical distancing of at least 6 feet (2 meters).
- Discourage crowded waiting areas by using phone app, text technology, or signs to alert patrons when their table is ready. Avoid using "buzzers" or other shared objects.
- Eliminate self-service food and drink options, such as self-service buffets, salad bars, and beverage stations.
- Provide eating utensils in a way that prevents handling by more than one person.
- Install physical barriers, such as sneeze guards and partitions in areas where it is difficult for individuals to maintain proper physical distance of at least 6 feet (2 meters), such as serving stations and food pick up areas.
- Provide physical guides, such as tape on decks and signage, to remind individuals to maintain physical distance of at least 6 feet (2 meters) where food and beverages are served.
- Provide and encourage outdoor dining and bar/beverage service options.
- Provide and encourage in-room passenger dining service.
- Limit any sharing of food, tools, equipment, or supplies by food workers, to the extent practicable.
- Ensure adequate supplies to minimize sharing of high-touch materials (e.g., serving spoons) to the extent practicable; otherwise, limit use of supplies and equipment by one group of food workers at a time and clean and disinfect between use.
- Avoid using or sharing of items that are reusable, such as menus, condiments, and any other food containers.
   Instead, use disposable menus, digital menus that can be disinfected between each use, online menus that can be retrieved on diners' personal cell phones, single serving condiments, and no-touch trash cans and doors.

#### Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider options for consumers to order ahead of time to limit the amount of time spent in the restaurant.
- Provide alternative meal services options, such as prepackaged grab-and-go meals, for consumption on open decks
  or in individual cabins to minimize risks associated with congregate indoor dining.
- Use touchless payment options as much as possible, if available. If pens are needed for some purposes, disinfect between uses and/or encourage customers to use their own pens.

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Numerous researchers have studied how long SARS-CoV-2 can survive on a variety of porous and non-porous surfaces. On porous surfaces, studies report inability to detect viable virus within minutes to hours; on non-porous surfaces, viable virus can be detected for days to weeks.

Cleaning of visibly dirty surfaces followed by disinfection helps prevent COVID-19 transmission. Cleaning with products containing soap or detergent reduces germs on surfaces by removing contaminants and may also weaken or damage some of the virus particles, which decreases risk of infection from surfaces. Disinfecting (using EPA's List N 🖸 ) kills any remaining germs on surfaces, which further reduces any risk of spreading infection.

Additional information on cleaning and disinfecting on cruise ships can be found on CDC's Interim Guidance for Ships on Managing Suspected Coronavirus Disease 2019 and Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Prioritize cleaning and disinfecting high-touch surfaces. Examples of high-touch surfaces include, but are not limited to: pens, counters, shopping carts, tables, doorknobs, light switches, handles, stair rails, elevator buttons, desks, keyboards, phones, toilets, faucets, and sinks.
- Use disinfectant products from the EPA List N 🖸 that are effective against COVID-19. Check that the EPA Registration number 🖸 on the product matches the registration number in the List N search tool. See Tips on using the List N Tool 🖸 .
  - If products on EPA List N 🖸 : Disinfectants for Coronavirus (COVID-19) are not available, bleach solutions can be used if appropriate for the surface.
- For RWFs: Clean and disinfect frequently touched surfaces multiple times a day, and shared objects before and after
  each time they are used. For example: handrails, slides, and structures for climbing or playing; lounge chairs,
  tabletops, pool noodles, and kickboards; and door handles and surfaces of toilet rooms, handwashing stations,
  diaper-changing stations, and showers. (Considerations for Public Pools, Hot Tubs, and Water Playgrounds During
  COVID-19)

# Shore Excursions & Transportation Services

Participating in shore excursions and group transportation increases a person's risk of getting and spreading COVID-19 by bringing people in close contact with others, often for prolonged periods. Additionally, participating in these activities in other communities and countries with high prevalence of COVID-19 further increases the risk of introduction of COVID-19 onto cruise ships.

#### **Fully Vaccinated Travelers**

• Cruise ship operators, at their discretion, may advise passengers and crew that—if they are fully vaccinated—they may engage in self-guided or independent exploration during port stops. The cruise ship operator is additionally advised that foreign jurisdictions may have their own requirements.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- For travelers who are not fully vaccinated, ensure all shore excursion tour companies facilitate physical distancing to allow for at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family; and adhere to mask wearing, cleaning and disinfection, and other COVID-19 public health measures throughout the tour.
- For travelers who are not fully vaccinated, restrict passenger and crew attendance so that proper physical distancing of at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family.

To further reduce the spread of SARS-CoV-2, cruise ship operators as a best practice should:

- Consider prohibiting self-guided or independent exploration during port stops by passengers and crew who are not fully vaccinated.
- Consider offering supervised shore excursions during port stops for passengers and crew who are not fully vaccinated where all participants wear a mask and maintain physical distance. The cruise ship operator is additionally advised that foreign jurisdictions may have their own requirements.
- Limit shore excursions in foreign ports of call to countries listed as Level 1: COVID-19 Low in CDC's COVID-19 Travel Recommendations by Destination.

# Embarkation/Disembarkation Procedures

Embarkation and disembarkation places large numbers of people in close proximity—including passengers, crew, and port personnel—in indoor and sometimes small, enclosed spaces (e.g., gangways, corridors, waiting areas). This close proximity can increase the risk of introduction and transmission of COVID-19 onto cruise ships and into communities.

#### Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure embarkation and disembarkation procedures follow the processes outlined in their Phase 2A port agreements.
- Ensure there is a private screening area for people identified as needing additional medical screening during the embarkation and check-in process.

#### Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Stagger or schedule embarkation/disembarkation times.
- Provide touchless check-in/check-out processes.
- Install signage and floor marking reminders and predetermined and spatially identified queue areas inside port terminals and onboard ships for passengers who are embarking and disembarking.
- Ensure written notifications about COVID-19 prevention and control are presented before passengers reach the check-in point to give them enough time to review prior to check-in.
- Use touchless garbage cans or pails and cashless payment options when possible. Otherwise, exchange cash or card by placing payment in a receipt tray, if available, or on the counter.
- Make alcohol-based hand sanitizer available to passengers, crew, and port personnel in these areas.

Page last reviewed: May 26, 2021

# Exhibit 4



#### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Centers for Disease Control and Prevention

July 9, 2021

Frank Del Rio Chief Executive Officer Norwegian Cruise Line Holdings

# RE: ACCEPTANCE OF PORT AGREEMENTS & APPROVAL OF COVID-19 CONDITIONAL SAILING CERTIFICATE

Dear Mr. Del Rio,

Congratulations! This letter constitutes CDC's approval of your application for a COVID-19 Conditional Sailing Certificate for the *Norwegian Gem* pursuant to the Framework for Conditional Sailing Order (CSO). This letter also constitutes CDC's acceptance of your Phase 2A Port Agreements for the *Norwegian Gem*.

You are reminded to follow CDC's requirements related to testing and quarantine of crew and passengers.

Please notify CDC by email at <u>eocevent349@cdc.gov</u> if the date of initial restricted voyage or itinerary should change.

We commend your company's efforts to provide a safer and healthier sailing environment for your passengers and crew and look forward to our continued partnership.

Sincerely,

CAPT Aimee Treffiletti, USPHS

Maritime Unit

Global Migration Task Force