

Request for Approval to Conduct a Simulated Voyage Prior to Issuance of COVID-19 Conditional Sailing Certificate



Instructions

A cruise ship operator must request CDC's approval to conduct a simulated voyage at least 30 calendar days prior to the proposed simulation.* The request for approval must specify the dates and locations of the proposed simulation and describe the protocols or practices to be simulated. The cruise ship operator must also identify and provide contact information for one or more persons who will be overseeing and implementing the proposed simulation. This must include at least one point of contact who will be physically present on the ship during the entire simulated voyage.

A cruise ship operator must meet all of CDC's requirements relating to the protection of crew onboard ships in U.S. waters before applying for approval to conduct a simulated voyage. The cruise ship operator's responsible officials must sign this application and certify under 18 U.S.C. § 1001 that these crew protection requirements have been met.

CDC will respond to this request in a timely manner. CDC may deny the request to conduct a simulation 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 simulation 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.

In lieu of conducting a simulated voyage, a cruise ship operator's 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.

* 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.

Cruise Ship Operator and Ship Information

Name of Cruise Ship Operator:

Name of Cruise Ship:

Name and Contact Information for Third-Party Auditor (if any):

Proposed Simulated Voyage

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Proposed dates of simulated voyage:
Proposed port of embarkation/debarkation:
Identify and provide contact information for one or more persons who will be overseeing and implementing the proposed simulation. This must include at least one point of contact who will be physically present on the ship during the entire simulated voyage: <i>(attached additional sheets as needed)</i>
Protocols or practices to be simulated: <i>(attached additional sheets as needed)</i>

Responsible Officials Information

The Chief Executive Officer (or equivalent), Chief Compliance Officer (or equivalent), and the highest-ranking Medical Officer, of the cruise ship's operating company and all parent companies must provide their contact information and signatures below.

Operating Company

Chief Executive Officer (or Equivalent) of Operating Company

Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email address:	
Address:		

Chief Compliance Officer (or Equivalent) of Operating Company

Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email address:	

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Address:		
Highest-Ranking Medical Officer of Operating Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:		Email address:
Address:		
Parent Company		
Chief Executive Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:		Email address:
Address:		
Chief Compliance Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:		Email address:
Address:		
Highest-Ranking Medical Officer of Parent Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:		Email address:
Address:		
Requirements for the Protection of Crew in U.S. Waters		
1.		I 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 have been satisfied.
2.		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

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		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. Please contact the Maritime Unit if this pertains to a ship that was not previously operating in U.S. waters during the period of the No Sail Order.
3.		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.
4.		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.
5.		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.
6.		If the cruise ship received any ship-to-ship transfers in the last 14 days, crew were only transferred from a cruise ship with no confirmed COVID-19 or COVID-like illness during the 14 days before the transfer occurred.
7.		If the cruise ship received any land-based embarking crew, such crew were laboratory tested for SARS-CoV-2 upon embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.

Requirements Relating to Phase 2A Agreements

		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 specifically includes the name of the cruise ship that will be conducting the simulation and meets the standards of the CSO and CDC’s technical instructions for Phase 2A of CDC’s CSO. The written agreement includes a:
8.		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;
		b) 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
		c) 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.

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Requirements Relating to Volunteer Passengers		
9.		The minimum number of required volunteer passengers for each simulated voyage will be at least 10% of the maximum number of passengers permitted onboard for restricted voyages as per the terms of the cruise ship operator's Phase 2A agreement with U.S. port and local health authorities.
10.		The cruise ship operator will advise volunteer passengers of CDC's Travel Health Notice for COVID-19 and Cruise Ship Travel 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.
11.		All volunteer passengers will 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 is attached.
12.		All volunteer passengers will 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.
13.		The cruise ship operator will ensure all volunteer passengers have either:
		<ul style="list-style-type: none"> a) 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 b) 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.
14.		The simulation will 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 will document this signed informed consent for each participant in writing, either on paper or electronically. The cruise ship operator will 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.
15.		All volunteer passengers will be evaluated for signs and symptoms of COVID-19 prior to embarkation and disembarkation. Cruise ship operators will 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.
16.		All volunteer passengers will agree in writing to post-disembarkation specimen collection for COVID-19 testing at 3 to 5 days after completion of the simulated voyage. Cruise ship operators are advised that as a condition of receiving a COVID-19 Conditional Sailing Certificate, at least 75% of all volunteer passengers will need to 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

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		75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
17.		To facilitate contact tracing, the cruise ship operator will 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 will 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		
18.		At least one simulation will be conducted for each ship for which the cruise ship operator intends to commence restricted passenger voyages. The simulation(s) will occur prior to the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate under the CSO.
19.		The cruise ship's color-coding status will 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 will 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 will notify CDC of the revised dates of the simulation.
20.		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) will include each U.S. port.
21.		The cruise ship operator will maintain a list of all passengers, crew, port personnel, and other persons who participated in the simulated voyage. This list will be preserved and made available to CDC upon request at any time while the CSO remains in effect.
22.		Simulated voyages will be between 2-7 days in length with a least one overnight stay 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.
23.		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 will 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.
24.		The cruise ship operator will 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.
25.		The cruise ship operator will modify meal service and entertainment venues to facilitate social distancing during the simulated voyage.
26.		The following activities will 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:

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		a) 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.
		b) Onboard activities, including seating and meal service at dining and entertainment venues.
		c) Medical evacuation procedures,
		d) Transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms.
		e) 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.
		f) 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.
27.		g) Private-island shore excursions if any are planned during restricted passenger voyages. The following measures will be observed on the private island: <ul style="list-style-type: none"> i. Only one ship can port at the island at any one time. ii. A routine screening testing protocol will be implemented for island staff who are expected to interact with volunteer passengers or crew. iii. Mask use and social distancing will be observed on the island.
28.		h) Port of call shore excursions if any are planned during restricted passenger voyages. The following measures will be observed on port of call shore excursions: <ul style="list-style-type: none"> i. Self-guided or independent exploration by passengers during port stops will be prohibited. ii. Shore excursions will only include passengers and crew from the same ship. iii. Cruise ship operator will ensure all shore excursion tour companies facilitate social distancing, mask wearing, and other COVID-19 public health measures throughout the tour. iv. Cruise ship operators will have a protocol for managing persons with COVID-19 and close contacts at all foreign ports of call. At a minimum, the protocol will include the following: <ul style="list-style-type: none"> - 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 foreign-based persons with COVID-19 and close contacts, cruise ship operators will consult with all relevant public health authorities.
Requirements Relating to Laboratory Testing		
29.		Day of Embarkation Testing: The cruise ship operator will conduct laboratory testing of all passengers, without documentation of recovery from COVID-19 (as defined below), on the day of embarkation with same day results using one of the following testing instruments and processes: <i>(please check which testing option(s) you will use during the simulated voyage)</i>

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		a) Previously approved Phase 1 shoreside laboratory, or
		b) Previously approved Phase 1 onboard point-of-care equipment, or
		c) Other testing instruments and processes approved by CDC <ul style="list-style-type: none"> i. Prior to collecting specimens and conducting testing: Cruise ship operators will contact CDC at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens. Include “Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]” in the subject line as part of your request for CDC approval. ii. 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.
30.		Day of Disembarkation Testing: The cruise ship operator will conduct laboratory testing of all passengers and any disembarking crew on the day of disembarkation with same day results using one of the following testing instruments and processes: <i>(please mark which testing option(s) you will use during the simulated voyage)</i>
		a) Previously approved Phase 1 shoreside laboratory, or
		b) Previously approved Phase 1 onboard point-of-care equipment, or
		c) Other testing instruments and processes approved by CDC <ul style="list-style-type: none"> i. 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. Include “Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]” in the subject line as part of your request for CDC approval. ii. 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.
31.		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. <ul style="list-style-type: none"> • As a condition of receiving a COVID-19 Conditional Sailing Certificate, cruise ship operators will need at least 75% of all passengers to provide their post disembarkation specimen to the selected laboratory for COVID-19 testing 3 to 5 days after completion of the simulated voyage for 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.
		<i>Please mark which post-disembarkation testing option(s) you will use during the simulated voyage.</i>
		Option 1: Cruise ship operator will supply all volunteer passengers with a self-collected nasal mid-turbinate nucleic acid amplification test (NAAT) specimen collection kit to be shipped directly to a laboratory. <ul style="list-style-type: none"> • All volunteer passengers must: <ul style="list-style-type: none"> ○ Receive education on self-collection technique.

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		<ul style="list-style-type: none"> ○ 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 $\leq 18,000$ 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.
		<p>Option 2: Cruise ship operator will 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.</p> <ul style="list-style-type: none"> ● 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 $\leq 18,000$ 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.
32.		<p>Cruise ship operators will 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.</p>
33.		<p>Cruise ship operators will 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 will 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.</p>
<p>Requirements Related to the Simulated Voyage After-Action Report (AAR)</p>		
34.		<p>The cruise ship operator will 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.</p>
35.		<p>The cruise ship operator will 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 will need to have at least 75% of all passengers provide their post disembarkation specimen to the selected laboratory for COVID-19 testing. CDC may lower</p>

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		the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
36.		The after-action report will 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.
37.		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.
38.		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.
39.		The after-action report will 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.
40.		The cruise ship operator acknowledges that 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 s 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 will be incorporated into the operator’s after-action report.

Certification and Signatures

I understand and acknowledge that I am submitting this form as part of an application to obtain permission to a simulated passenger voyage in U.S. waters and that the statements contained herein are true and correct to the best of my knowledge and belief.

I acknowledge that any false or misleading statements or omissions may endanger health and safety, including but not limited to the loss of lives and other irreparable harm. Therefore, false or misleading statements or omissions may result in criminal and civil actions for fines, penalties, damages, and imprisonment.

Chief Executive Officer (or Equivalent) of Operating Company

Last name:	First name:	Middle initial:
Signature:		Date:

Chief Compliance Officer (or Equivalent) of Operating Company

Last name:	First name:	Middle initial:
Signature:		Date:

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Highest-Ranking Medical Officer of Operating Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Chief Executive Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Chief Compliance Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Highest-Ranking Medical Officer of Parent Company		
Last name:	First name:	Middle initial:
Signature:		Date:
<i>For official use only:</i>		