

IN THE UNITED STATES DISTRICT
COURT FOR THE MIDDLE DISTRICT OF
FLORIDA TAMPA DIVISION

STATE OF FLORIDA,

Plaintiff,

v.

XAVIER BECERRA, Secretary of
Health and Human Services, in his
official capacity; HEALTH AND
HUMAN SERVICES; ROCHELLE
WALENSKY, Director of Centers for
Disease Control and Prevention, in
her official capacity; CENTERS
FOR DISEASE CONTROL AND
PREVENTION; UNITED STATES
OF AMERICA,

Defendants.

Case No.: 821-cv-00839-SDM-AAS

**MOTION FOR LEAVE TO FILE A SUPPLEMENT BRIEF OF
AMICUS CURIAE**

Marc Young filed a similar request to file an Amicus Curiae Brief in this case on May 3, 2021. Due to some recent development that have made some changes to the original submissions and in response to questions raised by the court at oral arguments at the preliminary injunction hearing on May 12, 2021, movant believes that the information provided could have bearing on the Florida request for injunctions and offers the attached amicus brief in support of both Florida's motion for preliminary and

permanent injunctions.

The motion to file the original amicus brief is still waiting for a ruling on by the Court. While this brief is considerably longer than the normal allowances based on appellate court rules, there are no local or federal rules of civil procedure at the District Court level, with all discretion left to the Court both as to the length and to its submission. The movant is of the belief that the material is important to the consideration of this case and is germane to its rulings and begs the Court's indulgence in its presentation to the Court.

LOCAL RULE 301(g) CERTIFICATION

Marc Young has consulted with counsel for plaintiff and counsel for defendants, The counsel for plaintiff has responded that he takes no position on to the submission. The counsel for the defendants has responded that the defendants oppose with respect to the motion for leave to file a supplemental amicus brief

DATED: May 24, 2021.

MARC S. YOUNG, PE*
PO Box 1693
Sealy, Texas 77474
979-877-0660
713-417-6147
marc.young.pe@gmail.com

Pro Se

*Licensed Chemical Engineer in Texas, Alaska, Arizona and Louisiana

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Defendants.

Case No.: 8:21-cv-00839-SDM-AAS

**SUPPLEMENTAL *AMICUS CURIAE* BRIEF OF MARC S. YOUNG IN
SUPPORT OF FLORIDA'S MOTION FOR PRELIMINARY AND
PERMANENT INJUNCTION(S)**

INTRODUCTION

Marc S. Young, PE a licensed chemical engineer in the State of Texas, Louisiana, Arizona and *Alaska* submits this supplemental *amicus curiae* brief in support of the State of Florida's motion for preliminary and permanent injunctions.¹ Mr. Young

¹ Dkt. 24. While Marc S. Young did not seek to intervene in this action as a plaintiff, Mr. Young may reserve the right refile his past litigation filed against the predecessors of these Defendants in the previous administration. *See* 4:20-cv-2299 In Federal District Court of South Texas, Houston Division.

was present on May 12 for Florida's and the DOJ's oral arguments. He submits this supplemental brief to provide the Court with better context related to his former *amicus curiae* brief and to suggest some answers to questions posed by the court more than once that did not seem to get satisfactory answers from either party. Mr. Young's interests are aligned with Florida's, Alaska's and Texas because a denial of Florida's motion may also inhibit Mr. Young from obtaining relief in time to save his July 2, 2021 fully paid cruise to Alaska and two other cruises prior to November 1, 2021.

STATEMENT OF FACTS: MARC YOUNG'S UNIQUE INTERESTS

A. Marc S. Young original statements

The statements of A. of the original *Amicus Curiae* Brief has changed. Effective 8:20 pm on May 21, Mr. Young has been notified that, even with the passage of the bills in Congress to allow for a direct cruise to Alaska from the U.S. Port in Seattle, bypassing the foreign stop requirements of the Passenger Vessel Services Act of 1886 (46 USC § 55103) until February 2022, his cruise to Alaska on July 2, 2021 has been cancelled. The remaining Statements in B. thru F. are the same and for the sake of brevity will not be repeated for the Court in this supplement.

QUESTIONS UNANSWERED

Questions posed by the Court in the preliminary injunction hearing on May 12, 2021, sometimes multiple times, seemed to remain unanswered. These were:

1. *“Does the CDC have the power or authority to make a NO SAIL ORDER or a CONDITIONAL SAIL ORDER?”*
2. *“Has the CDC ever quarantined a ship for six months, a year or longer and have they ever applied a Quarantine against an entire industry”*
3. *“If the Court were to vacate the Conditional Sail Order what regulations would take its place?”*
4. *“What ‘Local’ regulations would take the place of the CDC mandates?”*
and,
5. *Can the injury to the States, their economy and the obvious decimation of an entire cruise line industry be relieved by a court order vacating the CDC’s order?*

INITIAL RESPONSES

It seemed clear that nobody had a good answer for any of these questions.

The Defendant’s counsel argued, with respect to Question 1, that they had this power already via the NO SAIL provisions in the VSP (Vessel Sanitation Program) that the CDC already administers. Yet does the CDC have such authority under the VSP such that this is a satisfactory answer? The State of Florida’s Counsel did not seem to be able to answer that question at all.

For the Second Question, a series of questions on quarantine, the Defendant’s counsel only had an answer for the third part, trying to claim that somehow the

prohibition on importations of red ear turtles was somehow applicable to this case. The Court quickly saw through this response, replying that this might have been comparable if it had been the entire pet industry.

With respect to the Third Question, as to what regulations would take the CDC Order's place if the court vacated the CDC Order, multiple times the State of Florida seemed to imply things would return to self-regulation by the industry with an adoption by the Industry of the Healthy Sail Panel [HSP] protocols.

With respect to the fourth question, there was no answer as neither the counsel for the defendants, nor the counsel for the State of Florida was able to identify any "local" regulations that had been or would be in place. This was particularly pointed out in discussion on what was insufficient actions on the part of the states in preventing the spread of communicable disease thus allowing the Secretary to use 42 CFR §§70.2 to make their NO SAIL ORDER in the first place. More will be discussed later on the issue of the CDC claiming their rules preempt all local control.

With respect to the Fifth Question the Court is facing a decision that can best be described as a Gordian Knot. CDC has noted that prior to the "No Sail Order" there were significant outbreaks onboard vessels prior to the issuance of the order. It is clear the public, the regulatory and the cruise communities all desire to NOT see a return to the examples the U.S. regulators have documented. Yet the question has to be asked: Was a true cause and effect determined? Was the failure

caused by the cruise industry or was the extensive outbreaks caused by a failure of the regulatory agencies? A failure of the regulatory health agency was clearly the answer to a study commissioned by the New South Wales authorities in Australia with respect to an outbreak on the Ruby Princess.²

ARGUMENTS

Q1: CDC AUTHORITY FOR NO SAIL ORDER/CONDITIONAL SAIL ORDER

Based on the documentation on the CDC website with respect to Ship Sanitation Certificate Information [Exhibit A] the CDC appear to derive their authority for the VSP as “Competent Authority” under the IHR (2005) for US Ports of Entry. It should be noted that the CDC does not require a Ship Sanitation Control Certificate/Ship Sanitation Control Exemption Certificate (“Ship Sanitation Certificates” or SSCC/SSCEC) as of the October 13, 2015, but they reserve the right to inspect vessels. If a cruise ship needs a SSCC or SSCEC they can request one during a VSP Inspection, but it is the CDC VSP inspectors’ option if they have time to do the separate inspection. Because Cargo ships are not inspected under the VSP program, they cannot obtain such sanitation certificates.³

Further the CDC states, “The authority to issue, inspect, and require SSCCs/SSCECs within the United States or its territories resides solely with the

² [Report of the Special Commission of Inquiry into the Ruby Princess, 14 August 2020 ISBN: 978-0-646-82316-4 (online version)].

³ This answers the Court’s query to the Defendant’s Counsel as to “Does the CDC treat all ships the same?” Cargo ships are not treated the same as Cruise Lines Ships.

Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine (DGMQ), the 'Competent Authority' under the IHR (2005) for U.S. ports of entry. Any certificates issued by private companies in the United States are not valid.” The CDC does have a statutory right per 42 CFR §§71.41 to inspect for sanitary reasons any ship and to determine if there is an outbreak onboard if they have reason to suspect an outbreak on a vessel.

Based on the declarations by Capt. Treffiletti, in Exhibit A of the Defendant's Memorandum⁴, the Maritime Unit of the CDC found the HSP protocols “*inadequate to sufficiently mitigate the introduction, transmission, and amplification of COVID-19 on cruise ships and to U.S. communities*”. Further she stated, “*Accordingly, more emphasis was needed on actions to mitigate potentially infected travelers **from boarding ships in the first instance** so that fewer government resources would be needed from local, state, and federal agencies—as well as onshore medical facilities—to manage cases and outbreaks.*” (emphasis added)

Is the real reason that the NO SAIL ORDER was issued due to the exorbitant cost of manpower, cost for isolation and quarantine of ill and exposed passengers for the duration of an outbreak. Was it feared to be too great given the current budget of the CDC? If the WHO International Health Regulations are a guide, as noted in the original amicus curiae brief by Mr. Young, the CDC does appear to be

⁴ DKT 31-1 Page 19, paragraph 44

trying to shift to the cruise lines the risk and the cost of any such outbreak. If 42 CFR §§70.6 (b) and 42 CFR §§71.33 are the guides, the Director of the CDC is still responsible for arranging “for adequate food and water, appropriate accommodation, appropriate medical treatments and means of necessary communication for individuals who are apprehended or held in quarantine or isolation” under Part 70 or Part 71.

Although Mr. Young still agrees with the Florida arguments that the CDC goes beyond its authority to micromanage the cruise ship industry, after listening to the oral arguments and reviewing the declarations by Captain Aimee Treffiletti, it is understandable that the CDC felt it was in their remit to be able to institute a “No Sail Order” in March 2020. The DOJ attorney for the CDC alluded to a fact, not in evidence, that the CDC could issue a No Sail Order under the Vessel Sanitation Program. This may have been a misunderstanding by the DOJ attorney. An important fact and distinction, as can be seen in the latest VSP Operations Manual⁵ is that the VSP is a VOLUNTARY⁶ program. While it states under the administrative section of the VSP Operations Manual entitled “Recommendations That the Vessel Not Sail”, the CDC “can recommend or direct

⁵ Vessel Sanitation Program 2018 Operations Manual (www.cdc.gov/nceh/vsp/docs/vsp_operations_manual_2018-508.pdf)

⁶ 2018 VSP Operations Manual, 2.0 Authority, 2.1 Public Health Service Act, 2.1.1 Communicable Disease Prevention, 2.1.1.1 Communicable Disease Prevention: “**Although cooperation by vessels with VSP is voluntary**, the Public Health Service (PHS) is authorized by the Public Health Service Act (42 U.S.C. Section 264. QUARANTINE and Inspection - Regulations to control communicable diseases) to take measures necessary to prevent the introduction, TRANSMISSION, or spread of communicable diseases into the United States from a foreign country.” (emphasis added)

the master of a vessel not to sail when an IMMINENT HEALTH HAZARD or similar imminent threats to public health are found aboard a vessel”⁷ The CDC clearly has Quarantine Authority when an Imminent Health Hazard is found. Yet, for sanitation purposes, if it is a voluntary program, why would a master of the vessel have the obligation to follow such a recommendation unless it was a Quarantine Order? Is there potential liability that could attach for not following such imminent health warnings if it were just a recommendation? The key in the case is it must be an IMMINENT HAZARD found on board. This is defined for infectious disease as an OUTBREAK which could subject newly arriving passengers to disease.⁸ These facts clearly support the fact reported in Mr. Young’s prior amicus brief that the CDC’s Vessel Sanitation Program is a voluntary program not a mandate. Why is this an important distinction?

⁷ 2018 VSP Operations Manual, 12.0 Administrative Guidelines, Page 178; Subsection 12.9 Recommendations That the Vessel Not Sail: “12.9.2 Procedures: 12.9.2.2 **No Sail: “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. Such a **recommendation** will be signed by the VSP Chief, with concurrence of the Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry or the Director’s designee. (emphasis added)

⁸ 2018 VSP Operations Manual, Section 12.0 Administrative Guidelines, Page 178, 12.9 Recommendations That the Vessel Not Sail, 12.9.1 Imminent Health Hazard “An IMMINENT HEALTH HAZARD will be determined to be, but not limited to, one of the following situations:

- Free HALOGEN residual in the POTABLE WATER distribution system is less than 0.2 MG/L (ppm) and this deficiency is not corrected before the inspection ends.
- Inadequate facilities for maintaining safe temperatures for POTENTIALLY HAZARDOUS FOOD.
- Inadequate facilities for cleaning and sanitizing EQUIPMENT.
- Continuous problems with liquid and solid waste disposal, such as inoperative or overflowing toilets or shower stalls in passenger and crew member cabins.
- **Infectious disease OUTBREAK among passengers or crew, and where it is suspected that continuing normal operations may subject newly arriving passengers to disease.**

The CDC is given the power to issue Quarantine, Isolation or Conditional Release ORDERS [See Exhibit F] and No Sail **Recommendations**. Quarantine, Isolation or Conditional Release ORDERS also require, based on CFR §§70.15 Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional release, a reassessment (in 72 hours), by an independent officer other than officer issuing the order, and consideration by the Director of whether there is a less restrictive alternative, and a separate order giving the results of the reassessment and the decision as to whether it should be continued, modified or rescinded. If it is to be continued or modified as a result of the reassessment, it must also explain the process for requesting an appeal that includes a medical review as outlined in CFR §§70.16. Clearly the series of NO SAIL ORDERS and the CONDITIONAL SAIL ORDER by the CDC do not comply with all these requirements. So, this would seem to imply that while a NO SAIL RECOMMENDATION can be made, a NO SAIL ORDER should not. It should be a Quarantine, Isolation or Conditional Release Order for a specific ship on a case-by-case basis not an entire industry.

The CONDITIONAL SAIL ORDER as noted below is more aligned with Bills of Health that are not required by current regulations. This raises clear Administrative Procedures Act concerns because to change or eliminate a standing regulation, e.g., 42 CFR §§71.11⁹, should require proper notice and comment

⁹ 42 C.F.R. §§71.11 Bills of Health - A carrier at any foreign port clearing or departing for any U.S. port

periods? **The answer to Question 1) above must therefore be NO.**

**A1: The CDC Does Not Have the Authority to Issue A NO SAIL or
CONDITIONAL SAIL ORDER, Just A RECOMMENDATION.**

Q2: REASONABLE TIME FOR QUARANTINE OR ISOLATION

Based on the normal “Order for Quarantine” for COVID-19, the CDC would only impose quarantine or isolation under 42 USC §264 and 42 CFR §§70.6, 71.32(a) and 71.33, until a person is “no longer at risk of becoming ill and spreading the disease to others. This is commonly referred to as the incubation period for the disease. The incubation period for COVID-19 is currently believed to be up to 14 days.” On this basis it should be logical to assume that a reasonable time for quarantine or isolation is 14 days or less. How can the CDC justify “quarantine or isolation” of the entire worldwide fleet of cruise line ships that want to sail to or from U.S. Ports, the largest market for cruising in the world, for more than a year? Is it not the Reasonable Time for Quarantine and Isolation of a Vessel the time it takes to allow any virus onboard and its host to be detected and either removed or isolated or quarantined based on the same 14 day incubation period? Why is a ship any different? Particularly since the latest evidence is it is not the fomite transfer

shall not be required to obtain or deliver a bill of health.

that causes the infection it is the direct person to person transfer.¹⁰

A2: A Maximum 14 Day Period Without Testing Should Be

Reasonable. With Testing Even Less.

Q3: WHAT REASONABLE REGULATIONS WOULD TAKE THE PLACE OF THE CDC ORDERS?

Is there a major risk to the public and should the Court rely on non-health officials to help it in its determination? At issue is the needed expertise to make such a determination. The court clearly addressed this in its question to Florida on what public health authorities are they relying upon? They seem to have no response other than the “Healthy Sail Panel”. It is becoming clear the issues has become political as well, with the public on both sides having major concerns on which public health officials in this country can be believed. So, if the public health officials, officials who are defendants in this case, are not to be believed, who does the court believe? WHO are the alternative experts in the area of public health? The answer may well the question itself. The WHO or World Health Organization.¹¹ Due to the United States Senate in a Joint Congressional

¹⁰ Science Brief: SARS-CoV-2 and Surface (Fomite) Transmission for Indoor Community Environments Updated Apr. 5, 2021(<https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html>)

¹¹ This is not a recommendation that Mr. Young makes lightly or even without much chagrin. It is just the logical conclusion. Mr. Young is a former candidate for Texas State Representative in 2012 and was considered to be one of the most conservative of the slate of five candidates in the primary race for his state house seat. Given the more recent direction the World Health Organization has gravitated particularly with so called self-professed public health emergencies such as the Climate Change, that

Resolution¹² having ratified the Constitution of the WHO in 1948¹³ the United States has endorsed the World Health Organization as the lead public health experts with respect to international health. The primary purpose of the International Health Regulations are as outlined in their purpose and scope. “The purpose and scope of the IHR (2005) are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, **and which avoid unnecessary interference with international traffic and trade.**”

The Defendant, e.g., the CDC, acts as this countries ‘*National IHR Focal Point*’ and ‘*Competent Authority*’ responsible for the implementation and application of health measures under the International Health Regulations and Congress has given the Secretary of the HHS who has delegated that authority to the CDC pretty broad powers in the statutes. Thus, by doing so, Congress has in effect provided the required implementation of the legislative requirement, for the International Health Regulations to be considered as implemented by the CDC.

However, it should be noted that unlike the assertions made in the Mr. Young’s original *amicus curiae* brief, the reservations contained in the 1948

many in the conservative groups think is not a genuine health consideration, the suggestion that the World Health Organization may be the best suited for dealing with global pandemic response may be seen to some as being nothing short of heresy. Yet the United States has been involved for almost a century with various forms of Sanitation Agreements which have culminated in the International Health Regulations of 2005.

¹² Joint Resolution 62 STAT. 441 (Chapter 469) [Exhibit D]

¹³ Constitution of the World Health Organization, 62 STAT. 2679 TIAS 1808, 4 Bevans 119 [Exhibit E]

Congressional Joint Resolution do make it clear that the nothing in the constitution of the World Health Organization “commits the United States to enact any specific legislative program”. Thus, the International Health Regulations may not be self-implementing (as formerly stated and implied by a New York Federal Court) and should require implementation by congressional legislation.

This does not make them totally inapplicable. Apparently in many instances the CDC has assumed the authority they have in many particular areas of public health as being derived from the WHO and their International Health Regulations. Again, one area for this is with respect to Sanitation Certificates¹⁴ [Exhibit A]. So, the answer to Question 3) and 4) above may be addressed in part by the CDC website with respect to Ship Sanitation Certificates in the United States? There it is stated:

“Who is authorized to issue Ship Sanitation Certificates in the United States?”

“No port authorities, public agencies, or private organizations are authorized to issue SSCCs/SSCECs in the United States.” (emphasis added)

“The authority to issue, inspect, and require SSCCs/SSCECs within the United States or its territories resides solely with the Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine (DGMQ), the “Competent Authority” under the IHR (2005) for U.S. ports of entry. Any certificates issued by private companies in the United States are not valid.” (emphasis added)

“While CDC DGMQ is the Competent Authority under the IHR (2005), the authority to issue SSCCs/SSCECs for specific purposes has been delegated to certain

¹⁴ See Exhibit A which is copied from (<https://www.cdc.gov/quarantine/maritime/shipsanitation.html>)

U.S. government agencies/programs.” (emphasis added)

- *“The U.S. Navy and U.S. Coast Guard may conduct inspections and issue SSCCs/SSCECs for certain types of ships, primarily vessels of their services and those of the National Oceanic and Atmospheric Administration.”*
- *“The CDC Vessel Sanitation Program CVSP) may choose to issue SSCCs/SSCECs upon request during VSP inspections of cruise ships. Please contact VSP (vsp@cdc.gov) with questions about sanitation inspections on cruise ships.”*

Further, the CDC website states:

*“Port authorities, public agencies, and private organizations are prohibited from requiring SSCECs/SSCCs for seafaring vessels at U.S. ports of entry. **Such actions would contradict CDC's exercise of federal authority under the Supremacy Clause of the U.S. Constitution.**”*

The answer to Question 3) based on the above is that if the court vacated the Conditional Sail Order, the regulations that would take its place are the ones that are now in place. i.e., the Quarantine, Isolation and Conditional Release Orders that are in the cited regulations for 42 CFR Part 70 and 42 CFR Part 71. Only they should be implemented on a case-by-case basis with the CDC required to use evidentiary basis for identification of cases of exposure or infection per 42 USC §264(d).

As stated earlier in Mr. Young’s earlier brief in his similar action¹⁵, and his original *amicus curiae* brief to this Court, the United States has been party to some sort of sanitation agreement for many decades [See Exhibit B.2], the latest is the International Health Regulations by the World Health Organization that was

¹⁵ District Court of South Texas, Houston Division., Chief Judge Lee Rosenthal presiding (4:20-cv-2299)

ratified by the US in 2007.¹⁶ However, the key reservations to this agreement¹⁷ must be considered by the Court, along with Section 5¹⁸ of the ratification of the WHO constitution, and it is for the Court to read and interpret these reservations,¹⁹ both in the ratification of the WHO Constitution and the International Health Regulations for itself and determine how applicable they are to this case as an international treaty enforceable on the same basis as a federal statute.

There are some legal experts who argue that although a non-self-implementing congressional-executive agreement cannot on its own provide a basis or cause for a suit, the fact that the cause may be satisfied by other statutes,

¹⁶ WHO International Health Regulations, 3rd edition, [Exhibit C]

¹⁷ WHO International Health Regulations, 3rd edition, [Exhibit C Appendix 2 Page 60-61] and [Exhibit C.1 the Diplomatic Note] A key reservation is:

“The Mission, by means of this note, and in accordance with Article 22 of the Constitution of the World Health Organization and Article 59(1) of the IHRs, submits the following reservation on behalf of the Government of the United States of America:”

“The Government of the United States of America reserves the right to assume obligations under these Regulations in a manner consistent with its fundamental principles of federalism. With respect to obligations concerning the development, strengthening, and maintenance of the core capacity requirements set forth in Annex 1, these Regulations shall be implemented by the Federal Government or the state governments, as appropriate and in accordance with our Constitution, to the extent that the implementation of these obligations comes under the legal jurisdiction of the Federal Government. To the extent that such obligations come under the legal jurisdiction of the state governments, the Federal Government shall bring such obligations with a favorable recommendation to the notice of the appropriate state authorities.”

¹⁸ Joint Resolution 62 STAT. 441 (Chapter 469) [Exhibit D] Section #5

¹⁹ Does an “understanding” in an executive agreement rise to the same level as a “reservation” in a U.S. Ratified Congressional-Executive Agreement with respect to this case. The understanding is referenced in footnote 9 above and is stated as: ” The third understanding relates to the question of whether the IHRs create judicially enforceable private rights. Based on its delegation's participation in the negotiations of the IHRs, the Government of the United States of America does not believe that the IHRs were intended to create judicially enforceable private rights: The United States understands that the provisions of the Regulations do not create judicially enforceable private rights.”

as in this case the APA, the agreement as a treaty is still the law of the land. Per the Supremacy Clause it is still fair to be considered by the Court in deciding situations such as is presented in this case, where a statute is ambiguous and needs further interpretation by the Court.²⁰

Returning to Capt. Treffiletti comment. “Accordingly, *more emphasis was needed on actions to mitigate potentially infected travelers from boarding ships in the first instance*”. A major flaw in the Conditional Sail Order is the requirements it seems to place on the cruise lines onboard activities. i.e., detection of the virus once onboard, mask wearing, social distancing, having labs onboard to detect it, having facilities to handle it once a large number of passengers are exposed, how to handle it once they arrive back at a U.S. Port (required agreements in place) and limitations on revenue paying passengers on test cruises and the length of cruises. Is there a scientific basis for limiting a cruise to seven days? This eliminates many of the longer and relatively lower cost on a per day repositioning cruises like the Transatlantic Cruise the Young’s have scheduled in Late October.

This begs the question of how the Conditional Sail Order actions are any different from the requirements of a “Bill of Health” which based on the current regulations²¹ appear not to be required of any carrier from a foreign port destined

²⁰ See Oona A. Hathaway, et al, International Law at Home: Enforcing Treaties in U.S. Courts, Yale Journal of International Law, [Vol 37: 1 2012] with respect to the third means of indirect enforcement or “interpretive enforcement”. Pg. 88- 90.

²¹ See Footnote 9

for a US Port. In the 1985 Final Rule Publication²² of 42 CFR Part 70 and Part 71, Section 366(c) of the PHS Act (42 USC 269(c) was cited as conferring “the authority to prescribe regulations applicable to vessels in particular, ‘for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the sanitary condition of such vessels, their cargos, passengers and crews. In this context the Department believes the provisions for carrier inspection, detention, and remedial action are clearly supported by the enabling legislation (PHS Act) and is within the statutory scope of authority.”

What are the measures that could be employed in a proactive versus reactive manner? Are these not outlined in the Articles and Annexes of the International Health Regulations and in the WHO IHR Handbook for Management of Public Health Events on Board Ship? Why does the CDC insist on trying untried and unproven protocols? Have any of the requirements the CDC put forth by the Conditional Sail Orders been peer reviewed or even standardized as part of an International or National Health Panel or Group?

In the oral arguments the CDC’s counsel said that they did not go so far as to mandate all passengers be vaccinated. It was only offered to the cruise lines as an option to avoid the more troublesome test cruise requirements. It was noted by the Court, that if they had invoked a vaccine mandate, the simple dilemma of the

²² 50 FR 1519 Friday, January 11, 1985 / Rules and Regulations

State prohibitions against vaccination passports by businesses might have been preempted by the federal rule. But, by offering only an option to the cruise lines to avoid test cruises with non-revenue passengers by certification of a certain level of vaccination among the crew and the passengers, the cruise lines are not given a preemption of the state law.

The CDC seems to argue that they are the party responsible for making these requirements because the local community and state regulations are simply limited to their intrastate waters or local jurisdiction. How do these onboard rules being exerted against a foreign flagged ship have any jurisdiction beyond a U.S. Port or federal water, as the CDC seems to imply? Isn't this the jurisdiction of the flag state of a foreign flagged ship once in international waters? If the Flag state is a signatory party to World Health Organization and the other multinational treaties, is not it a violation of international law to force the ships' masters to comply with U.S. regulations or orders outside U.S. waters.

The CDC seems to lean heavily on 42 USC § 269 or the "Bills of Health" statute to provide them their authority, particularly with respect to the VSP program. Yet they do not argue that statute in their Orders or their filings in this case? Could it be because this is why the International Health Regulations, and the World Health Organization was empowered by 196 member nations to act as the coordinator of such international activity. It should be noted by the Court that

as far back as 1934,²³ in International Agreements that were eventually absorbed by the latest World Health Organization's International Health Regulations, the need for "Bills of Health" were eliminated. [See Exhibit B.1]. The Pan American Sanitation Agreement Treaty [Exhibit B.3] is cited by the State Department listing of Active Treaties [Exhibit B.2] as having the section related to Bills of Health [Article 16-26 of Exhibit B.3] replaced by the IHR in 1969 which was replaced by the IHR 2005. Even in 42 C.F.R §§71.11 "Bills of Health" it states that a carrier heading from a foreign port to a U.S. Port is not required to obtain or deliver one. Why is this regulation on the books when the federal statute 42 USC §269 Bills of Health is still in force?

Are the multitude of conditions being imposed on the cruise lines in the Conditional Sail Order considered all to be "sanitary conditions" that must be satisfied for a cruise ship to obtain a clean "Bill of Health"? Are these conditions prescribed by other health experts or best industry practices? Generally, those types of protocols that are contained in well vetted, peer reviewed and proven standards. The original VSP Operations Manual [Exhibit G], included the FDA 1976 Model Code for Food Service and the World Health Organization's Guide to Ship Sanitation and was published in 1989. Are the latest updates to the VSP Operations Manual based on the Conditional Sail Order really vetted or are they

²³ See International Agreements for Dispensing with Bills of Health and Consular Visas on Bills of Health in Article 58 of the International Health Regulations.

just the wishful musings of what some official thinks will work? What is the evidence of them successfully working in an actual cruise ship sailing environment? Why is it somehow more acceptable to “test the protocols” the government wants, and use them on a group of non-paying volunteers, versus a group of paying customers? Why are the cruise lines not allowed to restart from U.S. Ports with the set of protocols they have tested with reasonable results in Asia and Europe? Why can they not just give their passengers a fair assessment of the risks they are taking and ask them to sign a waiver? Given the higher vaccination rates, the number of persons who have been infected and recovered and may have acquired some immunity and the more knowledgeable public based on almost a year and a half of the world living with COVID-19, is the risk of a Diamond Princess reoccurrence really a possibility?

If the Healthy Sail Protocols which have been developed by a panel of health experts is not sufficient. What is? Maybe the full implementation of the requirements of the International Health Regulations, which puts the requirements of many of the items that Captain Treffiletti asked for in place. Does not the CDC providing more vetting of passengers prior to boarding using appropriate risk management measures and testing of high risk persons getting on board actually put more emphasis where it is needed. e.g. *“on actions to mitigate potentially infected travelers from boarding ships in the first instance”*

If the CDC would satisfy the IHR ANNEX 1 capabilities at key ports of entry

(and departure) to provide the requirements as outlined, many of their concerns would be addressed. Now if the cruise lines are willing to voluntarily provide these services, like they do with the VOLUNTARY VSP, then that is between them and the CDC. However, it should not be a mandatory ordered requirement to sail.

**A3: The International Health Regulations, Annexes and Handbooks
Should Be Used In Lieu Of CDC ORDERS.**

Q4: WHAT LOCAL REGULATIONS COULD TAKE THE PLACE OF THE CDC ORDERS?

As noted above in C) the CDC insists that due to the Supremacy Clause of the U.S. Constitution, and the powers derived from the Commerce Clause they preempt Local and State rules. Because almost all cruise lines are foreign flagged ships and the due to compliance with the Passenger Vessel Service Act (PVSA) which mandates a stop in a foreign port, almost all cruise lines are in international or foreign commerce, this is clearly the case where the Commerce Clause does apply. With the current waiver of the PVSA by bills unanimously passed by Congress, if signed by the President or of any veto overridden, the sailings to Alaska are now taking on simpler Interstate Travel. The provisions of 42 U.S.C. §264(c) and 42 U.S.C. §264(d) come into play which only allow 42 U.S.C. §264 to apply to only individuals entering from foreign countries or possessions, and the quarantine of individuals that are in qualifying state. Not ships or Vessels.

Yet in the area of interstate travel after a cruise or on entering a State from a Port of Entry, it is clearly the states responsibility for Quarantine and Isolation outside the Port of Entry federal jurisdiction area.

A4: No Local or State Regulations of Foreign Flagged Ships Can Take the Place with Respect to The CDC'S NO SAIL or CONDITIONAL SAIL Rules, Just the International Health Regulations.

Q5) CAN THE INJURY TO THE STATES, THEIR ECONOMY AND THE OBVIOUS DECIMATION OF AN ENTIRE CRUISE LINE INDUSTRY BE RELIEVED BY A COURT ORDER VACATING THE CDC'S ORDER?

The Conditional Sail Order and its overreaching protocols are currently the only thing preventing the cruise lines from sailing. This is evidenced by the plans for several of the cruise lines to start sailing again out of non-U.S. ports in the Caribbean starting in June, as well as out of Greece and Italy. The CLIA has embarked on a campaign called READY, SET, SAIL²⁴ to get the members of many of the cruise lines loyalty programs to "Take Action to Support the Return of Cruising in the United States" by contacting their representatives to demand legislative action if the CDC still refuses to drop their conditional sail order. It must be noted that Congress in a rare display of bipartisan support has unanimously passed by both the House and the Senate a bill to allow the

²⁴ <https://cruising.org/en/clia-action-center?vvsrc=%2fcampaigns%2f85099%2frespond%3fTrackingID%3dGSCSocial%26fbclid%3dIwAR0Ef8E5lzBp2WLud0cdnC8mYYxU5rlgtES4nzXqYvUaaw4gDwTJgnC7wQQ>

suspension of the PVSA for cruise to Alaska. Thus allowing the closed ports of Canada to be bypassed.

Given the high level of continued participation in future cruise reservations, all that is needed for a rapid recovery is for a Court Order vacating the CDC Order. It may also require a mandamus order to demand that the CDC provide the required level of testing or proof of vaccination to protect the public from the virus. The other prophylaxis protocols being ordered by the CDC are more reactive and do not seem to comply with the declarations of their own expert Captain Aimee Treffiletti who has stated the need *to mitigate potentially infected travelers from boarding ships in the first instance.*

A5: The Simple Requirement for Adequate Testing of Boarding Passengers or Proof of Vaccination is a Much Less Restrictive Alternative than the Conditional Sail Order Protocols Being Ordered.

FINAL ARGUMENT ON APPLICATION OF THE APA ON THIS CASE

Although not addressed above in the Questions that were asked but not fully answered, there were questions on the applicability of the Administrative Procedures Act and the questions related to standing that deserve some additional comment and discussion. In 2017 when the CDC was finalizing the FINAL RULE on 42 CFR Part 70 and Part 71 [CDC Docket No. CDC-2016-0068] RIN 0920-AA63

Control of Communicable Disease²⁵, in the response to comments the HHS/CDC states , “HHS/CDC received several comments on the Agency’s accountability system, encouraging that a ‘strong system of checks and balances’ should be in place for this regulation to be implemented. HHS/CDC agrees that there should be accountability and oversight **regarding the agency’s activities**. We note that these regulations do not affect the ability of Congress to conduct its oversight activities or affect the jurisdiction of federal courts to review federal agency actions under the Administrative Procedure Act (5 U.S.C. 704).” and HHS/CDC received a comment that there is no court supervision of HHS/CDC activities. We disagree. These regulations do not affect the jurisdiction of the Federal courts or the statutory rights of individuals to obtain judicial review of CDC’s actions and decisions through appropriate mechanisms such as the habeas corpus statute (28 U.S.C. 2241) or the Administrative Procedure Act (5 U.S.C. 704).”

**THE CDC HAS STATED FOR THE RECORD THAT THE
FEDERAL COURT HAS JURISDICTION FOR JUDICIAL REVIEW OF THE
AGENCY’S ACTIVITIES.**

CONCLUSION

If the Court were to vacate the CDC Order, what is necessary is a mandamus order by the court. The Mandamus Order would be a demand for the CDC to

²⁵ See 82 FR 6890 Thursday, January 19, 2017, Rules and Regulations [Exhibit H]

follow the International Health Regulations and their guidelines. The Order should also require nothing more than a high level of vaccination or testing by the CDC, or by the Cruise Lines, as long as the cruise lines are voluntarily doing it on behalf of the CDC. This must be done to limit the opportunity for the virus to get onboard. If the virus does get onboard, with a reduced number of susceptible recipients, it should not be able to effectively replicate, thus avoiding the Diamond Princess outbreak scenario. The cruise lines should be allowed to adopt the protocols they believe are most effective for their situation, in keeping with their obligations to keep their vessel free from such infectious agents under the International Health Regulations and not as “Sanitation Requirements”

DATED: May 20, 2021.

MARC S. YOUNG, PE*
PO Box 1693
Sealy, Texas 77474
979-877-0660
713-417-6147
marc.young.pe@gmail.com

Pro Se

*Licensed Chemical Engineer in Texas, Alaska, Arizona and Louisiana

List of Exhibits

Exhibit A – Ship Sanitation Certificate Information, Source CDC website:

<https://www.cdc.gov/quarantine/maritime/shipsanitation.html>

Exhibit B – Listing of Multinational Sanitation Agreement Treaties

Exhibit B.1 – Listing of Treaties Incorporated into the International Health Regulations (Article 58 of Exhibit C Below)

Exhibit B.2 – Listing of Multinational Treaties by U.S. State Department currently in force January 2020 (page 1 and Page 532)

Exhibit B.3 – The Pan American Sanitary Code, signed at Havana, 14 November 1924

Exhibit C – World Health Organization International Health Regulations (2005), 3rd Ed, 2005, Featured Publication: January 2016
Source: WHO website: <https://www.who.int/health-topics/international-health-regulations>

Exhibit C.1 – Reservation and Understanding of Ratification of International Health Regulations, Diplomatic Note No 369-06, Geneva, 13 December 2006

Exhibit D – Joint Resolution By Congress, June 14, 1948; 62 STAT.441 (Chapter 469)

Exhibit E – Constitution of the World Health Organization; 62 STAT. 2679 TIAS 1808, 4 Bevans 119

Exhibit F – Sample Quarantine Order, CDC Website:
https://www.cdc.gov/quarantine/pdf/Public-Health-Order_Generic_FINAL_02-13-2020-p.pdf

Exhibit G – 2018 VSP Operations Manual,
https://www.cdc.gov/nceh/vsp/docs/vsp_operations_manual_2018-508.pdf

Exhibit H – 82 FR 6890 Thursday, January 19, 2017, Rules and Regulations



EXHIBIT A

Ship Sanitation Certificate Information

Frequently Asked Questions about Ship Sanitation Certificates in the United States

Audience: This document is for cargo vessel crew, vessel companies, port authorities, private companies, maritime government agencies, and anyone interested in the status of ship sanitation control certificates in the United States.

Purpose: This document clarifies that the CDC currently does not require ships to present ship sanitation control certificates when calling on US ports and that cargo vessels cannot obtain a ship sanitation control or exemption certificate in the United States.

Background: On May 23, 2005, the World Health Organization (WHO) adopted a revised version of the International Health Regulations (IHR), effective for most countries on June 15, 2007. The IHR (2005) contained changes intended to increase international coordination of information, reporting, and response to public health emergencies, including a new ship certification scheme. The new certificates, entitled Ship Sanitation Control Certificate/Ship Sanitation Control Exemption Certificate ("Ship Sanitation Certificates" or SSCC/SSCEC), replaced the previous Deratting/Deratting Exemption Certificates (DC/DEC) provided for under the IHR (1969). Accordingly, legacy DCs are no longer valid as of December 15, 2007.

Who is authorized to issue Ship Sanitation Certificates in the United States?

No port authorities, public agencies, or private organizations are authorized to issue SSCCs/SSCECs in the United States.

The authority to issue, inspect, and require SSCCs/SSCECs within the United States or its territories resides solely with the Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine (DGMQ), the "Competent Authority" under the IHR (2005) for U.S. ports of entry. Any certificates issued by private companies in the United States are not valid.

While CDC DGMQ is the Competent Authority under the IHR (2005), the authority to issue SSCCs/SSCECs for specific purposes has been delegated to certain U.S. government agencies/programs.

- The U.S. Navy and U.S. Coast Guard may conduct inspections and issue SSCCs/SSCECs for certain types of ships, primarily vessels of their services and those of the National Oceanic and Atmospheric Administration.
- The CDC Vessel Sanitation Program (VSP) may choose to issue SSCCs/SSCECs upon request during VSP inspections of cruise ships. Please contact VSP (vsp@cdc.gov) with questions about sanitation inspections on cruise ships.

Are ships required to have a SSCC/SSCEC to enter United States ports?

No, CDC does not currently require these certificates for ships arriving at U.S. ports of entry to embark or disembark passengers, crew, or cargo within the United States. However, CDC reserves the right to inspect vessels if a public health concern is identified or suspected.

Under federal regulations found at 42 C.F.R. 571.31, CDC grants controlled free pratique to vessels entering U.S. ports of entry.

Port authorities, public agencies, and private organizations are prohibited from requiring SSCECs/SSCCs for seafaring vessels at U.S. ports of entry. Such actions would contradict CDC's exercise of federal authority under the Supremacy Clause of the U.S. Constitution.

What if a cargo ship at a U.S. port of entry needs a SSCC/SSCEC for its next destination?

The ship will not be able to obtain this certificate in the United States. The ship will need to obtain the certification in another country at one of the ports listed at the following link: http://www.who.int/ihr/ports_airports/portslanding/en/index.html.

There is NO authorized way for a cargo vessel to obtain a Ship Sanitation Certificate in the United States at this time.

Any certificates issued by private companies in the United States are not valid.

Who can I contact about questions regarding SSCCs/SSCECs in the United States?

For additional questions about Ship Sanitation Certificates, you can contact the Maritime Activity Team within CDC DGMQ at MaritimeAdmin@cdc.gov

If you have questions specifically about ship sanitation inspections on cruise ships, please contact CDC VSP at vsp@cdc.gov.

Page last reviewed: October 13, 2015

Article 58 International sanitary agreements and regulations

1. These Regulations, subject to the provisions of Article 62 and the exceptions hereinafter provided, shall replace as between the States bound by these Regulations and as between these States and WHO, the provisions of the following international sanitary agreements and regulations:

- (a) International Sanitary Convention, signed in Paris, 21 June 1926;
- (b) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;
- (c) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;
- (d) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22 December 1934;
- (e) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;
- (f) International Sanitary Convention, 1944, modifying the International Sanitary Convention of 21 June 1926, opened for signature in Washington, 15 December 1944;
- (g) International Sanitary Convention for Aerial Navigation, 1944, modifying the International Sanitary Convention of 12 April 1933, opened for signature in Washington, 15 December 1944;
- (h) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;
- (i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;
- (j) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and
- (k) the International Health Regulations of 1969 and the amendments of 1973 and 1981.

2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, shall remain in force with the exception of Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62, to which the relevant part of paragraph 1 of this Article shall apply.

Article 59 Entry into force; period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:

- (a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;

United States Department of State

Treaties in Force

A List of Treaties and Other International Agreements of the United States in Force on January 1, 2020

This publication lists treaties and other international agreements of the United States on record in the Department of State on January 1, 2020, which had not expired by their own terms or which had not been denounced by the parties, replaced, superseded by other agreements, or otherwise definitely terminated.



Compiled by the Treaty Affairs Staff,
Office of the Legal Adviser,
U.S. Department of State

Multilateral Treaties in Force as of January 1, 2020

HEALTH & MEDICAL COOPERATION

Agricultural commodities agreement for the sale of wheat, with memorandum of understanding.

Signed at Dar-es-Salaam February 18, and at Nairobi February 19, February 22, and March 4, 1966.

Entered into force March 4, 1966.

17 UST 628; TIAS 6010; 578 UNTS 57

Parties:

East African Common Services Organization

Kenya

Tanzania

Uganda

United States

Agreement for the establishment of the International Development Law Organization.

Signed at Rome February 5, 1988.

Entered into force April 28, 1989.

TIAS

Amendments:

June 30, 2002;

November 30, 2002

Depositary: Italy

Agreement establishing the Inter-American Institute for Global Change Research.

Done at Montevideo May 13, 1992.

Entered into force March 12, 1994.

TIAS

Depositary: Organization of American States

HEALTH & MEDICAL COOPERATION

The Pan American sanitary code.*

Signed at Habana November 14, 1924.

Entered into force June 26, 1925.

44 Stat. 2031; TS 714; 2 Bevans 483; 86 LNTS 43

Depositary: Cuba**Notes:**

* Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62 replaced by the international health regulations, adopted at Boston, July 25, 1969 (TIAS 7026).

Additional protocol amending the Pan American sanitary code of November 14, 1924.

Signed at Lima October 19, 1927.

Entered into force July 3, 1928.

45 Stat. 2613; TS 763; 2 Bevans 648; 87 LNTS 453

Depositary: Cuba

Constitution of the World Health Organization.

Done at New York July 22, 1946.

Entered into force April 7, 1948; for the United States June 21, 1948.

62 Stat. 2679; TIAS 1808; 4 Bevans 119; 14 UNTS 185

Amendments:

May 29, 1959 (TIAS 4643)

May 23, 1967 (26 UST 990; TIAS 8086)

May 22, 1973 (28 UST 2088; TIAS 8534)

May 17, 1976 (35 UST 4280; TIAS 10930)

May 12, 1986 (TIAS 12049)

May 16, 1998 (TIAS 12953)

Depositary: United Nations

Protocol for the termination of the Brussels agreement for the unification of pharmacopoeial formulas for potent drugs.

Done at Geneva May 20, 1952.

Entered into force May 20, 1952.

3 UST 5067; TIAS 2692; 219 UNTS 55

Depositary: Belgium

Statute of International Agency for Research on Cancer.

Done at Geneva May 20, 1965.

Entered into force September 15, 1965.

16 UST 1239; TIAS 5873

Amendment:

May 19, 1970 (21 UST 1567; TIAS 6919)

Depositary: World Health Organization

World Health Organization nomenclature regulations, 1967.

Adopted at Geneva May 22, 1967.

Entered into force January 1, 1968.

18 UST 3003; TIAS 6393

Depositary: World Health Organization

International health regulations, with annexes and appendices.*

Adopted at Geneva May 16-25, 2005.

Entered into force June 15, 2007; for the United States July 18, 2007.

TIAS

Depositary: World Health Organization**Note:**

* Replaces as between States bound by these regulations the international sanitary conventions, 1951 and the international health regulations, 1969, and any subsequent amendments to those conventions.

PAN AMERICAN SANITARY CODE

*Convention signed at Havana November 14, 1924, with appendix
Senate advice and consent to ratification February 23, 1925
Ratified by the President of the United States March 28, 1925
Ratification of the United States deposited at Havana April 13, 1925
Proclaimed by the President of the United States April 28, 1925
Entered into force June 26, 1925¹
Amended by additional protocol of October 19, 1927;² replaced in
part (arts. 2, 9–11, 16–53, 61, and 62) by International Sanitary
Regulations (World Health Organization Regulations No. 2) of
May 25, 1951,³ as between states bound by the regulations*

44 Stat. 2031; Treaty Series 714

PAN AMERICAN SANITARY CODE

The Presidents of Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Guatemala, Haiti, Honduras, Mexico, Salvador, Panama, Paraguay, Peru, United States of America, Uruguay and Venezuela, being desirous of entering into a sanitary convention for the purpose of better promoting and protecting the public health of their respective nations, and particularly to the end that effective cooperative international measures may be applied for the prevention of the international spread of the communicable infections of human beings and to facilitate international commerce and communication, have appointed as their plenipotentiaries, to-wit:

The Republic of Argentina
Dr. Gregorio Araoz Alfaro
Dr. Joaquín Llambías

The United States of Brazil
Dr. Nascimento Gurgel
Dr. Raúl Almeida Magalhaes

The Republic of Chile
Dr. Carlos Graf

The Republic of Colombia
Dr. R. Gutiérrez Lee

The Republic of Costa Rica
Dr. José Varela Zequeira

¹ Date of deposit of second instrument of ratification.

² TS 763, *post*, p. 648.

³ 7 UST 2255; TIAS 3625.

The Republic of Cuba	The Republic of Honduras
Dr. Mario G. Lebrede	Dr. Arístides Agramonte
Dr. José A. López del Valle	The Republic of Mexico
Dr. Hugo Roberts	Dr. Alfonso Pruneda
Dr. Diego Tamayo	The Republic of Panama
Dr. Francisco M. Fernández	Dr. Jaime de la Guardia
Dr. Domingo F. Ramos	
The Republic of El Salvador	The Republic of Paraguay
Dr. Leopoldo Paz	Dr. Andrés Gubetich
The United States of America	The Republic of Peru
Dr. Hugh S. Cumming	Dr. Carlos E. Paz Soldán
Dr. Richard Creel	The Dominican Republic
Mr. P. D. Cronin	Dr. R. Pérez Cabral
Dr. Francis D. Patterson	The Republic of Uruguay
The Republic of Guatemala	Dr. Justo F. González
Dr. José de Cubas y Serrate	The United States of Venezuela
The Republic of Haiti	Dr. Enrique Tejera
Dr. Charles Mathon	Dr. Antonio Smith

Who, having exchanged their full powers, found in good and due form, have agreed to adopt, ad referendum, the following

PAN AMERICAN SANITARY CODE

CHAPTER I

OBJECTS OF THE CODE AND DEFINITIONS OF TERMS USED THEREIN

ARTICLE 1. The objects of this code are:

- (a) The prevention of the international spread of communicable infections of human beings.
- (b) The promotion of cooperative measures for the prevention of the introduction and spread of disease into and from the territories of the signatory Governments.
- (c) The standardization of the collection of morbidity and mortality statistics by the signatory Governments.
- (d) The stimulation of the mutual interchange of information which may be of value in improving the public health, and combating the diseases of man.
- (e) The standardization of the measures employed at places of entry, for the prevention of the introduction and spread of the communicable diseases of man, so that greater protection against them shall be achieved and unnecessary hindrance to international commerce and communication eliminated.

ART. 2. DEFINITIONS. As herein used, the following words and phrases shall be taken in the sense hereinbelow indicated, except as a different meaning for the word or phrase in question may be given in a particular article, or is plainly to be collected from the context or connection where the term is used.

AIRCRAFT. Any vehicle which is capable of transporting persons or things through the air, including aeroplanes, seaplanes, gliders, helicopters, air ships, balloons and captive balloons.

AREA. A well determined portion of territory.

DISINFECTION. The act of rendering free from the causal agencies of disease.

FUMIGATION. A standard process by which the organisms of disease or their potential carriers are exposed to a gas in lethal concentrations.

INDEX, *Aedes aegypti*. The percentage ratio determined after examination between the number of houses in a given area and the number in which larvae or mosquitoes of the *Aedes aegypti* are found, in a fixed period of time.

INSPECTION. The act of examining persons, buildings, areas, or things which may be capable of harboring, transmitting or transporting the infectious agents of disease, or of propagating or favoring the propagation of such agents. Also the act of studying and observing measures put in force for the suppression or prevention of disease.

INCUBATION, PERIOD OF. For plague, cholera and yellow fever, each 6 days, for smallpox, 14 days, and for typhus fever 12 days.

ISOLATION. The separation of human beings or animals from other human beings or animals in such manner as to prevent the interchange of disease.

PLAGUE. Bubonic, septicemic, pneumonic or rodent plague.

PORT. Any place or area where a vessel or aircraft may seek harbor, discharge or receive passengers, crew, cargo or supplies.

RODENTS. Rats, domestic and wild, and other rodents.

CHAPTER II

SECTION 1. NOTIFICATION AND SUBSEQUENT COMMUNICATIONS TO OTHER COUNTRIES

ART. 3. Each of the signatory Governments agrees to transmit to each of the other signatory Governments and to the Pan American Sanitary Bureau, at intervals of not more than two weeks, a statement containing information as to the state of its public health, particularly that of its ports.

The following diseases are obligatorily reportable:

Plague, cholera, yellow fever, smallpox, typhus, epidemic cerebrospinal meningitis, acute epidemic poliomyelitis, epidemic lethargic encephalitis, influenza or epidemic la grippe, typhoid and paratyphoid fevers, and such

other diseases as the Pan American Sanitary Bureau may, by resolution, add to the above list.

ART. 4. Each signatory Government agrees to notify adjacent countries and the Pan American Sanitary Bureau immediately by the most rapid available means of communication, of the appearance in its territory of an authentic or officially suspected case or cases of plague, cholera, yellow fever, smallpox, typhus or any other dangerous contagion liable to be spread through the intermediary agency of international commerce.

ART. 5. This notification is to be accompanied, or very promptly followed, by the following additional information:

1. The area where the disease has appeared.
2. The date of its appearance, its origin, and its form.
3. The probable source or country from which introduced and manner of introduction.
4. The number of confirmed cases, and number of deaths.
5. The number of suspected cases and deaths.
6. In addition, for plague, the existence among rodents of plague, or of an unusual mortality among rodents; for yellow fever, the *Aedes aegypti* index of the locality.
7. The measures which have been applied for the prevention of the spread of the disease, and its eradication.

ART. 6. The notification and information prescribed in Articles 4 and 5 are to be addressed to diplomatic or consular representatives in the capital of the infected country, and to the Pan American Sanitary Bureau at Washington, which shall immediately transmit the information to all countries concerned.

ART. 7. The notification and the information prescribed in Articles 3, 4, 5, and 6 are to be followed by further communications in order to keep other Governments informed as to the progress of the disease or diseases. These communications will be made at least once weekly, and will be as complete as possible, indicating in detail the measures employed to prevent the extension of the disease. The telegraph, the cable, and the radio will be employed for this purpose, except in those instances in which the data may be transmitted rapidly by mail. Reports by telegraph, cable or radio will be confirmed by letter. Neighboring countries will endeavor to make special arrangements for the solution of local problems that do not involve widespread international interest.

ART. 8. The signatory Governments agree that in the event of the appearance of any of the following diseases, namely: cholera, yellow fever, plague, typhus fever or other pestilential diseases in severe epidemic form, in their territory, they will immediately put in force appropriate sanitary measures

for the prevention of the international carriage of any of the said diseases therefrom by passengers, crew, cargo and vessels, and mosquitoes, rats and vermin that may be carried thereon, and will promptly notify each of the other signatory Governments and the Pan American Sanitary Bureau as to the nature and extent of the sanitary measures which they have applied for the accomplishment of the requirements of this article.

SECTION 2. PUBLICATION OF PRESCRIBED MEASURES

ART. 9. Information of the first non-imported case of plague, cholera, or yellow fever justifies the application of sanitary measures against an area where said disease may have appeared.

ART. 10. The Government of each country obligates itself to publish immediately the preventive measures which will be considered necessary to be taken by vessels or other means of transport, passengers and crew at any port of departure or place located in the infected area. The said publication is to be communicated at once to the accredited diplomatic or consular representatives of the infected country, and to the Pan American Sanitary Bureau. The signatory Government also obligate themselves to make known in the same manner the revocation of these measures, or of modifications thereof that may be made.

ART. 11. In order that an area may be considered to be no longer infected, it must be officially established:

1. That there has neither been a death nor a new case as regards plague or cholera for ten days; and as regards yellow fever for twenty days, either since the isolation, or since the death or recovery of the last patient.

2. That all means for the eradication of the disease have been applied and, in the case of plague, that effective measures against rats have been continuously carried out, and that the disease has not been discovered among them within six months; in the case of yellow fever, that *Aedes aegypti* index of the infected area has been maintained at an average of not more than 2 per cent for the 30-day period immediately preceding, and that no portion of the infected area has had an index in excess of 5 per cent for the same period of time.

SECTION 3. MORBIDITY AND MORTALITY STATISTICS

ART. 12. The international classification of the causes of death is adopted as the Pan American Classification of the Causes of Death, and shall be used by the signatory nations in the interchange of mortality and morbidity reports.

ART. 13. The Pan American Sanitary Bureau is hereby authorized and directed to re-publish from time to time the Pan American Classification of the Causes of Death.

ART. 14. Each of the signatory Governments agrees to put in operation at the earliest practicable date a system for the collection and tabulation of vital statistics which shall include:

1. A central statistical office presided over by a competent official.
2. The establishment of regional statistical offices.
3. The enactment of laws, decrees or regulations requiring the prompt reporting of births, deaths and communicable diseases, by health officers, physicians, midwives and hospitals, and providing penalties for failure to make such reports.

ART. 15. The Pan American Sanitary Bureau shall prepare and publish standard forms for the reporting of deaths and cases of communicable disease, and all other vital statistics.

CHAPTER III

Sanitary Documents

SECTION 1. BILLS OF HEALTH

ART. 16. The master of any vessel or aircraft which proceeds to a port of any of the signatory Governments, is required to obtain at the port of departure and ports of call, a bill of health, in duplicate, issued in accordance with the information set forth in the appendix and adopted as the standard bill of health.

ART. 17. The bill of health will be accompanied by a list of the passengers, and stowaways if any, which shall indicate the port where they embarked and the port to which they are destined, and a list of the crew.

ART. 18. Consuls and other officials signing or countersigning bills of health should keep themselves accurately informed with respect to the sanitary conditions of their ports, and the manner in which this code is obeyed by vessels and their passengers and crews while therein. They should have accurate knowledge of local mortality and morbidity, and of sanitary conditions which may affect vessels in port. To this end, they shall be furnished with information they request pertaining to sanitary records, harbors and vessels.

ART. 19. The signatory Governments may assign medical or sanitary officers as public health attaches to embassies or legations, and as representatives to international conferences.

ART. 20. If at the port of departure there be no consul or consular agent of the country of destination, the bill of health may be issued by the consul or consular agent of a friendly Government authorized to issue such bill of health.

ART. 21. The bill of health should be issued not to exceed forty eight hours before the departure of the ship to which it is issued. The sanitary visa should not be given more than twenty-four hours before departure.

ART. 22. Any erasure or alteration of a bill of health shall invalidate the document, unless such alteration or erasure shall be made by competent authority, and notation thereof appropriately made.

ART. 23. A clean bill of health is one which shows the complete absence in the port of departure of cholera, yellow fever, plague, typhus fever, or of other pestilential disease in severe epidemic form, liable to be transported by international commerce. Provided, that the presence only of bona fide imported cases of such disease, when properly isolated, shall not compel the issuance of a foul bill of health, but notation of the presence of such cases will be made under the heading of "Remarks" on the Bill of health.

ART. 24. A foul bill of health is one which shows the presence of non-imported cases of any of the diseases referred to in Art. 23.

ART. 25. Specific bills of health are not required of vessels which, by reason of accident, storm or other emergency condition, including wireless change of itinerary, are obliged to put into ports other than their original destinations but such vessels shall be required to exhibit such bills of health as they possess.

ART. 26. It shall be the duty of the Pan American Sanitary Bureau to publish appropriate information which may be distributed by port health officers, for the purpose of instructing owners, agents and masters of vessels as to the methods which should be put in force by them for the prevention of the international spread of disease.

SECTION 2. OTHER SANITARY DOCUMENTS

ART. 27. Every vessel carrying a medical officer will maintain a sanitary log which will be kept by him, and he will record therein daily: the sanitary condition of the vessel, and its passengers and crew; a record showing the names of passengers and crew which have been vaccinated by him; name, age, nationality, home address, occupation and nature of illness or injury of all passengers and crew treated during the voyage; the source and sanitary quality of the drinking water of the vessel, the place where taken on board, and the method in use on board for its purification; sanitary conditions, observed in ports visited during the voyage; the measures taken to prevent the ingress and egress of rodents to and from the vessel; the measures which have been taken to protect the passengers and crew against mosquitoes, other insects, and vermin. The sanitary log will be signed by the master and medical officer of the vessel, and will be exhibited upon the request of any sanitary or consular officer. In the absence of a medical officer, the master shall record the above information in the log of the vessel, in so far as possible.

ART. 28. Equal or similar forms for Quarantine Declarations, Certificate of Fumigation, and Certificate of Vaccination, set forth in the appendix, are hereby adopted as standard forms.

CHAPTER IV

CLASSIFICATION OF PORTS

ART. 29. An infected port is one in which any of the following diseases exist, namely, plague, cholera, yellow fever, or other pestilential disease in severe epidemic form.

ART. 30. A suspected port is a port in which, or in the areas contiguous thereto, a non imported case or cases of any of the diseases referred to in Art. 23, have occurred within sixty days, or which has not taken adequate measures to protect itself against such diseases, but which is not known to be an infected port.

ART. 31. A clean port, Class A, is one in which the following conditions are fulfilled:

1. The absence of non-imported cases of any of the diseases referred to in Art. 23, in the port itself and in the areas contiguous thereto.
2. (a) The presence of a qualified and adequate health staff.
- (b) Adequate means of fumigation.
- (c) Adequate personnel and material for the capture or destruction of rodents.
- (d) An adequate bacteriological and pathological laboratory;
- (e) A safe water supply.
- (f) Adequate means for the collection of mortality and morbidity data;
- (g) Adequate facilities for the isolation of suspects and the treatment of infectious diseases.
- (h) Signatory Governments shall register in the Pan-American Sanitary Bureau those places that comply with these conditions.

ART. 32. A clean port, Class B, is one in which the conditions described in Art. 31, 1 and 2 (a) above, are fulfilled, but in which one or more of the other requirements of Art. 31, 2 are not fulfilled.

ART. 33. An unclassified port is one with regard to which the information concerning the existence or non-existence of any of the diseases referred to in Art. 23, and the measures which are being applied for the control of such diseases, is not sufficient to classify such port.

An unclassified port shall be provisionally considered as a suspected or infected port, as the information available in each case may determine, until definitely classified.

ART. 34. The Pan American Sanitary Bureau shall prepare and publish, at intervals, a tabulation of the most commonly used ports of the Western Hemisphere, giving information as to sanitary conditions.

CHAPTER V

CLASSIFICATION OF VESSELS

ART. 35. A clean vessel is one coming from a clean port, Class A or B, which has had no case of plague, cholera, yellow fever, small pox or typhus aboard during the voyage, and which has complied with the requirements of this code.

ART. 36. An infected or suspected vessel is:

1. One which has had on board during the voyage a case or cases of any of the diseases mentioned in Art. 35.
2. One which is from an infected or suspected port.
3. One which is from a port where plague or yellow fever exists.
4. Any vessel on which there has been mortality among rats.
5. A vessel which has violated any of the provisions of this code.

Provided that the sanitary authorities should give due consideration in applying sanitary measures to a vessel that has not docked.

ART. 37. Any master or owner of any vessel, or any person violating any provisions of this Code or violating any rule or regulation made in accordance with this Code, relating to the inspection of vessels, the entry or departure from any quarantine station, grounds or anchorages, or trespass thereon, or to the prevention of the introduction of contagious or infectious disease into any of the signatory countries, or any master, owner, or agent of a vessel making a false statement relative to the sanitary condition of a vessel, or its contents, or as to the health of any passenger, or person thereon, or who interferes with a quarantine or health officer in the proper discharge of his duty, or fails or refuses to present bills of health, or other sanitary document, or pertinent information to a quarantine or health officer, shall be punished in accordance with the provisions of such laws, rules or regulations, as may be or may have been enacted, or promulgated, in accordance with the provisions of this Code, by the Government of the country within whose jurisdiction the offense is committed.

CHAPTER VI

THE TREATMENT OF VESSELS

ART. 38. Clean vessels will be granted pratique by the port health authority upon acceptable evidence that they properly fulfill the requirements of Art. 35.

ART. 39. Suspected vessels will be subjected to necessary sanitary measures to determine their actual condition.

ART. 40. Vessels infected with any of the diseases referred to in Art. 23 shall be subjected to such sanitary measures as will prevent the continuance

thereon, and the spread therefrom, of any of said diseases to other or ports. The disinfection of cargo, stores and personal effects shall be limited to the destruction of the vectors of disease which may be contained therein, provided that things which have been freshly soiled with human excretions capable of transmitting disease, shall always be disinfected. Vessels on which there is undue prevalence of rats, mosquitoes, lice, or any other potential vector of communicable disease, may be disinfected irrespective of the classification of the vessel.

ART. 41. Vessels infected with plague shall be subjected to the following treatment.

1. The vessel shall be held for observation and necessary treatment.
2. The sick, if any, shall be removed and placed under appropriate treatment in isolation.
3. The vessel shall be simultaneously fumigated throughout for the destruction of rats. In order to render fumigation more effective, cargo may be wholly or partially discharged prior to such fumigation, but care will be taken to discharge no cargo which might harbor rats,⁴ except for fumigation.
4. All rats recovered after fumigation should be examined bacteriologically.
5. Healthy contacts, except those actually exposed to cases of pneumonic plague, will not be detained in quarantine.
6. The vessel will not be granted pratique until it is reasonably certain that it is free from rats and vermin.

ART. 42. Vessels infected with cholera shall be subjected to the following treatment.

1. The vessels shall be held for observation and necessary treatment.
2. The sick, if any, shall be removed and placed under appropriate treatment in isolation.
3. All persons on board shall be subjected to bacteriological examination, and shall not be admitted to entry until demonstrated free from cholera vibrios.
4. Appropriate disinfection shall be performed.

ART. 43. Vessels infected with yellow fever shall be subjected to the following treatment.

1. The vessel shall be held for observation and necessary treatment.

⁴ Explanatory Footnote:—The nature of the goods or merchandise likely to harbor rats (plague suspicious cargo), shall, for purpose of this section, be deemed to be the following, namely; rice or other grain (exclusive of flour); oilcake in sacks; beans in mats or sacks; goods packed in crates with straw or similar packing material; matting in bundles; dried vegetables in baskets or cases; dried and salted fish; peanuts in sacks; dry ginger; curios, etc., in fragile cases; copra, loose hemp in bundles; coiled rope in sacking; kapok; maize in bags; sea grass in bales; tiles, large pipes and similar articles; and bamboo poles in bundles. [Footnote in original.]

2. The sick, if any, shall be removed and placed under appropriate treatment in isolation from *Aedes aegypti* mosquitoes.

3. All persons on board non immune to yellow fever shall be placed under observation to complete six days from the last possible exposure to *Aedes aegypti* mosquitoes.

4. The vessel shall be freed from *Aedes aegypti* mosquitoes.

ART. 44. Vessels infected with smallpox shall be subjected to the following treatment.

1. The vessels shall be held for observation and necessary treatment.

2. The sick, if any, shall be removed and placed under appropriate treatment in isolation.

3. All persons on board shall be vaccinated. As an option the passenger may elect to undergo isolation to complete fourteen days from the last possible exposure to the disease.

4. All living quarters of the vessels shall be rendered mechanically clean, and used clothing and bedding of the patient disinfected.

ART. 45. Vessels infected with typhus shall be subjected to the following treatment.

1. The vessel shall be held for observation and necessary treatment.

2. The sick, if any, shall be removed and placed under appropriate treatment in isolation from lice.

3. All persons on board and their personal effects shall be deloused.

4. All persons on board who have been exposed to the infection shall be placed under observation to complete twelve days from the last possible exposure to the infection.

5. The vessel shall be deloused.

ART. 46. The time of detention of vessels for inspection or treatment shall be the least consistent with public safety and scientific knowledge. It is the duty of port health officers to facilitate the speedy movement of vessels to the utmost compatible with the foregoing.

ART. 47. The power and authority of quarantine will not be utilized for financial gain, and no charges for quarantine services will exceed actual cost plus a reasonable surcharge for administrative expenses and fluctuations in the market prices of materials used.

CHAPTER VII

FUMIGATION STANDARDS

ART. 48. Sulphur dioxide, hydrocyanic acid and cyanogen chloride gas mixture shall be considered as standard fumigants when used in accordance with the table set forth in the appendix, as regards hours of exposure and of quantities of fumigants per 1,000 cubic feet.

ART. 49. Fumigation of ships to be most effective should be performed periodically and preferably at six months intervals, and should include the entire vessel and its lifeboats. The vessels should be free of cargo.

ART. 50. Before the liberation of hydrogen cyanide or cyanogen chloride, all personnel of the vessel will be removed, and care will be observed that all compartments are rendered as nearly gas tight as possible.

CHAPTER VIII

MEDICAL OFFICERS OF VESSELS

ART. 51. In order to better protect the health of travelers by sea, to aid in the prevention of the international spread of disease and to facilitate the movement of international commerce and communication, the signatory Governments are authorized in their discretion to license physicians employed on vessels.

ART. 52. It is recommended that license not be issued unless the applicant therefor is a graduate in medicine from a duly chartered and recognized school of medicine, is the holder of an unrepealed license to practice medicine, and has successfully passed an examination as to his moral and mental fitness to be the surgeon or medical officer of a vessel. Said examination shall be set by the directing head of the national health service, and shall require of the applicant a competent knowledge of medicine and surgery. Said directing head of the national health service may issue a license to an applicant who successfully passes the examination, and may revoke said license upon conviction of malpractice, unprofessional conduct, offenses involving moral turpitude or infraction of any of the sanitary laws or regulations of any of the signatory Governments based upon the provisions of this code.

ART. 53. When duly licensed as aforesaid, said surgeons or medical officers of vessels may be utilized in aid of inspection as defined in this code.

CHAPTER IX

THE PAN AMERICAN SANITARY BUREAU

Functions and Duties

ART. 54. The organization, functions and duties of the Pan American Sanitary Bureau shall include those heretofore determined for the International Sanitary Bureau by the various International Sanitary and other Conferences of American Republics, and such additional administrative functions and duties as may be hereafter determined by Pan American Sanitary Conferences.

ART. 55. The Pan American Sanitary Bureau shall be the central coordinating sanitary agency of the various member Republics of the Pan American Union, and the general collection and distribution center of sanitary information to and from said Republics. For this purpose it shall, from time to time,

designate representatives to visit and confer with the sanitary authorities of the various signatory Governments on public health matters, and such representatives shall be given all available sanitary information in the countries visited by them in the course of their official visits and conferences.

ART. 56. In addition, the Pan American Sanitary Bureau shall perform the following specific functions:

To supply to the sanitary authorities of the signatory Governments through its publications, or in other appropriate manner, all available information relative to the actual status of the communicable diseases of man, new invasions of such diseases, the sanitary measures undertaken, and the progress effected in the control or eradication of such diseases; new methods for combating disease; morbidity and mortality statistics; public health organization and administration; progress in any of the branches of preventive medicine, and other pertinent information relative to sanitation and public health in any of its phases, including a bibliography of books and periodicals on public hygiene.

In order to more efficiently discharge its functions, it may undertake cooperative epidemiological and other studies; may employ at headquarters and elsewhere, experts for this purpose; may stimulate and facilitate scientific researches and the practical application of the results therefrom; and may accept gifts, benefactions and bequests, which shall be accounted for in the manner now provided for the maintenance funds of the Bureau.

ART. 57. The Pan American Sanitary Bureau shall advise and consult with the sanitary authorities of the various signatory Governments relative to public health problems, and the manner of interpreting and applying the provisions of this Code.

ART. 58. Officials of the National Health Services may be designated as representatives, ex-officio, of the Pan American Sanitary Bureau, in addition to their regular duties, and when so designated they may be empowered to act as sanitary representatives of one or more of the signatory Governments when properly designated and accredited to so serve.

ART. 59. Upon request of the sanitary authorities of any of the signatory Governments, the Pan American Sanitary Bureau is authorized to take the necessary preparatory steps to bring about an exchange of professors, medical and health officers, experts or advisers in public health or any of the sanitary sciences, for the purpose of mutual aid and advancement in the protection of the public health of the signatory Governments.

ART. 60. For the purpose of discharging the functions and duties imposed upon the Pan American Sanitary Bureau, a fund of not less than \$50,000 shall be collected by the Pan American Union, apportioned among the signatory Governments on the same basis as are the expenses of the Pan American Union.

CHAPTER X

AIRCRAFT

ART. 61. The provisions of this Convention shall apply to aircraft, and the signatory Governments agree to designate landing places for aircraft which shall have the same status as quarantine anchorages.

CHAPTER XI

SANITARY CONVENTION OF WASHINGTON

ART. 62. The provisions of Articles 5, 6, 13, 14, 15, 16, 17, 18, 25, 30, 32, 33, 34, 37, 38, 39, 40, 41, 42, 43, 44, 45, 49, and 50, of the Pan American Sanitary Convention concluded in Washington on October 14, 1905,⁶ are hereby continued in full force and effect, except in so far as they may be in conflict with the provisions of this Convention.

CHAPTER XII

Be it understood that this Code does not in any way abrogate or impair the validity or force of any existing treaty convention or agreement between any of the signatory governments and any other government.

CHAPTER XIII

TRANSITORY DISPOSITION

ART. 63. The Governments which may not have signed the present Convention are to be admitted to adherence thereto upon demand, notice of this adherence to be given through diplomatic channels to the Government of the Republic of Cuba.

Made and signed in the city of Havana, on the fourteenth day of the month of November, 1924, in two copies, in English and Spanish, respectively, which shall be deposited with the Department of Foreign Relations of the Republic of Cuba, in order that certified copies thereof, in both English and Spanish, may be made for transmission through diplomatic channels to each of the signatory Governments.

By the Republic of Argentina:
GREGORIO ARAOZ ALFARO
JOAQUIN LLAMBIAS

By the United States of Brazil:
NASCIMENTO GURGEL
RAUL ALMEIDA MAGALHAES

By the Republic of Chile:
CARLOS GRAF

By the Republic of Colombia:
R. GUTIERREZ LEE

By the Republic of Costa Rica:
JOSE VARELA ZEQUEIRA

⁶ TS 518, *ante*, vol. 1, p. 450.

By the Republic of Cuba:

MARIO G. LEBREDO
JOSE A. LOPEZ DEL VALLE
HUGO ROBERTS
DIEGO TAMAYO
FRANCISCO M. FERNANDEZ
DOMINGO F. RAMOS

By the Republic of El Salvador:

LEOPOLDO PAZ

By the United States of America:

HUGH S. CUMMING
RICHARD CREEL
P. D. CRONIN

By the Republic of Guatemala:

JOSE DE CUBAS Y SERRATE

By the Republic of Haiti:

CHARLES MATHON

By the Republic of Honduras:

ARISTIDES AGRAMONTE

By the Republic of Mexico:

ALFONSO PRUNEDA

By the Republic of Panama:

JAIME DE LA GUARDIA

By the Republic of Paraguay:

ANDRES GUBETICH

By the Republic of Peru:

CARLOS E. PAZ SOLDAN

By the Dominican Republic:

R. PEREZ CABRAL

By the Republic of Uruguay:

JUSTO F. GONZALEZ

By the United States of Venezuela:

ENRIQUE TEJERA
ANTONIO SMITH

APPENDIX

TABLE I

Quantities per 1,000 Cubic Feet

Chemicals	Sulphur Dioxide				Hydrocyanic Acid				Cyanogen Chloride Mixture			
	Mosqui- toes	Rats	Lice	Bed- bugs	Mosqui- toes	Rats	Lice	Bed- bugs	Mosqui- toes	Rats	Lice	Bed- bugs
Sulphur.....	2 lbs.	3 lbs.	4 lbs.	3 lbs.								
Sodium Cyanide....					½ oz.	5 oz.	10 oz.	5 oz.	½ oz.	4 oz.	8 oz.	4 oz.
Sulphuric Acid.....					½ oz.	5 oz.	10 oz.	5 oz.				
Sodium Chlorate....									¼ oz.	2 oz.	4 oz.	2 oz.
Hydrochloric Acid...									2½ oz.	17 oz.	34 oz.	17 oz.
Water.....					1¼ oz.	12½ oz.	25 oz.	12½ oz.	2½ oz.	17 oz.	34 oz.	17 oz.

TABLE II

Hours of Exposure

	Mosqui- toes	Rats	Lice	Bed- bugs	Mosqui- toes	Rats	Lice	Bed- bugs	Mosqui- toes	Rats	Lice	Bed- bugs
1 hr.	6 hrs.	6 hrs.	6 hrs.	½ hr.	2 hrs.	2 hrs.	2 hrs.	½ hr.	1½ hrs.	1½ hrs.	1½ hrs.	

Serial No.

.....Health Service
.....Quarantine Station.....

CERTIFICATE OF VACCINATION AGAINST SMALLPOX

Name.....Sex.....

Age.....Date of Vaccination.....

Height.....Date of Reaction.....

Result:

Immune Reaction
Vaccinoid
Successful Vaccination

Signed

Signature

.....Medical Officer in Charge

.....Health Service

498

MULTILATERAL AGREEMENTS 1918-1930

CERTIFICATE OF DISCHARGE FROM NATIONAL QUARANTINE

.....Quarantine Station

Port of....., 192

I CERTIFY that the.....
of....., from.....
bound for....., has in all respects complied with the
quarantine regulations prescribed under the authority of the laws of.....
....., and the Pan American Sanitary
(country)

Code, and that the vessel, cargo, crew, and passengers are, to the best of my knowledge and
belief, free from quarantinable diseases or danger of conveying the same. Said vessel is this
day granted.....pratique.

1. Rat guards of an accepted design to be placed on all lines leading from the vessels.
2. Gangways to be raised at night, or lighted and watched.
3. Vessels to be fumigated after discharge of cargo.

.....
Quarantine Officer

.....Health Service

CERTIFICATE OF FUMIGATION

(Not to be taken up by port authorities)

Port of....., 192

THIS IS TO CERTIFY that the.....
from.....has been fumigated at this station
for the destruction of....., as follows:

			Kilos or Pounds Sulphur	Grams or Ounces Cyanide	Grams or Ounces Cyanide and Sodium Chlorate	
Holds	1					Date.....
	2					Duration of exposure...
	3					
	4					Evidence of rats before fumigation.....
	5					Rats after fumigation: living....., dead.....
Engine-room & shaft alley.						Inspection made by
Bunkers.....						Opened by.....
Forepeak.....						Dunnage or other pro- tection to rats; how
Forecastle.....						treated prior to fumi- gation.....
Steerage.....						
Dining saloon (1st cabin)...						
Pantry (1st cabin).....						
Galley.....						
Second Cabin.....						
Second Cabin Pantry.....						
Provision storeroom.....						
Living quarters.....						
Staterooms.....						
Smoking Room.....						
Total.....						

.....
Quarantine Officer

On the reverse side make a report of all compartments which were not fumigated, why
they were not, and give treatment. Also report any other pertinent information.

QUARANTINE DECLARATION

.....Quarantine Station....., 192

Name of vessel.....; destination.....;

nationality.....; rig.....; tonnage.....;

date of arrival.....; port of departure.....;

intermediate ports.....;

days from port of departure.....; days from last port.....;

previous ports of departure and call.....;

officers and crew.....; cabin passengers.....; steerage

passengers.....; total number of persons on board.....;

cargo.....; ballast (tons).....; character

of.....; source..... If water

ballast, were tanks filled at the port of departure or at sea?.....

In ports of departure and call, did vessel lie at wharf or at moorings in harbor or roadstead?..... If vessel lay at

moorings, how far from shore?.....

Was there communication with the shore?..... What changes

in the personnel of the crew, if any?.....

Sickness, cases of, in port of departure. No.....; result.....

in intermediate ports. No.....; result.....

at sea. No.....; result.....

Were the sick sent to hospital or allowed to remain on board?.....

Was the bedding and clothing of those sick at sea frequently aired and washed?.....

Do you know of any circumstance affecting the health of the crew, or which renders the

ship dangerous to the health of any part of.....

(Country)

..... If so, state them.....

I certify that the foregoing statements, and the answers to the questions, are true to the best of my knowledge and belief.

Master.....

Ship's Surgeon.....

Vessel.....

Treatment of vessel.....;

disinfection of hold..... (Inspected and passed or detained)

(Method).....; cabin and forecabin..... (Method)

bedding, clothing, etc..... (Method)

Detained..... days; sickness in quarantine..... (Number of cases, and nature)

discharged in free pratique..... Port named in

certificate of discharge.....

.....

Quarantine Officer

INTERNATIONAL STANDARD FORM BILL OF HEALTH

Information Concerning the Vessel

I..... (Official title).....

(the person authorized to issue the bill, at the port of.....)

do hereby state that the vessel hereinafter named clears (or leaves) from the port of

..... under the following circumstances: Name of

vessel.....; nationality.....

Master.....; tonnage, gross.....;

net..... Name of medical officer.....

Number of officers.....; of crew, including petty officers.....;

500

MULTILATERAL AGREEMENTS 1918-1930

officers' families Passengers destined for
 (Country of destination)
 Embarking at this port First cabin; second
 cabin; steerage Total number of passen-
 gers on board
 Ports visited within preceding four months

 Location of vessel while in port—wharf; open
 bay; distance from shore
 If any passengers or members of crew disembarked on account of sickness, state disease . .

 Time vessel was in port (date and hour of arrival);
 (date and hour of departure)
 Character of communication with shore
 Sanitary condition of vessel
 Sanitary measures, if any, adopted while in port
 Date of last fumigation for the destruction of rodents
 Number of rodents obtained
 Port where fumigated and officials supervising the
 fumigation
 Method of fumigation used (for rodents);
 (for mosquitoes)

Information Concerning the Port

Sanitary conditions of port and vicinity
 Prevailing diseases at port and vicinity

*Number of Cases and Deaths from the Following Named Diseases During the Two
 Weeks Ending*

Diseases	Number of Cases ¹	Number of Deaths ¹	REMARKS (Any conditions affecting the public health existing in the port or vicinity to be here stated)
Yellow Fever			
Asiatic Cholera			
Cholera nostras or cholerae			
Smallpox			
Typhus Fever			
Plague			
Leprosy			

(¹ When there are no cases or deaths, entry to that effect must be made.)

Health Office of the Port of (When
 practicable this certificate should be signed by the Health Officer of the Port)

Date of last case of:

Cholera
 Yellow Fever
 Human Plague
 Typhus
 Rodent Plague

Measures, if any, imposed by the municipality against rats during the last six months . . .

Signature of Port Health Officer

*I certify that the vessel has complied with the rules and regulations made under the terms of the Pan
 American Sanitary Code, and with the laws and regulations of the country of destination. The vessel
 leaves this port bound for, via*

Given under my hand and seal this day of

., 192
 (Signature of consular officer)

[SEAL]

Countersigned by

Medical Officer

INTERNATIONAL HEALTH

REGULATIONS (2005)

SECOND EDITION



World Health
Organization

INTERNATIONAL HEALTH REGULATIONS (2005)
SECOND EDITION

INTERNATIONAL HEALTH REGULATIONS (2005)

SECOND EDITION



WHO Library Cataloguing-in-Publication Data

International health regulations (2005) -- 2nd ed.

1. Legislation, Health. 2. Communicable disease control - legislation. 3. Disease notification - legislation. 4. International cooperation. I. World Health Organization. II. Title: IHR (2005).

ISBN 978 92 4 158041 0

(NLM classification: WA 32.1)

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Printed in Switzerland

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FOREWORD

A central and historic responsibility for the World Health Organization (WHO) has been the management of the global regime for the control of the international spread of disease. Under Articles 21(a) and 22, the Constitution of WHO confers upon the World Health Assembly the authority to adopt regulations “designed to prevent the international spread of disease” which, after adoption by the Health Assembly, enter into force for all WHO Member States that do not affirmatively opt out of them within a specified time period.

The International Health Regulations (“the IHR” or “Regulations”) were adopted by the Health Assembly in 1969¹, having been preceded by the International Sanitary Regulations adopted by the Fourth World Health Assembly in 1951. The 1969 Regulations, which initially covered six “quarantinable diseases” were amended in 1973² and 1981³, primarily to reduce the number of covered diseases from six to three (yellow fever, plague and cholera) and to mark the global eradication of smallpox.

In consideration of the growth in international travel and trade, and the emergence or re-emergence of international disease threats and other public health risks, the Forty-eighth World Health Assembly in 1995 called for a substantial revision of the Regulations adopted in 1969⁴. In resolution WHA48.7, the Health Assembly requested the Director-General to take steps to prepare their revision, urging broad participation and cooperation in the process.

After extensive preliminary work on the revision by WHO’s Secretariat in close consultation with WHO Member States, international organizations and other relevant partners, and the momentum created by the emergence of severe acute respiratory syndrome (the first global public health emergency of the 21st century)⁵, the Health Assembly established an Intergovernmental Working Group in 2003 open to all Member States to review and recommend a draft revision of the Regulations to the Health Assembly⁶. The IHR (2005) were adopted by the Fifty-eighth World Health Assembly on 23 May 2005⁷. They entered into force on 15 June 2007.

The purpose and scope of the IHR (2005) are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.” The IHR (2005) contain a range of innovations, including: (a) a scope not limited to any specific disease or manner of transmission, but covering “illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans”; (b) State Party obligations to develop certain minimum core public health capacities; (c) obligations on States Parties to notify WHO of events that may constitute a public health emergency of international concern according to defined criteria; (d) provisions authorizing WHO to take into consideration unofficial reports of public health events and to obtain verification from States Parties concerning such events; (e) procedures for the determination by the Director-General of a “public health emergency of international concern” and issuance of corresponding temporary recommendations, after taking into account the views of an Emergency Committee; (f) protection of the human rights of persons and travellers; and (g) the

¹ See WHO Official Records, No. 176, 1969, resolution WHA22.46 and Annex I.

² See WHO Official Records, No. 209, 1973, resolution WHA26.55.

³ See document WHA34/1981/REC/1 resolution WHA34.13; see also WHO Official Records, No. 217, 1974, resolution WHA27.45, and resolution EB67.R13, Amendment of the International Health Regulations (1969).

⁴ See resolution WHA48.7.

⁵ See resolution WHA56.29.

⁶ See resolution WHA56.28.

⁷ See resolution WHA58.3.

establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and WHO.

By not limiting the application of the IHR (2005) to specific diseases, it is intended that the Regulations will maintain their relevance and applicability for many years to come even in the face of the continued evolution of diseases and of the factors determining their emergence and transmission. The provisions in the IHR (2005) also update and revise many of the technical and other regulatory functions, including certificates applicable to international travel and transport, and requirements for international ports, airports and ground crossings.

This second edition contains the text of the IHR (2005), the text of World Health Assembly resolution WHA58.3, the version of the Health Part of the Aircraft General Declaration that entered into force on 15 July 2007, appendices containing a list of States Parties and State Party reservations and other communications in connection with the IHR (2005).

REVISION OF THE INTERNATIONAL HEALTH REGULATIONS

The Fifty-eighth World Health Assembly,

Having considered the draft revised International Health Regulations¹;

Having regard to articles 2(k), 21(a) and 22 of the Constitution of WHO;

Recalling references to the need for revising and updating the International Health Regulations in resolutions WHA48.7 on revision and updating of the International Health Regulations, WHA54.14 on global health security: epidemic alert and response, WHA55.16 on global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health, WHA56.28 on revision of the International Health Regulations, and WHA56.29 on severe acute respiratory syndrome (SARS), with a view to responding to the need to ensure global public health;

Welcoming resolution 58/3 of the United Nations General Assembly on enhancing capacity building in global public health, which underscores the importance of the International Health Regulations and urges that high priority should be given to their revision;

Affirming the continuing importance of WHO's role in global outbreak alert and response to public health events, in accordance with its mandate;

Underscoring the continued importance of the International Health Regulations as the key global instrument for protection against the international spread of disease;

Commending the successful conclusion of the work of the Intergovernmental Working Group on Revision of the International Health Regulations,

1. ADOPTS the revised International Health Regulations attached to this resolution, to be referred to as the "International Health Regulations (2005)";
2. CALLS UPON Member States and the Director-General to implement fully the International Health Regulations (2005), in accordance with the purpose and scope set out in Article 2 and the principles embodied in Article 3;
3. DECIDES, for the purposes of paragraph 1 of Article 54 of the International Health Regulations (2005), that States Parties and the Director-General shall submit their first report to the Sixty-first World Health Assembly, and that the Health Assembly shall on that occasion consider the schedule for the submission of further such reports and the first review on the functioning of the Regulations pursuant to paragraph 2 of Article 54;
4. FURTHER DECIDES that, for the purposes of paragraph 1 of Article 14 of the International Health Regulations (2005), the other competent intergovernmental organizations or international bodies with which WHO is expected to cooperate and coordinate its activities, as appropriate, include the following: United Nations, International Labour Organization, Food and Agriculture Organization, International Atomic Energy Agency, International Civil Aviation Organization, International Maritime Organization, International Committee of the Red Cross, International Federation of Red

¹ See document A58/4.

Cross and Red Crescent Societies, International Air Transport Association, International Shipping Federation, and *Office International des Epizooties*;

5. URGES Member States:

- (1) to build, strengthen and maintain the capacities required under the International Health Regulations (2005), and to mobilize the resources necessary for that purpose;
- (2) to collaborate actively with each other and WHO in accordance with the relevant provisions of the International Health Regulations (2005), so as to ensure their effective implementation;
- (3) to provide support to developing countries and countries with economies in transition if they so request in the building, strengthening and maintenance of the public health capacities required under the International Health Regulations (2005);
- (4) to take all appropriate measures for furthering the purpose and eventual implementation of the International Health Regulations (2005) pending their entry into force, including development of the necessary public health capacities and legal and administrative provisions, and, in particular, to initiate the process for introducing use of the decision instrument contained in Annex 2;

6. REQUESTS the Director-General:

- (1) to give prompt notification of adoption of the International Health Regulations (2005) in accordance with paragraph 1 of Article 65 thereof;
- (2) to inform other competent intergovernmental organizations or international bodies of adoption of the International Health Regulations (2005) and, as appropriate, to cooperate with them in the updating of their norms and standards and to coordinate with them the activities of WHO under the International Health Regulations (2005) with a view to ensuring application of adequate measures for the protection of public health and strengthening of the global public-health response to the international spread of disease;
- (3) to transmit to the International Civil Aviation Organization (ICAO) the recommended changes to the Health Part of the Aircraft General Declaration,¹ and, after completion by ICAO of its revision of the Aircraft General Declaration, to inform the Health Assembly and replace Annex 9 of the International Health Regulations (2005) with the Health Part of the Aircraft General Declaration as revised by ICAO;
- (4) to build and strengthen the capacities of WHO to perform fully and effectively the functions entrusted to it under the International Health Regulations (2005), in particular through strategic health operations that provide support to countries in detection and assessment of, and response to, public health emergencies;
- (5) to collaborate with States Parties to the International Health Regulations (2005), as appropriate, including through the provision or facilitation of technical cooperation and logistical support;
- (6) to collaborate with States Parties to the extent possible in the mobilization of financial resources to provide support to developing countries in building, strengthening and maintaining the capacities required under the International Health Regulations (2005);

¹ Document A58/41 Add.2.

(7) to draw up, in consultation with Member States, guidelines for the application of health measures at ground crossings in accordance with Article 29 of the International Health Regulations (2005);

(8) to establish the Review Committee of the International Health Regulations (2005) in accordance with Article 50 of the Regulations;

(9) to take steps immediately to prepare guidelines for implementation and evaluation of the decision instrument contained in the International Health Regulations (2005), including elaboration of a procedure for review of its functioning, which shall be submitted to the Health Assembly for its consideration pursuant to paragraph 3 of Article 54 of the Regulations;

(10) to take steps to establish an IHR Roster of Experts and to invite proposals for its membership, pursuant to Article 47 of the International Health Regulations (2005).

INTERNATIONAL HEALTH REGULATIONS (2005)

PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES

Article 1 Definitions

1. For the purposes of the International Health Regulations (hereinafter “the IHR” or “Regulations”):

“affected” means persons, baggage, cargo, containers, conveyances, goods, postal parcels or human remains that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk;

“affected area” means a geographical location specifically for which health measures have been recommended by WHO under these Regulations;

“aircraft” means an aircraft making an international voyage;

“airport” means any airport where international flights arrive or depart;

“arrival” of a conveyance means:

- (a) in the case of a seagoing vessel, arrival or anchoring in the defined area of a port;
- (b) in the case of an aircraft, arrival at an airport;
- (c) in the case of an inland navigation vessel on an international voyage, arrival at a point of entry;
- (d) in the case of a train or road vehicle, arrival at a point of entry;

“baggage” means the personal effects of a traveller;

“cargo” means goods carried on a conveyance or in a container;

“competent authority” means an authority responsible for the implementation and application of health measures under these Regulations;

“container” means an article of transport equipment:

- (a) of a permanent character and accordingly strong enough to be suitable for repeated use;
- (b) specially designed to facilitate the carriage of goods by one or more modes of transport, without intermediate reloading;
- (c) fitted with devices permitting its ready handling, particularly its transfer from one mode of transport to another; and
- (d) specially designed as to be easy to fill and empty;

“container loading area” means a place or facility set aside for containers used in international traffic;

“contamination” means the presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

“conveyance” means an aircraft, ship, train, road vehicle or other means of transport on an international voyage;

“conveyance operator” means a natural or legal person in charge of a conveyance or their agent;

“crew” means persons on board a conveyance who are not passengers;

“decontamination” means a procedure whereby health measures are taken to eliminate an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

“departure” means, for persons, baggage, cargo, conveyances or goods, the act of leaving a territory;

“deratting” means the procedure whereby health measures are taken to control or kill rodent vectors of human disease present in baggage, cargo, containers, conveyances, facilities, goods and postal parcels at the point of entry;

“Director-General” means the Director-General of the World Health Organization;

“disease” means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;

“disinfection” means the procedure whereby health measures are taken to control or kill infectious agents on a human or animal body surface or in or on baggage, cargo, containers, conveyances, goods and postal parcels by direct exposure to chemical or physical agents;

“disinsection” means the procedure whereby health measures are taken to control or kill the insect vectors of human diseases present in baggage, cargo, containers, conveyances, goods and postal parcels;

“event” means a manifestation of disease or an occurrence that creates a potential for disease;

“*free pratique*” means permission for a ship to enter a port, embark or disembark, discharge or load cargo or stores; permission for an aircraft, after landing, to embark or disembark, discharge or load cargo or stores; and permission for a ground transport vehicle, upon arrival, to embark or disembark, discharge or load cargo or stores;

“goods” mean tangible products, including animals and plants, transported on an international voyage, including for utilization on board a conveyance;

“ground crossing” means a point of land entry in a State Party, including one utilized by road vehicles and trains;

“ground transport vehicle” means a motorized conveyance for overland transport on an international voyage, including trains, coaches, lorries and automobiles;

“health measure” means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;

“ill person” means an individual suffering from or affected with a physical ailment that may pose a public health risk;

“infection” means the entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk;

“inspection” means the examination, by the competent authority or under its supervision, of areas, baggage, containers, conveyances, facilities, goods or postal parcels, including relevant data and documentation, to determine if a public health risk exists;

“international traffic” means the movement of persons, baggage, cargo, containers, conveyances, goods or postal parcels across an international border, including international trade;

“international voyage” means:

(a) in the case of a conveyance, a voyage between points of entry in the territories of more than one State, or a voyage between points of entry in the territory or territories of the same State if the conveyance has contacts with the territory of any other State on its voyage but only as regards those contacts;

(b) in the case of a traveller, a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences the voyage;

“intrusive” means possibly provoking discomfort through close or intimate contact or questioning;

“invasive” means the puncture or incision of the skin or insertion of an instrument or foreign material into the body or the examination of a body cavity. For the purposes of these Regulations, medical examination of the ear, nose and mouth, temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; medical inspection; auscultation; external palpation; retinoscopy; external collection of urine, faeces or saliva samples; external measurement of blood pressure; and electrocardiography shall be considered to be non-invasive;

“isolation” means separation of ill or contaminated persons or affected baggage, containers, conveyances, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination;

“medical examination” means the preliminary assessment of a person by an authorized health worker or by a person under the direct supervision of the competent authority, to determine the person’s health status and potential public health risk to others, and may include the scrutiny of health documents, and a physical examination when justified by the circumstances of the individual case;

“National IHR Focal Point” means the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations;

“Organization” or “WHO” means the World Health Organization;

“permanent residence” has the meaning as determined in the national law of the State Party concerned;

“personal data” means any information relating to an identified or identifiable natural person;

“point of entry” means a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit;

“port” means a seaport or a port on an inland body of water where ships on an international voyage arrive or depart;

“postal parcel” means an addressed article or package carried internationally by postal or courier services;

“public health emergency of international concern” means an extraordinary event which is determined, as provided in these Regulations:

- (i) to constitute a public health risk to other States through the international spread of disease and
- (ii) to potentially require a coordinated international response;

“public health observation” means the monitoring of the health status of a traveller over time for the purpose of determining the risk of disease transmission;

“public health risk” means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger;

“quarantine” means the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination;

“recommendation” and “recommended” refer to temporary or standing recommendations issued under these Regulations;

“reservoir” means an animal, plant or substance in which an infectious agent normally lives and whose presence may constitute a public health risk;

“road vehicle” means a ground transport vehicle other than a train;

“scientific evidence” means information furnishing a level of proof based on the established and accepted methods of science;

“scientific principles” means the accepted fundamental laws and facts of nature known through the methods of science;

“ship” means a seagoing or inland navigation vessel on an international voyage;

“standing recommendation” means non-binding advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;

“surveillance” means the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary;

“suspect” means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease;

“temporary recommendation” means non-binding advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;

“temporary residence” has the meaning as determined in the national law of the State Party concerned;

“traveller” means a natural person undertaking an international voyage;

“vector” means an insect or other animal which normally transports an infectious agent that constitutes a public health risk;

“verification” means the provision of information by a State Party to WHO confirming the status of an event within the territory or territories of that State Party;

“WHO IHR Contact Point” means the unit within WHO which shall be accessible at all times for communications with the National IHR Focal Point.

2. Unless otherwise specified or determined by the context, reference to these Regulations includes the annexes thereto.

Article 2 Purpose and scope

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

Article 3 Principles

1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons.
2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.
3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.
4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.

Article 4 Responsible authorities

1. Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.
2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:
 - (a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and
 - (b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.
3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.
4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.

PART II – INFORMATION AND PUBLIC HEALTH RESPONSE

Article 5 Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.
2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances, and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Committee established under Article 50 (hereinafter the “Review Committee”). After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.
3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.
4. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.

Article 6 Notification

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), WHO shall immediately notify the IAEA.

2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Article 7 Information-sharing during unexpected or unusual public health events

If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information. In such a case, the provisions of Article 6 shall apply in full.

Article 8 Consultation

In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.

Article 9 Other reports

1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.

2. States Parties shall, as far as practicable, inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by exported or imported:

- (a) human cases;
- (b) vectors which carry infection or contamination; or
- (c) goods that are contaminated.

Article 10 Verification

1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:
 - (a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;
 - (b) within 24 hours, available public health information on the status of events referred to in WHO's request; and
 - (c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.
3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.
4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

Article 11 Provision of information by WHO

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.
2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:
 - (a) the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or
 - (b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or

- (c) there is evidence that:
 - (i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or
 - (ii) the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or
 - (d) the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures.
3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.
 4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.

Article 12 Determination of a public health emergency of international concern

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.
2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.
3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.
4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:
 - (a) information provided by the State Party;
 - (b) the decision instrument contained in Annex 2;
 - (c) the advice of the Emergency Committee;
 - (d) scientific principles as well as the available scientific evidence and other relevant information; and
 - (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

Article 13 Public health response

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.

2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Review Committee. After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

3. At the request of a State Party, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.

6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern.

*Article 14 Cooperation of WHO with intergovernmental organizations
and international bodies*

1. WHO shall cooperate and coordinate its activities, as appropriate, with other competent intergovernmental organizations or international bodies in the implementation of these Regulations, including through the conclusion of agreements and other similar arrangements.

2. In cases in which notification or verification of, or response to, an event is primarily within the competence of other intergovernmental organizations or international bodies, WHO shall coordinate its activities with such organizations or bodies in order to ensure the application of adequate measures for the protection of public health.

3. Notwithstanding the foregoing, nothing in these Regulations shall preclude or limit the provision by WHO of advice, support, or technical or other assistance for public health purposes.

PART III – RECOMMENDATIONS

Article 15 Temporary recommendations

1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.
2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.
3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern to which they relate.

Article 16 Standing recommendations

WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

Article 17 Criteria for recommendations

When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:

- (a) the views of the States Parties directly concerned;
- (b) the advice of the Emergency Committee or the Review Committee, as the case may be;
- (c) scientific principles as well as available scientific evidence and information;
- (d) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;
- (e) relevant international standards and instruments;
- (f) activities undertaken by other relevant intergovernmental organizations and international bodies; and
- (g) other appropriate and specific information relevant to the event.

With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations imposed by urgent circumstances.

Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels

1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:

- no specific health measures are advised;
- review travel history in affected areas;
- review proof of medical examination and any laboratory analysis;
- require medical examinations;
- review proof of vaccination or other prophylaxis;
- require vaccination or other prophylaxis;
- place suspect persons under public health observation;
- implement quarantine or other health measures for suspect persons;
- implement isolation and treatment where necessary of affected persons;
- implement tracing of contacts of suspect or affected persons;
- refuse entry of suspect and affected persons;
- refuse entry of unaffected persons to affected areas; and
- implement exit screening and/or restrictions on persons from affected areas.

2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:

- no specific health measures are advised;
- review manifest and routing;
- implement inspections;
- review proof of measures taken on departure or in transit to eliminate infection or contamination;
- implement treatment of the baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;
- the use of specific health measures to ensure the safe handling and transport of human remains;
- implement isolation or quarantine;

- seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful; and
- refuse departure or entry.

PART IV – POINTS OF ENTRY

Article 19 General obligations

Each State Party shall, in addition to the other obligations provided for under these Regulations:

- (a) ensure that the capacities set forth in Annex 1 for designated points of entry are developed within the timeframe provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;
- (b) identify the competent authorities at each designated point of entry in its territory; and
- (c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.

Article 20 Airports and ports

1. States Parties shall designate the airports and ports that shall develop the capacities provided in Annex 1.
2. States Parties shall ensure that Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates are issued in accordance with the requirements in Article 39 and the model provided in Annex 3.
3. Each State Party shall send to WHO a list of ports authorized to offer:
 - (a) the issuance of Ship Sanitation Control Certificates and the provision of the services referred to in Annexes 1 and 3; or
 - (b) the issuance of Ship Sanitation Control Exemption Certificates only; and
 - (c) extension of the Ship Sanitation Control Exemption Certificate for a period of one month until the arrival of the ship in the port at which the Certificate may be received.

Each State Party shall inform WHO of any changes which may occur to the status of the listed ports. WHO shall publish the information received under this paragraph.

4. WHO may, at the request of the State Party concerned, arrange to certify, after an appropriate investigation, that an airport or port in its territory meets the requirements referred to in paragraphs 1 and 3 of this Article. These certifications may be subject to periodic review by WHO, in consultation with the State Party.
5. WHO, in collaboration with competent intergovernmental organizations and international bodies, shall develop and publish the certification guidelines for airports and ports under this Article. WHO shall also publish a list of certified airports and ports.

Article 21 Ground crossings

1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the capacities provided in Annex 1, taking into consideration:
 - (a) the volume and frequency of the various types of international traffic, as compared to other points of entry, at a State Party's ground crossings which might be designated; and
 - (b) the public health risks existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.
2. States Parties sharing common borders should consider:
 - (a) entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 57; and
 - (b) joint designation of adjacent ground crossings for the capacities in Annex 1 in accordance with paragraph 1 of this Article.

Article 22 Role of competent authorities

1. The competent authorities shall:
 - (a) be responsible for monitoring baggage, cargo, containers, conveyances, goods, postal parcels and human remains departing and arriving from affected areas, so that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors and reservoirs;
 - (b) ensure, as far as practicable, that facilities used by travellers at points of entry are maintained in a sanitary condition and are kept free of sources of infection or contamination, including vectors and reservoirs;
 - (c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of baggage, cargo, containers, conveyances, goods, postal parcels and human remains or sanitary measures for persons, as appropriate under these Regulations;
 - (d) advise conveyance operators, as far in advance as possible, of their intent to apply control measures to a conveyance, and shall provide, where available, written information concerning the methods to be employed;
 - (e) be responsible for the supervision of the removal and safe disposal of any contaminated water or food, human or animal dejecta, wastewater and any other contaminated matter from a conveyance;
 - (f) take all practicable measures consistent with these Regulations to monitor and control the discharge by ships of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate the waters of a port, river, canal, strait, lake or other international waterway;
 - (g) be responsible for supervision of service providers for services concerning travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains at points of entry, including the conduct of inspections and medical examinations as necessary;

(h) have effective contingency arrangements to deal with an unexpected public health event; and

(i) communicate with the National IHR Focal Point on the relevant public health measures taken pursuant to these Regulations.

2. Health measures recommended by WHO for travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains arriving from an affected area may be reapplied on arrival, if there are verifiable indications and/or evidence that the measures applied on departure from the affected area were unsuccessful.

3. Disinsection, deratting, disinfection, decontamination and other sanitary procedures shall be carried out so as to avoid injury and as far as possible discomfort to persons, or damage to the environment in a way which impacts on public health, or damage to baggage, cargo, containers, conveyances, goods and postal parcels.

PART V – PUBLIC HEALTH MEASURES

Chapter I – General provisions

Article 23 Health measures on arrival and departure

1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, on arrival or departure:

(a) with regard to travellers:

(i) information concerning the traveller's destination so that the traveller may be contacted;

(ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or

(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;

(b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.

2. On the basis of evidence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular, with regard to a suspect or affected traveller, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.

3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 31, and in accordance with the law and international obligations of the State Party.

4. Travellers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis in accordance with the law and international obligations of the

State Party. States Parties shall inform medical practitioners of these requirements in accordance with the law of the State Party.

5. Any medical examination, medical procedure, vaccination or other prophylaxis which involves a risk of disease transmission shall only be performed on, or administered to, a traveller in accordance with established national or international safety guidelines and standards so as to minimize such a risk.

Chapter II – Special provisions for conveyances and conveyance operators

Article 24 Conveyance operators

1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:
 - (a) comply with the health measures recommended by WHO and adopted by the State Party;
 - (b) inform travellers of the health measures recommended by WHO and adopted by the State Party for application on board; and
 - (c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.
2. Specific provisions pertaining to conveyances and conveyance operators under this Article are provided in Annex 4. Specific measures applicable to conveyances and conveyance operators with regard to vector-borne diseases are provided in Annex 5.

Article 25 Ships and aircraft in transit

Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied by a State Party to:

- (a) a ship not coming from an affected area which passes through a maritime canal or waterway in the territory of that State Party on its way to a port in the territory of another State. Any such ship shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies;
- (b) a ship which passes through waters within its jurisdiction without calling at a port or on the coast; and
- (c) an aircraft in transit at an airport within its jurisdiction, except that the aircraft may be restricted to a particular area of the airport with no embarking and disembarking or loading and discharging. However, any such aircraft shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

Article 26 Civilian lorries, trains and coaches in transit

Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied to a civilian lorry, train or coach not coming from an affected area which passes through a territory without embarking, disembarking, loading or discharging.

Article 27 Affected conveyances

1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:

- (a) disinfect, decontaminate, disinfest or derat the conveyance, as appropriate, or cause these measures to be carried out under its supervision; and
- (b) decide in each case the technique employed to secure an adequate level of control of the public health risk as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority determines that other methods are as safe and reliable.

The competent authority may implement additional health measures, including isolation of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.

2. If the competent authority for the point of entry is not able to carry out the control measures required under this Article, the affected conveyance may nevertheless be allowed to depart, subject to the following conditions:

- (a) the competent authority shall, at the time of departure, inform the competent authority for the next known point of entry of the type of information referred to under subparagraph (b); and
- (b) in the case of a ship, the evidence found and the control measures required shall be noted in the Ship Sanitation Control Certificate.

Any such conveyance shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

3. A conveyance that has been considered as affected shall cease to be regarded as such when the competent authority is satisfied that:

- (a) the measures provided in paragraph 1 of this Article have been effectively carried out; and
- (b) there are no conditions on board that could constitute a public health risk.

Article 28 Ships and aircraft at points of entry

1. Subject to Article 43 or as provided in applicable international agreements, a ship or an aircraft shall not be prevented for public health reasons from calling at any point of entry. However, if the point of entry is not equipped for applying health measures under these Regulations, the ship or aircraft may be ordered to proceed at its own risk to the nearest suitable point of entry available to it, unless the ship or aircraft has an operational problem which would make this diversion unsafe.

2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused *free pratique* by States Parties for public health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of *free pratique* to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinfestation or deratting, or other measures necessary to prevent the spread of the infection or contamination.

3. Whenever practicable and subject to the previous paragraph, a State Party shall authorize the granting of *free pratique* by radio or other communication means to a ship or an aircraft when, on the basis of information received from it prior to its arrival, the State Party is of the opinion that the arrival of the ship or aircraft will not result in the introduction or spread of disease.

4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control as early as possible before arrival at the port or airport of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board as soon as such illnesses or public health risks are made known to the officer or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority.

5. The following shall apply if a suspect or affected aircraft or ship, for reasons beyond the control of the pilot in command of the aircraft or the officer in command of the ship, lands elsewhere than at the airport at which the aircraft was due to land or berths elsewhere than at the port at which the ship was due to berth:

(a) the pilot in command of the aircraft or the officer in command of the ship or other person in charge shall make every effort to communicate without delay with the nearest competent authority;

(b) as soon as the competent authority has been informed of the landing it may apply health measures recommended by WHO or other health measures provided in these Regulations;

(c) unless required for emergency purposes or for communication with the competent authority, no traveller on board the aircraft or ship shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the competent authority; and

(d) when all health measures required by the competent authority have been completed, the aircraft or ship may, so far as such health measures are concerned, proceed either to the airport or port at which it was due to land or berth, or, if for technical reasons it cannot do so, to a conveniently situated airport or port.

6. Notwithstanding the provisions contained in this Article, the officer in command of a ship or pilot in command of an aircraft may take such emergency measures as may be necessary for the health and safety of travellers on board. He or she shall inform the competent authority as early as possible concerning any measures taken pursuant to this paragraph.

Article 29 Civilian lorries, trains and coaches at points of entry

WHO, in consultation with States Parties, shall develop guiding principles for applying health measures to civilian lorries, trains and coaches at points of entry and passing through ground crossings.

Chapter III – Special provisions for travellers

Article 30 Travellers under public health observation

Subject to Article 43 or as authorized in applicable international agreements, a suspect traveller who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveller's expected arrival. On arrival, the traveller shall report to that authority.

Article 31 Health measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis:

- (a) when necessary to determine whether a public health risk exists;
- (b) as a condition of entry for any travellers seeking temporary or permanent residence;
- (c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or
- (d) which may be carried out pursuant to Article 23.

2. If a traveller for whom a State Party may require a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller. If there is evidence of an imminent public health risk, the State Party may, in accordance with its national law and to the extent necessary to control such a risk, compel the traveller to undergo or advise the traveller, pursuant to paragraph 3 of Article 23, to undergo:

- (a) the least invasive and intrusive medical examination that would achieve the public health objective;
- (b) vaccination or other prophylaxis; or
- (c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

Article 32 Treatment of travellers

In implementing health measures under these Regulations, States Parties shall treat travellers with respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress associated with such measures, including by:

- (a) treating all travellers with courtesy and respect;
- (b) taking into consideration the gender, sociocultural, ethnic or religious concerns of travellers; and
- (c) providing or arranging for adequate food and water, appropriate accommodation and clothing, protection for baggage and other possessions, appropriate medical treatment, means of necessary communication if possible in a language that they can understand and other appropriate assistance for travellers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

Chapter IV – Special provisions for goods, containers and container loading areas

Article 33 Goods in transit

Subject to Article 43 or unless authorized by applicable international agreements, goods, other than live animals, in transit without transshipment shall not be subject to health measures under these Regulations or detained for public health purposes.

Article 34 Container and container loading areas

1. States Parties shall ensure, as far as practicable, that container shippers use international traffic containers that are kept free from sources of infection or contamination, including vectors and reservoirs, particularly during the course of packing.
2. States Parties shall ensure, as far as practicable, that container loading areas are kept free from sources of infection or contamination, including vectors and reservoirs.
3. Whenever, in the opinion of a State Party, the volume of international container traffic is sufficiently large, the competent authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of container loading areas and containers in order to ensure that the obligations contained in these Regulations are implemented.
4. Facilities for the inspection and isolation of containers shall, as far as practicable, be available at container loading areas.
5. Container consignees and consignors shall make every effort to avoid cross-contamination when multiple-use loading of containers is employed.

PART VI – HEALTH DOCUMENTS

Article 35 General rule

No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.

Article 36 Certificates of vaccination or other prophylaxis

1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations, or to recommendations and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.
2. A traveller in possession of a certificate of vaccination or other prophylaxis issued in conformity with Annex 6 and, when applicable, Annex 7, shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.

Article 37 Maritime Declaration of Health

1. The master of a ship, before arrival at its first port of call in the territory of a State Party, shall ascertain the state of health on board, and, except when that State Party does not require it, the master shall, on arrival, or in advance of the vessel's arrival if the vessel is so equipped and the State Party requires such advance delivery, complete and deliver to the competent authority for that port a Maritime Declaration of Health which shall be countersigned by the ship's surgeon, if one is carried.
2. The master of a ship, or the ship's surgeon if one is carried, shall supply any information required by the competent authority as to health conditions on board during an international voyage.
3. A Maritime Declaration of Health shall conform to the model provided in Annex 8.
4. A State Party may decide:
 - (a) to dispense with the submission of the Maritime Declaration of Health by all arriving ships; or
 - (b) to require the submission of the Maritime Declaration of Health under a recommendation concerning ships arriving from affected areas or to require it from ships which might otherwise carry infection or contamination.

The State Party shall inform shipping operators or their agents of these requirements.

Article 38 Health Part of the Aircraft General Declaration

1. The pilot in command of an aircraft or the pilot's agent, in flight or upon landing at the first airport in the territory of a State Party, shall, to the best of his or her ability, except when that State Party does not require it, complete and deliver to the competent authority for that airport the Health Part of the Aircraft General Declaration which shall conform to the model specified in Annex 9.
2. The pilot in command of an aircraft or the pilot's agent shall supply any information required by the State Party as to health conditions on board during an international voyage and any health measure applied to the aircraft.
3. A State Party may decide:
 - (a) to dispense with the submission of the Health Part of the Aircraft General Declaration by all arriving aircraft; or
 - (b) to require the submission of the Health Part of the Aircraft General Declaration under a recommendation concerning aircraft arriving from affected areas or to require it from aircraft which might otherwise carry infection or contamination.

The State Party shall inform aircraft operators or their agents of these requirements.

Article 39 Ship sanitation certificates

1. Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates shall be valid for a maximum period of six months. This period may be extended by one month if the inspection or control measures required cannot be accomplished at the port.

2. If a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate is not produced or evidence of a public health risk is found on board a ship, the State Party may proceed as provided in paragraph 1 of Article 27.
3. The certificates referred to in this Article shall conform to the model in Annex 3.
4. Whenever possible, control measures shall be carried out when the ship and holds are empty. In the case of a ship in ballast, they shall be carried out before loading.
5. When control measures are required and have been satisfactorily completed, the competent authority shall issue a Ship Sanitation Control Certificate, noting the evidence found and the control measures taken.
6. The competent authority may issue a Ship Sanitation Control Exemption Certificate at any port specified under Article 20 if it is satisfied that the ship is free of infection and contamination, including vectors and reservoirs. Such a certificate shall normally be issued only if the inspection of the ship has been carried out when the ship and holds are empty or when they contain only ballast or other material, of such a nature or so disposed as to make a thorough inspection of the holds possible.
7. If the conditions under which control measures are carried out are such that, in the opinion of the competent authority for the port where the operation was performed, a satisfactory result cannot be obtained, the competent authority shall make a note to that effect on the Ship Sanitation Control Certificate.

PART VII – CHARGES

Article 40 Charges for health measures regarding travellers

1. Except for travellers seeking temporary or permanent residence, and subject to paragraph 2 of this Article, no charge shall be made by a State Party pursuant to these Regulations for the following measures for the protection of public health:
 - (a) any medical examination provided for in these Regulations, or any supplementary examination which may be required by that State Party to ascertain the health status of the traveller examined;
 - (b) any vaccination or other prophylaxis provided to a traveller on arrival that is not a published requirement or is a requirement published less than 10 days prior to provision of the vaccination or other prophylaxis;
 - (c) appropriate isolation or quarantine requirements of travellers;
 - (d) any certificate issued to the traveller specifying the measures applied and the date of application; or
 - (e) any health measures applied to baggage accompanying the traveller.
2. States Parties may charge for health measures other than those referred to in paragraph 1 of this Article, including those primarily for the benefit of the traveller.
3. Where charges are made for applying such health measures to travellers under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:
 - (a) conform to this tariff;

- (b) not exceed the actual cost of the service rendered; and
 - (c) be levied without distinction as to the nationality, domicile or residence of the traveller concerned.
4. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.
5. Nothing in these Regulations shall preclude States Parties from seeking reimbursement for expenses incurred in providing the health measures in paragraph 1 of this Article:
- (a) from conveyance operators or owners with regard to their employees; or
 - (b) from applicable insurance sources.
6. Under no circumstances shall travellers or conveyance operators be denied the ability to depart from the territory of a State Party pending payment of the charges referred to in paragraphs 1 or 2 of this Article.

Article 41 Charges for baggage, cargo, containers, conveyances, goods or postal parcels

1. Where charges are made for applying health measures to baggage, cargo, containers, conveyances, goods or postal parcels under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:
- (a) conform to this tariff;
 - (b) not exceed the actual cost of the service rendered; and
 - (c) be levied without distinction as to the nationality, flag, registry or ownership of the baggage, cargo, containers, conveyances, goods or postal parcels concerned. In particular, there shall be no distinction made between national and foreign baggage, cargo, containers, conveyances, goods or postal parcels.
2. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

PART VIII – GENERAL PROVISIONS

Article 42 Implementation of health measures

Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.

Article 43 Additional health measures

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:
- (a) achieve the same or greater level of health protection than WHO recommendations; or

(b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,

provided such measures are otherwise consistent with these Regulations.

Such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.

2. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:

(a) scientific principles;

(b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies; and

(c) any available specific guidance or advice from WHO.

3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.

4. After assessing information provided pursuant to paragraph 3 and 5 of this Article and other relevant information, WHO may request that the State Party concerned reconsider the application of the measures.

5. A State Party implementing additional health measures referred to in paragraphs 1 and 2 of this Article that significantly interfere with international traffic shall inform WHO, within 48 hours of implementation, of such measures and their health rationale unless these are covered by a temporary or standing recommendation.

6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article.

7. Without prejudice to its rights under Article 56, any State Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution.

8. The provisions of this Article may apply to implementation of measures concerning travellers taking part in mass congregations.

Article 44 Collaboration and assistance

1. States Parties shall undertake to collaborate with each other, to the extent possible, in:
 - (a) the detection and assessment of, and response to, events as provided under these Regulations;
 - (b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;
 - (c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
 - (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.
2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:
 - (a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;
 - (b) the provision or facilitation of technical cooperation and logistical support to States Parties; and
 - (c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.
3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

Article 45 Treatment of personal data

1. Health information collected or received by a State Party pursuant to these Regulations from another State Party or from WHO which refers to an identified or identifiable person shall be kept confidential and processed anonymously as required by national law.
2. Notwithstanding paragraph 1, States Parties may disclose and process personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:
 - (a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose;
 - (b) adequate, relevant and not excessive in relation to that purpose;
 - (c) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and
 - (d) not kept longer than necessary.
3. Upon request, WHO shall as far as practicable provide an individual with his or her personal data referred to in this Article in an intelligible form, without undue delay or expense and, when necessary, allow for correction.

*Article 46 Transport and handling of biological substances, reagents
and materials for diagnostic purposes*

States Parties shall, subject to national law and taking into account relevant international guidelines, facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes under these Regulations.

**PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY
COMMITTEE AND THE REVIEW COMMITTEE**

Chapter I – The IHR Roster of Experts

Article 47 Composition

The Director-General shall establish a roster composed of experts in all relevant fields of expertise (hereinafter the “IHR Expert Roster”). The Director-General shall appoint the members of the IHR Expert Roster in accordance with the WHO Regulations for Expert Advisory Panels and Committees (hereinafter the “WHO Advisory Panel Regulations”), unless otherwise provided in these Regulations. In addition, the Director-General shall appoint one member at the request of each State Party and, where appropriate, experts proposed by relevant intergovernmental and regional economic integration organizations. Interested States Parties shall notify the Director-General of the qualifications and fields of expertise of each of the experts they propose for membership. The Director-General shall periodically inform the States Parties, and relevant intergovernmental and regional economic integration organizations, of the composition of the IHR Expert Roster.

Chapter II – The Emergency Committee

Article 48 Terms of reference and composition

1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:
 - (a) whether an event constitutes a public health emergency of international concern;
 - (b) the termination of a public health emergency of international concern; and
 - (c) the proposed issuance, modification, extension or termination of temporary recommendations.
2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.
3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.

Article 49 Procedure

1. The Director-General shall convene meetings of the Emergency Committee by selecting a number of experts from among those referred to in paragraph 2 of Article 48, according to the fields of expertise and experience most relevant to the specific event that is occurring. For the purpose of this Article, “meetings” of the Emergency Committee may include teleconferences, videoconferences or electronic communications.
2. The Director-General shall provide the Emergency Committee with the agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance.
3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any advice on recommendations.
4. The Director-General shall invite the State Party in whose territory the event arises to present its views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.
5. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters.
6. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public.
7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.

Chapter III – The Review Committee

Article 50 Terms of reference and composition

1. The Director-General shall establish a Review Committee, which shall carry out the following functions:
 - (a) make technical recommendations to the Director-General regarding amendments to these Regulations;
 - (b) provide technical advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof;
 - (c) provide technical advice to the Director-General on any matter referred to it by the Director-General regarding the functioning of these Regulations.
2. The Review Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided in this Article.

3. The Members of the Review Committee shall be selected and appointed by the Director-General from among the persons serving on the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization.
4. The Director-General shall establish the number of members to be invited to a meeting of the Review Committee, determine its date and duration, and convene the Committee.
5. The Director-General shall appoint members to the Review Committee for the duration of the work of a session only.
6. The Director-General shall select the members of the Review Committee on the basis of the principles of equitable geographical representation, gender balance, a balance of experts from developed and developing countries, representation of a diversity of scientific opinion, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance.

Article 51 Conduct of business

1. Decisions of the Review Committee shall be taken by a majority of the members present and voting.
2. The Director-General shall invite Member States, the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote.

Article 52 Reports

1. For each session, the Review Committee shall draw up a report setting forth the Committee's views and advice. This report shall be approved by the Review Committee before the end of the session. Its views and advice shall not commit the Organization and shall be formulated as advice to the Director-General. The text of the report may not be modified without the Committee's consent.
2. If the Review Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.
3. The Review Committee's report shall be submitted to the Director-General, who shall communicate its views and advice to the Health Assembly or the Executive Board for their consideration and action.

Article 53 Procedures for standing recommendations

When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health risk, the Director-General shall seek the views of the Review Committee. In addition to the relevant paragraphs of Articles 50 to 52, the following provisions shall apply:

- (a) proposals for standing recommendations, their modification or termination may be submitted to the Review Committee by the Director-General or by States Parties through the Director-General;
- (b) any State Party may submit relevant information for consideration by the Review Committee;

(c) the Director-General may request any State Party, intergovernmental organization or nongovernmental organization in official relations with WHO to place at the disposal of the Review Committee information in its possession concerning the subject of the proposed standing recommendation as specified by the Review Committee;

(d) the Director-General may, at the request of the Review Committee or on the Director-General's own initiative, appoint one or more technical experts to advise the Review Committee. They shall not have the right to vote;

(e) any report containing the views and advice of the Review Committee regarding standing recommendations shall be forwarded to the Director-General for consideration and decision. The Director-General shall communicate the Review Committee's views and advice to the Health Assembly;

(f) the Director-General shall communicate to States Parties any standing recommendation, as well as the modifications or termination of such recommendations, together with the views of the Review Committee;

(g) standing recommendations shall be submitted by the Director-General to the subsequent Health Assembly for its consideration.

PART X – FINAL PROVISIONS

Article 54 Reporting and review

1. States Parties and the Director-General shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly.
2. The Health Assembly shall periodically review the functioning of these Regulations. To that end it may request the advice of the Review Committee, through the Director-General. The first such review shall take place no later than five years after the entry into force of these Regulations.
3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.

Article 55 Amendments

1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.
2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.
3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of these Regulations.

Article 56 Settlement of disputes

1. In the event of a dispute between two or more States Parties concerning the interpretation or application of these Regulations, the States Parties concerned shall seek in the first instance to settle

the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, the States Parties concerned may agree to refer the dispute to the Director-General, who shall make every effort to settle it.

3. A State Party may at any time declare in writing to the Director-General that it accepts arbitration as compulsory with regard to all disputes concerning the interpretation or application of these Regulations to which it is a party or with regard to a specific dispute in relation to any other State Party accepting the same obligation. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States applicable at the time a request for arbitration is made. The States Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final. The Director-General shall inform the Health Assembly regarding such action as appropriate.

4. Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.

5. In the event of a dispute between WHO and one or more States Parties concerning the interpretation or application of these Regulations, the matter shall be submitted to the Health Assembly.

Article 57 Relationship with other international agreements

1. States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.

2. Subject to paragraph 1 of this Article, nothing in these Regulations shall prevent States Parties having certain interests in common owing to their health, geographical, social or economic conditions, from concluding special treaties or arrangements in order to facilitate the application of these Regulations, and in particular with regard to:

- (a) the direct and rapid exchange of public health information between neighbouring territories of different States;
- (b) the health measures to be applied to international coastal traffic and to international traffic in waters within their jurisdiction;
- (c) the health measures to be applied in contiguous territories of different States at their common frontier;
- (d) arrangements for carrying affected persons or affected human remains by means of transport specially adapted for the purpose; and
- (e) deratting, disinsection, disinfection, decontamination or other treatment designed to render goods free of disease-causing agents.

3. Without prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization.

Article 58 International sanitary agreements and regulations

1. These Regulations, subject to the provisions of Article 62 and the exceptions hereinafter provided, shall replace as between the States bound by these Regulations and as between these States and WHO, the provisions of the following international sanitary agreements and regulations:

- (a) International Sanitary Convention, signed in Paris, 21 June 1926;
- (b) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;
- (c) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;
- (d) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22 December 1934;
- (e) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;
- (f) International Sanitary Convention, 1944, modifying the International Sanitary Convention of 21 June 1926, opened for signature in Washington, 15 December 1944;
- (g) International Sanitary Convention for Aerial Navigation, 1944, modifying the International Sanitary Convention of 12 April 1933, opened for signature in Washington, 15 December 1944;
- (h) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;
- (i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;
- (j) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and
- (k) the International Health Regulations of 1969 and the amendments of 1973 and 1981.

2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, shall remain in force with the exception of Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62, to which the relevant part of paragraph 1 of this Article shall apply.

Article 59 Entry into force; period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:

- (a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;

(b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62;

(c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and

(d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.

3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations within the period set out in paragraph 2 of this Article, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations for that State Party.

Article 60 New Member States of WHO

Any State which becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of Article 59, and which is not already a party to these Regulations, may communicate its rejection of, or any reservation to, these Regulations within a period of twelve months from the date of the notification to it by the Director-General after becoming a Member of WHO. Unless rejected, these Regulations shall enter into force with respect to that State, subject to the provisions of Articles 62 and 63, upon expiry of that period. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

Article 61 Rejection

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the period provided in paragraph 1 of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservations

1. States may make reservations to these Regulations in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.

2. Reservations to these Regulations shall be notified to the Director-General in accordance with paragraph 1 of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.

3. A rejection in part of these Regulations shall be considered as a reservation.

4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:

(a) if the reservation was made before the entry into force of these Regulations, request those Member States that have not rejected these Regulations to notify him or her within six months of any objection to the reservation, or

- (b) if the reservation was made after the entry into force of these Regulations, request States Parties to notify him or her within six months of any objection to the reservation.

States objecting to a reservation should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. Unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation.

6. If at least one-third of the States referred to in paragraph 4 of this Article object to the reservation by the end of six months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.

7. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of the reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 58.

8. If the reserving State does not withdraw the reservation within three months from the date of the notification by the Director-General referred to in paragraph 6 of this Article, the Director-General shall seek the view of the Review Committee if the reserving State so requests. The Review Committee shall advise the Director-General as soon as possible and in accordance with Article 50 on the practical impact of the reservation on the operation of these Regulations.

9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations shall enter into force for the reserving State, subject to its reservation.

Article 63 Withdrawal of rejection and reservation

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

Article 64 States not Members of WHO

1. Any State not a Member of WHO, which is a party to any international sanitary agreement or regulations listed in Article 58 or to which the Director-General has notified the adoption of these Regulations by the World Health Assembly, may become a party hereto by notifying its acceptance to the Director-General and, subject to the provisions of Article 62, such acceptance shall become effective upon the date of entry into force of these Regulations, or, if such acceptance is notified after that date, three months after the date of receipt by the Director-General of the notification of acceptance.
2. Any State not a Member of WHO which has become a party to these Regulations may at any time withdraw from participation in these Regulations, by means of a notification addressed to the Director-General which shall take effect six months after the Director-General has received it. The State which has withdrawn shall, as from that date, resume application of the provisions of any international sanitary agreement or regulations listed in Article 58 to which it was previously a party.

Article 65 Notifications by the Director-General

1. The Director-General shall notify all States Members and Associate Members of WHO, and also other parties to any international sanitary agreement or regulations listed in Article 58, of the adoption by the Health Assembly of these Regulations.
2. The Director-General shall also notify these States, as well as any other State which has become a party to these Regulations or to any amendment to these Regulations, of any notification received by WHO under Articles 60 to 64 respectively, as well as of any decision taken by the Health Assembly under Article 62.

Article 66 Authentic texts

1. The Arabic, Chinese, English, French, Russian and Spanish texts of these Regulations shall be equally authentic. The original texts of these Regulations shall be deposited with WHO.
2. The Director-General shall send, with the notification provided in paragraph 1 of Article 59, certified copies of these Regulations to all Members and Associate Members, and also to other parties to any of the international sanitary agreements or regulations listed in Article 58.
3. Upon the entry into force of these Regulations, the Director-General shall deliver certified copies thereof to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations.

ANNEX 1

**A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE
AND RESPONSE**

1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations, including with regard to:
 - (a) their surveillance, reporting, notification, verification, response and collaboration activities; and
 - (b) their activities concerning designated airports, ports and ground crossings.
2. Each State Party shall assess, within two years following the entry into force of these Regulations for that State Party, the ability of existing national structures and resources to meet the minimum requirements described in this Annex. As a result of such assessment, States Parties shall develop and implement plans of action to ensure that these core capacities are present and functioning throughout their territories as set out in paragraph 1 of Article 5 and paragraph 1 of Article 13.
3. States Parties and WHO shall support assessments, planning and implementation processes under this Annex.
4. At the local community level and/or primary public health response level

The capacities:

- (a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and
 - (b) to report all available essential information immediately to the appropriate level of health-care response. At the community level, reporting shall be to local community health-care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed; and
 - (c) to implement preliminary control measures immediately.
5. At the intermediate public health response levels

The capacities:

- (a) to confirm the status of reported events and to support or implement additional control measures; and
- (b) to assess reported events immediately and, if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

6. At the national level

Assessment and notification. The capacities:

- (a) to assess all reports of urgent events within 48 hours; and
- (b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

Public health response. The capacities:

- (a) to determine rapidly the control measures required to prevent domestic and international spread;
- (b) to provide support through specialized staff, laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);
- (c) to provide on-site assistance as required to supplement local investigations;
- (d) to provide a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;
- (e) to provide direct liaison with other relevant government ministries;
- (f) to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;
- (g) to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern; and
- (h) to provide the foregoing on a 24-hour basis.

B. CORE CAPACITY REQUIREMENTS FOR DESIGNATED AIRPORTS, PORTS AND GROUND CROSSINGS

1. At all times

The capacities:

- (a) to provide access to (i) an appropriate medical service including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;
- (b) to provide access to equipment and personnel for the transport of ill travellers to an appropriate medical facility;
- (c) to provide trained personnel for the inspection of conveyances;
- (d) to ensure a safe environment for travellers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms,

appropriate solid and liquid waste disposal services and other potential risk areas, by conducting inspection programmes, as appropriate; and

(e) to provide as far as practicable a programme and trained personnel for the control of vectors and reservoirs in and near points of entry.

2. For responding to events that may constitute a public health emergency of international concern

The capacities:

(a) to provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;

(b) to provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities for their isolation, treatment and other support services that may be required;

(c) to provide appropriate space, separate from other travellers, to interview suspect or affected persons;

(d) to provide for the assessment and, if required, quarantine of suspect travellers, preferably in facilities away from the point of entry;

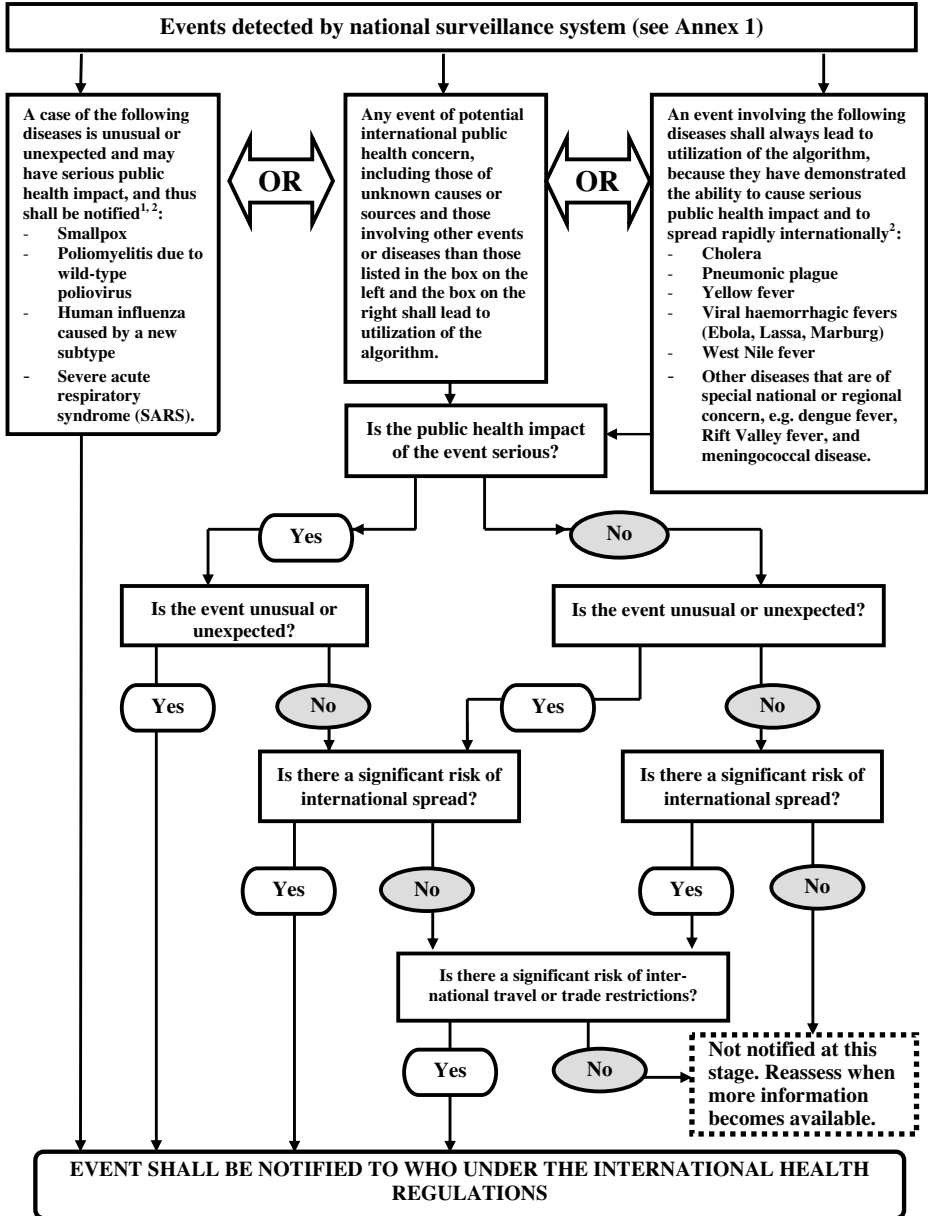
(e) to apply recommended measures to disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels including, when appropriate, at locations specially designated and equipped for this purpose;

(f) to apply entry or exit controls for arriving and departing travellers; and

(g) to provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travellers who may carry infection or contamination.

ANNEX 2

**DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION
OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY
OF INTERNATIONAL CONCERN**



¹ As per WHO case definitions.

² The disease list shall be used only for the purposes of these Regulations.

**EXAMPLES FOR THE APPLICATION OF THE DECISION INSTRUMENT FOR
THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE
A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN**

*The examples appearing in this Annex are not binding and are for indicative guidance
purposes to assist in the interpretation of the decision instrument criteria.*

DOES THE EVENT MEET AT LEAST TWO OF THE FOLLOWING CRITERIA?

Is the public health impact of the event serious?	I. Is the public health impact of the event serious?
	1. <i>Is the number of cases and/or number of deaths for this type of event large for the given place, time or population?</i>
	2. <i>Has the event the potential to have a high public health impact?</i>
	THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT CONTRIBUTE TO HIGH PUBLIC HEALTH IMPACT: ✓ Event caused by a pathogen with high potential to cause epidemic (infectiousness of the agent, high case fatality, multiple transmission routes or healthy carrier). ✓ Indication of treatment failure (new or emerging antibiotic resistance, vaccine failure, antidote resistance or failure). ✓ Event represents a significant public health risk even if no or very few human cases have yet been identified. ✓ Cases reported among health staff. ✓ The population at risk is especially vulnerable (refugees, low level of immunization, children, elderly, low immunity, undernourished, etc.). ✓ Concomitant factors that may hinder or delay the public health response (natural catastrophes, armed conflicts, unfavourable weather conditions, multiple foci in the State Party). ✓ Event in an area with high population density. ✓ Spread of toxic, infectious or otherwise hazardous materials that may be occurring naturally or otherwise that has contaminated or has the potential to contaminate a population and/or a large geographical area.
	3. <i>Is external assistance needed to detect, investigate, respond and control the current event, or prevent new cases?</i> THE FOLLOWING ARE EXAMPLES OF WHEN ASSISTANCE MAY BE REQUIRED: ✓ Inadequate human, financial, material or technical resources – in particular: – insufficient laboratory or epidemiological capacity to investigate the event (equipment, personnel, financial resources); – insufficient antidotes, drugs and/or vaccine and/or protective equipment, decontamination equipment, or supportive equipment to cover estimated needs; – existing surveillance system is inadequate to detect new cases in a timely manner.
	IS THE PUBLIC HEALTH IMPACT OF THE EVENT SERIOUS? Answer “yes” if you have answered “yes” to questions 1, 2 or 3 above.

Is the event unusual or unexpected?	II. Is the event unusual or unexpected?
	4. <i>Is the event unusual?</i>
	THE FOLLOWING ARE EXAMPLES OF UNUSUAL EVENTS:
	✓ The event is caused by an unknown agent or the source, vehicle, route of transmission is unusual or unknown. ✓ Evolution of cases more severe than expected (including morbidity or case-fatality) or with unusual symptoms. ✓ Occurrence of the event itself unusual for the area, season or population.
	5. <i>Is the event unexpected from a public health perspective?</i>
Is there a significant risk of international spread?	THE FOLLOWING ARE EXAMPLES OF UNEXPECTED EVENTS:
	✓ Event caused by a disease/agent that had already been eliminated or eradicated from the State Party or not previously reported.
	IS THE EVENT UNUSUAL OR UNEXPECTED? Answer “yes” if you have answered “yes” to questions 4 or 5 above.

Is the event unusual or unexpected?	III. Is there a significant risk of international spread?
	6. <i>Is there evidence of an epidemiological link to similar events in other States?</i>
	7. <i>Is there any factor that should alert us to the potential for cross border movement of the agent, vehicle or host?</i>
	THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT MAY PREDISPOSE TO INTERNATIONAL SPREAD:
	✓ Where there is evidence of local spread, an index case (or other linked cases) with a history within the previous month of: – international travel (or time equivalent to the incubation period if the pathogen is known); – participation in an international gathering (pilgrimage, sports event, conference, etc.); – close contact with an international traveller or a highly mobile population. ✓ Event caused by an environmental contamination that has the potential to spread across international borders. ✓ Event in an area of intense international traffic with limited capacity for sanitary control or environmental detection or decontamination.
Is there a significant risk of international spread?	IS THERE A SIGNIFICANT RISK OF INTERNATIONAL SPREAD? Answer “yes” if you have answered “yes” to questions 6 or 7 above.

Risk of international restrictions?	IV. Is there a significant risk of international travel or trade restrictions?
	8. <i>Have similar events in the past resulted in international restriction on trade and/or travel?</i>
	9. <i>Is the source suspected or known to be a food product, water or any other goods that might be contaminated that has been exported/imported to/from other States?</i>
	10. <i>Has the event occurred in association with an international gathering or in an area of intense international tourism?</i>
	11. <i>Has the event caused requests for more information by foreign officials or international media?</i>
	IS THERE A SIGNIFICANT RISK OF INTERNATIONAL TRADE OR TRAVEL RESTRICTIONS? Answer “yes” if you have answered “yes” to questions 8, 9, 10 or 11 above.

States Parties that answer “yes” to the question whether the event meets any two of the four criteria (I-IV) above, shall notify WHO under Article 6 of the International Health Regulations.

MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP SANITATION CONTROL CERTIFICATE

Port of Date:

This Certificate records the inspection and 1) exemption from control or 2) control measures applied

Name of ship or inland navigation vessel	Flag	Registration/IMO No.

At the time of inspection the holds were unladen/laden with tonnes of cargo

Name and address of inspecting officer

Ship Sanitation Control Exemption Certificate			
Areas, systems, and services inspected	Evidence found ¹	Sample results ²	Documents reviewed
Galley			Medical log
Pantry			Ship's log
Stores			Other
Hold(s)/cargo			
Quarters:			
- crew			
- officers			
- passengers			
- deck			
Potable water			
Sewage			
Ballast tanks			
Solid and medical waste			
Standing water			
Engine room			
Medical facilities			
Other areas specified - see attached			
Note areas not applicable, by marking N/A.			

No evidence found. Ship/vessel is exempted from control measures.

Name and designation of issuing officer

¹ (a) Evidence of infection or contamination, including: vectors in all stages of growth; animal reservoirs for vectors; rodents or other species that could carry human disease, microbiological, chemical and other risks to human health; signs of inadequate sanitary measures. (b) Information concerning any human cases (to be included in the Maritime Declaration of Health).

² Results from samples taken on board. Analysis to be provided to ship's master by most expedient means and, if re-inspection is required, to the next appropriate port of call coinciding with the re-inspection date specified in this certificate.

Sanitation Control Exemption Certificates and Sanitation Control Certificates are valid for a maximum of six months, but the validity period may be extended by one month if inspection cannot be carried out at the port and there is no evidence of infection or contamination.

[illegible]

Control measures indicated were applied on the date below.

Signature and seal Date

es of growth; animal reservoirs for vectors; rodents or other species that could carry human disease, sanitary measures. (b) Information concerning any human cases (to be included in the Maritime Declaration of

master by most expedient means and, if re-inspection is required, to the next appropriate port of call coinciding

ates are valid for a maximum of six months, but the validity period may be extended by one month if inspection

**ATTACHMENT TO MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP
SANITATION CONTROL CERTIFICATE**

Areas/facilities/systems inspected¹	Evidence found	Sample results	Documents reviewed	Control measures applied	Re-inspection date	Comments regarding conditions found
Food						
Source						
Storage						
Preparation						
Service						
Water						
Source						
Storage						
Distribution						
Waste						
Holding						
Treatment						
Disposal						
Swimming pools/spas						
Equipment						
Operation						
Medical facilities						
Equipment and medical devices						
Operation						
Medicines						
Other areas inspected						

¹ Indicate when the areas listed are not applicable by marking N/A.

ANNEX 4

**TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND
CONVEYANCE OPERATORS**

Section A Conveyance operators

1. Conveyance operators shall facilitate:
 - (a) inspections of the cargo, containers and conveyance;
 - (b) medical examinations of persons on board;
 - (c) application of other health measures under these Regulations; and
 - (d) provision of relevant public health information requested by the State Party.
2. Conveyance operators shall provide to the competent authority a valid Ship Sanitation Control Exemption Certificate or a Ship Sanitation Control Certificate or a Maritime Declaration of Health, or the Health Part of an Aircraft General Declaration, as required under these Regulations.

Section B Conveyances

1. Control measures applied to baggage, cargo, containers, conveyances and goods under these Regulations shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the baggage, cargo, containers, conveyances and goods. Whenever possible and appropriate, control measures shall be applied when the conveyance and holds are empty.
2. States Parties shall indicate in writing the measures applied to cargo, containers or conveyances, the parts treated, the methods employed, and the reasons for their application. This information shall be provided in writing to the person in charge of an aircraft and, in case of a ship, on the Ship Sanitation Control Certificate. For other cargo, containers or conveyances, States Parties shall issue such information in writing to consignors, consignees, carriers, the person in charge of the conveyance or their respective agents.

ANNEX 5

SPECIFIC MEASURES FOR VECTOR-BORNE DISEASES

1. WHO shall publish, on a regular basis, a list of areas where disinsection or other vector control measures are recommended for conveyances arriving from these areas. Determination of such areas shall be made pursuant to the procedures regarding temporary or standing recommendations, as appropriate.
2. Every conveyance leaving a point of entry situated in an area where vector control is recommended should be disinfected and kept free of vectors. When there are methods and materials advised by the Organization for these procedures, these should be employed. The presence of vectors on board conveyances and the control measures used to eradicate them shall be included:
 - (a) in the case of aircraft, in the Health Part of the Aircraft General Declaration, unless this part of the Declaration is waived by the competent authority at the airport of arrival;
 - (b) in the case of ships, on the Ship Sanitation Control Certificates; and
 - (c) in the case of other conveyances, on a written proof of treatment issued to the consignor, consignee, carrier, the person in charge of the conveyance or their agent, respectively.
3. States Parties should accept disinsecting, deratting and other control measures for conveyances applied by other States if methods and materials advised by the Organization have been applied.
4. States Parties shall establish programmes to control vectors that may transport an infectious agent that constitutes a public health risk to a minimum distance of 400 metres from those areas of point of entry facilities that are used for operations involving travellers, conveyances, containers, cargo and postal parcels, with extension of the minimum distance if vectors with a greater range are present.
5. If a follow-up inspection is required to determine the success of the vector control measures applied, the competent authorities for the next known port or airport of call with a capacity to make such an inspection shall be informed of this requirement in advance by the competent authority advising such follow-up. In the case of ships, this shall be noted on the Ship Sanitation Control Certificate.
6. A conveyance may be regarded as suspect and should be inspected for vectors and reservoirs if:
 - (a) it has a possible case of vector-borne disease on board;
 - (b) a possible case of vector-borne disease has occurred on board during an international voyage; or
 - (c) it has left an affected area within a period of time where on-board vectors could still carry disease.

7. A State Party should not prohibit the landing of an aircraft or berthing of a ship in its territory if the control measures provided for in paragraph 3 of this Annex or otherwise recommended by the Organization are applied. However, aircraft or ships coming from an affected area may be required to land at airports or divert to another port specified by the State Party for that purpose.

8. A State Party may apply vector control measures to a conveyance arriving from an area affected by a vector-borne disease if the vectors for the foregoing disease are present in its territory.

ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

1. Vaccines or other prophylaxis specified in Annex 7 or recommended under these Regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval. Upon request, the State Party shall provide to WHO appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under these Regulations.
2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the “certificate”) in the form specified in this Annex. No departure shall be made from the model of the certificate specified in this Annex.
3. Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO.
4. Certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.
5. Certificates shall be fully completed in English or in French. They may also be completed in another language, in addition to either English or French.
6. Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.
7. Certificates are individual and shall in no circumstances be used collectively. Separate certificates shall be issued for children.
8. A parent or guardian shall sign the certificate when the child is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person’s mark and the indication by another that this is the mark of the person concerned.
9. If the supervising clinician is of the opinion that the vaccination or prophylaxis is contraindicated on medical grounds, the supervising clinician shall provide the person with reasons, written in English or French, and where appropriate in another language in addition to English or French, underlying that opinion, which the competent authorities on arrival should take into account. The supervising clinician and competent authorities shall inform such persons of any risk associated with non-vaccination and with the non-use of prophylaxis in accordance with paragraph 4 of Article 23.
10. An equivalent document issued by the Armed Forces to an active member of those Forces shall be accepted in lieu of an international certificate in the form shown in this Annex if:
 - (a) it embodies medical information substantially the same as that required by such form; and
 - (b) it contains a statement in English or in French and where appropriate in another language in addition to English or French recording the nature and date of the vaccination or prophylaxis and to the effect that it is issued in accordance with this paragraph.

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

This is to certify that [name], date of birth, sex,
nationality, national identification document, if applicable
whose signature follows

has on the date indicated been vaccinated or received prophylaxis against:

(name of disease or condition)

in accordance with the International Health Regulations.

Vaccine or prophylaxis	Date	Signature and professional status of supervising clinician	Manufacturer and batch No. of vaccine or prophylaxis	Certificate valid from until	Official stamp of administering centre
1.					
2.					

This certificate is valid only if the vaccine or prophylaxis used has been approved by the World Health Organization.

This certificate must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.

Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

The validity of this certificate shall extend until the date indicated for the particular vaccination or prophylaxis. The certificate shall be fully completed in English or in French. The certificate may also be completed in another language on the same document, in addition to either English or French.

ANNEX 7

**REQUIREMENTS CONCERNING VACCINATION OR
PROPHYLAXIS FOR SPECIFIC DISEASES**

1. In addition to any recommendation concerning vaccination or prophylaxis, the following diseases are those specifically designated under these Regulations for which proof of vaccination or prophylaxis may be required for travellers as a condition of entry to a State Party:

Vaccination against yellow fever.

2. Recommendations and requirements for vaccination against yellow fever:

(a) For the purpose of this Annex:

(i) the incubation period of yellow fever is six days;

(ii) yellow fever vaccines approved by WHO provide protection against infection starting 10 days following the administration of the vaccine;

(iii) this protection continues for 10 years; and

(iv) the validity of a certificate of vaccination against yellow fever shall extend for a period of 10 years, beginning 10 days after the date of vaccination or, in the case of a revaccination within such period of 10 years, from the date of that revaccination.

(b) Vaccination against yellow fever may be required of any traveller leaving an area where the Organization has determined that a risk of yellow fever transmission is present.

(c) If a traveller is in possession of a certificate of vaccination against yellow fever which is not yet valid, the traveller may be permitted to depart, but the provisions of paragraph 2(h) of this Annex may be applied on arrival.

(d) A traveller in possession of a valid certificate of vaccination against yellow fever shall not be treated as suspect, even if coming from an area where the Organization has determined that a risk of yellow fever transmission is present.

(e) In accordance with paragraph 1 of Annex 6 the yellow fever vaccine used must be approved by the Organization.

(f) States Parties shall designate specific yellow fever vaccination centres within their territories in order to ensure the quality and safety of the procedures and materials employed.

(g) Every person employed at a point of entry in an area where the Organization has determined that a risk of yellow fever transmission is present, and every member of the crew of a conveyance using any such point of entry, shall be in possession of a valid certificate of vaccination against yellow fever.

(h) A State Party, in whose territory vectors of yellow fever are present, may require a traveller from an area where the Organization has determined that a risk of yellow fever transmission is present, who is unable to produce a valid certificate of vaccination against

yellow fever, to be quarantined until the certificate becomes valid, or until a period of not more than six days, reckoned from the date of last possible exposure to infection, has elapsed, whichever occurs first.

(i) Travellers who possess an exemption from yellow fever vaccination, signed by an authorized medical officer or an authorized health worker, may nevertheless be allowed entry, subject to the provisions of the foregoing paragraph of this Annex and to being provided with information regarding protection from yellow fever vectors. Should the travellers not be quarantined, they may be required to report any feverish or other symptoms to the competent authority and be placed under surveillance.

ANNEX 8

MODEL OF MARITIME DECLARATION OF HEALTH

To be completed and submitted to the competent authorities by the masters of ships arriving from foreign ports.

Submitted at the port of Date

Name of ship or inland navigation vessel Registration/IMO No arriving from sailing to
(Nationality)(Flag of vessel) Master's name

Gross tonnage (ship)

Tonnage (inland navigation vessel)

Valid Sanitation Control Exemption/Control Certificate carried on board? Yes No Issued at date

Re-inspection required? Yes No

Has ship/vessel visited an affected area identified by the World Health Organization? Yes No

Port and date of visit

List ports of call from commencement of voyage with dates of departure, or within past thirty days, whichever is shorter:
.....

Upon request of the competent authority at the port of arrival, list crew members, passengers or other persons who have joined ship/vessel since international voyage began or within past thirty days, whichever is shorter, including all ports/countries visited in this period (add additional names to the attached schedule):

(1) Name joined from: (1) (2) (3)

(2) Name joined from: (1) (2) (3)

(3) Name joined from: (1) (2) (3)

Number of crew members on board

Number of passengers on board

Health questions

- (1) Has any person died on board during the voyage otherwise than as a result of accident? Yes No
If yes, state particulars in attached schedule. Total no. of deaths
- (2) Is there on board or has there been during the international voyage any case of disease which you suspect to be of an infectious nature? Yes..... No..... If yes, state particulars in attached schedule.
- (3) Has the total number of ill passengers during the voyage been greater than normal/expected? Yes No
How many ill persons?
- (4) Is there any ill person on board now? Yes No If yes, state particulars in attached schedule.
- (5) Was a medical practitioner consulted? Yes No If yes, state particulars of medical treatment or advice provided in attached schedule.
- (6) Are you aware of any condition on board which may lead to infection or spread of disease? Yes No
If yes, state particulars in attached schedule.
- (7) Has any sanitary measure (e.g. quarantine, isolation, disinfection or decontamination) been applied on board? Yes No
If yes, specify type, place and date
- (8) Have any stowaways been found on board? Yes No If yes, where did they join the ship (if known)?
- (9) Is there a sick animal or pet on board? Yes No

Note: In the absence of a surgeon, the master should regard the following symptoms as grounds for suspecting the existence of a disease of an infectious nature:

- (a) fever, persisting for several days or accompanied by (i) prostration; (ii) decreased consciousness; (iii) glandular swelling; (iv) jaundice; (v) cough or shortness of breath; (vi) unusual bleeding; or (vii) paralysis.
- (b) with or without fever: (i) any acute skin rash or eruption; (ii) severe vomiting (other than sea sickness); (iii) severe diarrhoea; or (iv) recurrent convulsions.

I hereby declare that the particulars and answers to the questions given in this Declaration of Health (including the schedule) are true and correct to the best of my knowledge and belief.

Signed

Master

Countersigned

Ship's Surgeon (if carried)

Date

ATTACHMENT TO MODEL OF MARITIME DECLARATION OF HEALTH

Name	Class or rating	Age	Sex	Nationality	Port, date joined ship/vessel	Nature of illness	Date of onset of symptoms	Reported to a port medical officer?	Disposal of case¹	Drugs, medicines or other treatment given to patient	Comments

¹ State: (1) whether the person recovered, is still ill or died; and (2) whether the person is still on board, was evacuated (including the name of the port or airport), or was buried at sea.

ANNEX 9

**THIS DOCUMENT IS PART OF THE AIRCRAFT GENERAL DECLARATION,
PROMULGATED BY THE INTERNATIONAL CIVIL AVIATION ORGANIZATION**

HEALTH PART OF THE AIRCRAFT GENERAL DECLARATION¹

Declaration of Health

Name and seat number or function of persons on board with illnesses other than airsickness or the effects of accidents, who may be suffering from a communicable disease (a fever - temperature 38°C/100 °F or greater - associated with one or more of the following signs or symptoms, e.g. appearing obviously unwell; persistent coughing; impaired breathing; persistent diarrhoea; persistent vomiting; skin rash; bruising or bleeding without previous injury; or confusion of recent onset, increases the likelihood that the person is suffering a communicable disease) as well as such cases of illness disembarked during a previous stop

Details of each disinsecting or sanitary treatment (place, date, time, method) during the flight. If no disinsecting has been carried out during the flight, give details of most recent disinsecting

Signature, if required, with time and date

Crew member concerned

¹ This version of the Aircraft General Declaration entered into force on 15 July 2007. The full document may be obtained from the website of the International Civil Aviation Organization at <http://www.icao.int>.

APPENDIX 1

**STATES PARTIES TO THE INTERNATIONAL HEALTH
REGULATIONS (2005)¹**

Except as otherwise indicated, the International Health Regulations (2005) entered into force on 15 June 2007 for the following States:

Afghanistan, Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, Chad, Chile, China², Colombia, Comoros, Congo, Cook Islands, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece², Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Holy See, Honduras, Hungary, Iceland, India (8 August 2007)², Indonesia, Iran (Islamic Republic of)², Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Kuwait, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia (Federated States of), Moldova, Monaco, Mongolia, Montenegro (5 February 2008), Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norway, Oman, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal², Qatar, Republic of Korea, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, The former Yugoslav Republic of Macedonia, Timor-Leste, Togo, Tonga², Trinidad and Tobago, Tunisia, Turkey², Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America (18 July 2007)², Uruguay, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia, Zimbabwe.

¹ At 5 February 2008.

² Indicates that a State Party has submitted, to the Director-General of WHO, documentation related to the International Health Regulations (2005), which has been circulated by the Director-General to all Member States of WHO as well as to other States eligible to become Parties to the Regulations pursuant to Article 64 thereof.

APPENDIX 2

RESERVATIONS AND OTHER STATE PARTY COMMUNICATIONS IN CONNECTION WITH THE INTERNATIONAL HEALTH REGULATIONS (2005)^{1, 2}

I. RESERVATIONS AND UNDERSTANDINGS

INDIA

I am directed to refer to Reservations in respect of India mentioned in Annexure-II to IHR 1969 (Revised upto 1983) {copy enclosed} and to request you to notify the following Reservations in respect of India for notification under Article 62 of the recently circulated IHR 2005 :-

Proposed Reservation to IHR 2005:-

1. The Government of India reserves the right to consider the whole territory of a country as infected with yellow fever whenever yellow fever has been notified under Article 6 and other relevant articles in this regard of IHR (2005). The Government of India reserves the right to continue to regard an area as infected with yellow fever until there is definite evidence that yellow-fever infection has been completely eradicated from that area.
2. Yellow Fever disease will be treated as disease of Public health emergency of international concern and all health measures being applied presently like disinsection of conveyance, vaccination requirements and quarantine of passengers and crew (as may be required) (as per Article 7, 9.2(b), 42 and relevant annexures) will be continued as has been stipulated under Annex-II of IHR-1969 (Revised in 1983).

UNITED STATES OF AMERICA

The Mission, by means of this note, informs the Acting Director-General of the World Health Organization that the Government of the United States of America accepts the IHRs, subject to the reservation and understandings referred to below.

The Mission, by means of this note, and in accordance with Article 22 of the Constitution of the World Health Organization and Article 59(1) of the IHRs, submits the following reservation on behalf of the Government of the United States of America:

The Government of the United States of America reserves the right to assume obligations under these Regulations in a manner consistent with its fundamental principles of federalism. With respect to obligations concerning the development, strengthening, and maintenance of the core capacity requirements set forth in Annex 1, these Regulations shall be implemented by the Federal Government

¹ At 5 February 2008.

² This Appendix reproduces the relevant parts of the communications submitted by States, which have been edited by the Secretariat of WHO, or translations thereof. Copies of the original communications are available at <http://www.who.int/ihr>.

or the state governments, as appropriate and in accordance with our Constitution, to the extent that the implementation of these obligations comes under the legal jurisdiction of the Federal Government. To the extent that such obligations come under the legal jurisdiction of the state governments, the Federal Government shall bring such obligations with a favorable recommendation to the notice of the appropriate state authorities.

The Mission, by means of this note, also submits three understandings on behalf of the Government of the United States of America. The first understanding relates to the application of the IHRs to incidents involving natural, accidental or deliberate release of chemical, biological or radiological materials:

In view of the definitions of “disease,” “event,” and “public health emergency of international concern” as set forth in Article 1 of these Regulations, the notification requirements of Articles 6 and 7, and the decision instrument and guidelines set forth in Annex 2, the United States understands that States Parties to these Regulations have assumed an obligation to notify to WHO potential public health emergencies of international concern, irrespective of origin or source, whether they involve the natural, accidental or deliberate release of biological, chemical or radionuclear materials.

The second understanding relates to the application of Article 9 of the IHRs:

Article 9 of these Regulations obligates a State Party “as far as practicable” to notify the World Health Organization (WHO) of evidence received by that State of a public health risk occurring outside of its territory that may result in the international spread of disease. Among other notifications that could prove to be impractical under this article, it is the United States’ understanding that any notification that would undermine the ability of the U.S. Armed Forces to operate effectively in pursuit of U.S. national security interests would not be considered practical for purposes of this Article.

The third understanding relates to the question of whether the IHRs create judicially enforceable private rights. Based on its delegation’s participation in the negotiations of the IHRs, the Government of the United States of America does not believe that the IHRs were intended to create judicially enforceable private rights:

The United States understands that the provisions of the Regulations do not create judicially enforceable private rights.

II. OBJECTIONS TO RESERVATIONS AND UNDERSTANDINGS

IRAN (Islamic Republic of)

The Permanent Mission of the Islamic Republic of Iran to the United Nations Office and other International Organizations in Geneva presents its compliments to the World Health Organization and with reference to note verbale No. C.L.2.2007 dated 17 January 2007 concerning the Reservation and Understandings of the Government of the United States of America on the International Health Regulations (IHR), has the honor to convey the official objection of the Government of the Islamic Republic of Iran to the same Reservation and Understandings, based on the following:

According to the IHR, while “States may make reservations to these Regulations”, “such reservations shall not be incompatible with the object and purpose of these regulations”. Furthermore, in accordance with the IHR, “the implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease”.

The Government of the Islamic Republic of Iran believes that, by giving more prominence to federalism than its obligations under the IHR, the reserving Government attempts to evade its due responsibilities and obligations. The aforementioned Government, by adopting a selective approach, provides its states with the option of exempting themselves from full compliance with the provisions of the IHR. Since implementation of the IHR largely depends on the development, strengthening and maintenance of the core capacity requirements set forth in Annex 1, reservation of such a general nature leads to undermining the IHR foundations as well as its integrity and universal applicability. Such reservation is considered to be incompatible with the object and purpose of these Regulations and is, therefore, unacceptable.

Moreover, the understandings and interpretations assumed by a government, too, should not affect the obligations to be undertaken by that government and must not be incompatible with the object and purpose of the Regulations.

As regards to the first Understanding of the reserving Government, it must be recalled that the majority of W.H.O. Member States participating in the IHR negotiations, categorically rejected the inclusion of the related interpretation within the provisions of the IHR. Their rejections were prompted to avoid confusion over respective obligations of the State Parties under the IHR and to preempt overlapping of the competencies and duplication of work among the relevant intergovernmental organizations or international bodies. Article 6.1 and 14.2 of the IHR address such concerns.

The second Understanding attempts to dilute the obligations of the U.S. Government under the IHR. It is an attempt to place national interests above the treaty obligations by excluding the U.S. Armed Forces from the IHR bindings. The universal applicability of the IHR for the protection of all peoples of the world from the international spread of diseases leaves no room for exempting the American Armed Forces, in particular those operating abroad. Such an exemption could not be conceded to, taking into account the nature, direction and possible public health consequences of the U.S. Armed Forces operations. It should be recalled that during IHR negotiations, the majority of W.H.O. Member States strongly rejected the above exclusion proposed by the U.S. Government. It is, therefore, in violation of the U.S. obligations under the IHR and is incompatible with the object and purpose of these regulations, to which the Government of the Islamic Republic of Iran strongly objects.

The Government of the Islamic Republic of Iran reiterates that it does not consider the Reservation and the two Understandings stated by the U.S. Government, as legally binding.

III. DECLARATIONS AND STATEMENTS

CHINA¹

1. The Government of the People's Republic of China decides that the *International Health Regulations (2005)* (hereinafter referred to as "the IHR") applies to the entire territory of the People's Republic of China, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region and the Taiwan Province.

2. The Ministry of Health of the People's Republic of China is designated as China's National Focal Point, pursuant to Paragraph 1 of Article 4 of the IHR. The local health administrative authorities are the health authorities responsible for the implementation of the IHR in their respective

¹ English translation provided by the Government.

jurisdictions. The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China and its local offices are the competent authorities of the points of entry referred to in Article 22 of the IHR.

3. To meet the needs of applying the IHR, the Government of the People's Republic of China is revising the *Frontier Health and Quarantine Law of the People's Republic of China*. It has incorporated the development, enhancement and maintenance of the core capability-building for rapid and effective response to public health hazards and public health emergencies of international concern into its program of establishing a national health emergency response system during the 11th Five-year Plan for National Economic and Social Development. It is formulating the technical standards for the surveillance, reporting, assessment, determination and notification of public health emergencies of international concern. It has established an inter-agency information-sharing and coordination mechanism for implementing the IHR. And it has conducted cooperation and exchanges with relevant states parties on the implementation of the IHR.

4. The Government of the People's Republic of China endorses and will implement the resolution of the 59th World Health Assembly calling upon its member states to comply immediately, on a voluntary basis, with provisions of the IHR considered relevant to the risk posed by the avian influenza and pandemic influenza.

GREECE

Reply dated 24 January 2007 to the statement made by the Republic of Turkey on 14 December 2006

The Permanent Mission of Greece to the United Nations Office and other International Organizations in Geneva presents its compliments to the Director General of the World Health Organization and, with reference to the latter's Note Verbale under ref.no. C.L.3.2007, dated January 17th, 2007, and the Note Verbale enclosed therein of the Permanent Mission of the Republic of Turkey ref. no 520.20/2006/BMCO DT/12201, dated December 14th, 2006, has the honour to draw the attention of the Director General to the fact that the correct title of the Montreux Convention regarding the regime of the straights of the Dardanelles, the Marmara sea and the Bosphorus is: "The Convention Regarding the Regime of the Straights signed at Montreux on July 20th, 1936".

Furthermore, concerning the reference made in the aforementioned Note Verbale of the Permanent Mission of Turkey to the maritime traffic regulations unilaterally adopted in Turkey in 1998, we would like to remind the Director General that they are in contravention to the provisions of the International Law of the Sea, the Montreux Convention and the relevant rules and Recommendations of the International Maritime Organization adopted on June 1st, 1994.

Reply dated 16 April 2007 to the Note Verbale from the Permanent Mission of Turkey dated 1 March 2007

A. Firstly, it should be noted that there is no substantive link between the content of the Turkish statement contained in Note Verbale 520.20/BMCO DT/12201 dated 14th December 2006 and the new International Health Regulations. In fact, the Turkish statement seeks to elicit tacit acceptance or recognition of the national regulations, adopted by Turkey, concerning maritime traffic through the Straits.

However, these regulations were adopted unilaterally and were not approved by the International Maritime Organization or the parties of the Montreux Convention of 1936 which governs the issue.

Concerning its precise content, the statement goes on to assert that Turkey rightly points out that as far as the implementation of the new International Health Regulations for maritime traffic in the Straits is concerned, this should be done in accordance with the provisions of the Montreux Convention of 1936 regarding the regime of the Straits. It is, however, self-evident that the new Health Regulations do not influence the existing international regime of navigation through the Straits, neither could they do so, as there is no connection of substance between them.

The Turkish statement goes on to assert that the Turkish Maritime Traffic Regulations of 1998 will also be taken into account. This means that the Turkish Authorities will enforce the International Health Regulations subject to certain ill-defined national modifications, which are in fact themselves in contravention of the international obligations Turkey has undertaken under the Montreux Convention.

Furthermore, the Turkish Authorities reserve the right to also take into account any further revision of their national traffic regulations, to be adopted in the same unilateral way in the future. In fact, this would seem simply that, in so far as the Straits are concerned, Turkey may implement the new International Health Regulations as it sees fit.

The reference, therefore, to national legislation and to any future revisions of this legislation, while irrelevant to the subject at hand, is nonetheless problematic because it seeks to subject international conventional obligations to national rules and regulations.

B. Furthermore, the Turkish Regulations concerning traffic in the Straits are themselves not in conformity with:

- The 1936 Montreux Convention: this Convention enshrines full freedom of navigation (articles 1 and 2) through the Straits without any restrictions whatsoever (apart from sanitary control) and without any formalities, irrespective of the kind of cargo or the timing of the transit. Thus, the Turkish Regulations by, amongst other things, imposing a compulsory reporting system (Reg. 6, 25 and al.) and, particularly, by providing for the possibility of the total suspension of traffic (Reg.20) are incompatible with the Montreux Convention.
- The IMO Rules and Regulations: Paragraphs 1.2 and 1.3 foresee that only in the case where a vessel is unable to comply with the Traffic Separation Scheme do the Turkish Authorities have the right to temporarily suspend two-way traffic and to regulate the resulting one way traffic. The IMO Rules and Regulations on no account foresee a total suspension of traffic in the Straits. The Turkish Regulations, on the other hand, provide for the possibility to completely suspend traffic in general for a wide variety of reasons.
- The international law of the sea regarding navigation through international straits: such law encourages cooperation in order to ensure the safe transit of vessels through the Straits and in order to protect the environment. The Turkish Regulations, however, were adopted unilaterally, in contravention of the law of the sea and the relevant law of treaties.

C. As to the Turkish Note dated 1st March 2007 (Ref. No: 520.20/2007/BMCO DT/1711), the information contained there in is inaccurate on several points. More specifically, the said Turkish Note states:

- that the Turkish Regulations “have been put into effect taking into account Turkey's obligations and rights arising from the Montreux Convention”, whereas the latter contains and rights arising from the Montreux Convention”, whereas the latter contains no provision which authorizes Turkey to unilaterally issue traffic regulations.

- that Turkey “informed IMO of the safety measures taken in the Straits”, whereas Turkey has consistently refused to officially submit its national regulations to IMO for discussion and examination, alleging that it is a matter of exclusive Turkish jurisdiction.
- that “...Traffic Separation Schemes and Reporting System... were adopted by IMO together with some other rules in 1995”, whereas only Traffic Separation Schemes were adopted by that Organization, together with the relevant IMO Rules and Recommendations. The Reporting System included in the Turkish Regulations was never adopted by IMO.
- that “...the maritime Safety Committee of the IMO confirmed at its 71st session that the routing system and the associated IMO Rules and Recommendations... had contributed significantly to an increase in safety ...” in an attempt to create the impression that the IMO is referring to the Turkish Regulations, whereas it is only referring to the measures adopted within the IMO itself.

In the light of the above, Greece considers the statement made by Turkey in its Note Verbale 520.20/2006/BMCO DT/12201 dated 14th December 2006 as irrelevant to the International Health Regulations, thus having no legal effect as to the latter's implementation. Furthermore, Greece reiterates the point made in her Note Verbale no. (331) 6395/6/AS 168 dated 24 January 2007 as to the importance of using the correct terminology when referring to international instruments such as the Montreux Convention.

PORTUGAL

Declaration of the Presidency of the Council of the European Union (EU) on the reservation of the Government of the United States of America concerning the International Health Regulations

The International Health Regulations (IHR) are a very effective tool for reinforcing the connection between the surveillance systems and in establishing rapid reaction mechanisms. The EC and its 27 Member States have strongly supported the revised IHR, which recently came into force, and we will continue this support for the implementation of the IHR in full and without restrictions.

The EC and its 27 Member States take note of the above mentioned reservation and declare that they understand it to mean that, in accordance with the principle that a Party may not invoke the provisions of its internal law as justification for its failure to perform its international obligations, this reservation in no way intends to question the obligations stemming from the IHR. The EC and its 27 Member States understand that the Federal Government of the United States of America fully recognises those obligations and that it will exercise every effort to ensure that the provisions of the IHR are fully implemented and given full effect by the pertinent authorities in the United States of America.

Declaration of the Presidency of the Council of the European Union (EU) on the statement of the Government of Turkey concerning the International Health Regulations

The International Health Regulations (IHR) are a very effective tool for reinforcing the connection between the surveillance systems and in establishing rapid reaction mechanisms. The EC and its 27 Member States have strongly supported the revised IHR, which recently came into force, and we will continue this support for the implementation of the IHR in full and without restrictions.

The EC and its 27 Member States take note of Turkey's intention to implement the provisions of the IHR in accordance with the Convention regarding the regime of the Straits, signed at Montreux on 20 July 1936.

The EC and its 27 Member States understand the desire of the Turkish authorities to respect their international obligations, such as the Montreux Convention regarding traffic in the Straits. In this respect they would like to refer to Article 57 of the IHR, which provides that States parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State party deriving from other international agreements.

Concerning the reference by Turkey to internal legislation which has no direct bearing on the implementation of the IHR, the EC and its 27 Member States understand that Turkey will ensure that the application of its internal legislation fully respects the letter and spirit of the IHR and the regime of freedom of navigation in the Straits as established by the Montreux Convention.

Declaration of the Presidency of the Council of the European Union (EU) on the reservation of the Government of India concerning the International Health Regulations

The International Health Regulations (IHR) are a very effective tool for reinforcing the connection between the surveillance systems and in establishing rapid reaction mechanisms. The EC and its 27 Member States have strongly supported the revised IHR, which recently came into force, and we will continue this support for the implementation of the IHR in full and without restrictions.

The EC and its 27 Member States understand the willingness of the Government of India to apply strong measures in order to keep the territory of India free of yellow fever. The EC and its 27 Member States recognise the challenges in ensuring the surveillance and protection of such a large territory, considering the existence of factors (e.g. presence of aedes) which may facilitate the spread of contamination.

The EC and its 27 Member States nevertheless expect that this reservation will be implemented in a reasonable way, considering the potentially unnecessary interference it could have with international traffic and trade from the largest part of the geographical territory of the EC in the case of a yellow fever outbreak in an outermost region of the EU or in a non-European part of a Member State of the EC (e.g. Guyana, Antilles). The fact that the Government of India considers yellow fever to be a notifiable disease should not trigger disproportionate control measures.

The commitment of the EC and its 27 Member States to ensure the rapid and comprehensive implementation of the IHR will reinforce the measures already implemented to maintain the whole territory of the EC free of yellow fever.

TURKEY

Statement made by the Republic of Turkey on 14 December 2006

Turkey will implement the provisions of the International Health Regulations in accordance with the Convention regarding the regime of the Turkish Straits, signed at Montreux on 20 July 1936, as well as by taking into account Turkish 1998 Maritime Traffic Regulations for the Turkish Straits and any future revisions to be made thereto.

Reply dated 1 March 2007 to the Note Verbale from the Permanent Mission of Greece dated 24 January 2007

The Maritime Traffic Regulations for the Turkish Straits have been put into effect taking into account Turkey's obligations and rights arising from the Montreux Convention. The said Regulations do not contain any element that is in contravention of international law or International Maritime Organization's (IMO) Rules and Recommendations and are being implemented accordingly.

The measures taken in the Turkish Straits in accordance with the said Regulations are aimed at improving the safety of navigation, human life, cultural and environmental heritage. Moreover, the safety measures are needed vis-à-vis the risks and dangers of passage of the increased number of tanker traffic in the Straits.

Turkey has duly informed IMO of the safety measures taken in the Straits. Besides, Traffic Separation Schemes and Reporting System, established within the framework of the Turkish Straits Regulations, were adopted by IMO together with some other rules in 1995.

Furthermore, the Maritime Safety Committee of the IMO confirmed at its 71st session on May 1999 that the routing system and the associated IMO Rules and Recommendations relating to the Turkish Straits have proven to be effective and successful and had contributed significantly to an increase in safety and a reduction of the risk of collisions.

The Turkish Straits Vessel Traffic Services which have been functioning since 31 December 2003 within the framework of the Montreux Convention, IMO Rules and the Turkish Straits Regulations, provide traffic arrangements successfully with high standard technical equipment and qualified expert personnel.

Accordingly, the arguments in the above-mentioned Note of the Permanent Mission of Greece are unfounded and the statement of Turkey registered in our Note dated 14 December 2006 (Ref. no: 520.20/2006/BMCO DT/12201) remains unchanged and valid.

Reply dated 18 May 2007 to the Note Verbale from the Permanent Mission of Greece dated 16 April 2007

The Permanent Mission of the Republic of Turkey to the United Nations Office at Geneva and other International Organizations in Switzerland presents its compliments to the Director-General of the World Health Organization (WHO) and with reference to the latter's Note dated 9 May 2007 (Ref. no: C.L.22.2007) and the Note enclosed therein of the Permanent Mission of Greece dated 16 April 2007 (Ref. no: 6395(3160)/22/AS 783) has the honour to inform the Director-General of the following.

The Permanent Mission of the Republic of Turkey would like to underline that the statement in this Mission's Note of December 14, 2006 (No: 520.20/BMCO DT/12201) was a factual representation of the state of affairs.

Furthermore, the Permanent Mission would like to point out that the arguments and assertions raised in the Greek Delegation's above-mentioned Note are unfounded. Turkey's position on the Maritime Traffic Regulations for the Turkish Straits is also acknowledged by the International Maritime Organization (IMO) and remains unchanged. In fact, Turkish Straits Vessel Traffic Services (TSVTS) center is effectively providing traffic information, navigational assistance and traffic organization under the existing regulations to all vessels passing through the Straits.

As to the terminology used when referring to the Montreux Convention, the Permanent Mission, with all due respect to the wording of the said Convention, would like to emphasize the fact that the Straits subject of the said Convention are the "Turkish Straits", namely, the "Strait of İstanbul" and the "Strait of Çanakkale".

IV. DECLARATIONS UNDER ARTICLE 59, PARAGRAPH 3, OF THE IHR (2005)

TONGA

Following their adoption by the World Health Assembly in May 2005, the International Health Regulations (IHR) 2005 will enter into force on 15 June 2007.

The Kingdom of Tonga supports the important contribution the IHR 2005 will make to the strengthening of national and global systems for the protection of public health from the spread of disease.

The Kingdom of Tonga understands that in order to be effective, the IHR 2005 will need to operate at various levels within each country, as well as between countries internationally and the World Health Organization. With this in mind, Tonga has, with support from regional partners including WHO, taken a number of steps to prepare for the entry into force of the new regime. However, it is not possible to confirm that all the required adjustments will be able to be achieved by 15 June 2007.

Therefore, on behalf of the Kingdom of Tonga, and in accordance with paragraph 3 of Article 59 of the IHR 2005, I declare that the following adjustments may not be completed by June 2007.

The outstanding adjustments are as follows:

1. Complete the review of the Public Health Act 1992 to ensure legislative consistency with the IHR 2005;
2. Strengthen existing systems for the regular, national reporting of notifiable diseases, including the reporting of any events of potential public health significance, irrespective of their source;
3. Various enhancements to border health protection functions, including improved reporting and response capacities for public health events at Fua'amotu Airport and surveillance and control of vector/reservoir species at Fua'amotu airport and the seaport at Nuku'alofa.

The Kingdom of Tonga is, and will remain, committed to playing its part in the collective actions that contribute to the protection of public health for all people of the world. It is my intention that the outstanding adjustments will be achieved by 31 December 2007, and certainly no later than 15 June 2008.

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as was the case in the first edition.*

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The purpose and scope of the International Health Regulations (2005) are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade”. Because the IHR (2005) are not limited to specific diseases but apply to new and ever-changing public health risks, they are intended to have long-lasting relevance in the international response to the emergence and spread of disease. The IHR (2005) also provide the legal basis for important health documents applicable to international travel and transport and sanitary protections for the users of international airports, ports, and ground crossings.

This second edition contains the text of the IHR (2005), the text of World Health Assembly resolution WHA58.3, the version of the Health Part of the Aircraft General Declaration that entered into force on 15 July 2007, appendices containing a list of States Parties and State Party reservations and other communications in connection with the IHR (2005).

ISBN 978 92 4 158041 0



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Exhibit C.1

Geneva, 13 December 2006

No. 369-06

The Permanent Mission of the United States of America to the United Nations Office and Other International Organizations in Geneva presents its compliments to the World Health Organization and refers to the International Health Regulations (2005) adopted in Geneva on May 24, 2005 (the IHRs). The Mission, by means of this note, informs the Acting Director-General of the World Health Organization that the Government of the United States of America accepts the IHRs, subject to the reservation and understandings referred to below.

The Mission, by means of this note, and in accordance with Article 22 of the Constitution of the World Health Organization and Article 59(1) of the IHRs, submits the following reservation on behalf of the Government of the United States of America:

The Government of the United States of America reserves the right to assume obligations under these Regulations in a manner consistent with its fundamental principles of federalism. With respect to obligations concerning the development, strengthening, and maintenance of the core capacity requirements set forth in Annex 1, these Regulations shall be implemented by the Federal Government or the state governments, as appropriate and in accordance with our Constitution, to the extent that the implementation of these obligations comes under the legal jurisdiction of the Federal Government. To the extent that such obligations come under the legal jurisdiction of the state governments, the Federal Government shall bring such obligations with a favorable recommendation to the notice of the appropriate state authorities.

The Mission, by means of this note, also submits three understandings on behalf of the Government of the United States of America. The first understanding relates to the application of the IHRs to incidents involving the natural, accidental or deliberate release of chemical, biological or radiological materials:

In view of the definitions of "disease," "event," and "public health emergency of international concern" as set forth in Article 1 of these Regulations, the notification requirements of Articles 6 and 7, and the decision instrument and guidelines set forth in Annex 2, the United States understands that States Parties to these Regulations have assumed an obligation to notify to WHO potential public health emergencies of international concern, irrespective of origin or source, whether they involve the natural, accidental or deliberate release of biological, chemical or radionuclear materials.

The second understanding relates to the application of Article 9 of the IHRs:

Article 9 of these Regulations obligates a State Party "as far as practicable" to notify the World Health Organization (WHO) of evidence received by that State of a public health risk occurring outside of its territory that may result in the international spread of disease. Among other

DIPLOMATIC NOTE

notifications that could prove to be impractical under this article, it is the United States' understanding that any notification that would undermine the ability of the U.S. Armed Forces to operate effectively in pursuit of U.S. national security interests would not be considered practical for purposes of this Article.

The third understanding relates to the question of whether the IHRs create judicially enforceable private rights. Based on its delegation's participation in the negotiations of the IHRs, the Government of the United States of America does not believe that the IHRs were intended to create judicially enforceable private rights:

The United States understands that the provisions of the Regulations do not create judicially enforceable private rights.

The Permanent Mission of the United States of America avails itself of this opportunity to renew to the World Health Organization the assurances of its highest consideration.



[CHAPTER 469]

JOINT RESOLUTION

Providing for membership and participation by the United States in the World Health Organization and authorizing an appropriation therefor.

June 14, 1948
[S. J. Res. 98]
[Public Law 643]

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled, That the President is hereby authorized to accept membership for the United States in the World Health Organization (hereinafter referred to as the Organization), the constitution of which was adopted in New York on July 22, 1946, by the International Health Conference for the establishment of an International Health Organization, and deposited in the archives of the United Nations.

World Health Organization.
Acceptance of membership for U. S.

SEC. 2. The President shall designate from time to time to attend a specified session or specified sessions of the World Health Assembly of the Organization not to exceed three delegates of the United States and such number of alternates as he may determine consistent with the rules of procedure of the World Health Assembly. One of the delegates shall be designated as the chief delegate. Whenever the United States becomes entitled to designate a person to serve on the Executive Board of the Organization, under article 24 of the constitution of the Organization, the President shall designate a representative of the United States, by and with the advice and consent of the Senate, and may designate not to exceed one alternate to attend sessions of the Executive Board. Such representative must be a graduate of a recognized medical school and have spent not less than three years in active practice as a physician or surgeon. Such representative shall be entitled to receive compensation at a rate not to exceed \$12,000 per annum and any such alternate shall be entitled to receive compensation at a rate not to exceed \$10,000 per annum for such period or periods as the President may specify, except that no Member of the Senate or House of Representatives or officer of the United States who is thus designated shall be entitled to receive such compensation: *Provided*, That no person shall serve as such representative, delegate, or alternate until such person has been investigated as to loyalty and security by the Federal Bureau of Investigation.

Designation of representatives, etc.

Loyalty and security investigations.

SEC. 3. There is hereby authorized to be appropriated annually to the Department of State—

Appropriation authorized.
Post, p. 1047.

(a) such sums, not to exceed \$1,920,000 per annum, as may be necessary for the payment by the United States of its share of the expenses of the Organization, including those incurred by the Interim Commission, as apportioned by the Health Assembly in accordance with Article 56 of the Constitution of the Organization; and

(b) such additional sums, not to exceed \$83,000 for the fiscal year beginning July 1, 1947, as may be necessary to pay the expenses incident to participation by the United States in the activities of the Organization, including—

(1) salaries of the representative and alternate provided for in section 2 hereof, and appropriate staff, including personal services in the District of Columbia and elsewhere, without regard to the civil-service laws and the Classification Act of 1923, as amended; services as authorized by section 15 of Public Law 600, Seventy-ninth Congress; under such rules and regulations as the Secretary of State may prescribe, allowances for living quarters, including heat, fuel, and light and cost of living allowances to persons temporarily stationed abroad; printing and binding without regard to section 11 of the Act of March 1, 1919 (44 U. S. C. 111), and section 3709 of the Revised Statutes, as amended; and

42 Stat. 1488.
5 U. S. C. §§ 661-674.
60 Stat. 810.
5 U. S. C. § 55a.

40 Stat. 1270.
41 U. S. C. § 5.

60 Stat. 714.
22 U. S. C. § 287r.

Withdrawal from
Organization.

Financial obliga-
tions of U. S.

(2) such other expenses as the Secretary of State deems necessary to participation by the United States in the activities of the Organization: *Provided*, That the provisions of section 6 of the Act of July 30, 1946, Public Law 565, Seventy-ninth Congress, and regulations thereunder, applicable to expenses incurred pursuant to that Act shall be applicable to any expenses incurred pursuant to this paragraph (b) (2).

SEC. 4. In adopting this joint resolution the Congress does so with the understanding that, in the absence of any provision in the World Health Organization Constitution for withdrawal from the Organization, the United States reserves its right to withdraw from the Organization on a one-year notice: *Provided, however*, That the financial obligations of the United States to the Organization shall be met in full for the Organization's current fiscal year.

SEC. 5. In adopting this joint resolution, the Congress does so with the understanding that nothing in the Constitution of the World Health Organization in any manner commits the United States to enact any specific legislative program regarding any matters referred to in said Constitution.

Approved June 14, 1948.

[CHAPTER 470]

AN ACT

June 15, 1948
[S. 1987]
[Public Law 644]

To authorize the Secretary of the Interior to construct the Preston Bench project, Idaho, in accordance with the Federal reclamation laws.

Preston Bench proj-
ect, Idaho.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Secretary of the Interior through the Bureau of Reclamation is hereby authorized to construct, maintain, and operate, pursuant to the Federal reclamation laws, the Preston Bench project, Idaho, substantially in accordance with the report of the regional director of the Bureau of Reclamation, region IV, dated September 15, 1947, as concurred in by the Commissioner of Reclamation and the Secretary of the Interior: *Provided*, That the total cost of the project shall be reimbursable under the Federal reclamation laws within repayment periods fixed by the Secretary of the Interior at not to exceed seventy-four years.

Appropriation au-
thorized.
Post, p. 1040.

SEC. 2. There are hereby authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be required for the purposes of this Act.

Approved June 15, 1948.

[CHAPTER 471]

AN ACT

June 15, 1948
[S. 2137]
[Public Law 645]

To provide for the protection of potato and tomato production from the golden nematode, and for other purposes.

Golden Nematode
Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That, to protect potato and tomato production in the United States from the destructive pest known as the golden nematode which subsists on the roots of potatoes and tomatoes, causes marked reduction in yield, persists in the soil for many years in an inactive state in the absence of preferred hosts, and becomes active and destructive when potatoes or tomatoes are again planted, it is the policy of the Government of the United States, independently or in cooperation with State and local governmental agencies, and other public and private organizations, associations, and individuals, to eradicate, suppress, control, and prevent the spread of, this pest.

EXHIBIT E

WORLD HEALTH ORGANIZATION

*Constitution opened for signature at New York July 22, 1946, and signed for the United States, subject to approval, July 22, 1946 Accepted by the United States June 14, 1948, subject to the provisions of a Senate joint resolution of June 14, 1948*¹

Acceptance by the United States deposited with the United Nations June 21, 1948

*Entered into force April 7, 1948; for the United States June 21, 1948 Articles 24 and 25 amended by World Health Assembly May 28, 1959*²

62 Stat. 2679; Treaties and Other
International Acts Series 1808

CONSTITUTION OF THE WORLD HEALTH ORGANIZATION

The States parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

¹ Secs. 4 and 5 of the joint resolution (62 Stat. 441) read as follows:

"SEC. 4. In adopting this joint resolution the Congress does so with the understanding that, in the absence of any provision in the World Health Organization Constitution for withdrawal from the Organization, the United States reserves its right to withdraw from the Organization on a one-year notice: *Provided, however,* That the financial obligations of the United States to the Organization shall be met in full for the Organization's current fiscal year.

"SEC. 5. In adopting this joint resolution, the Congress does so with the understanding that nothing in the Constitution of the World Health Organization in any manner commits the United States to enact any specific legislative program regarding any matters referred to in said Constitution."

² 11 UST 2553; TIAS 4643. A further amendment to arts. 24 and 25 was adopted by the Assembly May 23, 1967, and an amendment to art. 7 was adopted May 20, 1965; both are subject to acceptance by two-thirds of the members of WHO.

The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.

The achievement of any State in the promotion and protection of health is of value to all.

Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.

Healthy development of the child is of basic importance; the ability to live harmoniously in a changing total environment is essential to such development.

The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.

Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people.

Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.

Accepting these principles, and for the purpose of co-operation among themselves and with others to promote and protect the health of all peoples, the contracting parties agree to the present Constitution and hereby establish the World Health Organization as a specialized agency within the terms of Article 57 of The Charter of the United Nations.³

CHAPTER I

OBJECTIVE

Article 1

The objective of the World Health Organization (hereinafter called the Organization) shall be the attainment by all peoples of the highest possible level of health.

CHAPTER II

FUNCTIONS

Article 2

In order to achieve its objective, the functions of the Organization shall be:

(a) to act as the directing and co-ordinating authority on international health work;

(b) to establish and maintain effective collaboration with the United Nations, specialized agencies, governmental health administrations, professional groups and such other organizations as may be deemed appropriate;

³ TS 993, *ante*, vol. 3, p. 1167.

- (c) to assist governments, upon request, in strengthening health services;
- (d) to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of governments;
- (e) to provide or assist in providing, upon the request of the United Nations, health services and facilities to special groups, such as the peoples of trust territories;
- (f) to establish and maintain such administrative and technical services as may be required, including epidemiological and statistical services;
- (g) to stimulate and advance work to eradicate epidemic, endemic and other diseases;
- (h) to promote, in co-operation with other specialized agencies where necessary, the prevention of accidental injuries;
- (i) to promote, in co-operation with other specialized agencies where necessary, the improvement of nutrition, housing, sanitation, recreation, economic or working conditions and other aspects of environmental hygiene;
- (j) to promote co-operation among scientific and professional groups which contribute to the advancement of health;
- (k) to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective;
- (l) to promote maternal and child health and welfare and to foster the ability to live harmoniously in a changing total environment;
- (m) to foster activities in the field of mental health, especially those affecting the harmony of human relations;
- (n) to promote and conduct research in the field of health;
- (o) to promote improved standards of teaching and training in the health, medical and related professions;
- (p) to study and report on, in co-operation with other specialized agencies where necessary, administrative and social techniques affecting public health and medical care from preventive and curative points of view, including hospital services and social security;
- (q) to provide information, counsel and assistance in the field of health;
- (r) to assist in developing an informed public opinion among all peoples on matters of health;
- (s) to establish and revise as necessary international nomenclatures of diseases, of causes of death and of public health practices;
- (t) to standardize diagnostic procedures as necessary;
- (u) to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products;
- (v) generally to take all necessary action to attain the objective of the Organization.

CHAPTER III

MEMBERSHIP AND ASSOCIATE MEMBERSHIP

Article 3

Membership in the Organization shall be open to all States.

Article 4

Members of the United Nations may become Members of the Organization by signing or otherwise accepting this Constitution in accordance with the provisions of Chapter XIX and in accordance with their constitutional processes.

Article 5

The States whose governments have been invited to send observers to the International Health Conference held in New York, 1946, may become Members by signing or otherwise accepting this Constitution in accordance with the provisions of Chapter XIX and in accordance with their constitutional processes provided that such signature or acceptance shall be completed before the first session of the Health Assembly.

Article 6

Subject to the conditions of any agreement between the United Nations and the Organization, approved pursuant to Chapter XVI, States which do not become Members in accordance with Articles 4 and 5 may apply to become Members and shall be admitted as Members when their application has been approved by a simple majority vote of the Health Assembly.

Article 7

If a Member fails to meet its financial obligations to the Organization or in other exceptional circumstances the Health Assembly may, on such conditions as it thinks proper, suspend the voting privileges and services to which a Member is entitled. The Health Assembly shall have the authority to restore such voting privileges and services.

Article 8

Territories or groups of territories which are not responsible for the conduct of their international relations may be admitted as Associate Members by the Health Assembly upon application made on behalf of such territory or group of territories by the Member or other authority having responsibility for their international relations. Representatives of Associate Members to the Health Assembly should be qualified by their technical competence in the field of health and should be chosen from the native population. The nature and extent of the rights and obligations of Associate Members shall be determined by the Health Assembly.

CHAPTER IV

ORGANS

Article 9

The work of the Organization shall be carried out by:

- (a) The World Health Assembly (herein called the Health Assembly);
- (b) The Executive Board (hereinafter called the Board);
- (c) The Secretariat.

CHAPTER V

THE WORLD HEALTH ASSEMBLY

Article 10

The Health Assembly shall be composed of delegates representing Members.

Article 11

Each Member shall be represented by not more than three delegates, one of whom shall be designated by the Member as chief delegate. These delegates should be chosen from among persons most qualified by their technical competence in the field of health, preferably representing the national health administration of the Member.

Article 12

Alternates and advisers may accompany delegates.

Article 13

The Health Assembly shall meet in regular annual session and in such special sessions as may be necessary. Special sessions shall be convened at the request of the Board or of a majority of the Members.

Article 14

The Health Assembly, at each annual session, shall select the country or region in which the next annual session shall be held, the Board subsequently fixing the place. The Board shall determine the place where a special session shall be held.

Article 15

The Board, after consultation with the Secretary-General of the United Nations, shall determine the date of each annual and special session.

Article 16

The Health Assembly shall elect its President and other officers at the beginning of each annual session. They shall hold office until their successors are elected.

Article 17

The Health Assembly shall adopt its own rules of procedure.

Article 18

The functions of the Health Assembly shall be:

- (a) to determine the policies of the Organization;
- (b) to name the Members entitled to designate a person to serve on the Board;
- (c) to appoint the Director-General;
- (d) to review and approve reports and activities of the Board and of the Director-General and to instruct the Board in regard to matters upon which action, study, investigation or report may be considered desirable;
- (e) to establish such committees as may be considered necessary for the work of the Organization;
- (f) to supervise the financial policies of the Organization and to review and approve the budget;
- (g) to instruct the Board and the Director-General to bring to the attention of Members and of international organizations, governmental or non-governmental, any matter with regard to health which the Health Assembly may consider appropriate;
- (h) to invite any organization, international or national, governmental or non-governmental, which has responsibilities related to those of the Organization, to appoint representatives to participate, without right of vote, in its meetings or in those of the committees and conferences convened under its authority, on conditions prescribed by the Health Assembly; but in the case of national organizations, invitations shall be issued only with the consent of the government concerned;
- (i) to consider recommendations bearing on health made by the General Assembly, the Economic and Social Council, the Security Council or Trusteeship Council of the United Nations, and to report to them on the steps taken by the Organization to give effect to such recommendations;
- (j) to report to the Economic and Social Council in accordance with any agreement between the Organization and the United Nations;
- (k) to promote and conduct research in the field of health by the personnel of the Organization, by the establishment of its own institutions or by co-operation with official or non-official institutions of any Member with the consent of its government;

- (l) to establish such other institutions as it may consider desirable;
- (m) to take any other appropriate action to further the objective of the Organization.

Article 19

The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements which shall come into force for each Member when accepted by it in accordance with its constitutional processes.

Article 20

Each Member undertakes that it will, within eighteen months after the adoption by the Health Assembly of a convention or agreement, take action relative to the acceptance of such convention or agreement. Each Member shall notify the Director-General of the action taken and if it does not accept such convention or agreement within the time limit, it will furnish a statement of the reasons for non-acceptance. In case of acceptance, each Member agrees to make an annual report to the Director-General in accordance with Chapter XIV.

Article 21

The Health Assembly shall have authority to adopt regulations concerning:

- (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;
- (b) nomenclature with respect to diseases, causes of death, and public health practices;
- (c) standards with respect to diagnostic procedures for international use;
- (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;
- (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce.

Article 22

Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice.

Article 23

The Health Assembly shall have authority to make recommendations to Members with respect to any matter within the competence of the Organization.

CHAPTER VI

THE EXECUTIVE BOARD

Article 24

The Board shall consist of eighteen persons designated by as many Members. The Health Assembly, taking into account an equitable geographical distribution, shall elect the Members entitled to designate a person to serve on the Board. Each of these Members should appoint to the Board a person technically qualified in the field of health, who may be accompanied by alternates and advisers.

Article 25

These Members shall be elected for three years and may be reelected; provided that of the Members elected at the first session of the Health Assembly, the terms of six Members shall be for one year and the terms of six Members shall be for two years, as determined by lot.

Article 26

The Board shall meet at least twice a year and shall determine the place of each meeting.

Article 27

The Board shall elect its Chairman from among its members and shall adopt its own rules of procedure.

Article 28

The functions of the Board shall be:

- (a) to give effect to the decisions and policies of the Health Assembly;
- (b) to act as the executive organ of the Health Assembly;
- (c) to perform any other functions entrusted to it by the Health Assembly;
- (d) to advise the Health Assembly on questions referred to it by that body and on matters assigned to the Organization by conventions, agreements and regulations;
- (e) to submit advice or proposals to the Health Assembly on its own initiative;
- (f) to prepare the agenda of meetings of the Health Assembly;
- (g) to submit to the Health Assembly for consideration and approval a general programme of work covering a specific period;
- (h) to study all questions within its competence;
- (i) to take emergency measures within the functions and financial resources of the Organization to deal with events requiring immediate action. In particular it may authorize the Director-General to take the necessary steps to combat epidemics, to participate in the organization of health relief

to victims of a calamity and to undertake studies and research the urgency of which has been drawn to the attention of the Board by any Member or by the Director-General.

Article 29

The Board shall exercise on behalf of the whole Health Assembly the powers delegated to it by that body.

CHAPTER VII

THE SECRETARIAT

Article 30

The Secretariat shall comprise the Director-General and such technical and administrative staff as the Organization may require.

Article 31

The Director-General shall be appointed by the Health Assembly on the nomination of the Board on such terms as the Health Assembly may determine. The Director-General, subject to the authority of the Board, shall be the chief technical and administrative officer of the Organization.

Article 32

The Director-General shall be *ex officio* Secretary of the Health Assembly, of the Board, of all commissions and committees of the Organization and of conferences convened by it. He may delegate these functions.

Article 33

The Director-General or his representative may establish a procedure by agreement with Members, permitting him, for the purpose of discharging his duties, to have direct access to their various departments, especially to their health administrations and to national health organizations, governmental or non-governmental. He may also establish direct relations with international organizations whose activities come within the competence of the Organization. He shall keep Regional Offices informed on all matters involving their respective areas.

Article 34

The Director-General shall prepare and submit annually to the Board the financial statements and budget estimates of the Organization.

Article 35

The Director-General shall appoint the staff of the Secretariat in accordance with staff regulations established by the Health Assembly. The para-

mount consideration in the employment of the staff shall be to assure that the efficiency, integrity and internationally representative character of the Secretariat shall be maintained at the highest level. Due regard shall be paid also to the importance of recruiting the staff on as wide a geographical basis as possible.

Article 36

The conditions of service of the staff of the Organization shall conform as far as possible with those of other United Nations organizations.

Article 37

In the performance of their duties the Director-General and the staff shall not seek or receive instructions from any government or from any authority external to the Organization. They shall refrain from any action which might reflect on their position as international officers. Each Member of the Organization on its part undertakes to respect the exclusively international character of the Director-General and the staff and not to seek to influence them.

CHAPTER VIII

COMMITTEES

Article 38

The Board shall establish such committees as the Health Assembly may direct and, on its own initiative or on the proposal of the Director-General, may establish any other committees considered desirable to serve any purpose within the competence of the Organization.

Article 39

The Board, from time to time and in any event annually, shall review the necessity for continuing each committee.

Article 40

The Board may provide for the creation of or the participation by the Organization in joint or mixed committees with other organizations and for the representation of the Organization in committees established by such other organizations.

CHAPTER IX

CONFERENCES

Article 41

The Health Assembly or the Board may convene local, general, technical or other special conferences to consider any matter within the competence

of the Organization and may provide for the representation at such conferences of international organizations and, with the consent of the government concerned, of national organizations, governmental or non-governmental. The manner of such representation shall be determined by the Health Assembly or the Board.

Article 42

The Board may provide for representation of the Organization at conferences in which the Board considers that the Organization has an interest.

CHAPTER X

HEADQUARTERS

Article 43

The location of the headquarters of the Organization shall be determined by the Health Assembly after consultation with the United Nations.

CHAPTER XI

REGIONAL ARRANGEMENTS

Article 44

(a) The Health Assembly shall from time to time define the geographical areas in which it is desirable to establish a regional organization.

(b) The Health Assembly may, with the consent of a majority of the Members situated within each area so defined, establish a regional organization to meet the special needs of such area. There shall not be more than one regional organization in each area.

Article 45

Each regional organization shall be an integral part of the Organization in accordance with this Constitution.

Article 46

Each regional organization shall consist of a Regional Committee and a Regional Office.

Article 47

Regional Committees shall be composed of representatives of the Member States and Associate Members in the region concerned. Territories or groups of territories within the region, which are responsible for the conduct of

their international relations and which are not Associate Members, shall have the right to be represented and to participate in Regional Committees. The nature and extent of the rights and obligations of these territories or groups of territories in Regional Committees shall be determined by the Health Assembly in consultation with the Member or other authority having responsibility for the international relations of these territories and with the Member States in the region.

Article 48

Regional Committees shall meet as often as necessary and shall determine the place of each meeting.

Article 49

Regional Committees shall adopt their own rules of procedure.

Article 50

The functions of the Regional Committee shall be:

- (a) to formulate policies governing matters of an exclusively regional character;
- (b) to supervise the activities of the Regional Office;
- (c) to suggest to the Regional Office the calling of technical conferences and such additional work or investigation in health matters as in the opinion of the Regional Committee would promote the objective of the Organization within the region;
- (d) to co-operate with the respective regional committees of the United Nations and with those of other specialized agencies and with other regional international organizations having interests in common with the Organization;
- (e) to tender advice, through the Director-General, to the Organization on international health matters which have wider than regional significance;
- (f) to recommend additional regional appropriations by the governments of the respective regions if the proportion of the central budget of the Organization allotted to that region is insufficient for the carrying out of the regional functions;
- (g) such other functions as may be delegated to the Regional Committee by the Health Assembly, the Board or the Director-General.

Article 51

Subject to the general authority of the Director-General of the Organization, the Regional Office shall be the administrative organ of the Regional Committee. It shall, in addition, carry out within the region the decisions of the Health Assembly and of the Board.

Article 52

The head of the Regional Office shall be the Regional Director appointed by the Board in agreement with the Regional Committee.

Article 53

The staff of the Regional Office shall be appointed in a manner to be determined by agreement between the Director-General and the Regional Director.

Article 54

The Pan American sanitary organization represented by the Pan American Sanitary Bureau and the Pan American Sanitary Conferences, and all other inter-governmental regional health organizations in existence prior to the date of signature of this Constitution, shall in due course be integrated with the Organization. This integration shall be effected as soon as practicable through common action based on mutual consent of the competent authorities expressed through the organizations concerned.

CHAPTER XII

BUDGET AND EXPENSES

Article 55

The Director-General shall prepare and submit to the Board the annual budget estimates of the Organization. The Board shall consider and submit to the Health Assembly such budget estimates, together with any recommendations the Board may deem advisable.

Article 56

Subject to any agreement between the Organization and the United Nations, the Health Assembly shall review and approve the budget estimates and shall apportion the expenses among the Members in accordance with a scale to be fixed by the Health Assembly.

Article 57

The Health Assembly or the Board acting on behalf of the Health Assembly may accept and administer gifts and bequests made to the Organization provided that the conditions attached to such gifts or bequests are acceptable to the Health Assembly or the Board and are consistent with the objective and policies of the Organization.

Article 58

A special fund to be used at the discretion of the Board shall be established to meet emergencies and unforeseen contingencies.

CHAPTER XIII

VOTING

Article 59

Each Member shall have one vote in the Health Assembly.

Article 60

(a) Decisions of the Health Assembly on important questions shall be made by a two-thirds majority of the Members present and voting. These questions shall include: the adoption of conventions or agreements; the approval of agreements bringing the Organization into relation with the United Nations and inter-governmental organizations and agencies in accordance with Articles 69, 70 and 72; amendments to this Constitution.

(b) Decisions on other questions, including the determination of additional categories of questions to be decided by a two-thirds majority, shall be made by a majority of the Members present and voting.

(c) Voting on analogous matters in the Board and in committees of the Organization shall be made in accordance with paragraphs (a) and (b) of this Article.

CHAPTER XIV

REPORTS SUBMITTED BY STATES

Article 61

Each Member shall report annually to the Organization on the action taken and progress achieved in improving the health of its people.

Article 62

Each Member shall report annually on the action taken with respect to recommendations made to it by the Organization and with respect to conventions, agreements and regulations.

Article 63

Each Member shall communicate promptly to the Organization important laws, regulations, official reports and statistics pertaining to health which have been published in the State concerned.

Article 64

Each Member shall provide statistical and epidemiological reports in a manner to be determined by the Health Assembly.

Article 65

Each Member shall transmit upon the request of the Board such additional information pertaining to health as may be practicable.

CHAPTER XV

LEGAL CAPACITY, PRIVILEGES AND IMMUNITIES

Article 66

The Organization shall enjoy in the territory of each Member such legal capacity as may be necessary for the fulfilment of its objective and for the exercise of its functions.

Article 67

(a) The Organization shall enjoy in the territory of each Member such privileges and immunities as may be necessary for the fulfilment of its objective and for the exercise of its functions.

(b) Representatives of Members, persons designated to serve on the Board and technical and administrative personnel of the Organization shall similarly enjoy such privileges and immunities as are necessary for the independent exercise of their functions in connection with the Organization.

Article 68

Such legal capacity, privileges and immunities shall be defined in a separate agreement to be prepared by the Organization in consultation with the Secretary-General of the United Nations and concluded between the Members.

CHAPTER XVI

RELATIONS WITH OTHER ORGANIZATIONS

Article 69

The Organization shall be brought into relation with the United Nations as one of the specialized agencies referred to in Article 57 of the Charter of the United Nations. The agreement or agreements bringing the Organization into relation with the United Nations shall be subject to approval by a two-thirds vote of the Health Assembly.

Article 70

The Organization shall establish effective relations and co-operate closely with such other inter-governmental organizations as may be desirable. Any formal agreement entered into with such organizations shall be subject to approval by a two-thirds vote of the Health Assembly.

Article 71

The Organization may, on matters within its competence, make suitable arrangements for consultation and co-operation with non-governmental international organizations and, with the consent of the government concerned, with national organizations, governmental or non-governmental.

Article 72

Subject to the approval by a two-thirds vote of the Health Assembly, the Organization may take over from any other international organization or agency whose purpose and activities lie within the field of competence of the Organization such functions, resources and obligations as may be conferred upon the Organization by international agreement or by mutually acceptable arrangements entered into between the competent authorities of the respective organizations.

CHAPTER XVII

AMENDMENTS

Article 73

Texts of proposed amendments to this Constitution shall be communicated by the Director-General to Members at least six months in advance of their consideration by the Health Assembly. Amendments shall come into force for all Members when adopted by a two-thirds vote of the Health Assembly and accepted by two-thirds of the Members in accordance with their respective constitutional processes.

CHAPTER XVIII

INTERPRETATION

Article 74

The Chinese, English, French, Russian and Spanish texts of this Constitution shall be regarded as equally authentic.

Article 75

Any question or dispute concerning the interpretation or application of this Constitution which is not settled by negotiation or by the Health Assembly shall be referred to the International Court of Justice in conformity with the Statute of the Court,⁴ unless the parties concerned agree on another mode of settlement.

⁴ TS 993, *ante*, vol. 3, p. 1179.

Article 76

Upon authorization by the General Assembly of the United Nations or upon authorization in accordance with any agreement between the Organization and the United Nations, the Organization may request the International Court of Justice for an advisory opinion on any legal question arising within the competence of the Organization.

Article 77

The Director-General may appear before the Court on behalf of the Organization in connection with any proceedings arising out of any such request for an advisory opinion. He shall make arrangements for the presentation of the case before the Court including arrangements for the argument of different views on the question.

CHAPTER XIX

ENTRY INTO FORCE

Article 78

Subject to the provisions of Chapter III, this Constitution shall remain open to all States for signature or acceptance.

Article 79

(a) States may become parties to this Constitution by

- (i) signature without reservation as to approval;
- (ii) signature subject to approval followed by acceptance; or
- (iii) acceptance.

(b) Acceptance shall be effected by the deposit of a formal instrument with the Secretary-General of the United Nations.

Article 80

This Constitution shall come into force when twenty-six Members of the United Nations have become parties to it in accordance with the provisions of Article 79.

Article 81

In accordance with Article 102 of the Charter of the United Nations, the Secretary-General of the United Nations will register this Constitution when it has been signed without reservation as to approval on behalf of one State or upon deposit of the first instrument of acceptance.

Article 82

The Secretary-General of the United Nations will inform States parties to this Constitution of the date when it has come into force. He will also inform them of the dates when other States have become parties to this Constitution.

In faith whereof the undersigned representatives having been duly authorized for that purpose, sign this Constitution.

Done in the City of New York this twenty-second day of July 1946, in a single copy in the Chinese, English, French, Russian and Spanish languages, each text being equally authentic. The original texts shall be deposited in the archives of the United Nations. The Secretary-General of the United Nations will send certified copies to each of the Governments represented at the Conference.

For Argentina:
Ad referendum
ALBERTO ZWANCK

For Australia:
Subject to approval and acceptance by
Government of Commonwealth
of Australia.
A. H. TANGE

For the Kingdom of Belgium:
Subject to ratification [translation].
DR. M. DE LAET

For Bolivia:
Ad referendum
LUIS V. SOTELO

For Brazil:
Ad referendum
GERALDO H. DE PAULA SOUZA

For the Byelorussian Soviet Socialist
Republic:
Subject to ratification by the Govern-
ment [translation].
N. EVSTAFIEV

For Canada:
Subject to approval.
BROOKE CLAXTON
BROCK CHISHOLM

For Chile:
Subject to constitutional approval
[translation].
JULIO BUSTOS

For China:
SHEN, J. K.
I. CHIN YUAN
SZEMING SZE

For Colombia:
Ad referendum
CARLOS URIBE AGUIRRE

For Costa Rica:
Ad referendum
JAIME BENAVIDES

For Cuba:
Ad referendum
DR. PEDRO NOGUEIRA
VÍCTOR SANTAMARINA

For Czechoslovakia:
Ad referendum
DR. JOSEF CANČÍK

For Denmark:
Ad referendum
J. OERSKOV

For the Dominican Republic:
Ad referendum
DR. L. F. THOMEN

For Ecuador:
Ad referendum
R. NEVAREZ VÁSQUEZ

For Egypt:
Subject to ratification.
DR. A. T. CHOUGHA
TAHA ELSAYED NASR BEY
M. S. ABAZA

For El Salvador:
Ad referendum
ARÍSTIDES MOLL

For Ethiopia:
Subject to ratification.
G. TESEMMA

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- For France:
Ad referendum
J. PARISOT
- For Greece:
Ad referendum
DR. PHOKION KOPANARIS
- For Guatemala:
Ad referendum
G. MORÁN
J. A. MUÑOZ
- For Haiti:
Ad referendum
RULX LEÓN
- For Honduras:
Ad referendum
JUAN MANUEL FIALLOS
- For India:
Subject to ratification. These signatures are appended in agreement with His Majesty's Representative for the exercise of the functions of the Crown in its relations with the Indian States.
C. K. LAKSHMANAN
C. MANI
- For Iran:
Subject to ratification by the Iranian Parliament (Madjliss).
GHASSEME GHANI
H. HAFEZI
- For Iraq:
Ad referendum
S. AL-ZAHAWI
DR. IHSAN DOGRAMAJI
- For Lebanon:
Ad referendum
GEORGES HAKIM
DR. A. MAKHLIOUS
- For Liberia:
Ad referendum
JOSEPH NAGBE TOGBA
JOHN B. WEST
- For the Grand Duchy of Luxembourg:
Subject to ratification [translation].
DR. M. DE LAET
- For Mexico:
Ad referendum
MONDRAGON
- For the Kingdom of the Netherlands:
Ad referendum
C. VAN DEN BERG
C. BANNING
W. A. TIMMERMAN
- For New Zealand:
Ad referendum
T. R. RITCHIE
- For Nicaragua:
Ad referendum
A. SEVILLA-SACASA
- For the Kingdom of Norway:
Ad referendum
HANS TH. SANDBERG
- For Panama:
Ad referendum
J. J. VALLARINO
- For Paraguay:
Ad referendum
ANGEL R. GINÉS
- For Peru:
Ad referendum
CARLOS ENRIQUE PAZ SOLDÁN
A. TORANZO
- For the Republic of the Philippines:
Ad referendum
H. LARA
WALFRIDO DE LEON
- For Poland:
Ad referendum
EDWARD GRZEGORZEWSKI
- For Saudi Arabia:
Subject to ratification [translation].
DR. YAHIA NASRI
DR. MEDHAT CHEIKH-AL-ARDH
- For Syria:
Subject to ratification.
DR. C. TREFI
- For Turkey:
Subject to ratification. I sign subject to approval and confirmation by my Government [translation].
Z. N. BARKER
- For the Ukrainian Soviet Socialist Republic:
Subject to ratification by the Supreme Council of the Ukrainian Soviet Socialist Republic [translation].
L. I. MECVED
I. I. KALTCHENKO
- For the Union of Soviet Socialist Republics:
Subject to ratification by the Presidium of the Supreme Council of the Union of Soviet Socialist Republics [translation].
F. G. KROTKOV

For the Union of South Africa: Ad referendum H. S. GEAR	For Bulgaria: Subject to ratification. DR. D. P. ORAHOVATZ
For the United Kingdom of Great Britain and Northern Ireland: MELVILLE D. MACKENZIE G. E. YATES	For Eire: Subject to acceptance. JOHN D. MACCORMACK
For the United States of America: Subject to approval. THOMAS PARRAN MARTHA M. ELIOT FRANK G. BOUDREAU	For Finland: Ad referendum OSMOS TURPEINEN
For Uruguay: Ad referendum José A. MORA R. RIVERO CARLOS M. BARBEROUSSE	For Hungary:
For Venezuela: Ad referendum A. ARREAZA GUZMÁN	For Iceland:
For Yugoslavia: With reservation as to ratification. DR. A. STAMPAR	For Italy: Subject to ratification. GIOVANNI ALBERTO CANAPERIA
For Afghanistan:	For Portugal: Subject to ratification. FRANCISCO C. CAMBOURNAG
For Albania: With reservation [translation]. T. JAKOVA	For Romania:
For Austria: With reservation. DR. MARIUS KAISER	For Siam: Subject to approval. BUNLIANG TAMTHA
	For Sweden:
	For Switzerland: Subject to ratification [translation]. DR. J. EUGSTER A. SAUTER
	For Transjordan: Subject to ratification. DR. D. P. TUTUNJI
	For Yemen:

[The constitution was signed for Hungary, subject to ratification, on February 19, 1947; for Sweden, subject to ratification, on January 13, 1947; for Yemen on November 20, 1953; and for Zambia on February 2, 1965.]

EXHIBIT F

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

**ORDER FOR QUARANTINE
UNDER SECTION 361 OF THE PUBLIC HEALTH SERVICE ACT
42 CODE OF FEDERAL REGULATIONS PART 70 (INTERSTATE)
AND PART 71 (FOREIGN)**

SECTION A: SUBJECT PERSON

[NAME OF SUBJECT PERSON], WHO WAS DETERMINED TO HAVE BEEN IN HUBEI PROVINCE, PEOPLE'S REPUBLIC OF CHINA, (CHINA) IN THE LAST 14 DAYS, WHO WAS ONBOARD [AIRLINE] FLIGHT #[X] ARRIVING AT [NAME OF AIRPORT].

SECTION B: FINDINGS

Based on the attached medical declaration, I find:

1. Based on the scientific evidence collected concerning COVID-19, the disease meets the definition of "severe acute respiratory syndromes" as specified under Executive Order 13295, as amended by Executive Orders 13375 and 13674.
2. The Director General of the World Health Organization has declared that the 2019-nCoV/COVID-19 constitutes a Public Health Emergency of International Concern. The Secretary of the U.S. Department of Health and Human Services has declared that 2019-nCoV/COVID-19 constitutes a public health emergency.
3. CDC reasonably believes that the subject person arriving into the United States is infected with or has been exposed to COVID-19.¹ 42 C.F.R. §§ 71.32(a), 71.33.
4. COVID-19 is a quarantinable communicable disease in the United States, meaning that CDC may quarantine and restrict the movement of individuals who are arriving into the United States and have been infected with or exposed to the disease.

¹ For the reasons set forth in this Declaration, the individual listed in this order additionally meets the standards for quarantine under 42 C.F.R. § 70.6 because the subject person is reasonably believed to be in a qualifying stage of the disease and if released from the place of quarantine would be moving or are about to move from one State into another or constitute a probable source of infection to others who may be moving from one State into another.

Qualifying stage is defined under 42 U.S.C. § 264(d)(2) and 42 C.F.R. § 70.1 to mean:

- (1) The communicable stage of the of a quarantinable communicable disease; or
- (2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

5. Quarantine² is authorized by section 361 of the Public Health Service Act (42 U.S.C. § 264) and federal regulations at 42 CFR §§ 70.6, 71.32(a) and 71.33. The facts listed in the attached medical declaration support the conclusion that quarantine is appropriate. This order meets the requirements of 42 CFR §§ 70.14, 71.37.
6. Based on these reasonable beliefs, I find that the subject person meets the standard for federal quarantine under 42 U.S.C. § 264 and 42 CFR §§ 70.14, 71.37.
7. CDC may legally detain you until it finds that you are no longer at risk of becoming ill and spreading the disease to others. This is commonly referred to as the incubation period for the disease. The incubation period for COVID-19 is currently believed to be up to 14 days. You will be reassessed while you are detained. CDC will count the beginning of the incubation period from when you left Hubei Province, China.
8. This order will take effect immediately.

SECTION C: PLACE OF QUARANTINE

You will be housed at [Location, City, State].

SECTION D: REQUIREMENTS

1. While under quarantine, you must take precautions, as directed by healthcare staff and CDC personnel, to prevent the possible spread of the quarantinable communicable disease to others.
2. You must cooperate with the efforts of federal and state or local health authorities to contact other exposed people to prevent the possible spread of the quarantinable communicable disease. This includes providing information regarding people you had contact with, places you visited or traveled to, and your medical history.
3. This order prohibits you from traveling in any manner onboard any type of transportation without a written travel permit issued by the CDC Director under 42 C.F.R. § 70.5. Contact information for questions about travel permits is provided under “How to Obtain More Information about This Order” below.

SECTION E: NOTICE OF LEGAL RIGHTS

² Quarantine means separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who is/are not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

1. **Legal Authority.** CDC has ordered that you be quarantined because it reasonably believes that you arrived into the United States and have been infected with or exposed to COVID-19. Quarantine is authorized by section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 CFR §§ 70.6, 71.32(a) and 71.33.
2. **Conditions of Quarantine.** Components of the Department of Health and Human Services (HHS), together with state and local public health partners, will arrange for adequate food and water, a continued place to stay on [place of quarantine], medical treatment, and a way for you to communicate with a family member or another representative while you are held in federal quarantine.
3. **Medical Examination.** Under 42 CFR §§ 70.12, 71.36, CDC may require you to provide information and undergo such testing, as may be reasonably necessary, to diagnose or confirm the presence, absence, or extent of infection with COVID-19. Medical examination and other testing will be performed by authorized, licensed healthcare staff who will explain the process and ask for your consent to the examination and any procedures. The healthcare staff will also be responsible for your medical care. CDC will discuss with healthcare staff your diagnosis and management, and ways to prevent spread of the disease.
4. **Health Monitoring.** CDC or its cooperating partners at HHS or state and local public health who will monitor your health condition so that the time you remain under federal quarantine will not last longer than is needed to prevent the spread of the quarantinable communicable disease to others. You must cooperate with the instructions of healthcare staff and other authorized personnel during the time you are in quarantine.
5. **Automatic 72-Hour Reassessment.** As indicated by 42 CFR §§ 70.15, 71.38, CDC will reassess this quarantine order no later than 72 hours after it has been served. As part of this reassessment, CDC will review all the relevant data it considered in issuing this order, as well as any relevant new information. At that time, CDC will also determine whether less restrictive alternatives would adequately protect public health. After this reassessment, CDC will issue a written order directing that the quarantine be continued, changed, or ended.
6. **Request for Medical Review.** If after the reassessment described above, CDC orders you to stay in quarantine, 42 CFR §§ 70.16, 71.39 allows you to request a medical review at any time while you are still under quarantine. The medical review will not be automatic; you must specifically request a medical review and may do so by calling CDC's Emergency Operations Center at (770) 488-7100 and asking to speak to the Quarantine Medical Officer on duty. If you request a medical review, CDC will arrange for it to take place as soon as possible.
7. **Medical Review.** During the medical review, you may present medical facts or other evidence to a medical reviewer (a CDC official), call witnesses, give testimony, and be represented by an advocate (such as an attorney, family member, or doctor) at your own expense. If you qualify as indigent (unable to pay), CDC will appoint an attorney knowledgeable of public health practices and a medical professional qualified in the

diagnosis and treatment of infectious diseases for you at the government's expense. CDC will ask you to fill out a form to determine if you qualify as indigent (unable to pay).

8. **Penalties for Violating This Order.** You must cooperate with the requirements in this order to protect the public's health. As authorized by 42 U.S.C. § 271; 18 U.S.C. §§ 3559, 3571; and 42 CFR §§ 70.18, 71.2 or as otherwise provided by federal law, violations of this order may subject you to a criminal fine and/or up to one year in jail.

9. **Court Review.** This order does not affect any constitutional or statutory rights that you may have to ask a federal court to review your federal quarantine, including any rights to habeas review under 28 U.S.C. § 2241.

10. **Translation and Interpretation Services.** CDC will provide translation and interpretation services for this order and the medical review as needed.

11. **How to Obtain More Information about This Order.** If you have any questions about this order, you can call CDC's Emergency Operations Center at (770) 488-7100 and ask to speak to the Quarantine Medical Officer on duty.

SECTION F: AUTHORIZING OFFICIAL

Signature of Authorizing Official

[name and title]

Date

NOTICE TO U.S. CUSTOMS OFFICERS, U.S. COAST GUARD OFFICERS, OR OTHER FEDERAL, STATE, AND LOCAL LAW ENFORCEMENT OFFICIALS:

Under 42 U.S.C. § 268, U.S. Customs and U.S. Coast Guard Officers are required to aid in the enforcement of federal quarantine rules and regulations. Under 42 U.S.C. § 243, the U.S. Department of Health and Human Services is authorized to cooperate with and aid state and local authorities in the enforcement of their quarantine and other health regulations and to accept state and local assistance in the enforcement of federal quarantine rules and regulations.

Violation of this order, in whole or in part, as well as other federal quarantine rules and regulations, constitutes a criminal misdemeanor, punishable by a fine and/or imprisonment pursuant to federal law, including 42 U.S.C. § 271 and 18 U.S.C. §§ 3559 and 3571, as may be amended from time to time.

DISPLAY COPY

Vessel Sanitation Program 2018 Operations Manual



Vessel Sanitation Program 2018 Operations Manual

U.S. Department of Health and Human Services

U.S. Public Health Service

Centers for Disease Control and Prevention/
National Center for Environmental Health



Vessel Sanitation Program
Centers for Disease Control and Prevention
4770 Buford Highway, NE F-59
Atlanta, GA 30341-3717
Phone: 770-488-7070
Fax: 770-488-4127
E-mail: vsp@cdc.gov

Vessel Sanitation Program
Centers for Disease Control and Prevention
1800 Eller Drive, Suite 222
Fort Lauderdale, FL 33316-4209
Phone: 800-323-2132 or 954-356-6650
Fax: 954-356-6671
E-mail: vsp@cdc.gov

The *VSP 2018 Operations Manual* and updates are available at www.cdc.gov/nceh/vsp.

Use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

Information that has changed from the 2011 version of the *VSP Operations Manual* is marked with a

VSP 2018 Operations Manual

Foreword

The Centers for Disease Control and Prevention (CDC) established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. The program assists the cruise ship industry in fulfilling its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for acute gastroenteritis. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced inspections and, when necessary, reinspection.

VSP operated continuously at all major U.S. ports from the early 1970s through 1986, when CDC terminated portions of the program. Industry and public pressures resulted in Congress directing CDC through specific language included in CDC appropriations to resume the program. CDC's National Center for Environmental Health (NCEH) became responsible for VSP in 1986.

NCEH held a series of public meetings to determine the needs and desires of the public and cruise ship industry and on March 1, 1987, a restructured program began. In 1988, the program was further modified by introducing user fees to reimburse the U.S. government for costs. A fee based on the vessel's size is charged for inspections and reinspections. A *VSP Operations Manual* based on the Food and Drug Administration (FDA) 1976 model code for food service and the World Health Organization's *Guide to Ship Sanitation* was published in 1989 to assist the cruise ship industry in educating shipboard personnel.

In 1998, it became apparent that it was time to update the 1989 version of the *VSP Operations Manual*. Changes in the FDA *Food Code*, new science on food safety and protection, and newer technology in the cruise ship industry contributed to the need for a revised operations manual. Over the next 2 years, VSP solicited comments from and conducted public meetings with representatives of the cruise industry, the general public, FDA, and the international public health community to ensure that the 2000 manual would appropriately address current public health issues related to cruise ship sanitation. A similar process was followed to update the *VSP 2000 Operations Manual* in 2005 and the *VSP 2005 Operations Manual* in 2011.

Although the *VSP 2011 Operations Manual* was in use for almost 6 years, new technology, advanced food science, and emerging pathogens require updates to the manual. The *VSP 2018 Operations Manual* reflects comments and corrections submitted by cooperative partners in government and private industry as well as the public. We would like to thank all those who submitted comments and participated throughout this process.

As new information, technology, and input are received, we will continue to review and record that information and maintain a public process to keep the *VSP Operations Manual* current.

The *VSP 2018 Operations Manual* continues the more than 40 years of government and industry working together to achieve a successful and cooperative program that benefits millions of travelers each year.

Aimee Treffiletti (CDR, USPHS)
Vessel Sanitation Program

Acknowledgments

VSP would like to acknowledge the following organizations and companies for their cooperative efforts in the revisions of the *VSP 2018 Operations Manual*.

Cruise Lines

- Carnival Maritime (AIDA Cruises and Costa Cruises)
- Carnival Corporation & PLC
- Carnival Cruise Line
- Carnival UK (P&O Cruises and Cunard)
- Disney Cruise Line
- Holland America Group (Holland America Line and Princess Cruises)
- MSC Cruises
- Royal Caribbean Cruises Ltd. (Royal Caribbean International, Celebrity Cruises, and Azamara Cruises)
- Silversea Cruises
- Star Cruises/Crystal Cruises
- Virgin Cruises

Shipyards

- Brodosplit Shipyard – Croatia, Split
- Fincantieri Cantieri Navali Italiani SpA
- Meyer Werft GmbH
- Meyer Turku
- STX France T. Mariotti SpA

Other Organizations

• ALMACO Group, SAS	• DL SERVICES	• Pall Life Sciences
• Anchor Hygiene Services	• EU SHIPSAN	• Precetti SpA
• ANVISA	• Georg Fischer, LLC	• Prescott Consulting
• The Apollo Group	• Halton Marine Oy	• Prisma S.p.A.
• aquagroup AG	• Helga B. Jungwirth	• ProMinent Fluid Controls, Inc.
• Bill Aleman, Inc.	• HOBART Global Marine	• Public Health Agency of Canada
• BC Cagle Consulting	• Howell Laboratories	• SeaKing Ltd.
• Color Line AS	• IDEXX	• TGMG, Inc.
• Connie Centrella Consulting	• JP Schnoor Consulting	• Walt Disney Imagineering
• CPI International	• MEIKO Maschinenbau GmbH & CO KG	• World Health Organization
• Culligan Italiana S.p.A.	• MEIKO USA	
• Cruise Lines International Association (CLIA)	• Menker - Laundry Management Consultants	
• D2 Marine Solutions, Inc.	• MKN GmbH & Co.	
• DL Forney Consulting	• O.T. S.r.l	
	• Oxin	
	• Owings Public Health	

Cover art design: J.D. Freeland.

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Information to Assist the User on the Manual Format

Organization

The *Vessel Sanitation Program Operations Manual* is divided into chapters and subsections that focus on each operational area important to safeguarding public health aboard vessels.

Section Number

The international numbering system is used to organize the guidelines in this document.

Keywords

Each guideline is formatted with a title, keyword, or phrase after the section number.

Description

The public health compliance recommendation is provided in this statement.

Green Bold Text

Portions of some sections of these guidelines are written in **green bold**. These provisions are not requirements. They are provided to convey relevant information about specific exceptions and alternative means for compliance.

Inspection Report Number

The individual inspection report item number is shown in parentheses after the section number and keywords; for example, 7.2.5.1.1 Hair Restraints (14).

Critical Items

Critical compliance items are written in **bold red underlined text** in parentheses after the section number and keywords; for example, **7.5.5.1 Food-Contact Surfaces (24 C)**. The number in parentheses is the individual inspection report item number.

Noncritical Items

Noncritical compliance items are the other items in this manual.

Changes

Information that has changed from the 2011 version of the *VSP Operations Manual* is marked with a yellow highlight and a vertical rule.

Manual Update Process

Revisions to the *VSP Operations Manual* and *VSP Construction Guidelines* are made via a change request process. Change requests include information on the public health significance for the reason and benefit of the suggested change. They are also substantiated based on technical information, published scientific studies, evidence of experience, and other references.

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To update these versions of the documents, VSP provided a change request form format and instructions to industry partners March 2015 for revisions. VSP and stakeholders held 14 days of in-person meetings and two web-based meetings between April 2015 and October 2016 to review the change requests. During these meetings, submitters presented their changes and discussed the reasons and evidence for requesting the changes. During group discussion, VSP accepted change requests as submitted, accepted them as amended, or did not take action.

A total of 307 change requests were submitted during the review process for the *VSP Operations Manual* and *VSP Construction Guidelines*. Of these, 112 were accepted as submitted or as amended, and 34 were withdrawn.

After the revision meetings ended, VSP staff updated the documents, sent drafts to industry for a 45-day review period, and announced availability of the documents for review in the *Federal Register*.

1.0 Introduction

This section includes the following subsections:

- 1.1 Introduction and Background
- 1.2 Activities
- 1.3 Operations Manual

1.1 Introduction and Background

1.1.1 Cooperative Activity

1.1.1.1 History

The Centers for Disease Control and Prevention (CDC) established the Vessel Sanitation Program (VSP) in 1975 as a cooperative activity with the cruise ship industry. This program assists the cruise ship industry in fulfilling its responsibility for developing and implementing comprehensive performance-based systems to protect the health of the traveling public.

1.1.1.2 Cooperation

The program fosters cooperation between the cruise ship industry and government to define and reduce health risks associated with vessels and to ensure a healthful and clean environment for vessels' passengers and crew. The industry's aggressive and ongoing efforts to achieve and maintain high standards of FOOD safety and environmental sanitation are critical to the success of protecting public health.

1.2 Activities

1.2.1 Prevention

1.2.1.1 Inspections

VSP conducts a comprehensive FOOD safety and environmental sanitation inspection on vessels that have a foreign itinerary, call on a U.S. port, and carry 13 or more passengers.

1.2.1.2 Surveillance

The program conducts ongoing surveillance of ACUTE GASTROENTERITIS (AGE) and coordinates/conducts OUTBREAK investigations on vessels.

1.2.2 Information

1.2.2.1 Training

VSP provides FOOD safety and environmental sanitation training

seminars for vessel and shore operations management personnel.

1.2.2.2 Plan Review

The program provides consultative services for reviewing plans for renovations and new construction.

1.2.2.3 Construction Inspections

The program conducts construction inspections at the shipyards and when the vessel makes its initial call at a U.S. port.

1.2.2.4 Information

The program disseminates information to the public.

1.3 Operations Manual

1.3.1 Revisions

1.3.1.1 Manual

The *VSP 2018 Operations Manual* has been modified to address emerging public health issues, industry recommendations, introduction of new technologies within the industry, new guidance from sources used in the previous edition, and CDC's experience.

1.3.1.2 Program Guidance

Program operations and inspections are based on this manual.

1.3.1.3 Periodic Review

The *VSP 2018 Operations Manual* will be reviewed at the annual meeting with written submissions for revision based on emerging public health issues and new technologies that may better address the public health issues on vessels.

1.3.1.3.1 Clarifications

VSP will circulate proposed clarifications to the operations manual along with supporting information on their public health significance in advance of the annual meeting. These clarifications will be considered during the meeting.

Proposed clarifications VSP considers time critical can be circulated to the industry and others for review and coordination through other collaborative means (e.g., email, web-based forum, etc.) for more timely dissemination and further review, as needed, during the annual meeting.

2.0 Authority

This section includes the following subsections:

- 2.1 Public Health Service Act
- 2.2 Jurisdiction

2.1 Public Health Service Act

2.1.1 Communicable Disease Prevention

2.1.1.1 Communicable Disease Prevention

Although cooperation by vessels with VSP is voluntary, the Public Health Service (PHS) is authorized by the Public Health Service Act (42 U.S.C. Section 264. QUARANTINE and Inspection - Regulations to control communicable diseases) to take measures necessary to prevent the introduction, TRANSMISSION, or spread of communicable diseases into the United States from a foreign country.

2.1.1.2 Regulation Promulgation

In addition, the Public Health Service Act (42 U.S.C. Section 269. QUARANTINE and Inspection - Bills of Health) authorizes the promulgation of regulations applicable to vessels for preventing the introduction into the United States of “any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews.”

2.1.1.3 Inspections

Regulations promulgated to carry out these duties authorize PHS to conduct sanitary inspections on carriers traveling to a U.S. port from a foreign area (42 CFR Section 71.41. General Provisions, Foreign QUARANTINE - Requirements Upon Arrival at U.S. Ports: Sanitary Inspection). The purpose of the inspection is to determine the existence of vermin, contaminated FOOD or water, or other insanitary conditions that may contribute to the introduction, spread, or TRANSMISSION of communicable disease.

2.2 Jurisdiction

VSP’s mission is to prevent AGE TRANSMISSION to U.S. ports by ships sailing from foreign ports. Cruise lines should be aware that although ships sail outside of U.S. waters, there could be occasions when a ship violates the *VSP Operations Manual* while sailing outside of the United States and this violation has a potential to impact a U.S. port. During an operational inspection, VSP must review both present and past practices to evaluate the ship’s compliance with the requirements set out in the *VSP Operations Manual*.

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The *VSP Operations Manual* requires several types of records to be maintained on board for periods of 30 days to 1 year, including the following:

- Medical.
- POTABLE WATER.
- Recreational water.
- FOOD safety.
- Housekeeping.

These records are reviewed during operational inspections. VSP has and will continue to cite violations identified in the record review, even if the ship was not sailing in U.S. waters when the violation occurred. If the record review reveals violations that could result in illness when the ship arrives in a U.S. port, points may be deducted according to the violations identified during the inspection. An example of these violations is ships producing water in ports, HARBORS, and polluted waterways.

3.0 Definitions

This section includes the following subsections:

- 3.1 Scope
- 3.2 Definitions
- 3.3 Acronyms

3.1 Scope

This *VSP 2018 Operations Manual* provides definitions to clarify commonly used terminology in this manual. The definition section is organized alphabetically. Where a definition specifically applies to a section of the manual, it will be noted in the definition.

Terms defined in section 3.2 are identified in the text of these guidelines by CAPITAL LETTERS. For example, section 5.7.1.1.4 states “A CROSS-CONNECTION control program must include at a minimum: ...” CROSS-CONNECTION is in CAPITAL LETTERS and is defined in section 3.2.

3.2 Definitions

Accessible: Exposed for cleaning and inspection with the use of simple tools including a screwdriver, pliers, or wrench. This definition applies to use in FOOD AREAS of the vessel only.

Accredited program: A FOOD protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

- An accredited program refers to the certification process and is a designation based on an independent evaluation of factors such as the sponsor’s mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, recertification, discipline and grievance procedures; and test development and administration.
- Accredited program does not refer to training functions or educational programs.

Activity pools: An indoor or outdoor RECREATIONAL WATER FACILITY that provides flowing water without any additional features. This includes wave pools, catch pools, open water slides, lazy rivers, action rivers, vortex pools, continuous surface pools, etc.

Acute gastroenteritis (AGE): Irritation and inflammation of the digestive tract characterized by sudden onset of symptoms of diarrhea and/or vomiting, as well as other constitutional symptoms such as fever, abdominal cramps, headache, or muscle aches.

AGE case: See REPORTABLE AGE CASE.

AGE outbreak: Cases of ACUTE GASTROENTERITIS, characterized by diarrhea and vomiting, that are in excess of background rates. For the purposes of this manual, more than 3% is considered in excess of background rates. In addition, an AGE outbreak may be based on two or more laboratory-confirmed cases associated with FOOD or water consumption during the cruise.

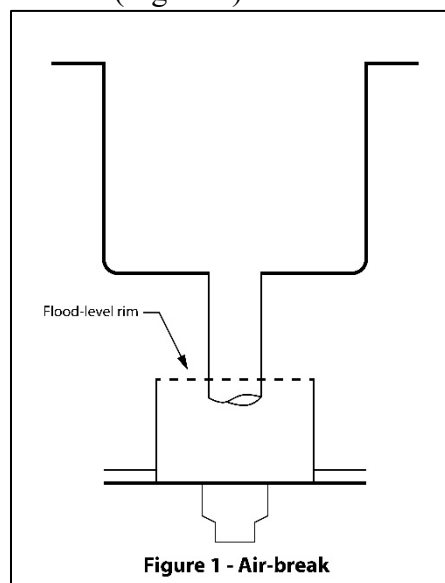
Additive

- **FOOD additive:** as stated in the Federal FOOD, Drug, and Cosmetic Act, §201(s) and 21 CFR 170.
- **Color additive:** as stated in the Federal FOOD, Drug, and Cosmetic Act, §201(t) and 21 CFR 70.

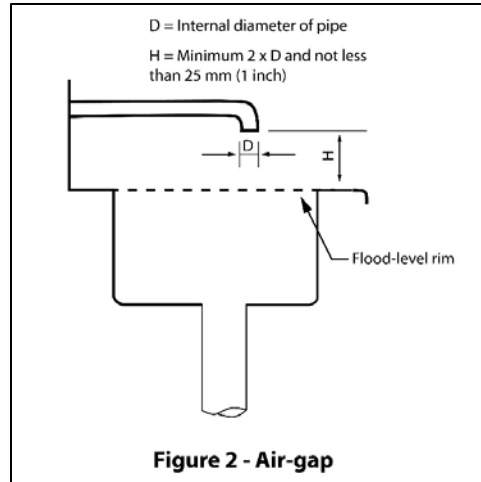
Adequate: Sufficient in number, features, or capacity to accomplish the purpose for which something is intended and to such a degree that there is no unreasonable risk to health or safety.

Adulterated: As stated in the Federal FOOD, Drug, and Cosmetic Act, §402.

Air-break: A piping arrangement in which a drain from a fixture, appliance, or device discharges indirectly into another fixture, receptacle, or interceptor at a point below the flood-level rim (Figure 1).



Air gap (AG): The unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, PLUMBING FIXTURE, or other device and the flood-level rim of the receptacle or receiving fixture. The AIR GAP must be at least twice the inside diameter of the supply pipe or faucet and not less than 25 millimeters (1 inch) (Figure 2).



Antientanglement cover: A cover for a drain/SUCTION FITTING designed to prevent hair from tangling in a drain cover or SUCTION FITTING in a RECREATIONAL WATER FACILITY.

Antientrapment cover: A cover for a drain/SUCTION FITTING designed to prevent any portion of the body or hair from becoming lodged or otherwise forced onto a drain cover or SUCTION FITTING in a RECREATIONAL WATER FACILITY.

Approved: Acceptable based on a determination of conformity with principles, practices, and generally recognized standards that protect public health, federal regulations, or equivalent international standards and regulations. Example of these standards include those from the American National Standards Institute (ANSI), National Sanitation Foundation International (NSF International), American Society of Mechanical Engineers (ASME), American Society of Safety Engineers (ASSE), and Underwriter's Laboratory (UL).

Attack rate: (1) The proportion of individuals exposed to an infectious agent who become clinically ill. (2) The cumulative incidence of infection in a group observed over a period during an epidemic.

Atmospheric vacuum breaker (AVB): A BACKFLOW PREVENTION DEVICE that consists of an air inlet valve, a check seat or float valve, and air inlet ports. The device is not APPROVED for use under continuous water pressure and must be installed downstream of the last valve.

Automatic pump shut-off (APS): System device that can sense a BLOCKABLE DRAIN blockage and shut off the pumps in a RECREATIONAL WATER FACILITY.

Aw (water activity): Measurement of the free moisture content in a FOOD.

Baby-only water facility: RECREATIONAL WATER FACILITY designed for use by children in diapers or who are not completely toilet trained. This facility must have zero water depth. Control measures for this facility would be detailed in a VARIANCE.

Backflow: The reversal of flow of water or other liquids, mixtures, or substances into the distribution pipes of a potable supply of water from any source or sources other than the source of POTABLE WATER supply. BACKSIPHONAGE and BACKPRESSURE are forms of backflow.

Backflow prevention device: An APPROVED backflow prevention plumbing device that must be used on POTABLE WATER distribution lines where there is a direct connection or a potential CROSS-CONNECTION between the POTABLE WATER distribution system and other liquids, mixtures, or substances from any source other than the POTABLE WATER supply. Some devices are designed for use under continuous water pressure, whereas others are noncontinuous pressure types.

(See also:

- ATMOSPHERIC VACUUM BREAKER [AVB].
- CONTINUOUS PRESSURE BACKFLOW PREVENTION DEVICE.
- DUAL CHECK VALVE with intermediate atmospheric vent.
- HOSE BIB CONNECTION VACUUM BREAKER.
- PRESSURE VACUUM BREAKER ASSEMBLY.
- REDUCED PRESSURE PRINCIPLE BACKFLOW PREVENTION ASSEMBLY.)

Backpressure: An elevation of pressure in the downstream piping system (by pump, elevation of piping, or steam and/or air pressure) above the supply pressure at the point of consideration that would cause a reversal of normal direction of flow.

Backsiphonage: The reversal or flowing back of used, contaminated, or polluted water from a PLUMBING FIXTURE or vessel or other source into a water supply pipe as a result of negative pressure in the pipe.

Barometric loop: A continuous section of supply piping that rises at least 35 feet above the supply point and returns back down to the supply. Typically the loop will be in the shape of an upside-down “U.” A barometric loop only protects against BACKSIPHONAGE because it operates under the principle that a water column cannot rise above 33.9 feet at sea-level pressure.

Beverage: A liquid for drinking, including water.

Black water: Wastewater from toilets, urinals, medical sinks, and other similar facilities.

Blast chiller: A unit specifically designed for rapid intermediate cooling of FOOD products from 57°C (135°F) to 21°C (70°F) within 2 hours and 21°C (70°F) to 5°C (41°F) within an additional 4 hours.

Blockable drain/suction fitting: A drain or suction fitting in a RECREATIONAL WATER FACILITY that that can be completely covered or blocked by a 457 millimeter x 584 millimeter (18 inch x 23 inch) body-blocking element as set forth in ASME A112.19.8M.

Bulkhead: A dividing wall covering an area constructed from several panels, also known as the visible part of the lining.

Certified data security features: Features that ensure the values recorded by the data logger cannot be manipulated by the user.

CFR (Code of Federal Regulations): Compilation of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the federal government. The CFR is published annually by the U.S. Government Printing Office and contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40 CFR, and Wildlife and Fisheries rules in 50 CFR.

Chemical disinfectant: A chemical agent used to kill microbes.

Child activity center: A facility for child-related activities where children under the age of 6 are placed to be cared for by vessel staff.

Children’s pool: A pool that has a depth of 1 meter (3 feet) or less and is intended for use by children who are toilet trained.

Child-size toilet: Toilets whose toilet seat height is no more than 280 millimeters (11 inches) and the toilet seat opening is no greater than 203 millimeters (8 inches).

CIP (cleaned in place): Use of a detergent solution, water rinse, and sanitizing solution by circulating or flowing mechanically through a piping system onto or over EQUIPMENT surfaces that require cleaning (for example, the method used—in part—to clean and sanitize a frozen dessert machine). **CIP does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers subjected to in-place manual cleaning without the use of a CIP system.**

Cleaning locker: A room or cabinet specifically designed or modified for storage of cleaning EQUIPMENT such as mops, brooms, floor-scrubbing machines, and cleaning chemicals.

Comminuted: Reduced in size by chopping, flaking, grinding, or mincing. **Examples include FISH or MEAT products reduced in size and restructured or reformulated (e.g., gefilte FISH, gyros, ground beef, and sausage) and mixtures of two or more types of MEAT that have been reduced in size and combined (e.g., sausages made from two or more MEATS).**

Confirmed disease outbreak: A FOODBORNE or WATERBORNE DISEASE OUTBREAK in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the FOOD or water as the source of the illness.

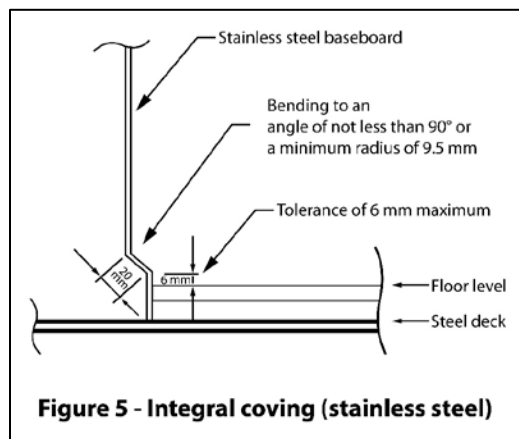
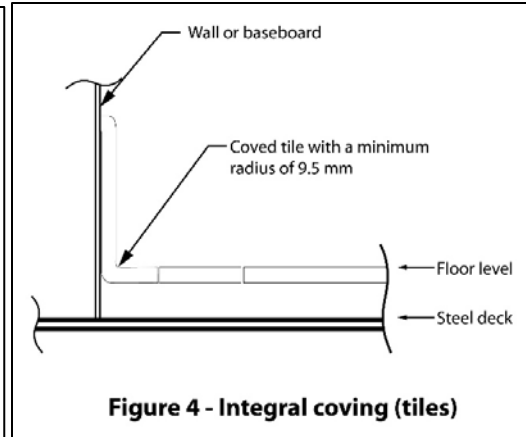
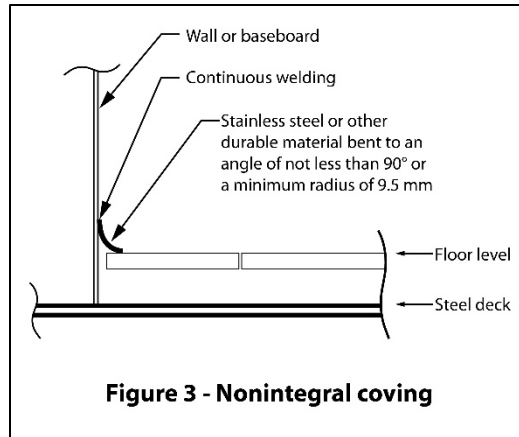
Consumer: A person who takes possession of FOOD, is not functioning as an operator of a FOOD establishment or FOOD-PROCESSING PLANT, and does not offer the FOOD for resale.

Contamination: The presence of an infectious agent on a body surface, in clothes, in bedding, on toys, on surgical instruments or dressings, or on other inanimate articles or substances including FOOD and water.

Continuous pressure (CP) backflow prevention device: A device generally consisting of two check valves and an intermediate atmospheric vent that has been specifically designed to be used under conditions of continuous pressure (greater than 12 hours out of a 24-hour period).

Coving: A concave surface, molding, or other design that eliminates the usual angles of 90° or less at deck junctures (Figures 3, 4, and 5).

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Critical item: A provision of these guidelines that, if in noncompliance, is more likely than other deficiencies to contribute to FOOD or water CONTAMINATION, illness, or environmental HEALTH HAZARD. These are denoted in these guidelines in **bold red underlined text** in parentheses after the section number and keywords; for example, **7.5.5.1 Food-Contact Surfaces (24 C)**. The number indicates the individual inspection report item number.

Critical control point: A point or procedure in a specific system where loss of control may result in an unacceptable health risk.

Critical limit: The maximum or minimum value at a CRITICAL CONTROL POINT to which a physical, biologic, or chemical parameter must be controlled to minimize the occurrence of risk from an identified safety HAZARD.

Cross-connection: An actual or potential connection or structural arrangement between a POTABLE WATER system and any other source or system through which it is possible to introduce into any part of the POTABLE WATER system any used water, industrial fluid, gas, or substance other than the intended POTABLE WATER with which the system is supplied.

CT value: Numerical value used for identifying level at which pathogen destruction/inactivation occurs. **For the purposes of this manual, CT values will be based on free chlorine levels in MG/L (ppm) and time in minutes (CT value=MG/L x minutes).**

Cut leafy greens: Fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. Leafy greens include iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (that is, immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula, and chard. Herbs such as cilantro or parsley are not considered leafy greens.

Date/time of onset: Date/time on which the first symptom appeared.

Deck drain: The physical connection between decks, SCUPPERS, or DECK SINKS and the GRAY WATER or BLACK WATER systems.

Deckhead: The deck overhead covering the ceiling area constructed from several panels, also known as the visible part of the ceiling.

Deck sink: A sink recessed into the deck and sized to contain waste liquids from tilting kettles and pans.

Diarrheal disease: Three or more episodes of loose stools in a 24-hour period or a greater than normal (for the person) number of loose stools.

Disinfectant: A chemical or physical agent used to kill microbes.

Disinfection: A process (physical or chemical) that destroys many or all pathogenic microorganisms, except bacterial and mycotic spores, on inanimate objects.

Distillate water: Water condensed from vapor during the evaporation process.

Distillate water lines: Pipes carrying water condensed from the evaporators and that may be directed to the POTABLE WATER system. This is the VSP definition for pipe striping purposes.

Double check (DC) valve assembly: A BACKFLOW PREVENTION ASSEMBLY consisting of two internally loaded, independently operating check valves located between two resilient-seated shutoff valves. These assemblies include four resilient-seated test cocks. **These devices do not have an intermediate vent to the atmosphere and are not APPROVED for use on CROSS-CONNECTIONS to the POTABLE WATER system of cruise vessels. VSP accepts only vented BACKFLOW PREVENTION DEVICES.**

Dual check valve with an intermediate atmospheric vent (DCIV): A BACKFLOW PREVENTION DEVICE with dual check valves and an intermediate atmospheric vent located between the two check valves.

Drinking water: See POTABLE WATER.

Drip tray: READILY REMOVABLE tray to collect dripping fluids or FOOD from FOOD dispensing EQUIPMENT.

Dry storage area: A room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not potentially hazardous and dry goods such as SINGLE-SERVICE ITEMS.

Easily cleanable: A characteristic of a surface that

- Allows effective removal of soil by normal cleaning methods;
- Is dependent on the material, design, construction, and installation of the surface; and
- Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.

Easily movable: EQUIPMENT that

- Is PORTABLE or mounted on casters, gliders, or rollers or has a mechanical means to safely tilt it for cleaning; and
- Has no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length that allows it to be moved for cleaning of the EQUIPMENT and adjacent area.

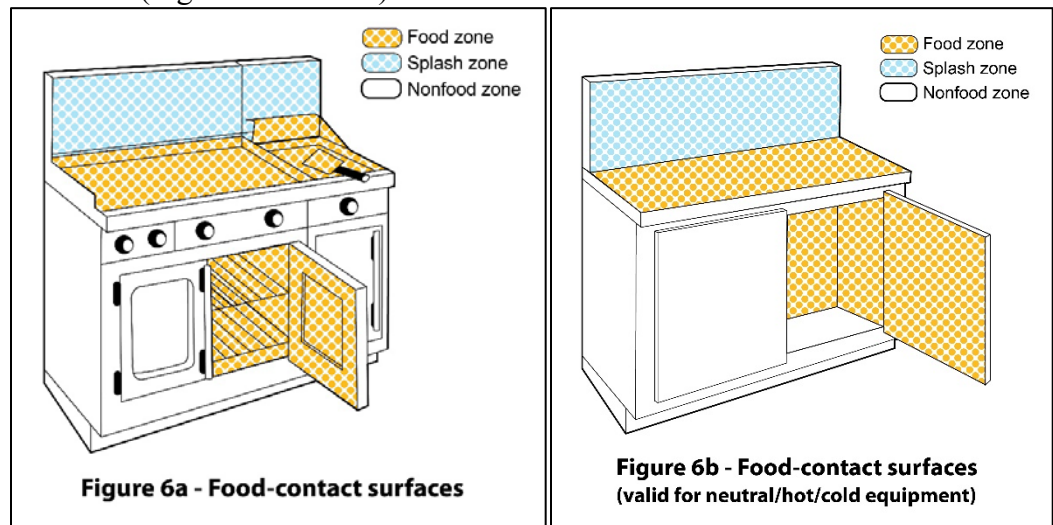
Equipment: An article used in the operation of a FOOD establishment, such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE-MEASURING DEVICE for ambient air, vending machine, or WAREWASHING machine. **Equipment does not include items used for handling or storing large quantities of PACKAGED FOODS received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.**

Fish: Fresh water or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin, and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption. **Fish includes an edible human FOOD product derived in whole or in part from fish, including fish processed in any manner.**

Food: Raw, cooked, or processed edible substance; ice; BEVERAGE; or ingredient used or intended for use or for sale in whole or in part for human consumption. Chewing gum is classified as FOOD.

Food area: Includes food and BEVERAGE display, handling, preparation, service, and storage areas; warewash areas; clean EQUIPMENT storage areas; and LINEN storage and handling areas.

Food-contact surface: Surfaces (food zone, splash zone) of EQUIPMENT and UTENSILS with which food normally comes in contact and surfaces from which food may drain, drip, or splash back into a food or surfaces normally in contact with food (Figures 6a and 6b).



Food display areas: Any area where food is displayed for consumption by passengers and/or crew. Applies to displays served by vessel staff or self-service.

Food employee: A person working with unpackaged food, food EQUIPMENT or UTENSILS, LINENS, or FOOD-CONTACT SURFACES.

Food-handling areas: Any area where food is stored, processed, prepared, or served.

Food preparation areas: Any area where food is processed, cooked, or prepared for service.

Food-processing plant: A commercial operation that manufactures, packages, labels, or stores food for human consumption and does not provide food directly to a CONSUMER.

Food service areas: Any area where food is presented to passengers or crew members (excluding individual cabin service).

Food storage areas: Any area where food or food products are stored.

Food transportation corridors: Areas primarily intended to move food during food preparation, storage, and service operations (e.g., service lift [elevator] vestibules to food preparation service and storage areas, provision corridors, and corridors connecting preparation areas and service areas). Corridors primarily intended to move only closed beverages and packaged foods (e.g., bottled/canned beverages, crackers, chips, etc.) are not considered food transportation corridors, but the deck/BULKHEAD juncture must be coved. **Excluded:**

- **Passenger and crew corridors, public areas, individual cabin service, and dining rooms connected to galleys.**
- **Food loading areas used solely for delivery of food to the vessel.**

Food waste system: A system used to collect, transport, and process food waste from FOOD AREAS to a waste disposal system (e.g., pulper, vacuum system).

Foodborne disease outbreak: An incident in which two or more persons experience a similar illness resulting from the ingestion of a common food.

Game animal: An animal, the products of which are food, that is not classified as

- Cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Subchapter A - Mandatory MEAT Inspection, Part 301,
- POULTRY in 9 CFR Subchapter C - Mandatory POULTRY Products Inspection, Part 381, or
- FISH as defined under Subparagraph 1-201.10(B)(25).

Game animal includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

Game animal does not include RATITES such as ostrich, emu, and rhea.

Gap: An open juncture of more than 3 millimeters (1/8 inch).

General-use pesticide: A pesticide not classified by EPA for restricted use as specified in 40 CFR 152.175.

Grade A standards: Requirements of the FDA Grade A Pasteurized Milk Ordinance and Grade A Condensed and Dry Milk Ordinance with which certain fluid and dry milk and milk products comply.

Gravity drain: A drain fitting used to drain the body of water in a RECREATIONAL WATER FACILITY by gravity and with no pump downstream of the fitting.

Gravity drainage system: A water collection system whereby a collection tank is located between the RECREATIONAL WATER FACILITY and the suction pumps.

Gray water: Wastewater from galley EQUIPMENT and DECK DRAINS, dishwashers, showers and baths, laundries, washbasins, DECK DRAINS, and recirculated RECREATIONAL WATER FACILITIES. Gray water does not include BLACK WATER or bilge water from the machinery spaces.

Gutterway: See SCUPPER.

HACCP (Hazard Analysis Critical Control Point) plan: A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for FOODS.

Halogen: The group of elements including chlorine, bromine, and iodine used for DISINFECTION of water.

Hand antiseptic: Antiseptic products applied to human skin.

Harbor: The portion of a port area set aside for vessel anchorage or for ports including wharves; piers; quays; and service areas, the boundaries are the high-water shore line; and others as determined by legal definition, citation of coordinates, or other means.

Hazard: A biological, chemical, or physical property that may cause an unacceptable CONSUMER health risk.

Heated (RWF): Any RECREATIONAL WATER FACILITY with a water temperature exceeding 32°C (90°F).

Health hazard: An impairment that creates an actual hazard to the public health through poisoning or through the spread of disease. For example, water quality that creates an actual hazard to the public health through the spread of disease by SEWAGE, industrial fluids, waste, etc. (e.g., sluice machine connection).

Hermetically sealed container: A container designed to be secure against the entry of microorganisms and, in the case of low-acid canned FOODS, to maintain the commercial sterility of its contents after processing.

Hose bib connection vacuum breaker (HVB): A BACKFLOW PREVENTION DEVICE that attaches directly to a hose bib by way of a threaded head. This device uses a single check valve and vacuum breaker vent. It is a form of an AVB specifically designed for a hose connection. A hose bib connection vacuum breaker is not APPROVED for use under CONTINUOUS PRESSURE (e.g., when a shut-off valve is located downstream from the device).

Immediate contact: Someone sharing a cabin either full-time or part-time or sharing a cabin's bathroom facilities. This includes boyfriends, girlfriends, spouses, and significant others.

Imminent health hazard: A significant threat or danger to health that is considered to exist when evidence is sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury.

Injected meats: Manipulating MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as with juices, which may be referred to as injecting, pinning, or stitch pumping. This does not include routine temperature monitoring.

Integrated pest management (IPM): A documented, organized system of controlling pests through a combination of methods including inspections, baits, traps, effective sanitation and maintenance, and judicious use of chemical compounds.

Interactive recreational water facility: An indoor or outdoor recreational water facility that includes misting, jetting, waterfalls, or sprinkling features that involve water recirculation systems that come into contact with bathers. Additional features or facilities, such as decorations or fountains, will designate the facility as an interactive RWF if there is any piping connected through the recirculation system. These facilities may be zero depth. Fully or partially enclosed water slides are considered interactive recreational water facilities.

Isolation: The separation of persons who have a specific infectious illness from those who are healthy and the restriction of ill persons' movement to stop the spread of that illness. **For VSP's purposes, isolation for passengers with AGE symptoms is advised and isolation for crew with AGE symptoms is required.**

Kitchenware: FOOD preparation and storage UTENSILS.

Law: Applicable local, state, federal, or other equivalent international statutes, regulations, and ordinances.

Linens: Fabric items such as cloth hampers, cloth napkins, tablecloths, wiping cloths, and work garments including cloth gloves.

Making way: Progressing through the water by mechanical or wind power.

Meat: The flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, **except FISH, POULTRY, and wild GAME ANIMALS.**

Mechanically tenderized: Manipulating MEAT with deep penetration by processes that may be referred to as blade tenderizing; jaccarding; pinning; needling; or using blades, pins, needles, or any mechanical device. This does not include processes by which solutions are injected into MEAT.

mg/L: Milligrams per liter, the metric equivalent of parts per million (ppm).

Molluscan shellfish: Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, **except when the scallop product consists only of the shucked adductor muscle.**

Noncorroding: Material that maintains its original surface characteristics through prolonged influence by the use environment, FOOD contact, and normal use of cleaning compounds and sanitizing solutions.

Nonfood-contact surfaces (nonfood zone): All exposed surfaces, other than FOOD-CONTACT SURFACES, of EQUIPMENT located in FOOD AREAS (Figures 6a and 6b).

Outbreak: See AGE OUTBREAK.

Packaged: Bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a FOOD establishment or a FOOD-PROCESSING PLANT. **Packaged does not include a wrapper, carry-out box, or other nondurable container used to facilitate FOOD protection during service and receipt of FOOD by the CONSUMER.**

Permeate water: Water produced by a reverse osmosis unit.

Permeate water lines: Pipes carrying PERMEATE WATER from the reverse osmosis unit that may be directed to the POTABLE WATER SYSTEM. This is the VSP definition for pipe stripping purposes.

Person in charge: The individual present on a vessel who is responsible for the FOOD operation at the time of inspection such as the FOOD and BEVERAGE Manager, FOOD Manager, or Chef.

Personal-care items: Items or substances that may be poisonous, toxic, or a source of CONTAMINATION and are used to maintain or enhance a person's health, hygiene, or appearance. **Personal-care items include items such as medicines, first-aid supplies, and cosmetics and toiletries (e.g., toothpaste, mouthwash).**

Pesticide: Any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest. For the purposes of this manual, pesticides are considered either general use or restricted use.

pH (potens hydrogen): The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. **Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is neutral.**

Plumbing fixture: A receptacle or device that

- Is permanently or temporarily connected to the water-distribution system of the vessel and demands a supply of water from the system; or
- Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the vessel.

Plumbing system: The water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary sewer drains and vessel drains, including their respective connections, devices, and appurtenances within the vessel; and water-treating EQUIPMENT.

Poisonous or toxic materials: Substances not intended for ingestion. These substances are in four categories:

- Cleaners and SANITIZERS, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals.
- PESTICIDES [except SANITIZERS] that include substances such as insecticides and rodenticides.
- Substances necessary for the operation and maintenance of the establishment such as nonfood-grade lubricants and PERSONAL-CARE ITEMS that may be deleterious to health.
- Substances not necessary for the operation and maintenance of the vessel and are on the vessel, such as petroleum products and paints.

Pollution: The presence of any foreign substance (organic, inorganic, radiologic, or biologic) that tends to degrade water quality to create a HEALTH HAZARD.

Portable: A description of EQUIPMENT that is READILY REMOVABLE or mounted on casters, gliders, or rollers; provided with a mechanical means so that it can be tilted safely for cleaning; or readily movable by one person.

Potable water: Water that is halogenated and pH controlled and is intended for

- Drinking, washing, bathing, or showering;
- Using in fresh water SWIMMING POOLS and WHIRLPOOL SPAS;
- Using in the vessel's hospital;
- Handling, preparing, or cooking FOOD; and

- Cleaning FOOD STORAGE and FOOD PREPARATION areas, UTENSILS, and EQUIPMENT.

Potable water is free from impurities in amounts sufficient to cause disease or harmful physiological effects. The water quality must conform to requirements of the World Health Organization DRINKING WATER standards.

Potable water tanks: All tanks in which POTABLE WATER is stored.

Potentially hazardous food (PHF) (or time/temperature control for safety food [TCS]): Natural or synthetic food that requires time/temperature control because it is in a form capable of supporting one of the following:

- Rapid and progressive growth of infectious or toxigenic microorganisms.
- Growth and toxin production of *Clostridium botulinum*.
- Growth of *Salmonella enteritidis* [in raw shell eggs].

PHF includes an animal FOOD (a FOOD of animal origin) that is raw or heat-treated; a FOOD of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; CUT LEAFY GREENS; cut tomatoes or mixtures of cut tomatoes; and garlic and oil mixtures that are not acidified or otherwise modified at a FOOD-PROCESSING PLANT in a way that results in mixtures that do not support growth as specified under subparagraph (a) of this definition or any FOOD classified by the FDA as a PHF/TCS.

PHF does not include the following:

- An air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable *Salmonellae*.**
- A FOOD with an Aw value of 0.85 or less.**
- A FOOD with a pH level of 4.6 or below when measured at 24°C (75°F).**
- A FOOD in an unopened HERMETICALLY SEALED CONTAINER that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution.**
- A FOOD for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *S. enteritidis* in eggs or *C. botulinum* cannot occur, such as a FOOD that has an Aw and a pH above the levels specified under subparagraphs (b) and (c) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms.**

- f. **A FOOD that may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness, but that does not support the growth of microorganisms as specified under subparagraph (a) of this definition.**

Poultry:

- Any domesticated bird such as chicken, turkey, duck, goose, or guinea, whether live or dead, as defined in 9 CFR 381 Poultry Products Inspection Regulations.
- Any migratory waterfowl, game bird, or squab such as pheasant, partridge, quail, grouse, or guinea, whether live or dead, as defined in 9 CFR 362 Voluntary Poultry Inspection Program.

Poultry does not include RATITE.

Pressure vacuum breaker assembly (PVB): A device consisting of an independently loaded internal check valve and a spring-loaded air inlet valve. This device is also equipped with two resilient seated gate valves and test cocks.

Primal cut: A basic major cut into which carcasses and sides of MEAT are separated, such as a beef round, pork loin, lamb flank, or veal breast.

Quarantine: The limitation of movement of apparently well persons who have been exposed to a case of communicable (infectious) disease during its period of communicability to prevent disease TRANSMISSION during the incubation period if infection should occur.

Ratite: A flightless bird such as an emu, ostrich, or rhea.

Readily accessible: Exposed or capable of being exposed for cleaning or inspection without the use of tools.

Readily removable: Capable of being detached from the main unit without the use of tools.

Ready-to-eat (RTE) food: Food in a form that is edible without washing, cooking, or additional preparation by the food establishment or the CONSUMER and is reasonably expected to be consumed in that form.

RTE food includes

- **POTENTIALLY HAZARDOUS FOOD that is unpackaged and cooked to the temperature and time required for the specific food.**
- **Raw, washed, cut fruits and vegetables.**
- **Whole, raw fruits and vegetables presented for consumption without the need for further washing, such as at a buffet.**

- **Other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks, or shells are removed.**
- **Fruits and vegetables cooked for hot holding, as specified under section 7.3.4.1.3.**
- **Substances derived from plants such as spices, seasonings, and sugar.**
- **A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety.**
- **Products produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks.**
- **Foods manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods PACKAGED in HERMETICALLY SEALED CONTAINERS.**

Recreational water facility (RWF): A water facility that has been modified, improved, constructed, or installed for the purpose of public swimming or recreational bathing. RWFs include, but are not limited to,

- ACTIVITY POOLS.
- BABY-ONLY WATER FACILITIES.
- CHILDREN’S POOLS.
- Diving pools.
- Hot tubs.
- Hydrotherapy pools.
- INTERACTIVE RECREATIONAL WATER FACILITIES.
- Slides.
- SPA POOLS.
- SWIMMING POOLS.
- Therapeutic pools.
- WADING POOLS.
- WHIRLPOOLS.

Recreational seawater: Seawater taken onboard while MAKING WAY at a position at least 12 miles at sea and routed directly to the RWFs for either sea-to-sea exchange or recirculation.

Reduced pressure principle backflow prevention assembly (RP assembly):

An assembly containing two independently acting internally loaded check valves together with a hydraulically operating, mechanically independent pressure differential relief valve located between the check valves and at the same time below the first check valve. The unit must include properly located resilient seated test cocks and tightly closing resilient seated shutoff valves at each end of

the assembly.

Refuse: Solid waste not carried by water through the SEWAGE system.

Registered design professional: An individual registered or licensed to practice his or her respective design profession as defined by the statutory requirements of the professional registration LAWS of the state or jurisdiction in which the project is to be constructed (per ASME A112.19.8-2007).

Regulatory authority: Local, state, or federal or equivalent international enforcement body or authorized representative having jurisdiction over FOOD processing, transportation, or warehousing or other FOOD establishment.

Removable: Capable of being detached from the main unit with the use of simple tools such as a screwdriver, pliers, or an open-end wrench.

Reportable AGE case (VSP definition): A case of AGE with one of the following characteristics:

- Diarrhea (three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, e.g., individuals with underlying medical conditions) **OR**
- Vomiting and one additional symptom including one or more episodes of loose stools in a 24-hour period, or abdominal cramps, or headache, or muscle aches, or fever (temperature of $\geq 38^{\circ}\text{C}$ [100.4°F]); **AND**
- Reported to the master of the vessel, the medical staff, or other designated staff by a passenger or a crew member.

Nausea, although a common symptom of AGE, is specifically excluded from this definition to avoid misclassifying seasickness (nausea and vomiting) as ACUTE GASTROENTERITIS.

Restricted-use pesticide: A pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use and is limited to use by or under the direct supervision of a certified applicator.

Safety vacuum release system (SVRS): A system capable of releasing a vacuum at a suction outlet caused by a high vacuum due to a blockage in the outlet flow. These systems shall be designed and certified in accordance with ASTM F2387-04 or ANSI/ASME A 112.19.17-2002.

Sanitizer: Chemical or physical agents that reduce microorganism CONTAMINATION levels present on inanimate environmental surfaces.

Two classes of sanitizers:

- **Sanitizers of NONFOOD-CONTACT SURFACES:** The performance standard used by the U.S. Environmental Protection Agency (EPA)

for these sanitizers requires a reduction of the target microorganism by 99.9% or 3 logs (1000, 1/1000, or 10³) after 5 minutes of contact time.

- **Sanitizers of FOOD-CONTACT SURFACES:** The EPA performance standard for these sanitizers requires a 99.999% or 5-log reduction of the target microorganism in 30 seconds.

Sanitization: The application of cumulative heat or chemicals on cleaned FOOD-CONTACT and NONFOOD-CONTACT SURFACES that, when evaluated for efficacy, provides a sufficient reduction of pathogens.

Scupper: A conduit or collection basin that channels liquid runoff to a DECK DRAIN.

Sealant: Material used to fill SEAMS.

Seam: An open juncture greater than 0.8 millimeters (1/32 inch) but less than 3 millimeters (1/8 inch).

Sewage: Liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

Shellstock: Raw, in-shell MOLLUSCAN SHELLFISH.

Shucked shellfish: MOLLUSCAN SHELLFISH with one or both shells removed.

Single-service articles: TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers designed and constructed for one-time, one-person use.

Single-use articles: UTENSILS and bulk FOOD containers designed and constructed to be used once and discarded. **Single-use articles include items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans that do not meet materials, durability, strength, and cleanability specifications.**

Slacking: Process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as spinach.

Smooth:

- A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100-grit)

number 3 stainless steel.

- A NONFOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale.
- Deck, BULKHEAD, or DECKHEAD that has an even or level surface with no roughness or projections to make it difficult to clean.

Spa pool: A POTABLE WATER or saltwater-supplied pool with temperatures and turbulence comparable to a WHIRLPOOL SPA.

- Depth of more than 1 meter (3 feet) and
- Tub volume of more than 6 tons of water.

Spill-resistant vacuum breaker (SVB): A specific modification to a PRESSURE VACUUM BREAKER ASSEMBLY to minimize water spillage.

Spray pad: Play and water contact area designed to have no standing water.

Suction fitting: A fitting in a RECREATIONAL WATER FACILITY under direct suction through which water is drawn by a pump.

Swimming pool: A RECREATIONAL WATER FACILITY greater than 1 meter in depth. This does not include SPA POOLS that meet this depth.

Table-mounted equipment: EQUIPMENT that is not PORTABLE and is designed to be mounted off the floor on a table, counter, or shelf.

Tableware: Eating, drinking, and serving UTENSILS for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

Technical water: Water that has not been chlorinated or pH controlled on board the vessel and that originates from a bunkering or condensate collection process, or seawater processed through the evaporators or reverse osmosis plant and is intended for storage and use in the technical water system.

Temperature-measuring device (TMD): A thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water and is numerically scaled in Celsius and/or Fahrenheit.

Time/temperature control for safety food (TCS): See POTENTIALLY HAZARDOUS FOOD (PHF).

Transmission (of infection): Any mechanism by which an infectious agent is spread from a source or reservoir to another person. These mechanisms are defined as follows:

- Direct transmission (includes person-to-person transmission): Direct and essentially immediate transfer of infectious agents to a receptive portal of

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entry through which human or animal infection may take place.

- **Indirect transmission:** When an infectious agent is transferred or carried by some intermediate item, organism, means, or process to a susceptible host, resulting in disease. This includes airborne, foodborne, waterborne, vehicleborne (e.g., fomites), and vectorborne modes of transmission.

Turnover: The circulation, through the recirculation system, of a quantity of water equal to the pool volume.

Unblockable drain/suction fitting: A drain or SUCTION FITTING in a RECREATIONAL WATER FACILITY that cannot be completely covered or blocked by a 457 millimeters x 584 millimeters (18 inches x 23 inches) body-blocking element and that is rated by the test procedures or by the appropriate calculation in accordance with ASME A112.19.8M.

Utensil: A FOOD-contact implement or container used in storing, preparing, transporting, dispensing, selling, or serving FOOD. Examples: multiuse, SINGLE-SERVICE, or SINGLE-USE KITCHENWARE or TABLEWARE; gloves used in contact with FOOD; FOOD TEMPERATURE-MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

Utility sink: Any sink located in FOOD SERVICE AREAS not intended for handwashing and/or WAREWASHING.

Variance: A written document issued by VSP that authorizes a modification or waiver of one or more requirements of these guidelines if, in the opinion of VSP, a HEALTH HAZARD or nuisance will not result from the modification or waiver.

Wading pool: RECREATIONAL WATER FACILITY with a maximum depth of less than 1 meter.

Warewashing: The cleaning and sanitizing of TABLEWARE, UTENSILS, and FOOD-CONTACT SURFACES of EQUIPMENT.

Waterborne outbreak: An OUTBREAK involving at least two people who experience a similar illness after ingesting or using water intended for drinking or after being exposed to or unintentionally ingesting or inhaling fresh or marine water used for recreational purposes and epidemiological evidence implicates the water as the source of illness. A single case of chemical poisoning or a laboratory-confirmed case of primary amebic meningoencephalitis is considered an OUTBREAK.

Whirlpool spa: A freshwater or seawater pool equipped with either water or air jets and designed to operate at a minimum temperature of 32°C (90°F) and a

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maximum temperature of 40°C (104°F).

Whole-muscle, intact beef: Whole-muscle beef that is not injected, MECHANICALLY TENDERIZED, reconstructed, or scored and marinated; and from which beef steaks may be cut.

3.3

Acronyms

AGE	ACUTE GASTROENTERITIS
ANSI	American National Standards Institute
ASHRAE	American Society of Heating, Refrigeration and Air-Conditioning Engineers
ASME	American Society of Mechanical Engineers
ASSE	American Society of Safety Engineers
ASTM	American Society for Testing and Materials
C	Celsius
CDC	Centers for Disease Control and Prevention
CFR	CODE OF FEDERAL REGULATIONS
CIP	CLEAN IN PLACE
CT VALUE	CONTACT TIME VALUE
DGMQ	Division of Global Migration and Quarantine
<i>E. coli</i>	<i>Escherichia coli</i>
EHO	Environmental Health Officer
EPA	U.S. Environmental Protection Agency
F	Fahrenheit
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FDA	U.S. FOOD and Drug Administration
HACCP	HAZARD ANALYSIS AND CRITICAL CONTROL POINTS
HVAC	heating, ventilation, and air conditioning
IATA	International Air Transport Association
IHR	International Health Regulations
IPM	INTEGRATED PEST MANAGEMENT
IPS	iron pipe size
ISO	International Standards Organization
MSDS	material safety data sheets
MG/L	MILLIGRAMS PER LITER
mV	millivolt
NCEH	National Center for Environmental Health
NSF International	National Sanitation Foundation International
OPRP	OUTBREAK Prevention and Response Plan
ORP	oxidation reduction potential
pH	POTENS HYDROGEN
PHF	POTENTIALLY HAZARDOUS FOOD
PHS	U.S. Public Health Service (also USPHS)
ppm	parts per million
RP ASSEMBLY	REDUCED PRESSURE PRINCIPLE BACKFLOW

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	PREVENTION ASSEMBLY
RO	reverse osmosis
RTE	READY TO EAT
RWF	RECREATIONAL WATER FACILITY
USC	United States Code
USDA	U.S. Department of Agriculture
USPHS	U.S. Public Health Service
UV	ultraviolet light
VSP	Vessel Sanitation Program
WHO	World Health Organization

4.0 Acute Gastroenteritis (AGE) Surveillance

This section includes the following subsections:

- 4.1 Data Collection
- 4.2 Notification
- 4.3 Clinical Specimens
- 4.4 Requirements for Isolating Symptomatic and Primary Contacts of Crew and Passengers with AGE
- 4.5 Knowledge

References for 4.0 Acute Gastroenteritis (AGE) Surveillance can be found in Annex 14.4.

4.1 Data Collection

4.1.1 Reportable Cases

4.1.1.1 Definition

4.1.1.1.1 Reportable Case Definition (02)

A REPORTABLE case of AGE is only a case reported to the master of the vessel, the medical staff, or other designated staff by a passenger or a crew member and meets the definition below.

A case is defined as

- Diarrhea (three or more episodes of loose stools in a 24-hour period or what is above normal for the individual. See section 4.1.2.1.3, illness symptoms); OR
- Vomiting and one additional symptom including one or more episodes of loose stools in a 24-hour period, or abdominal cramps, or headache, or muscle aches, or fever (temperature of $\geq 38^{\circ}\text{C}$ [100.4°F]).

Nausea, although a common symptom of AGE, is specifically excluded from this definition to avoid misclassifying seasickness (nausea and vomiting) as AGE.

4.1.1.2 Onset Time (02)

The REPORTABLE AGE CASES must include crew members with a symptom onset time of up to 3 days before boarding the vessel. Maintain documentation of the 3-day assessment for each crew member with symptoms on the vessel for review during inspections. Retain this documentation for 12 months.

4.1.1.3 Definition Purpose

Use these case definitions for identifying and classifying cases for reporting purposes. These case definitions should not be used as criteria for clinical intervention or public health action. For many conditions of public health importance, action to contain disease should be initiated as soon as a problem is identified; in many circumstances, appropriate public health action should be undertaken even though insufficient information is available to determine whether cases meet the case definition.

4.1.1.4 Foreign Quarantine Regulations

U.S. foreign QUARANTINE regulations (42 CFR Part 71) require ships to immediately report on-board deaths and certain communicable illnesses to CDC's Division of Global Migration and QUARANTINE (DGMQ). These reports should be made to the CDC QUARANTINE Station with jurisdiction over the ship's next port of entry

www.cdc.gov/quarantine/quarantinestationcontactlistfull.html).

Reporting requirements for ill passengers or crew are posted at www.cdc.gov/quarantine/maritime/federal-regulations-reporting-illness-death-ships-destined-united-states.html.

The preferred method of reporting illnesses and deaths to DGMQ is electronically via the Maritime Illness and Death Reporting PDF Form. If there are issues with the PDF form, ships can email, call, or fax the report to the CDC QUARANTINE Station with jurisdiction over the ship's next U.S. port of entry

(www.cdc.gov/quarantine/quarantinestationcontactlistfull.html).

For significant events or emergencies, ships should notify the appropriate CDC QUARANTINE Station by telephone. If the QUARANTINE station cannot be contacted immediately, please call the CDC Emergency Operations Center at 770-488-7100.

General inquiries and information about QUARANTINE regulations:

Centers for Disease Control and Prevention

Division of Global Migration and QUARANTINE

Roybal Campus

1600 Clifton Road - MS E28

Atlanta, GA 30329-4027

Website: www.cdc.gov/quarantine/maritime/index.html

Email: MaritimeAdmin@cdc.gov (Monday–Friday 08:00–16:00 Eastern)

4.1.2 Records**4.1.2.1 Log****4.1.2.1.1 Responsibility (02)**

A standardized AGE surveillance log for each cruise must be maintained daily by the master of the vessel, the medical staff, or other designated staff.

4.1.2.1.2 Required Information (02)

The AGE surveillance log must list

- The name of the vessel, cruise dates, and cruise number.
- All REPORTABLE CASES of AGE.
- All passengers and crew members who are dispensed antidiarrheal medication from the master of the vessel, medical staff, or other designated staff.

4.1.2.1.3 Log Details (02)

The AGE surveillance log must include a header containing the following information about the voyage:

- Vessel name.
- Voyage number.
- Date from.
- Date to.
- Total number of passengers.*
- Reportable total number of passengers ill.
- Total number of crew.*
- Reportable total number of crew ill.

*Total number of passengers and total number of crew must be the totals at the beginning of the voyage (i.e., totals on “date from”).

The AGE surveillance log entry for each passenger or crew member must contain the following information in separate columns:

- Patient I.D.
- Date of the first medical visit or report to staff of illness.
- Time of the first medical visit or report to staff of illness.
- Person’s last name.
- Person’s first name.
- Person’s age.
- Person’s sex.
- Designation as passenger or crew member.
- Cabin number.
- Crew member position or job on the vessel, if applicable.

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- DATE OF ILLNESS ONSET.
- TIME OF ILLNESS ONSET.
- Illness symptoms, including the presence or absence of the following selected signs and symptoms, with a separate column for each of the following:
 - Number of episodes of diarrhea in a 24-hour period.
 - Bloody stools (yes/no).
 - Number of episodes of vomiting in a 24-hour period.
 - Fever (yes/no).
 - Recorded temperature.
 - Abdominal cramps (yes/no).
 - Headaches (yes/no).
 - Myalgia (yes/no).
 - Date of last symptom.
 - Time of last symptom.
 - Entry (yes/no) for whether a specimen was requested.
 - Entry (yes/no) for whether a specimen was received.
 - Entry (yes/no) for antidiarrheal medications sold or dispensed by designated medical staff.
 - Entry (yes/no) for whether this was a REPORTABLE CASE.
 - Presence of underlying medical conditions that may affect interpretation of AGE; for example, diabetic diarrhea, inflammatory bowel disease, gastrectomy, antibiotic-induced diarrhea, vomiting from chemotherapy, ear infections in children or others. If none, write “none,” “not applicable,” “N/A,” or similar wording. **Comments may also be added to the log in this column after the information about underlying illness.**

The AGE surveillance log must contain the above information in this exact order and entered in the template in Annex 13.2.2. The log data must be exported in the exact order as in the example template in Annex 13.2.2 with analyzable formats such as Microsoft Excel or Microsoft Access. Any additional data fields must be entered only outside of the form margins exported to VSP.

4.1.2.1.4 Medications Sold or Dispensed (02)

Antidiarrheal medications must not be sold or dispensed to passengers or crew except by designated medical staff.

4.1.2.2 Questionnaires

4.1.2.2.1 Food/Beverage Questionnaire (02)

Questionnaires detailing activities and meal locations for the 72 hours before illness onset must be distributed to all passengers and crew members who are identified as REPORTABLE CASES. At a minimum, self-administered questionnaires must contain the following data elements:

- Vessel name.
- Voyage number.
- Person's name.
- Person's age.
- Person's sex.
- Designation as a passenger or crew member.
- Cabin number.
- Total number in cabin.
- Meal seating information (seating and table number).
- DATE AND TIME OF ILLNESS ONSET.
- Other people with the same symptoms.
- Travel and boarding information prior to joining the vessel.
- Tour group information, if applicable.
- Ports went ashore prior to illness onset.
- Excursions attended.
- FOOD and BEVERAGE consumption while ashore, including drinks with ice.
- Meals and activities aboard the vessel for 72 hours before illness (breakfast, lunch, dinner, snacks).
- Activities attended onboard.

An example questionnaire template containing all of the required data elements can be found in Annex 13.2.2.

To assist passengers and crew members with filling out the self-administered questionnaires, the following information for the most current cruise may be maintained at the medical center:

- **Menus, FOOD, and drink selections available at each venue on the vessel, from room service, and on private islands.**
- **Menus, FOOD, and drink selections available for each vessel-sponsored excursion.**
- **Organized activities on the vessel or private islands.**
- **Cruise line sponsored pre-embarkation activities.**

To assist memory recall for guests and crew completing the 72-hour self-administered questionnaire, an electronic listing of

the above information on an interactive system available via an onboard video system can be substituted for the package in the medical center.

4.1.2.3 Retention

4.1.2.3.1 Retention and Review (02)

The following records must be maintained on board for 12 months and available for review by VSP during inspections and OUTBREAK investigations:

- Medical log/record.
- AGE surveillance log.
- 72-hour self-administered questionnaires.
- Interviews with cabin mates and IMMEDIATE CONTACTS of crew members with AGE (initial, 24-, and 48-hour).
- Documentation of the 3-day assessment of crew members **with AGE** symptoms before joining the vessel.
- Documentation of the date and time of last symptom and clearance to return to work for FOOD and nonfood EMPLOYEES.
- Documentation of the date and time of verbal interviews with asymptomatic cabin mates and IMMEDIATE CONTACTS of symptomatic crew.

Electronic records of these documents are acceptable as long as the data are complete and can be retrieved during inspections and OUTBREAK investigations.

4.1.2.4 Confidentiality

4.1.2.4.1 Privacy

All personal medical information received by CDC personnel must be protected in accordance with applicable federal LAW, including

- 5 U.S.C. Section 552a. Privacy Act - Records maintained on individuals and
- Freedom of Information Act 5 U.S.C. Section 552. Administrative Procedure - Public information; agency rules, opinions, orders, records, and proceedings.

4.2 Notification

4.2.1 Routine Report

4.2.1.1 Routine Report Timing

4.2.1.1.1 24-Hour Report (01 C)

The master, medical staff, or other designated staff of a vessel destined for a U.S. port from a foreign port must submit at least one standardized AGE report based on the number of REPORTABLE CASES in the AGE log to VSP no less than 24 hours—but not more than 36 hours—before the vessel's expected arrival at the U.S. port.

4.2.1.1.2 4-Hour Update Report (01 C)

If the number of cases changes after submission of the initial report, an updated report must be submitted no less than 4 hours before the vessel's arrival at the U.S. port. The 4-hour update report must be a cumulative total count of the reported crew and passengers during the entire cruise, including the additional cases.

If there is an update to the AGE surveillance log after the 4-hour report is submitted, an additional 4-hour report must be submitted only if the vessel is still more than 4 hours from arrival in the U.S. port.

If the vessel is less than 4 hours from arrival in the U.S. port, no additional 4-hour report is needed.

4.2.1.1.3 Report Submission (02)

Submit routine 24-hour and 4-hour update reports electronically.

In lieu of electronic notification, the reports may be submitted by telephone or fax. The vessel must maintain proof onboard that the report was successfully received by VSP.

4.2.1.2 Report Contents

4.2.1.2.1 Contents (01 C)

The AGE report must contain the following:

- Name of the vessel.
- Port of embarkation.
- Date of embarkation.
- Port of disembarkation.
- Date of disembarkation.
- Total numbers of REPORTABLE CASES of AGE among passengers, including those who have disembarked because

- of illness—even if the number is 0 (zero reporting).
- Total numbers of REPORTABLE CASES of AGE among crew members, including those who have disembarked because of illness—even if the number is 0 (zero reporting).
- Total number of passengers and crew members on the cruise.

4.2.1.2.2 Cruise Length

For cruises lasting longer than 15 days before entering a U.S. port, the AGE report may include only those REPORTABLE CASES and total numbers of passengers and crew members for the 15 days before the expected arrival at a U.S. port.

4.2.2 Special Report

4.2.2.1 Special Report Timing

4.2.2.1.1 2% and 3% Illness Report (01 C)

The master or designated corporate representative of a vessel with an international itinerary destined for a U.S. port must submit a special report at any time during a cruise, including between two U.S. ports,

- When the cumulative percentage of REPORTABLE CASES **for the entire voyage** entered in the AGE surveillance log reaches 2% among passengers or 2% among crew AND
- The vessel is within 15 days of expected arrival at a U.S. port.

For segmented voyages where those segments are 8 days or less, a special AGE report must be made to VSP

- **When a cumulative percentage of REPORTABLE CASES of either 2% or 3% is reached among passengers or crew within one segment or two consecutive segments AND**
- **The vessel is within 15 days of expected arrival at a U.S. port.**

The AGE surveillance log must include all segments from the start of the voyage, unless 67% (two-thirds) or more of the passengers are disembarked in any one segment.

For cruises lasting longer than 15 days before entering a U.S. port, the 2% or 3% special AGE report must include all cases for the entire voyage.

A telephone notification to VSP must accompany the special 2% report.

A second special report must be submitted when the cumulative percentage of REPORTABLE CASES entered in the AGE surveillance log reaches 3% among passengers or 3% among crew and the vessel is within 15 days of expected arrival at a U.S. port.

4.2.2.1.2 *Daily Updates (01)*

Daily updates of illness status must be submitted as requested by VSP after the initial submission of a special report. **Daily updates may be submitted electronically, by telephone, by fax, by email, or as requested by VSP.**

4.2.2.1.3 *Routine Reporting Continues (01)*

Routine reports (24-hour and 4-hour) must continue to be submitted by the master or designated corporate representative of a vessel that has submitted a special report.

4.2.3 Report Retention

4.2.3.1 Retention

4.2.3.1.1 *Retention (02)*

The 24-hour, 4-hour, and special reports must be maintained on the vessel for 12 months.

4.2.3.1.2 *Review (02)*

The reports must be available for review by VSP during inspections and OUTBREAK investigations.

4.3 Clinical Specimens

4.3.1 Clinical Specimen Submission

See Annex 13.4 for a list of recommended specimen collection supplies.

4.3.1.1 Specimen/Shipping Containers (02)

The medical staff will be responsible for maintaining a supply of at least 10 clinical specimen collection containers for both viral and bacterial agents (10 for each), as well as a shipping container that meets the latest shipping requirements of the International Air Transport Association (IATA) and U.S. Department of Transportation for Biological Substances, Category B designated shipments (or higher).

The vessel must maintain the appropriate labels and markings required for shipping Biological Substances, Category B shipments. The vessel must

maintain appropriate refrigerant materials to keep clinical specimens cool. For guidance, see Annex 13.4 of this manual.

4.3.2 Clinical Specimen Submission Collection Procedures

4.3.2.1 When to Collect (02)

When a vessel reaches 2% REPORTABLE AGE in either passengers or crew members, the medical staff will begin collecting clinical specimens (stool or vomitus specimens) for bacterial and/or viral analysis. If the etiologic agent is suspected to be parasitic, the medical staff should consult with VSP epidemiology staff for clinical specimen collection requirements.

Specimens should be requested before issuing antibiotic medications, but this patient treatment should not be contingent on specimen collection.

Specimens collected after administration of antibiotic medications must not be submitted for CDC analysis unless directed by VSP.

4.3.2.2 Proper Packing (02)

Before the specimens are PACKAGED and shipped for laboratory testing, VSP will give instructions to vessel/cruise line medical staff about the specific container (i.e., bacterial or viral) for transport to a laboratory.

All clinical specimens must be packed and shipped in accordance with the guidelines outlined in Annex 13.4. The specimen packaging must include the proper documentation as required by the receiving laboratory.

4.4 Requirements for Isolating Symptomatic and Primary Contacts of Crew and Passengers with Gastroenteritis

4.4.1 Crew, Staff, Officers, and Other Employees

4.4.1.1 Isolate Ill Crew

4.4.1.1.1 Symptomatic and Meeting the Case Definition for Acute Gastroenteritis (AGE) (11 C)

FOOD EMPLOYEES:

- Isolate in cabin or designated restricted area until symptom-free for a minimum of 48 hours.
- Follow-up with and receive approval by designated medical personnel before returning crew to work.

- Document date and time of last symptom and clearance to return to work.

The FOOD EMPLOYEE's supervisor or PERSON IN CHARGE must conduct an assessment of FOOD prepared or served by the FOOD EMPLOYEE while symptomatic and take appropriate corrective actions.

Corrective actions taken as a result of the assessment must be documented. Records must be maintained for 1 year and available for review during inspections.

- Review [when possible] any AGE CASES among passengers or crew reported after the ill FOOD EMPLOYEE's symptom onset for epidemiologic link/connection.

Appropriate corrective actions could include discarding READY-TO-EAT FOOD, thoroughly cooking raw FOOD, and disinfecting the FOOD AREA and EQUIPMENT.

Nonfood employees:

- ISOLATION in cabin or designated restricted area until symptom-free for a minimum of 24 hours.
- Follow-up with and receive approval by designated medical personnel before returning crew to work.
- Document the date and time of last symptom and clearance to return to work.

4.4.1.1.2 Hygiene and Handwashing Facts (02)

Advise symptomatic crew of hygiene and handwashing facts and provide written handwashing and hygiene fact sheets.

4.4.1.2 Cabin Mates/Contacts (02)

4.4.1.2.1 Asymptomatic Cabin Mates or Immediate Contacts of Symptomatic Crew

FOOD and nonfood employees:

- Restrict exposure to symptomatic crew member(s).
- Undergo a verbal interview with medical or supervisory staff, who will confirm their condition, provide facts and a written fact sheet about hygiene and handwashing, and instruct them to report immediately to medical if they develop illness symptoms.
- Complete a verbal interview daily with medical or supervisory staff until 48 hours after the ill crew members'

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symptoms began. The first verbal interview must be conducted within 8 hours from the time the ill crew member initially reported to the medical staff. If the asymptomatic IMMEDIATE CONTACT or cabin mate is at work, he or she must be contacted by medical or supervisory staff as soon as possible. The date and time of verbal interviews must be documented.

An IMMEDIATE CONTACT is someone sharing a cabin either full-time or part-time or sharing a cabin's bathroom facilities. This includes boyfriends, girlfriends, spouses, and significant others.

If the symptomatic crew member has no cabin mate or other IMMEDIATE CONTACT, this must be documented.

4.4.2 Passengers

4.4.2.1 Isolate Ill Passengers (11 C)

Advise symptomatic passengers and those meeting the case definition to remain isolated in their cabins until well for a minimum of 24 hours after symptom resolution.

Follow-up by infirmary personnel is advised.

4.4.2.2 Hygiene and Handwashing Facts (02)

Advise symptomatic passengers of hygiene and handwashing facts and provide written handwashing and hygiene fact sheets.

4.5 Acute Gastroenteritis Surveillance Knowledge

4.5.1 Demonstration of Knowledge (44)

The supervisor or PERSON IN CHARGE of medical operations related to AGE on the vessel must demonstrate to VSP—on request during inspections—knowledge of medical operations related to AGE.

The supervisor or PERSON IN CHARGE must demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector's questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of medical operations related to AGE on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

5.0 Potable Water

This section includes the following subsections:

- 5.1 Source
- 5.2 Bunker and Production Halogenation and pH Control
- 5.3 POTABLE WATER System
- 5.4 POTABLE WATER System Chemical Treatment
- 5.5 POTABLE WATER System HALOGEN Monitoring
- 5.6 Microbiologic Monitoring
- 5.7 Water Distribution System Protection
- 5.8 Knowledge

References for 5.0 Potable Water can be found in Annex 14.5.

5.1 Source

5.1.1 Bunkering

5.1.1.1 Standards

5.1.1.1.1 **Safe Source (03 C)**

DRINKING WATER bunkered from shore supplies must be from a potable source that meets World Health Organization standards for POTABLE WATER.

5.1.1.2 Microbiologic Sample Reports

5.1.1.2.1 **Water Report (06)**

Where available, the vessel must have a copy of the most recent microbiologic report from each port before bunkering POTABLE WATER to verify that the water meets potable standards. The date of the analysis report must be 30 days or less from the date of POTABLE WATER bunkering and must include an analysis for *Escherichia coli* at a minimum.

5.1.1.2.2 **Onboard Test (06)**

Water samples collected and analyzed by the vessel for the presence of *E. coli* may be substituted for the microbiologic report from each port water system. Samples must be analyzed using a method accepted in Standard Methods for the Examination of Water and Wastewater or international Environmental Protection Agency (EPA) APPROVED equivalent. Test kits, incubators, and associated EQUIPMENT must be operated and maintained in accordance with the manufacturers' specifications. If a vessel bunkers POTABLE WATER from the same port more

than once per month, only one test per month is required.

5.1.1.2.3 Review (06)

These records must be maintained on the vessel for 12 months and must be available for review during inspections.

5.1.2 Water Production

5.1.2.1 Location

5.1.2.1.1 Polluted Harbors (03 C)

A reverse osmosis unit, distillation plant, or other process that supplies water to the vessel's POTABLE WATER system must only operate while the vessel is MAKING WAY. These processes must not operate in polluted areas, HARBORS, or at anchor.

5.1.2.1.2 Technical Water

A reverse osmosis unit or evaporator with a completely separate plant/process, piping system, and connections from the POTABLE WATER system may be used to produce TECHNICAL WATER while in polluted areas, HARBORS, at anchor, or while not MAKING WAY.

5.1.2.1.3 Onboard Water Sources

Onboard water sources such as TECHNICAL WATER, air conditioning condensate, or wastewater of any kind (treated or untreated) are not allowed for POTABLE WATER production.

5.2 Bunkering and Production Halogenation and pH Control

5.2.1 Procedures

5.2.1.1 Residual Halogen and pH

5.2.1.1.1 Halogen and pH Level (03 C)

POTABLE WATER must be continuously halogenated to at least 2.0 MG/L (ppm) free residual HALOGEN at the time of bunkering or production with an automatic halogenation device. Adjust the pH so it does not exceed 7.8.

The amount of HALOGEN injected during bunkering or production must be controlled by a flow meter or a free HALOGEN analyzer.

5.2.1.1.2 Within 30 Minutes (08)

The free HALOGEN residual level must be adjusted to at least 2.0 MG/L (ppm) and the pH adjusted not to exceed 7.8 within 30 minutes of the start of the bunkering and production processes.

5.2.1.2 Monitoring**5.2.1.2.1 Bunkering Pretest (08)**

A free HALOGEN residual and pH test must be conducted on the shore-side water supply before starting the POTABLE WATER bunkering process to establish the correct HALOGEN dosage.

The results of the pretest must be recorded and available for review during inspections.

5.2.1.2.2 Bunkering/Production Test (08)

After the free residual HALOGEN level of at least 2.0 MG/L (ppm) and pH level not exceeding 7.8 have been reached, the free residual HALOGEN and pH monitoring must be performed at least hourly during the bunkering of POTABLE WATER.

After the free residual HALOGEN level of at least 2.0 MG/L (ppm) and pH level not exceeding 7.8 have been reached, the free residual HALOGEN and pH monitoring must be performed at least once every 4 hours during the bunkering of POTABLE WATER.

A test kit must be available for testing free HALOGEN levels and pH.

Test kits must be accurate to within 0.2 MG/L (ppm) for HALOGEN and must have a testing range of free residual HALOGEN normally maintained in the POTABLE WATER system. Test kits for pH must be accurate to within 0.2.

5.2.1.2.3 Records (08)

Accurate records of this monitoring must be maintained aboard for 12 months and must be available for review during inspections.

5.2.1.2.4 Analyzer-Chart Recorders (06)

HALOGEN and pH analyzer-chart recorders used in lieu of manual tests and logs must be calibrated at the beginning of bunkering or production, and the calibration must be recorded on a chart or in a logbook.

The free residual HALOGEN and pH measured by the HALOGEN/pH analyzer must be accurate to within 0.2 mg/L (ppm) of the free residual HALOGEN and 0.2 of the pH as measured by the manual test.

Calibration is required at the beginning of bunkering or production and each time bunkering or production is restarted.

5.2.1.2.5 Construction (06)

HALOGEN and pH analyzer-chart recorders used on bunker water systems must be constructed and installed according to the manufacturer's guidelines.

5.2.1.2.6 Data Logger

Electronic data loggers with CERTIFIED DATA SECURITY FEATURES may be used in lieu of chart recorders.

If electronic data loggers are used, written documentation from the data logger manufacturer, such as a letter or instruction manual, must be provided to verify that the features are secure.

5.2.1.2.7 Halogen Injection (08)

Water samples for HALOGEN and pH testing must be obtained from a sample cock and/or a HALOGEN analyzer probe located on the bunker or production water line at least 3 meters (10 feet) after the HALOGEN injection point and before the storage tank.

A static mixer may be used to reduce the distance between the HALOGEN injection point and the sample cock or HALOGEN analyzer sample point. If used, the mixer must be installed per the manufacturer's recommendations. A copy of all manufacturers' literature for installation, operation, and maintenance must be maintained.

5.2.1.2.8 Tank Sample

In the event of EQUIPMENT failure, bunker or production water HALOGEN samples may also be taken from previously empty POTABLE WATER TANKS.

5.3 Potable Water System

5.3.1 Potable Water Tanks

5.3.1.1 Protection

5.3.1.1.1 Potable Water Tank Walls (07 C)

POTABLE WATER TANKS must not share a common wall with the hull of the vessel or with tanks or piping containing nonpotable water or other liquids.

5.3.1.1.2 Nonpotable Piping (08)

Piping systems carrying SEWAGE or other nonpotable liquids must not pass through POTABLE WATER TANKS. Minimize the use of nonpotable lines above POTABLE WATER TANKS. Nonpotable lines above POTABLE WATER TANKS must not have any mechanical couplings.

For SCUPPER lines, factory assembled transition fittings for steel to plastic pipes are allowed when manufactured per American Society for Testing and Materials (ASTM) F1973 or equivalent standard.

5.3.1.1.3 Coatings (08)

Interior coatings on POTABLE WATER TANKS must be APPROVED for POTABLE WATER contact by a certification organization. Follow all manufacturers' recommendations for application, drying, and curing.

The following must be maintained on board for the tank coatings used:

- Written documentation of approval from the certification organization (independent of the coating manufacturer).
- Manufacturers' recommendations for application, drying, and curing.
- Written documentation that the manufacturers' recommendations have been followed for application, drying, and curing.

5.3.1.2 Tank Construction

5.3.1.2.1 Identification (08)

POTABLE WATER TANKS must be identified with a number and the words "**POTABLE WATER**" in letters at least 13 millimeters (0.5 inch) high.

5.3.1.2.2 Sample Cocks (08)

POTABLE WATER TANKS must have labeled, turned-down sample cocks. They must be identified and numbered with the appropriate tank number.

5.3.1.2.3 Vent/Overflow (08)

The POTABLE WATER TANKS, vents, and overflows must be protected from CONTAMINATION.

5.3.1.2.4 Level Measurement (08)

Any device for determining the depth of water in the POTABLE WATER TANKS must be constructed and maintained so as to prevent contaminated substances or liquids from entering the tanks.

5.3.1.2.5 Manual Sounding (08)

Manual sounding of POTABLE WATER TANKS must be performed only in emergencies and must be performed in a sanitary manner.

5.3.2 Potable Water Piping**5.3.2.1 Protection****5.3.2.1.1 Identification (08)**

POTABLE WATER lines must be striped or painted either in accordance with ISO 14726 (blue/green/blue) or blue only.

DISTILLATE and PERMEATE lines directed to the POTABLE WATER system must be striped or painted in accordance with ISO 14726 (blue/gray/blue).

Other lines must not have the above color designations.

These lines must be striped or painted at 5 meter (15 feet) intervals and on each side of partitions, decks, and BULKHEADS except where decor would be marred by such markings. This includes POTABLE WATER supply lines in technical lockers.

POTABLE WATER lines after REDUCED PRESSURE ASSEMBLIES must not be striped or painted as POTABLE WATER.

Striping is not required in FOOD AREAS of the vessel because only POTABLE WATER is permitted in these areas.

All refrigerant brine lines and nonpotable chilled water lines **in all FOOD AREAS**, such as on ice machines, ice cream machines, etc., must be identified **with either ISO 14726 (blue/white/blue)** or by another uniquely identifiable method to prevent CROSS-CONNECTIONS.

5.3.2.1.2 Protection (07 C)

POTABLE WATER piping must not pass under or through tanks holding nonpotable liquids.

5.3.2.1.3 Bunker Connection (08)

The POTABLE WATER bunker filling line must begin either horizontally or pointing downward and at a point at least 460 millimeters (18 inches) above the bunker station deck.

5.3.2.1.4 Cap/Keeper Chain (08)

The POTABLE WATER filling line must have a screw cap fastened by a NONCORRODING cable or chain to an adjacent BULKHEAD or surface in such a manner that the cap cannot touch the deck when hanging free.

The hose connections must be unique and fit only the POTABLE WATER hoses.

5.3.2.1.5 Identification (08)

Each bunker station POTABLE WATER filling line must be striped or painted blue or in accordance with the color designation in ISO 14726 (blue/green/blue) and clearly labeled “**POTABLE WATER FILLING**” in letters at least 13 millimeters (0.5 inch) high, stamped on a noncorrosive label plate or the equivalent, and located at or near the point of the hose connection.

5.3.2.1.6 Technical Water (08)

If used on the vessel, TECHNICAL WATER must be bunkered through separate piping using fittings incompatible for POTABLE WATER bunkering.

This does not apply to water bunkered from shore-side municipal water supply.

5.3.2.1.7 Different Piping (08)

TECHNICAL WATER must flow through a completely different piping system.

5.3.3 Potable Water Hoses

5.3.3.1 Construction

5.3.3.1.1 *Fittings (08)*

POTABLE WATER hoses must have unique fittings from all other hose fittings on the vessel.

5.3.3.1.2 *Identification (08)*

POTABLE WATER hoses must be labeled for use with the words “POTABLE WATER ONLY” in letters at least 13 millimeters (0.5 inch) high at each connecting end.

5.3.3.1.3 *Construction (08)*

All hoses, fittings, and water filters used in the bunkering of POTABLE WATER must be constructed of safe, EASILY CLEANABLE materials APPROVED for POTABLE WATER use and must be maintained in good repair.

5.3.3.1.4 *Other Equipment (08)*

Other EQUIPMENT and tools used in the bunkering of POTABLE WATER must be constructed of safe, EASILY CLEANABLE materials, dedicated solely for POTABLE WATER use, and maintained in good repair.

5.3.3.1.5 *Locker Construction (08)*

POTABLE WATER hose lockers must be constructed of SMOOTH, nontoxic, corrosion resistant, EASILY CLEANABLE material and must be maintained in good repair.

5.3.3.1.6 *Locker Identification (08)*

POTABLE WATER hose lockers must be labeled “POTABLE WATER HOSE AND FITTING STORAGE” in letters at least 13 millimeters (0.5 inch) high.

5.3.3.1.7 *Locker Height (08)*

POTABLE WATER hose lockers must be mounted at least 460 millimeters (18 inches) above the deck and must be self-draining.

5.3.3.1.8 *Locker Closed (08)*

Locker doors must be closed when not in use.

5.3.3.1.9 Locker Restriction (08)

The locker must not be used for any other purpose than storing POTABLE WATER EQUIPMENT such as hoses, fittings, sanitizing buckets, SANITIZER solution, etc.

5.3.3.2 Handling**5.3.3.2.1 Limit Use (08)**

POTABLE WATER hoses must not be used for any other purpose.

5.3.3.2.2 Handling (08)

All hoses, fittings, water filters, buckets, EQUIPMENT, and tools used for connection with the bunkering of POTABLE WATER must be handled and stored in a sanitary manner.

5.3.3.2.3 Contamination Prevention (08)

POTABLE WATER hoses must be handled with care to prevent CONTAMINATION from dragging their ends on the ground, pier, or deck surfaces, or from dropping the hose into contaminated water, such as on the pier or in the HARBOR.

5.3.3.2.4 Flush/Drain (08)

POTABLE WATER hoses must be flushed with POTABLE WATER before being used and must be drained after each use.

5.3.3.2.5 Storage (08)

POTABLE WATER hoses must be rolled tight with the ends capped, on reels or on racks or with ends coupled together, and stowed in POTABLE WATER hose lockers.

5.3.4 Potable Water System Contamination**5.3.4.1 Cleaning and Disinfection****5.3.4.1.1 *Disinfecting (07 C)***

POTABLE WATER TANKS and all affected parts of the POTABLE WATER distribution system must be cleaned, disinfected, and flushed with POTABLE WATER:

- Before being placed in service;
- Before returning to operation after repair, replacement; or
- After being subjected to any CONTAMINATION, including entry into a POTABLE WATER tank.

During dry docks and wet docks, if any work is done to the POTABLE WATER distribution system and piping system that affects a POTABLE WATER TANK(s), the affected POTABLE

WATER TANK(s) must be cleaned and disinfected.

5.3.4.1.2 Inspection (08)

POTABLE WATER TANKS must be inspected, cleaned, and disinfected **at least** every 2 years.

5.3.4.1.3 Record Retention (08)

Documentation of all inspections, maintenance, cleaning, and DISINFECTION must be maintained for 12 months and must be available for review during inspections.

Records must include method of DISINFECTION, concentration and contact time of the DISINFECTANT, and a recorded HALOGEN value of less than or equal to 5 ppm before the tank is put back into service.

5.3.4.1.4 Disinfection Residual (07 C)

DISINFECTION after potential CONTAMINATION must be accomplished by increasing the free residual HALOGEN to at least 50 MG/L (ppm) throughout the affected area and maintaining this concentration for 4 hours or by way of another procedure submitted to and accepted by VSP.

In an emergency, this contact time may be shortened to 1 hour by increasing free residual HALOGEN to at least 200 MG/L (ppm) throughout the affected area.

Refer to Annex 13.6 for DISINFECTION method examples.

5.3.4.1.5 Documentation (08)

The free HALOGEN residual level must be documented.

5.3.4.1.6 Flush (08)

The disinfected parts of the system must be flushed with POTABLE WATER or otherwise dechlorinated until the free residual HALOGEN is ≤ 5.00 MG/L (ppm). The free HALOGEN test result must be documented.

5.3.5 Potable Water Tank Disinfection Methods

5.3.5.1 Method for Disinfecting Filled Tanks (08)

DISINFECTION must be accomplished by increasing the free residual HALOGEN to at least 50 MG/L (ppm) throughout the tank and maintaining it for 4 hours. Maintain a pH value of 7.8 or less. The DISINFECTION concentration and contact time must be documented.

Verify that the free residual HALOGEN level is ≤ 5.0 MG/L (ppm) and document the measured level before placing the tank back into service.

5.3.5.2 Method for Disinfecting Empty Tanks (08)

The empty tank cleaning and DISINFECTION procedure is **only** APPROVED for routine cleaning and DISINFECTION. It is **not** APPROVED for known or suspected contaminated tanks.

1. Remove (strip) all water from the tank.
2. Clean all tank surfaces, including filling lines, with an appropriate detergent.
3. Rinse all surfaces of the tank thoroughly with POTABLE WATER.
4. Remove (strip) the rinse water from the tank.
5. Wet all surfaces of the tank with at least a 200-MG/L (ppm) solution of chlorine (this can be done using new, clean mops, rollers, sprayers, etc.). Ensure the tank surfaces remain wet with the chlorine solution for at least 2 hours. Check, monitor, and document the DISINFECTION concentration and contact time.
6. Refill the tank and verify the free residual HALOGEN is ≤ 5.0 MG/L (ppm) before placing the tank back into service. Document the free residual HALOGEN level.

5.4 Potable Water System Chemical Treatment

5.4.1 Chemical Injection Equipment

5.4.1.1 Construction and Installation

5.4.1.1.1 Recommended Engineering Practices (06)

All distribution water system chemical injection EQUIPMENT must be constructed and installed in accordance with recommended engineering practices.

5.4.1.2 Operation

5.4.1.2.1 Halogen Residual (04 C)

The halogenation injection EQUIPMENT must provide continuous halogenation of the POTABLE WATER distribution system and must maintain a free residual HALOGEN of ≥ 0.2 MG/L (ppm) and ≤ 5.0 MG/L (ppm) throughout the distribution system.

5.4.1.2.2 Controlled (08)

The amount of chemicals injected into the POTABLE WATER system must be analyzer controlled.

5.4.1.2.3 Halogen Backup Pump (06)

At least one backup HALOGEN pump must be installed with an active, automatic switchover feature to maintain the free residual HALOGEN in the event that the primary pump fails, an increase in demand occurs, or the low chlorine alarm sounds.

5.4.1.2.4 Chemical Injection Dosing Point (06)

A check valve or nonreturn valve must be installed between the distribution halogen and pH pumps and the injection points. In addition,

- The potable water distribution halogenation and pH chemical injection dosing points must be located on the delivery line downstream of the potable water pumps, OR
- If the injection dosing point is before the potable water pumps, it must be located above the chemical dosing tanks.

5.5 Potable Water System Halogen Monitoring**5.5.1 Halogen Analyzer-Chart Recorder****5.5.1.1 Installation****5.5.1.1.1 Distant Point (06)**

A HALOGEN analyzer-chart recorder must be installed at a distant point in the POTABLE WATER distribution system where a significant water flow exists and represents the entire distribution system. In cases where multiple distribution loops exist and no pipes connect the loops, there must be an analyzer and chart recorder for each loop.

5.5.1.1.2 Data Logger

Electronic data loggers with CERTIFIED DATA SECURITY FEATURES may be used in lieu of chart recorders.

If used, written documentation from the data logger manufacturer, such as a letter or instruction manual, must be provided to verify that the features are secure.

5.5.1.2 Operation**5.5.1.2.1 Maintenance (06)**

The HALOGEN analyzer-chart recorder must be properly maintained and must be operated in accordance with the manufacturer's instructions.

A manual comparison test must be conducted daily to verify calibration. Calibration must be made whenever the manual test value is >0.2 MG/L (ppm) higher or lower than the analyzer reading.

5.5.1.2.2 Calibration (06)

The daily manual comparison test or calibration must be recorded either on the recorder chart or in a log.

5.5.1.2.3 Accuracy (05)

The free residual HALOGEN measured by the HALOGEN analyzer must be ± 0.2 MG/L (ppm) of the free residual HALOGEN measured by the manual test.

5.5.1.2.4 Test Kit (06)

The HALOGEN test kit used to calibrate the HALOGEN analyzer must be accurate to within 0.2 MG/L (ppm) for HALOGEN and graduated in increments no greater than 0.2 MG/L (ppm) in the range of free residual HALOGEN normally maintained in the POTABLE WATER system.

Ensure all reagents used with the test kit are not past their expiration dates.

Where available, ensure appropriate secondary standards are onboard for electronic test kits to verify test kit operation.

5.5.2 Halogen Analyzer Charts

5.5.2.1 Chart Design

5.5.2.1.1 Range (06)

HALOGEN analyzer-chart recorder charts must have a range of 0.0 to 5.0 MG/L (ppm) and have a recording period of—and limited to—24 hours.

5.5.2.1.2 Data Logger (06)

Electronic data loggers with CERTIFIED DATA SECURITY FEATURES used in lieu of chart recorders must produce records that conform to the principles of operation and data display required of the analog charts, including printing the records.

5.5.2.1.3 Increments (06)

Electronic data logging must be in increments of ≤ 15 minutes.

5.5.2.2 Operation

5.5.2.2.1 Charts (06)

HALOGEN analyzer-chart recorder charts must be changed, initialed, and dated daily. Charts must contain notations of any unusual events in the POTABLE WATER system.

If electronic data loggers are used in lieu of chart recorders, notations of any unusual events in the POTABLE WATER system must be recorded in a log.

5.5.2.2.2 Retention (06)

HALOGEN analyzer-chart recorder charts must be retained for at least 12 months and must be available for review during inspections.

5.5.2.2.3 Chart Review (06)

Records from the HALOGEN analyzer-chart recorder must verify the free residual HALOGEN of ≥ 0.2 MG/L (ppm) and ≤ 5.0 MG/L (ppm) in the water distribution system for at least 16 hours in each 24-hour period since the last inspection of the vessel.

5.5.3 Manual Halogen Monitoring

5.5.3.1 Equipment Failure

5.5.3.1.1 Every 4 hours (06)

Free residual HALOGEN must be measured by a manual test kit at the HALOGEN analyzer at least every 4 hours in the event of EQUIPMENT failure.

5.5.3.1.2 Recording (06)

Manual readings must be recorded on a chart or log, retained for at least 12 months, and available for review during inspections.

5.5.3.1.3 Limit (06)

Repairs on malfunctioning HALOGEN analyzer-chart recorders must be completed within 10 days of EQUIPMENT failure.

5.5.3.1.4 Alarm (06)

Provide an audible alarm in a continuously occupied watch station (e.g., the engine control room) to indicate low and high free HALOGEN readings at the distant point analyzer.

5.6 Microbiologic Monitoring

5.6.1 Sampling and Analysis

5.6.1.1 Methodology

5.6.1.1.1 Samples (06)

A minimum of four POTABLE WATER samples per month must be collected and analyzed for the presence of *E. coli*. Samples must be collected from the forward, aft, upper, and lower decks of the vessel.

Sample sites must be changed each month ensure effectively monitoring of all of the POTABLE WATER distribution system.

Follow-up sampling must be conducted for each positive test result.

Microbiological samples from ice machines and POTABLE WATER storage tanks do not count toward the monthly routine distribution system monitoring.

5.6.1.1.2 Analysis (06)

Samples must be analyzed using a method accepted in Standard Methods for the Examination of Water and Wastewater or international Environmental Protection Agency (EPA) APPROVED equivalent. Test kits, incubators, and associated EQUIPMENT must be operated and maintained in accordance with the manufacturers' specifications.

5.6.1.2 Records

5.6.1.2.1 Records (06)

Sample results must be maintained onboard the vessel for at least 12 months and must be available for review during inspections.

5.7 Water Distribution System Protection

5.7.1 Cross-connection Control

5.7.1.1 Program

5.7.1.1.1 Cross-Connections (07 C)

The POTABLE WATER distribution system must be maintained free of CROSS-CONNECTIONS.

5.7.1.1.2 Protection (07 C)

The POTABLE WATER system must be protected against BACKFLOW or other CONTAMINATION by BACKFLOW PREVENTION DEVICES or AIR GAPS. The PERMEATE lines and DISTILLATE lines directed toward the POTABLE WATER system must also be protected.

5.7.1.1.3 Control/Program (08)

The vessel must provide a comprehensive CROSS-CONNECTION control program.

The following connections to the POTABLE WATER system must be protected against BACKFLOW (BACKSIPHONAGE or BACKFLOW) with AIR GAPS or mechanical BACKFLOW PREVENTION DEVICES:

- RWFs such as SWIMMING POOLS, CHILDREN'S/WADING POOLS, WHIRLPOOL SPAS, and similar facilities.
- Decorative water features/fountains.
- Cabin shower hoses, toilets, whirlpool tubs, and similar facilities.
- Photographic laboratory developing machines and UTILITY SINKS.
- Beauty and barber shop spray-rinse hoses.
- Spa steam generators where essential oils can be added.
- Hose-bib connections.
- Garbage grinders and FOOD WASTE SYSTEMS.
- Automatic galley hood washing systems.
- FOOD service EQUIPMENT such as coffee machines, ice machines, juice dispensers, combination ovens, and similar EQUIPMENT.
- Mechanical WAREWASHING machines.
- Detergent dispensers.
- Hospital and laundry EQUIPMENT.
- Air conditioning expansion tanks.
- Boiler feed water tanks.
- Fire system.
- Public toilets, urinals, and shower hoses.
- POTABLE WATER, bilge, and pumps that require priming.
- Freshwater or saltwater ballast systems.
- International fire and fire sprinkler water connections. An RP ASSEMBLY is the only allowable device for this connection.
- POTABLE WATER supply to automatic window washing

systems that can be used with chemicals or chemical mix tanks.

- Water softeners for nonpotable fresh water.
- Water softener and mineralizer drain lines including backwash drain lines. The only allowable protections for these lines are an AIR GAP or an RP ASSEMBLY.
- High saline discharge line from evaporators. The only allowable protections for these lines are an AIR GAP or an RP ASSEMBLY.
- Chemical tanks.
- Other connections between the POTABLE WATER system and a nonpotable water system such as the GRAY WATER system, laundry system, or TECHNICAL WATER system. The only allowable forms of protection for these connections are an AIR GAP or an RP ASSEMBLY.
- BLACK WATER or combined GRAY WATER/BLACK WATER systems. An AIR GAP is the only allowable protection for these connections.
- Any other connection to the POTABLE WATER system where CONTAMINATION or BACKFLOW can occur.
- Hi-Fog or similar suppression systems connected to POTABLE WATER TANKS.

5.7.1.1.4 Log (08)

A CROSS-CONNECTION control program must include, at a minimum, a complete listing of CROSS-CONNECTIONS and the BACKFLOW prevention method or device for each so there is a match to the PLUMBING SYSTEM component and location. AIR GAPS must be included in the listing.

AIR GAPS on faucet taps do not need to be included on the CROSS-CONNECTION control program listing.

The program must set a schedule for inspection frequency. **Repeat devices such as toilets may be grouped under a single device type.**

A log documenting the inspection and maintenance in written or electronic form must be maintained and be available for review during inspections.

5.7.1.2 Device Installation

5.7.1.2.1 Air Gaps and Backflow Prevention Devices (08)

AIR GAPS should be used where feasible and where water under pressure is not required.

BACKFLOW PREVENTION DEVICES must be installed when AIR GAPS are impractical or when water under pressure is required. Provide an AIR GAP for the atmospheric vent of all BACKFLOW PREVENTION DEVICES.

A mechanical BACKFLOW PREVENTION DEVICE must have an atmospheric vent.

5.7.1.2.2 2X Diameter (08)

AIR GAPS must be at least twice the diameter of the delivery fixture opening and a minimum of 25 millimeters (1 inch).

5.7.1.2.3 Flood-Level Rim (08)

An ATMOSPHERIC VACUUM BREAKER must be installed at least 150 millimeters (6 inches) above the flood-level rim of the fixtures.

5.7.1.2.4 After Valve (08)

An ATMOSPHERIC VACUUM BREAKER must be installed only in the supply line on the discharge side of the last control valve.

5.7.1.2.5 Continuous Pressure (08)

A CONTINUOUS PRESSURE-type BACKFLOW PREVENTION DEVICE must be installed when a valve is located downstream from the BACKFLOW PREVENTION DEVICE.

5.7.1.2.6 Backflow Prevention Devices (08)

BACKFLOW PREVENTION DEVICES must be provided on all fixtures using POTABLE WATER and that have submerged inlets.

5.7.1.2.7 Vacuum Toilets (08)

An ATMOSPHERIC VACUUM BREAKER must be installed on a POTABLE WATER supply connected to a vacuum toilet system. An ATMOSPHERIC VACUUM BREAKER must be located on the discharge side of the last control valve (flushing device).

5.7.1.2.8 Diversion Valves (08)

Lines to divert POTABLE WATER to other systems by valves or interchangeable pipe fittings must have an AIR GAP after the valve.

5.7.1.2.9 Location (08)

BACKFLOW PREVENTION DEVICES and AIR GAPS must be ACCESSIBLE for inspection, testing, service, and maintenance. If access panels are required, provide panels large enough for testing, service, and maintenance.

5.7.1.3 Air Supply Connections**5.7.1.3.1 Air Supply (08)**

A compressed air system that supplies pressurized air to both nonpotable and POTABLE WATER pneumatic tanks must be connected through a press-on (manual) air valve or hose.

5.7.1.3.2 Separate Compressor

A fixed connection may be used when the air supply is from a separate compressor used exclusively for POTABLE WATER pneumatic tanks.

5.7.2 Backflow Prevention Device Inspection and Testing**5.7.2.1 Maintenance****5.7.2.1.1 Maintained (08)**

BACKFLOW PREVENTION DEVICES must be maintained in good repair.

5.7.2.2 Inspection and Service**5.7.2.2.1 Schedule (08)**

BACKFLOW PREVENTION DEVICES should be periodically inspected and any failed units must be replaced.

A visual check must be completed for all nontestable BACKFLOW PREVENTION DEVICES and AIR GAPS at least annually.

5.7.2.2.2 Test Annually (08)

BACKFLOW PREVENTION DEVICES requiring testing (e.g., reduced pressure BACKFLOW PREVENTION DEVICES and PRESSURE VACUUM BREAKERS) must be inspected and tested with a test kit after installation and at least annually. Test results showing the pressure differences on both sides of the valves must be maintained for each device.

5.7.2.2.3 Records (08)

The visual inspection and/or test results for BACKFLOW PREVENTION DEVICES and AIR GAPS must be retained for at least 12 months and must be available for review during inspections.

5.8 Potable Water Knowledge**5.8.1 Demonstration of Knowledge (44)**

The supervisor or PERSON IN CHARGE of POTABLE WATER operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of POTABLE WATER operations. The supervisor or PERSON IN CHARGE must demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector's questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of POTABLE WATER operations on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

6.0 Recreational Water Facilities (RWFs)

This section includes the following subsections:

- 6.1 RWFs
- 6.2 Flow-Through Seawater RWFs
- 6.3 Recirculating RWFs
- 6.4 WHIRLPOOL SPAS and SPA POOLS
- 6.5 Maintenance and Operating Standards for Combined Facilities
- 6.6 Private Cabin Operations
- 6.7 Individual Hydrotherapy Pools
- 6.8 Safety
- 6.9 Restrictions
- 6.10 Knowledge

References for 6.0 Recreational Water Facilities (RWFs) can be found in Annex 14.6.

6.1 RWFs

6.1.1 Source

6.1.1.1 Potable Water or Seawater (09 C)

The water source for all RWFs must be POTABLE WATER or RECREATIONAL SEAWATER.

6.1.2 Maintenance

6.1.2.1 Management

RWFs must be kept clean of debris, organic materials, and slime/biofilm in ACCESSIBLE areas in the water and on surfaces.

It is recommended to conduct periodic biofilm management in WHIRLPOOL SPAS, SPA POOLS, and interactive RWFs.

6.2 Flow-Through Seawater RWFs

6.2.1 Operation

6.2.1.1 At Sea

6.2.1.1.1 12 miles (10)

Flow-through seawater supply systems for RWFs must be used only while the vessel is MAKING WAY and at sea beyond 20 kilometers (12 miles) from nearest land.

6.2.1.2 In Port

6.2.1.2.1 ***Drained or Switched to Recirculation (10)***

Before arriving to a port or HARBOR, the RWF must be drained before the vessel reaches the 20-kilometer (12-mile) mark or any point of land-based discharge as detailed in section 6.2.1.1.1 and it must remain empty while in port or at anchor.

OR

The RECREATIONAL SEAWATER filling system must be shut off 20 kilometers (12 miles) before reaching the nearest land or land-based discharge point, and a recirculation system must be used with appropriate filtration and halogenation systems.

6.2.1.2.2 ***Halogen and pH (09 C)***

When switching from flow-through operations to recirculation operations, the RWF must be closed until the free residual HALOGEN and pH levels are within the acceptable limits of this manual. The sample must be taken from the body of the RWF, not from the pump room.

While the RWF is closed, batch HALOGEN and pH control chemicals may be used to obtain ADEQUATE free HALOGEN residuals and pH levels in a more-timely manner. Sufficient time should be allowed before opening the RWF for use to ensure proper mixing of batch chemicals.

6.3 Recirculating RWFs

(See individual sections for additional requirements for whirlpools and SPA POOLS. See Annex 13.8 for requirements for BABY-ONLY WATER FACILITIES.)

6.3.1 Operation

6.3.1.1 **Fill Level and Turnover Rates (10)**

For RWF with skim gutters, the fill level of the RWF must be to the skim gutter level.

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TURNOVER rates: Recirculation systems and EQUIPMENT, including chemical control EQUIPMENT, UV DISINFECTION systems, filters, and pumps, must be designed to maintain ADEQUATE water chemistry control while operating at the following TURNOVER rates:

RECREATIONAL WATER FACILITY	TURNOVER Rate
SWIMMING POOL (VSP 2005 Construction Guidelines or earlier)	6 hours
SWIMMING POOL (VSP 2011 Construction Guidelines or later)	4 hours
CHILDREN'S POOL	0.5 hours
WADING POOL	1 hours
WHIRLPOOL SPA	0.5 hours
SPA POOL	2 hours
INTERACTIVE RWF or ACTIVITY POOL (<610 millimeters [24 inches] deep)	1 hours
INTERACTIVE RWF or ACTIVITY POOL (>610 millimeters [24 inches] deep)	2 hours
BABY-ONLY WATER FACILITY	0.5 hours

SPA POOLS that were constructed before June 1, 2005, and were originally considered SWIMMING POOLS may have a TURNOVER rate not to exceed 6 hours in a 24-hour period. This does not apply to SWIMMING POOLS that have been converted to SPA POOLS.

An RWF slide combined with a pool must have a TURNOVER rate that matches the rate for the pool.

Use flow rates from flow meters to calculate TURNOVER rates. Do not use the manufacturer's pump rate to calculate TURNOVER rates.

The pool in "An RWF slide combined with a pool must have a TURNOVER rate that matches the rate for the pool" refers to either WADING or SWIMMING POOLS but not to CHILDREN'S POOLS. In addition, the water for the slide must come directly from the basin of the pool and return directly to the basin of the pool.

For facilities that meet the definition of more than one type of RWF, the more protective TURNOVER rate applies. For example, if a CHILDREN'S POOL also has features of an interactive RWF or ACTIVITY POOL, the TURNOVER rate must be 0.5 hours. The only exception is that when a slide is combined with a pool, the TURNOVER rate for the combined system may match the rate for the pool. However, if a pool and slide combination is also combined with another facility, the most protective TURNOVER rate applies. Finally, if a facility is modified, the most protective TURNOVER rate applies.

6.3.1.2 Filtration Systems

6.3.1.2.1 *Filtered (10)*

Recirculated RWF water must be filtered.

6.3.1.2.2 *Filter Backwash and Cleaning (10)*

Filter pressure differentials must be monitored. Granular filter media must be backwashed until the water viewed through a sight glass runs clear and at the following frequency:

- WHIRLPOOL SPA and SPA POOL: every 72 hours, or sooner if the WHIRLPOOL SPA is drained.
- BABY-ONLY WATER FACILITY: daily.
- All other RWFs: at a frequency recommended by the manufacturer.

For automatic backwashing systems, an individual must be present in the filter room to ensure that backwashing is repeated as necessary until the water runs clear.

Cartridge filters must be cleaned according to the manufacturer's recommendations.

A written or electronic record of the filter backwashing and cleaning must be available for review during inspections.

6.3.1.2.3 *Granular Filter Inspection, Core Sample Test, and Filter Change (10)*

Granular filter media must be examined for channels, mounds, or holes. A core sample of the filter media must be inspected for excessive organic material accumulation using a recommended sedimentation method.

Inspections and sedimentation tests must be conducted quarterly for all RWFs.

Inspection method:

Drain the water from the filter housing and inspect the granular filter for channels, mounds, or holes.

Core sample method:

1. **After inspection, take a sand sample from the filter core and place it in a clear container. A core sample can be taken by inserting a rigid hollow tube or pipe into the filter media.**
2. **Add clean water to the container, cover, and shake.**
3. **Allow the container to rest undisturbed for 30 minutes.**

4. **Consider media replacement if after 30 minutes of settling, a measurable layer of sediment is within or on top of the filter media or fine, colored particles are suspended in the water. This condition can mean the organic loading may be excessive.**

Granular filter media for WHIRLPOOL SPAS and SPA POOLS must be changed based on the inspection and sedimentation test results or every 12 months, whichever is more frequent. For all other RWFs, granular filter media must be changed based on the inspection and sedimentation results or per the manufacturer's recommendations, whichever is more frequent.

Results of both the filter inspection and sedimentation test must be recorded.

6.3.1.2.4 Cartridge Filter Inspection and Filter Change (10)

Cartridge or canister-type filters must be inspected weekly for WHIRLPOOL SPAS and SPA POOLS. For all other RWFs, cartridge filters must be inspected every 2 weeks, or in accordance with the manufacturer's recommendation, whichever is more frequent.

The filters must be inspected for cracks, breaks, damaged components, and excessive organic accumulation. Cartridge or canister-type filters must be changed based on the inspection results, or as recommended by the manufacturer, whichever is more frequent.

At least one replacement cartridge or canister-type filter must be available.

6.3.1.2.5 Other Filter Media (10)

Inspect and change filters based on the manufacturer's recommendations.

6.3.1.2.6 Filter Housing Cleaning and Disinfection (10)

The filter housing must be cleaned, rinsed, and disinfected before the new filter media is placed in it. DISINFECTION must be accomplished with an appropriate HALOGEN-based DISINFECTANT. At a minimum, a 50-ppm solution for 1 minute, or equivalent CT VALUE, must be used. Records must be maintained on all inspection and cleaning procedures.

The filter housing must be cleaned, rinsed, and disinfected each time the filter media—including cartridge filter—is changed.

6.3.1.2.7 Hair and Lint Strainer (10)

The hair and lint strainer and hair and lint strainer housing on all RWFs must be cleaned, rinsed, and disinfected weekly.

DISINFECTION must be accomplished with an appropriate HALOGEN-based DISINFECTANT. At a minimum, a 50-ppm solution for 1 minute, or equivalent CT VALUE, must be used. Records must be maintained on all inspection and cleaning procedures.

If there is not a hair and lint strainer but there is a filter before the pump, this filter must be cleaned, rinsed, and disinfected weekly.

6.3.1.2.8 All Filters (10)

The manufacturer's maintenance procedures and recommendations for all filters must be maintained on the vessel.

6.3.1.3 Gauges (10)

RWF filter pressure gauges, flow meters, and valves must be replaced when they are defective.

6.3.1.4 Manuals (10)

The operating manuals for all RWF components such as filters, pumps, halogenation and PH control systems, and UV DISINFECTION systems must be maintained in a location ACCESSIBLE to crew members responsible for the technical operation and maintenance of these facilities.

6.3.1.5 Bather Loads (10)

Documentation must be maintained on the maximum bather load for each RWF. The maximum bather load must be based on the following factor: One person per five gallons (19 liters) per minute of recirculation flow.

Use flow rates from flow meters to calculate bather loads. Do not use the manufacturer's pump rate to calculate bather loads.

6.3.1.6 Water Quality**6.3.1.6.1 Water Chemistry (10)**

The RWF's flow rates, free and combined HALOGEN levels, pH, total alkalinity, and clarity must be monitored and adjusted as recommended by the manufacturer to maintain optimum public health protection and water chemistry.

Evaluate bather load and make adjustments to water parameters to maintain optimum water quality.

Install flow meters to monitor flow rates. Only combined chlorine must be monitored.

Combined bromine does not need to be monitored.

“Manufacturer” refers to the RWF manufacturer and also to manufacturers of the pumps, filters, flow meters, and any other associated EQUIPMENT.

6.3.1.6.2 Fecal and Vomit Accident (10)

A fecal and vomit accident response procedure that meets or exceeds the procedure provided in Annex 13.9 must be available for review during inspections.

6.3.1.6.3 Record of Fecal and Vomit Accidents (10)

A written or electronic record must be made of all accidents involving fecal material or vomit. The record must include the name of the RWF, date and time of the accident, type of accident, response steps taken, and free residual HALOGEN level and contact time reached during DISINFECTION. For a fecal accident, the record must also include whether the fecal material was formed or loose.

6.3.2 Halogenation

6.3.2.1 Residual Halogen: Halogen and pH Dosing Systems (10)

Automated systems must be installed for HALOGEN-based DISINFECTION and pH control dosing. The amounts injected must be controlled by flow meters or free HALOGEN and pH analyzers.

When conducting manual tests, consideration should be given to the HALOGEN and pH levels in the RWF over the HALOGEN and pH readings from the pump room.

Initial chemistry balance can be achieved by manual dosing methods following events such as fecal or vomit accidents and when changing from flow-through seawater to recirculation mode.

6.3.2.1.1 Residual (09 C)

A free residual HALOGEN in the range detailed in the table below must be maintained in recirculated RWFs.

RECREATIONAL WATER FACILITY	Free HALOGEN Residual, MG/L (ppm)
SWIMMING POOL	≥ 1.0 and ≤ 5.0
CHILDREN'S POOL	≥ 1.0 and ≤ 5.0
WADING POOL	≥ 1.0 and ≤ 5.0
INTERACTIVE RWF (ACTIVITY POOL)	≥ 2.0 and ≤ 5.0
BABY-ONLY WATER FACILITY	≥ 3.0 and ≤ 10.0 free chlorine ≥ 4.0 and ≤ 10.0 bromine
WHIRLPOOL SPA and SPA POOL	≥ 3.0 and ≤ 10.0 free chlorine ≥ 4.0 and ≤ 10.0 bromine

For facilities that meet the definition of more than one type of RWF, the more protective HALOGEN residual applies. For example, if a CHILDREN'S POOL also has features of an interactive RWF or ACTIVITY POOL, the HALOGEN range must be 2.0 to 5.0 MG/L (ppm). Finally, if a facility is modified, the most-protective HALOGEN residual applies.

6.3.2.1.2 pH (09 C)

The pH level in all RWFs must be maintained between 7.0 and 7.8. Facilities not maintained within these HALOGEN and pH ranges must be immediately closed.

6.3.2.1.3 Maintenance (10)

Halogenation and pH control systems must be maintained in good repair and operated in accordance with the manufacturer's recommendations.

6.3.2.1.4 Procedures for Water Sampling (10)

Manual samples from the RWF tub must be compared to the analyzer samples in the pump (mechanical) room to assess potential water quality differences in the RWF.

Recommended manual sampling procedures—All samples should be obtained from a location with the following qualities:

- At least 18 inches (45.7 cm) below the surface of the water, and
- At water depth of between 3 and 4 feet (91.4 cm to 1.2 m) when available, and
- Between water inlets.

6.3.2.2 Residual Halogen and pH Monitoring

6.3.2.2.1 Test Kit (10)

A test kit must be available for testing water quality parameters including free and total HALOGEN levels (chlorine and bromine, where applicable), pH, and total alkalinity.

Test kits must be accurate to within 0.2 MG/L (ppm) for HALOGEN and must have a testing range of free residual HALOGEN normally maintained in the RWF. Test kits for PH must be accurate to within 0.2.

Reagents must not be not past their expiration dates.

6.3.2.2.2 Test Kit Maintenance and Verification (10)

Where available, appropriate secondary standards must be onboard for electronic test kits to verify test kit operation.

6.3.2.2.3 Automated Free Halogen Residual and pH Testing (10)

Install chart recorders or electronic data loggers with **CERTIFIED DATA** SECURITY FEATURES that record PH and HALOGEN measurements for each individual RWF. The sample line for the analyzer probe (monitoring) must be either directly from the RWF or on the return line from each RWF and before the compensation tank. Install appropriate sample taps for analyzer calibration.

In the event of EQUIPMENT failure, free residual HALOGEN and pH must be measured by a manual test kit at the RWF or return line at least hourly for WHIRLPOOL SPAS, SPA POOLS, CHILDREN'S POOLS, and WADING POOLS and every 4 hours for all other RWFs.

If two RWFs are combined and the water for one RWF comes from and returns to the basin of the other RWF (not the compensation tank), separate monitoring systems are not required. Monitoring is then only required on the main RWF (e.g., a slide and SWIMMING POOL). Note: During operational inspections, VSP will take manual samples of both RWFs.

Manual samples from the RWF tub should be compared to the analyzer samples in the pump room to assess potential water quality differences in the RWF.

Recommended manual sampling procedures—All samples should be obtained from a location with the following qualities:

- **At least 18 inches (45.7 cm) below the surface of the water, and**
- **At water depth of between 3 and 4 feet (91.4 cm to 1.2 m) when available, and**
- **Between water inlets.**

Manual readings must be recorded on a chart or log, retained for at least 12 months, and available for review during inspections.

Repairs on malfunctioning HALOGEN analyzer-chart recorders must be completed within 30 days of EQUIPMENT failure.

Provide an audible alarm in a continuously occupied watch station (e.g., the engine control room) to indicate low and high free HALOGEN and pH readings in each RWF.

6.3.2.2.4 Whirlpool and Spa Pool Probes (10)

For WHIRLPOOL SPAS and SPA POOLS, the analyzer probes for dosing and recording systems must be capable of measuring and recording levels up to 10 MG/L (10 ppm).

6.3.2.2.5 Analyzer-Chart Recorder (10)

The HALOGEN and PH analyzer-chart recorder must be properly maintained and operated in accordance with the manufacturer's instructions.

A manual comparison test must be conducted before opening the RWF to verify calibration for free HALOGEN residual and PH. The analyzer reading must be within 0.2 MG/L (ppm) for free HALOGEN and between pH 7.0–7.8.

For RWFs open longer than 24 hours, a manual comparison test must be conducted every 24 hours.

6.3.2.2.6 Data Logger (10)

If an electronic data logger is used in lieu of a chart recorder, it must have CERTIFIED DATA SECURITY FEATURES.

Manual comparison tests for free HALOGEN residual and pH must be conducted before opening the RWF to verify calibration. The analyzer reading must be within 0.2 MG/L (ppm) for free HALOGEN and 0.2 for pH.

For RWFs open longer than 24 hours, a manual comparison test must be conducted every 24 hours.

Electronic data logging must be in increments of ≤ 15 minutes.

6.3.2.2.7 *Charts (10)*

HALOGEN analyzer-chart recorder charts must be initialed, dated, and changed daily.

Strip recorder charts must be initialed and dated daily and 24-hour increments must be indicated.

Dual-scale HALOGEN analyzer-chart recorder charts used in RWFs must be able to measure the full range of HALOGEN/pH of the facility type to which the chart is installed; for example, chlorine/bromine to 10.0 MG/L (ppm) and pH 0-14 for WHIRLPOOL SPAS.

6.3.2.2.8 *Logs (10)*

Logs and charts must contain notations outlining actions taken when the free HALOGEN residual or pH levels are outside of the acceptable ranges in this manual.

Additionally, records must include any major maintenance work on the filtration and halogenation systems and UV DISINFECTION systems.

A written or electronic log of RWF filter inspection results, granular filter sedimentation test results, backwashing frequency and length of backwashing, and date and time of water dumping must be available for review during inspections.

6.3.2.2.9 *Retention (10)*

Logs and charts must be retained for 12 months and must be available for review during inspections.

6.4 Whirlpool Spas and Spa Pools

6.4.1 Public Operations

6.4.1.1 Filters

6.4.1.1.1 *Replacement (10)*

At least one replacement cartridge or canister-type filter must be available.

6.4.1.2 Water Quality

6.4.1.2.1 *Changed (10)*

The WHIRLPOOL SPA water, including compensation tank, filter housing, and associated piping, must be changed every 72 hours, provided that the system is operated continuously and that the correct water chemistry levels are maintained during that period, including daily shock halogenation.

SPA POOL water must be changed as often as necessary to maintain proper water chemistry. The water must be changed at least every 30 days.

The date and time of WHIRLPOOL SPA and SPA POOL water changes must be recorded in the log.

6.4.2 Halogenation

6.4.2.1 Residual Halogen

6.4.2.1.1 *Prolonged Maintenance (10)*

For facilities undergoing maintenance for longer than 72 hours, the free HALOGEN residual and pH levels must be maintained or the entire system must be drained completely of all water. This includes the WHIRLPOOL SPA and SPA POOL tubs, compensation tanks, filter housings, and all associated piping and blowers.

Records must be maintained for the free HALOGEN and pH levels or the complete draining of the system.

6.4.2.1.2 *Shock Halogenation (10)*

The free residual HALOGEN must be increased to at least 10.0 MG/L (ppm) and circulated for at least 1 hour every 24 hours.

The free residual HALOGEN must be tested at both the start and completion of shock halogenation.

The water in the entire RWF system must be superhalogenated to 10 ppm to include the WHIRLPOOL SPA/SPA POOL tub, compensation tank, filter housing, and all associated piping before starting the 1-hour timing.

HEATED ACTIVITY POOLS, including interactive RWFs, that have features that break the water surface of the RWF or create a mist must be shock halogenated as described. This includes

ACTIVITY POOLS and INTERACTIVE RWFs that can be HEATED by the sun and/or exterior temperature.

Batch halogenation of the tub and compensation tank may help in reaching the minimum 10 ppm residual quickly.

Facilities filled only with seawater are exempt from this requirement.

6.4.2.1.3 Records (10)

A written or electronic record of the date and time of water dumping and shock halogenation (concentration in MG/L [ppm] at the start and completion and time) must be available for review during inspections.

6.4.2.1.4 Retention (10)

Records must be retained on the vessel for 12 months.

6.5. Maintenance and Operating Standards for Combined Facilities

6.5.1 Pool with Attached Whirlpool Spa (10)

For any pool with an attached WHIRLPOOL SPA where the water, recirculation system EQUIPMENT, or filters are shared with the spa, all elements of the WHIRLPOOL SPA standards must apply to the pool.

6.5.1.2 Fecal Accidents (10)

For combined facilities subject to fecal accidents, fecal accident procedures must include all features of these combined facilities.

6.6 Private Cabin Operations

WHIRLPOOL SPAS similar in design and construction to public WHIRLPOOL SPAS but located for the sole use of an individual cabin or groups of cabins must comply with the public WHIRLPOOL SPA requirements if the WHIRLPOOL SPA

- **Has a tub capacity of more than 4 individuals OR**
- **Can be accessed without entering the cabin.**

6.6.1 Maintenance

6.6.1.1 Cleaning (10)

Private WHIRLPOOL SPAS located in individual passenger cabins must be cleaned and disinfected, including associated recirculation systems, between occupancies or weekly, whichever is more frequent.

DISINFECTION must be accomplished with an appropriate HALOGEN-based DISINFECTANT at 10 ppm for 60 minutes, or an equivalent CT VALUE.

6.6.1.2 Maintenance (10)

Manufacturer's operation and maintenance instructions must be available to personnel who service the units.

6.6.1.3 Records (10)

A record must be maintained outlining the frequency of cleaning and DISINFECTION. The record must include the type, concentration, and contact time of the DISINFECTANT.

Records must be retained on the vessel for 12 months.

6.7 Individual Hydrotherapy Pools

6.7.1 Maintenance

6.7.1.1 Cleaning (10)

Individual hydrotherapy pools must be cleaned and disinfected, including associated recirculation systems, between customers. DISINFECTION must be accomplished with an appropriate HALOGEN-based DISINFECTANT at 10 ppm for 60 minutes, or an equivalent CT VALUE.

6.7.1.2 Maintenance (10)

Manufacturer's operation and maintenance instructions must be available to personnel who service the units.

6.7.1.3 Records (10)

A record must be maintained outlining the frequency of cleaning and DISINFECTION. The record must include the type, concentration, and contact time of the DISINFECTANT.

Records must be retained on the vessel for 12 months.

6.8 Safety

6.8.1 RWFs

6.8.1.1 Signs and Markings

6.8.1.1.1 General RWF Signs (10)

Safety signs must be provided for all RWFs except BABY-ONLY WATER FACILITIES.

The signs at a minimum must include the following words:

- Do not use these facilities if you are experiencing diarrhea, vomiting, or fever.
- No children in diapers or who are not toilet trained.
- Shower before entering the facility.
- Bather load #.

Pictograms may replace words, as appropriate or available.

For children's RWF signs, include the exact wording "TAKE CHILDREN ON FREQUENT BATHROOM BREAKS" or "TAKE CHILDREN ON FREQUENT TOILET BREAKS."

It is advisable to post additional cautions and concerns on signs.

See section 6.3.1.5 for bather load calculations.

6.8.1.1.2 Depth Markers (10)

The depth of each RWF deeper than 1 meter (3 feet) must be displayed prominently so it can be seen from the deck and in the pool. Depth markers should be labeled in both feet and meters. Additionally, depth markers must be installed for every 1-meter (3-foot) change in depth.

6.8.1.1.3 Spas (10)

In addition to the safety sign requirements in section 6.7.1.1.1, install a sign at each WHIRLPOOL SPA and SPA POOL entrance listing precautions and risks associated with the use of these facilities. At a minimum, include cautions against use by the following:

- Individuals who are immunocompromised.
- Individuals on medication or who have underlying medical conditions such as cardiovascular disease, diabetes, or high or low blood pressure.
- Children, pregnant women, and elderly persons.

Additionally, caution against exceeding 15 minutes of use.

Vessels can submit existing signs for review by VSP.

It is advisable to post additional cautions and concerns on signs.

Those under 16 years of age are considered children for the purpose of whirlpool safety sign requirements.

6.8.1.2 Equipment

6.8.1.2.1 *Life Saving (10)*

A rescue or shepherd's hook and an APPROVED flotation device must be provided at a prominent location (visible from the full perimeter of the pool) at each RWF that has a depth of 1 meter (3 feet) or greater. These devices must be mounted in a manner that allows for easy access during an emergency.

- The pole of the rescue or shepherd's hook must be long enough to reach the center of the deepest portion of the pool from the side plus 0.6 meters (2 feet). It must be a light, strong, nontelelescoping material with rounded, nonsharp ends.
- The APPROVED flotation device must include an attached rope that is at least two-thirds of the maximum pool width.

The rescue or shepherd's hook must be long enough to touch the bottom center of the deepest portion of the RWF plus 2 feet (0.6 meters) as measured from the closest edge without an obstruction. This edge can only be used for measurement if someone could freely walk down both sides without an obstruction such as a waterfall, fountain, statue, etc.

For a rectangular pool, the shorter distance would be from the long side of the rectangle as long as there are no obstructions (Figure 6-1). The 2 feet (0.6 meters) is measured from where the shepherd's hook crosses the fill line of the RWF.

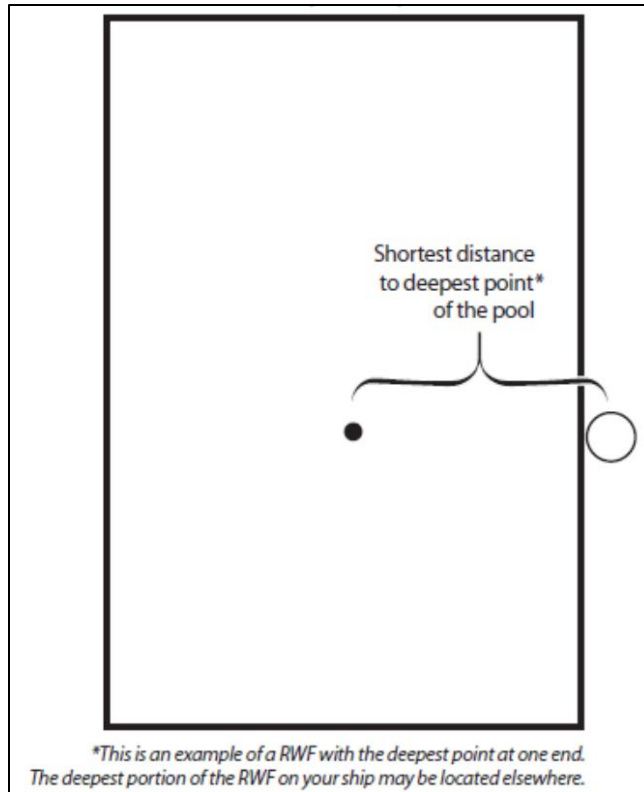


Figure 6-1 - Shortest distance in a rectangular pool

For RWFs with a beach level, the measurement can be from the edge of the tub (Figure 6-2).

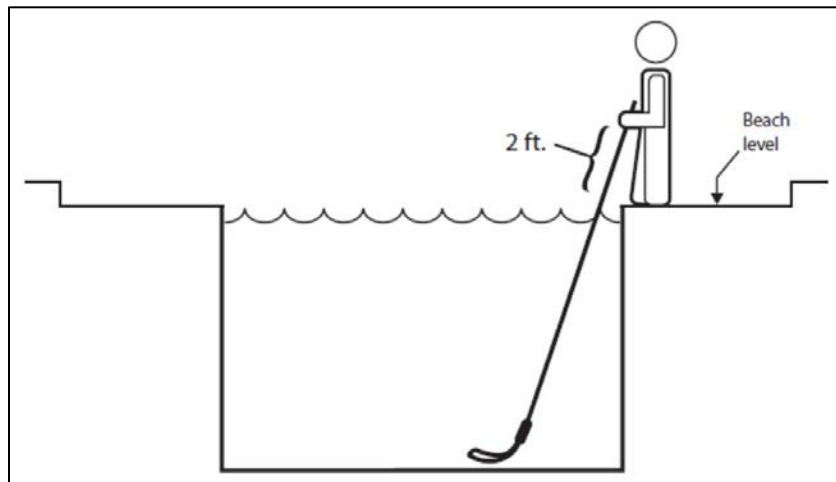


Figure 6-2 - Measurement in RWFs with a beach level

6.8.1.2.2 Antientrapment Drain (10)

ANTIENRAPMENT/ANTIENANGLEMENT requirements for drain covers and SUCTION FITTINGS in RWFs are shown in Table 6.7.1.2.2. **This does not apply to facilities with zero depth where the drains are not under direct suction.**

VSP is aware that the requirements shown in Table 6.7.1.2.2 for existing vessels may not fully meet the letter of the Virginia Graeme Baker Act, but we also recognize the life-safety concerns for rapid dumping of RWFs in conditions of instability at sea. Therefore, it is the owner's decision to meet or exceed the VSP requirements.

Testing of manufactured drain covers must be by a nationally or internationally recognized testing laboratory.

The information below must be stamped on each manufactured ANTIENTRAPMENT drain cover:

- Certification standard and year.
- Type of drain use (single or multiple).
- Maximum flow rate (in gallons or liters per minute).
- Type of fitting (suction outlet).
- Life expectancy of cover.
- Mounting orientation (wall, floor, or both).
- Manufacturer's name or trademark.
- Model designation.

The design of custom/shipyard constructed (field fabricated) drain covers and SUCTION FITTINGS must be fully specified by a REGISTERED DESIGN PROFESSIONAL in accordance with ASME A112.19.8-2007. The specifications must fully address cover/grate loadings, durability, hair, finger and limb entrapment issues, cover/grate secondary layer of protection, related sump design, and features specific to the RWF.

A letter from the shipyard must accompany each custom/shipyard constructed (field fabricated) drain cover fitting. At a minimum the letter must specify the shipyard, name of the vessel, specifications and dimensions of the drain cover, as detailed above, as well as the exact location of the RWF for which it was designed. The name of and contact information for the REGISTERED DESIGN PROFESSIONAL and signature must be on the letter.

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Table 6.8.1.2.2 ANTIENTRAPMENT Requirements for Recreational Water Facilities

Option*	Type	Drainage/Recirculation System	Cover Design	Secondary ANTI-ENTRAPMENT Requirement**
1	GRAVITY only	Multiple drains (2 or more drains greater than 3 feet apart)	Standard design (not compliant with ASME A112.19.8)	Alarm
2	GRAVITY only	Multiple drains (2 or more drains greater than 3 feet apart)	ASME A112.19.8 compliant cover	None
3	GRAVITY only	Single UNBLOCKABLE drain (per ASME A112.19.8)	Standard design (not compliant with ASME A112.19.8)	Alarm
4	GRAVITY only	Single UNBLOCKABLE drain (per ASME A112.19.8)	ASME A112.19.8 compliant cover	None
5	GRAVITY only	Single BLOCKABLE drain or multiple drains (less than 3 feet apart)	ASME A112.19.8 compliant cover	GDS
6	SUCTION FITTING	Multiple drains (2 or more drains per pump with drains greater than 3 feet apart)	ASME A112.19.8 compliant cover	None
7	SUCTION FITTING	Single UNBLOCKABLE drain (per ASME A112.19.8-2007)	ASME A112.19.8 compliant cover	SVRS or APS
8	SUCTION FITTING	Single BLOCKABLE drain or multiple drains (less than 3 feet apart)	ASME A112.19.8 compliant cover	SVRS or APS

*Options 1 through 5 are for fittings not under direct suction. These include both fittings to drain the RWF and fittings used to recirculate the water. Options 6 through 8 are for fittings under direct suction. These include fittings to drain the RWF and fittings used to recirculate the water.

**Definitions:

- Alarm: The audible alarm must sound in a continuously manned space AND at the RWF. This alarm is for all draining: accidental, routine, and emergency.
- GDS (GRAVITY DRAINAGE system): A drainage system that uses a collector tank from which the pump draws water. Water moves from the RWF to the collector tank due to atmospheric pressure, gravity, and the displacement of water by bathers. There is no direct suction at the RWF.
- SVRS (safety vacuum release system): A system that stops operation of the pump, reverses the circulation flow, or otherwise provides a vacuum release at a suction outlet when a blockage is detected. System must be tested by an independent third party and found to conform with ASME/ANSI A112.19.17 or ASTM standard F2387.
- APS (automatic pump shut-off system): A device that detects a blockage and shuts off the pump system. A manual shut-off near the RWF does not qualify as an APS.

ASME A112.19.8-2007 has been replaced by ANSI/APSP-16 2011. ANTIENTRAPMENT protection EQUIPMENT (covers, SUCTION FITTINGS, safety vacuum release system—SVRS**, etc.) must comply with ASME A112.19.8-2007—or any successor standards—whether the EQUIPMENT is manufactured or field fabricated.

6.8.1.2.3 Temperature (10)

A temperature-control mechanism to prevent the temperature from exceeding 40°C (104°F) must be provided on WHIRLPOOL SPAS and SPA POOLS. The water temperature must be measured within the WHIRLPOOL SPA or SPA POOL tub itself.

6.9 RWF Showers and Toilet Facilities

Vessels constructed to the 2018 Construction Guidelines or later must have toilets and showers installed.

6.9.1 Temperature and Location

Showers must provide POTABLE WATER at a temperature not to exceed 43°C (110°F) during normal operations. Showers must be installed within 10 meters (33 feet) of every entry point to each RWF. For beach entry RWFs, a minimum of one showerhead must be installed per 10 meters (33 feet) of perimeter within 10 meters (33 feet) of the beach perimeter. A minimum of one shower must be installed at each water slide staircase entrance.

6.9.2 Showers for Children

RWFs designed for use by children under 6 years of age must have appropriately sized shower facilities. Standard height is acceptable, but the mechanism to operate the flow of water must not be more than 1 meter above the deck.

6.9.3 Toilet Facilities

Toilet facilities must be located within one fire zone (approximately 48 meters [157 feet]) of each RWF and on the same deck or adjacent decks if there is no obstruction between RWF area and entrances to the toilets. If toilets are not located on the same deck they must be easily visible and ACCESSIBLE from the RWF area. A minimum of two separate toilet rooms (either two unisex or one male and one female) must be installed. Each toilet facility must include a toilet and a handwashing facility. Urinals may be installed in addition to the required toilet, but may not replace the toilet.

6.10 Restrictions

6.10.1 Diapers (10)

Children in diapers or who are not toilet trained must be prohibited from using any RWF not specifically designed and APPROVED for use by children in diapers.

Specifications and requirements for BABY-ONLY WATER FACILITIES can be found in Annex 13.8.

6.11 Recreational Water Facilities Knowledge

6.11.1 Demonstration of Knowledge (44)

The supervisor or PERSON IN CHARGE of RECREATIONAL WATER FACILITIES operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of RWF operations. The supervisor or PERSON IN CHARGE must demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector’s questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of RWF operations on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

7.0 Food Safety

This section includes the following subsections:

- 7.1 Reserved
- 7.2 Personnel
- 7.3. FOOD
- 7.4 EQUIPMENT and UTENSILS
- 7.5 WAREWASHING
- 7.6 Poisonous and Toxic Materials
- 7.7 Facilities

References for 7.0 Food Safety can be found in Annex 14.7.

7.1 Reserved

7.2 Personnel

7.2.1 Food Safety Management

7.2.1.1 Food Safety Knowledge

7.2.1.1.1 Knowledge (13 C)

Because of the risks for foodborne illness inherent to the FOOD operation, the supervisor or PERSON IN CHARGE of FOOD operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of foodborne disease prevention, application of the HAZARD ANALYSIS CRITICAL CONTROL POINT principles, and the FOOD safety guidelines in this manual. The supervisor or PERSON IN CHARGE must demonstrate this knowledge

- By compliance with these guidelines,
- By being a domestically or foreign certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM, or
- By responding correctly to the inspector's questions as they relate to the specific FOOD operation.

The areas of knowledge must include

- Describing the relation between prevention of foodborne disease and personal hygiene of a FOOD EMPLOYEE.
- Explaining the responsibility of the supervisor or PERSON IN CHARGE to prevent TRANSMISSION of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease.

- Describing the symptoms associated with diseases transmissible through FOOD.
- Explaining the significance of the relation between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD and the prevention of foodborne illness.
- Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, eggs, and FISH.
- Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD, including MEAT, POULTRY, eggs, and FISH.
- Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD.
- Describing the relation between prevention of foodborne illness and management and control of the following: CROSS-CONTAMINATION, hand contact with READY-TO-EAT FOODS, handwashing, and maintaining FOOD operations in a clean condition and in good repair.
- Explaining the relation between FOOD safety and providing EQUIPMENT that is sufficient in number and capacity as well as properly designed, constructed, located, installed, operated, maintained, and cleaned.
- Explaining correct procedures for cleaning and sanitizing UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.
- Identifying POISONOUS OR TOXIC MATERIALS on the vessel and the procedures necessary to ensure they are safely stored, dispensed, used, and disposed of according to LAW.
- Identifying critical-control points in the operation from purchasing through service that when not controlled may contribute to the TRANSMISSION of foodborne illness and explaining steps taken to ensure the points are controlled in accordance with the guidelines in this manual.

7.2.1.2 Food Safety Duties

7.2.1.2.1 *Monitoring Duties (13 C)*

The supervisor or PERSON IN CHARGE of FOOD operations on the vessel must ensure that

- FOOD operations are not conducted in a room used as living or sleeping quarters.
- Persons unnecessary to the FOOD operation are not allowed in the FOOD PREPARATION, FOOD STORAGE, or WAREWASHING areas. **However, brief**

visits and tours may be authorized if steps are taken to ensure that exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from CONTAMINATION.

- Employees and other persons such as delivery and maintenance persons and PESTICIDE applicators entering the FOOD PREPARATION, FOOD STORAGE, and WAREWASHING areas comply with the guidelines in this manual.
- FOOD EMPLOYEES are effectively cleaning their hands (by routinely monitoring the employees' handwashing).
- Employees are observing FOODS as they are received to determine that they are from APPROVED sources, delivered at the required temperatures, protected from CONTAMINATION, unadulterated, and accurately presented (by routinely monitoring the employees' observations and periodically evaluating FOODS as they are received).
- Employees are properly cooking POTENTIALLY HAZARDOUS FOOD, being particularly careful in cooking FOODS known to cause severe foodborne illness and death, such as eggs and COMMINUTED MEATS (through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate properly scaled and calibrated TEMPERATURE-MEASURING DEVICES).
- Employees are using proper methods to rapidly cool POTENTIALLY HAZARDOUS FOODS that are not held hot or are not for consumption within 4 hours (through daily oversight of the employees' routine monitoring of FOOD temperatures during cooling).
- CONSUMERS who order raw or partially cooked READY-TO-EAT FOODS of animal origin are informed that the FOOD is not cooked sufficiently to ensure its safety.
- Employees are properly sanitizing cleaned multiuse EQUIPMENT and UTENSILS before they are reused (through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing).
- CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets.

- Employees are preventing CROSS-CONTAMINATION of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.
- Employees are properly trained in FOOD safety, including FOOD allergy awareness, as it relates to their assigned duties.
- FOOD EMPLOYEES are informed of their responsibility to report to the supervisor or PERSON IN CHARGE information about their health and activities as they relate to diseases transmissible through FOOD.

7.2.2 Employee Health

7.2.2.1 Communicable Diseases and Symptoms

7.2.2.1.1 ***Communicable Diseases (11 C)***

FOOD EMPLOYEES suspected of, diagnosed with, or exposed to any communicable disease caused by *Salmonella* typhi, *Shigella* spp., *E. coli* O157:H7, hepatitis A virus, norovirus, or other communicable diseases that can be transmitted by FOOD, must be excluded from working in any FOOD or FOOD-related areas or operations, including working with exposed FOOD, WAREWASHING, EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE ARTICLES, and SINGLE-USE ARTICLES. The excluded individual must not be allowed to return to the above duties until they are symptom free for a minimum of 48 hours.

7.2.2.1.2 ***Other Symptoms (11 C)***

FOOD EMPLOYEES who have conditions or symptoms of boils, open sores, infected wounds, diarrhea, jaundice, fever, vomiting, sore throat with fever, or discharges from the nose or mouth must report these conditions or symptoms to the vessel's medical staff and must be restricted from working with exposed FOOD, WAREWASHING, clean EQUIPMENT, UTENSILS, LINENS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.2.2.1.3 ***Sneeze/Cough (11 C)***

FOOD EMPLOYEES experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth must not work with exposed FOOD; WAREWASHING; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

7.2.2.1.4 *Restrictions Removal (11 C)*

The restriction must not be removed until the supervisor or PERSON IN CHARGE of the FOOD operation obtains written approval from the vessel's physician or equivalent medical staff.

7.2.2.1.5 *Record of Restriction and Release (02)*

A written or electronic record of both the work restriction and release from restriction must be maintained onboard the vessel for 12 months for inspection review.

7.2.3 Employee Cleanliness**7.2.3.1 Hands and Arms****7.2.3.1.1 *Hands and Arms Clean (12 C)***

FOOD EMPLOYEES must keep their hands and exposed portions of their arms clean.

7.2.3.1.2 *Cleaning Procedures (12 C)*

FOOD EMPLOYEES must clean their hands and exposed portions of their arms with a cleaning compound in a handwashing sink by vigorously rubbing together the surfaces of their lathered hands and arms for at least 20 seconds and thoroughly rinsing with clean water. Employees must pay particular attention to the areas underneath the fingernails and between the fingers.

7.2.3.1.3 *When to Wash Hands (12 C)*

FOOD EMPLOYEES must clean their hands and exposed portions of their arms immediately before engaging in FOOD preparation, including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES and

- After touching bare human body parts other than clean hands and clean, exposed portions of arms.
- After using the toilet room.
- After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking.
- After handling soiled EQUIPMENT or UTENSILS.
- During FOOD preparation (as often as necessary to remove soil and CONTAMINATION and to prevent CROSS-CONTAMINATION when changing tasks).
- When switching between working with raw FOOD and working with READY-TO-EAT FOOD.
- Before putting on gloves for working with FOOD or clean EQUIPMENT and between glove changes.

- After engaging in other activities that contaminate the hands.

7.2.3.1.4 Hand Antiseptic (14)

A HAND ANTISEPTIC, a HAND ANTISEPTIC used as a hand dip, or a HAND ANTISEPTIC soap must comply with applicable formulation and use LAWS under FDA 21 CFR 170.39, 178, 182, 184, or 186.

7.2.3.1.5 Apply to Clean Hands (12 C)

HAND ANTISEPTIC, HAND ANTISEPTIC used as a hand dip, or HAND ANTISEPTIC soap must only be applied to hands cleaned as described in section 7.2.3.1.2.

7.2.3.2 Fingernails**7.2.3.2.1 Fingernails (14)**

FOOD EMPLOYEES must keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

7.2.3.2.2 Fingernail Polish/Artificial Nails (14)

A FOOD EMPLOYEE must not wear fingernail polish or artificial fingernails when preparing exposed FOOD.

7.2.3.3 Jewelry**7.2.3.3.1 Jewelry (14)**

While preparing FOOD, FOOD EMPLOYEES, including bartenders, must not wear jewelry on their arms and hands. **FOOD EMPLOYEES may wear a plain ring such as a SMOOTH simple wedding band.**

7.2.3.4 Food Service Uniform or Apron**7.2.3.4.1 Uniform or Apron (14)**

FOOD EMPLOYEES must wear a clean uniform or apron to prevent CONTAMINATION of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.2.4 Hygienic Practices

7.2.4.1 Eating, Drinking, or Using Tobacco

7.2.4.1.1 *Eating, Drinking, and Using Tobacco (12 C)*

An employee must not eat, drink, or use any form of tobacco in designated areas where the CONTAMINATION of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can occur.

7.2.5.1 Hair Restraints

7.2.5.1.1 *Hair Restraints (14)*

FOOD EMPLOYEES must wear hair restraints—such as hats, hair coverings or nets, beard restraints—and clothing that covers body hair. These items must be designed and worn to effectively keep their hair from contacting exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

This applies to partial beards (such as goatees) and to heavy, pronounced mustaches.

This section does not apply to FOOD EMPLOYEES such as counter staff who serve only BEVERAGES and wrapped or PACKAGED FOODS, hostesses, and wait staff if they present a minimal risk for contaminating exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.2.4.3 Toilet Rooms Use (14)

7.2.4.3.1 *Toilet Room Use (Food Employees)*

While in working uniforms, FOOD EMPLOYEES must not use toilet rooms designated for passenger use.

FOOD EMPLOYEES at bars where the only FOOD preparation includes garnish slicing in the pantry and drink making in the pantry and bar are excluded.

7.3 Food

7.3.1 Food Condition

7.3.1.1 Safe and Unadulterated

7.1.1.1.1 Sound Condition (15 C)

FOOD must be safe and unadulterated.

7.3.2 Food Sources

7.3.2.1 Lawful Sourcing

7.3.2.1.1 Comply with Law (15 C)

FOOD must be obtained from sources that comply with applicable local, state, federal, or country of origin's statutes, regulations, and ordinances.

7.3.2.1.2 Food from Private Home (15 C)

FOOD prepared in a private home must not be used or offered for human consumption on a vessel.

7.3.2.1.3 Fish for Undercooked Consumption

FISH—other than MOLLUSCAN SHELLFISH—intended for consumption in their raw form may be served if they are obtained from a supplier that freezes the FISH to destroy parasites or if they are frozen on the vessel and records are retained.

7.3.2.1.4 Steaks (15 C)

WHOLE-MUSCLE, INTACT BEEF steaks intended for consumption in an undercooked form without a CONSUMER advisory must be

- Obtained from a FOOD-PROCESSING PLANT that packages the steaks and labels them to indicate they meet the definition of WHOLE-MUSCLE, INTACT BEEF; **or**
- Cut individually on a vessel from WHOLE-MUSCLE, INTACT BEEF labeled by a FOOD-PROCESSING PLANT to indicate the beef meets the definition of WHOLE-MUSCLE, INTACT BEEF, and prepared so they remain intact.

7.3.2.1.5 Hermetically Sealed Container (15 C)

FOOD in a HERMETICALLY SEALED CONTAINER must be obtained from a FOOD-PROCESSING PLANT regulated by the FOOD regulatory agency that has jurisdiction over the plant.

7.3.2.1.6 Milk (15 C)

Fluid milk and milk products by U.S. suppliers must be obtained from sources that comply with GRADE A STANDARDS as specified in LAW. Milk received in interstate commerce must be from sources listed in the FDA Interstate Milk Shippers List. Non-U.S. sourced fluid milk and milk products must be obtained from sources that meet or exceed the standards of the health authorities from the source country.

7.3.2.1.7 Fish and Molluscan Shellfish Sources (15 C)

FISH received for service must be commercially and legally caught or harvested or otherwise APPROVED for service by VSP through an APPROVED VARIANCE.

Recreationally caught MOLLUSCAN SHELLFISH must not be received for service.

MOLLUSCAN SHELLFISH must be obtained from sources according to LAW and the requirements specified in the FDA National Shellfish Sanitation Program *Guide for the Control of MOLLUSCAN SHELLFISH*, or equivalent standards.

MOLLUSCAN SHELLFISH received in interstate commerce must be from sources listed in the FDA Interstate Certified Shellfish Shippers List or equivalent foreign certified shellfish listing.

7.3.2.1.8 Wild Mushrooms (15 C)

Mushroom species picked in the wild must be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom identification expert.

This requirement does not apply to

- Cultivated wild mushroom species grown, harvested, and processed in an operation regulated by the FOOD regulatory agency that has jurisdiction over the operation.
- Wild mushroom species if they are in PACKAGED form and are the product of a FOOD-PROCESSING PLANT regulated by the FOOD regulatory agency that has jurisdiction over the plant.

7.3.2.1.9 Game Animals (15 C)

If GAME ANIMALS are received for sale or service, they must be

- Commercially raised for FOOD and raised, slaughtered, and processed under LAW; or
- Under a voluntary inspection program administered by USDA for GAME ANIMALS such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison)

inspected and APPROVED in accordance with 9 CFR 352 (Voluntary Exotic Animal Program) or rabbits inspected and certified in accordance with 9 CFR 354 (Rabbit Inspection Program); or

- Under an equivalent regulatory program specifically for GAME ANIMALS. The packaging must also be stamped/labeled by the REGULATORY AUTHORITY.

A GAME ANIMAL must not be received for service if it is a species of wildlife listed in 50 CFR 17 Endangered and Threatened Wildlife and Plants.

7.3.2.2 Receiving Condition

7.3.2.2.1 *Receiving Temperatures (16 C)*

Receiving temperatures must be as follows:

- Refrigerated POTENTIALLY HAZARDOUS FOOD must be at a temperature of 5°C (41°F) or below when received.
If a temperature other than 5°C (41°F) for a POTENTIALLY HAZARDOUS FOOD is specified in LAW governing its distribution, such as LAWS governing milk, MOLLUSCAN SHELLFISH, and shell eggs, the FOOD may be received at the specified temperature.
- POTENTIALLY HAZARDOUS FOOD that is cooked and received hot must be at a temperature of 57°C (135°F) or above.
- A FOOD labeled and shipped frozen by a FOOD-PROCESSING PLANT must be received frozen.
- Upon receipt, POTENTIALLY HAZARDOUS FOOD must be free of evidence of previous temperature abuse.

7.3.2.2.2 *Food Additives (15 C)*

FOOD must not contain unapproved FOOD ADDITIVES or ADDITIVES that exceed amounts specified in LAW, as specified in the current version of the FDA *FOOD Code*, including annexes.

7.3.2.2.3 *Shell Eggs (15 C)*

Shell eggs must be received clean and sound and must not exceed the restricted egg tolerances specified in LAW, as specified in the current version of the FDA *FOOD Code*, including annexes.

7.3.2.2.4 *Egg and Milk Products (15 C)*

Eggs and milk products must be received as follows:

- Liquid, frozen, and dry eggs and egg products must be obtained pasteurized.

- Fluid and dry milk and milk products complying with GRADE A STANDARDS as specified in LAW must be obtained pasteurized.
- Frozen milk products, such as ice cream, must be obtained pasteurized as specified in 21 CFR 135 Frozen Desserts.
- Cheese must be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 Cheeses and Related Cheese Products for curing certain cheese varieties.

7.3.2.2.5 Package Integrity (15 C)

FOOD packages must be in good condition and protect the integrity of the contents so the FOOD is not exposed to adulteration or potential contaminants. Canned goods with dents on end or side SEAMS must not be used.

7.3.2.2.6 Ice (15 C)

Ice for use as a FOOD or a cooling medium must be made from DRINKING WATER.

7.3.2.2.7 Shucked Shellfish (15 C)

Raw SHUCKED SHELLFISH must be obtained in nonreturnable packages that bear a legible label as specified in the FDA National Shellfish Sanitation Program *Guide for the Control of MOLLUSCAN SHELLFISH*.

7.3.2.2.8 Shellstock Shellfish (15 C)

SHELLSTOCK must be obtained in containers bearing legible source identification tags or labels affixed by the harvester and by each dealer that depurates (cleanses), ships, or reships the SHELLSTOCK, as specified in the National Shellfish Sanitation Program *Guide for the Control of MOLLUSCAN SHELLFISH*.

7.3.2.2.9 Shellstock Condition (19)

SHELLSTOCK must be reasonably free of mud, dead shellfish, and shellfish with broken shells when received by a vessel. Dead shellfish or SHELLSTOCK with badly broken shells must be discarded.

7.3.2.3 Maintaining Molluscan Shellfish Identification

7.3.2.3.1 Shucked Identification (15 C)

Shucked MOLLUSCAN SHELLFISH must not be removed from the container in which they are received other than immediately before preparation for service.

7.3.2.3.2 Shellstock Identification (15 C)

SHELLSTOCK shellfish tags must

- Remain attached to the container in which the SHELLSTOCK are received until the container is empty.
- Be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date the container is emptied by using an APPROVED record-keeping system that keeps the tags or labels in chronologic order correlated to the date when the SHELLSTOCK are served. The date when the last SHELLSTOCK from the container is served must be recorded on the tag or label.

7.3.3 Food Protection**7.3.3.1 Employee Contamination****7.3.3.1.1 Wash Hands (12 C)**

FOOD EMPLOYEES must wash their hands.

7.3.3.1.2 RTE Food – Hand Contact Prohibited (12 C)

Except when washing fruits and vegetables or when otherwise APPROVED, FOOD EMPLOYEES must not contact exposed, READY-TO-EAT FOOD with their bare hands. They must use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.

7.3.3.1.3 Not RTE Food – Minimize Contact (19)

FOOD EMPLOYEES must minimize bare hand and arm contact with exposed FOOD not in a READY-TO-EAT form.

7.3.3.1.4 Tasting (12 C)

A FOOD EMPLOYEE must not use the same UTENSIL more than once to taste FOOD that will be served.

7.3.3.2 Food and Ingredient Contamination**7.3.3.2.1 Cross-Contamination (18 C)**

FOOD must be protected from cross-CONTAMINATION or other sources of CONTAMINATION by the following methods:

- Physically separating raw animal FOODS during storage, preparation, holding, and display from raw READY-TO-EAT FOOD (including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as vegetables, and cooked READY-TO-EAT FOOD) so products do not

physically touch and so that one product does not drip into another.

- Separating types of raw animal FOODS such as beef, FISH, lamb, pork, and POULTRY from each other—except when combined as ingredients—during storage, preparation, holding, and display by using separate EQUIPMENT for each type, or by arranging each type of FOOD in EQUIPMENT so that CROSS-CONTAMINATION of one type with another is prevented, or by preparing each type of FOOD at different times or in separate areas. **Frozen, commercially processed and PACKAGED raw animal FOOD may be stored or displayed with or above frozen, commercially processed and PACKAGED, READY-TO-EAT FOOD.**
- Cleaning and sanitizing EQUIPMENT and UTENSILS.
- Storing the FOOD in packages, covered containers, or wrappings.
- Cleaning visible soil on HERMETICALLY SEALED CONTAINERS of FOOD before opening.
- Protecting FOOD containers that are received PACKAGED together in a case or overwrapped from cuts when the case or overwrap is opened.
- Separating damaged, spoiled, or recalled FOOD being held on the vessel.
- Separating unwashed fruits and vegetables from READY-TO-EAT FOOD.

Storage exceptions: Storing the FOOD in packages, covered containers, or wrappings does not apply to

- **Whole, uncut, raw fruits and vegetables and nuts in the shell that require peeling or hulling before consumption.**
- **PRIMAL CUTS, quarters, or sides of raw MEAT or slab bacon hung on clean, sanitized hooks or placed on clean, sanitized racks.**
- **Whole, uncut, processed MEATS such as country hams, and smoked or cured sausages placed on clean, sanitized racks.**
- **FOOD being cooled.**
- **SHELLSTOCK.**

7.3.3.2.2 Container Identity (19)

Containers holding FOOD or FOOD ingredients removed from their original packages for use on the vessel, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar must be identified with the common name of the FOOD.

Containers holding FOOD that can be readily and unmistakably recognized such as dry pasta do not need to be identified.

Ingredients located at active cooking or preparation stations do not need to be identified.

7.3.3.2.3 Pasteurized Eggs (18 C)

Pasteurized eggs or egg products must be substituted for raw shell eggs in the preparation of FOODS such as Caesar salad, hollandaise or béarnaise sauce mayonnaise, eggnog, ice cream, and egg-fortified BEVERAGES or dessert items that are not cooked.

7.3.3.2.4 Wash Fruits/Vegetables (19)

Raw fruits and vegetables must be thoroughly rinsed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form.

7.3.3.2.5 Vegetable Washes

Fruits and vegetables may be washed by using chemicals specified under 21 CFR 173.315 (Annex 13.12).

7.3.3.3 Ice as Coolant**7.3.3.3.1 Ice Used as a Coolant (19)**

Ice must not be used as FOOD after use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT.

7.3.3.3.2 Coolant (19)

PACKAGED FOOD must not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container, or its positioning in the ice or water.

7.3.3.3.3 Undrained Ice (19)

Except as specified in 7.3.3.3.4 through 7.3.3.3.6, unpackaged FOOD must not be stored in direct contact with undrained ice.

7.3.3.3.4 Raw Fruit/Vegetables

Whole, raw fruits or vegetables; cut, raw vegetables such as celery, carrot sticks, or cut potatoes; and tofu may be immersed in ice or water.

7.3.3.3.5 Raw Chicken/Fish

Raw chicken and raw FISH received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, or service.

7.3.3.3.6 Ongoing Meal Service

Other unpackaged FOODS in a raw, cooked, or partially cooked state may be immersed in ice as part of an ongoing meal service process, such as liquid egg product, individual eggs, pasta, and reconstituted powdered mixes.

7.3.3.4 Equipment, Utensils, and Linens**7.3.3.4.1 Cleaned/Sanitized (26 C)**

FOOD must only contact surfaces of cleaned and sanitized EQUIPMENT and UTENSILS.

7.3.3.4.2 Storage During Use (19)

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS must be stored in one of the following ways:

- In the FOOD with their handles above the top of the FOOD and the container.
- In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon.
- On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT SURFACE of the FOOD preparation table or cooking EQUIPMENT are cleaned and sanitized at least every 4 hours.
- In running water of sufficient velocity to flush particulates to the drain (if used with moist FOOD such as ice cream or mashed potatoes).
- In a clean, protected location (if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS).
- In a container of water (if the water is maintained at a temperature of at least 57°C [135°F] and the container is frequently cleaned and sanitized).

7.3.3.4.3 Linen/Napkins (19)

LINENS and napkins must not be used in contact with FOOD unless they are used to line a container for the service of FOODS and the LINENS and napkins are replaced each time the container is refilled for a new CONSUMER.

7.3.3.4.4 Wiping Cloths (25)

Wiping cloths must be restricted to the following:

- Cloths used for wiping FOOD spills must be used for no other purpose.
- Cloths used for wiping FOOD spills must be dry and used for wiping FOOD spills from TABLEWARE and SINGLE-SERVICE ARTICLES **OR** wet and cleaned, stored in a chemical SANITIZER, and used for wiping spills from FOOD-CONTACT and NONFOOD-CONTACT SURFACES of EQUIPMENT.
- Dry or wet cloths used with raw animal FOODS must be kept separate from cloths used for other purposes. Wet cloths used with raw animal FOODS must be kept in a separate sanitizing solution.
- Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths must be free of FOOD debris and visible soil.

7.3.3.4.5 Glove Use (19)

Gloves must be used as follows:

- SINGLE-USE gloves must be used for only **one hand-contact** task with READY-TO-EAT FOOD and no other purpose. These SINGLE-USE gloves must be discarded when damaged or soiled or when operation is interrupted.
- Slash-resistant gloves used to protect hands during operations requiring cutting must be used in direct contact only with FOOD that is subsequently cooked (such as frozen FOOD or a PRIMAL CUT of MEAT).
- Slash-resistant gloves may be used with READY-TO-EAT FOOD that will not be subsequently cooked if the slash-resistant gloves have a SMOOTH, durable, and nonabsorbent outer surface **or** if the slash-resistant gloves are covered with a SMOOTH, durable, nonabsorbent glove or a SINGLE-USE glove.
- Cloth gloves must not be used in direct contact with FOOD unless the FOOD is subsequently cooked (such as frozen FOOD or a PRIMAL CUT of MEAT).

7.3.3.4.6 Second Portions and Refills (19)

Procedures for second portions and refills must be as follows:

- FOOD EMPLOYEES must not use TABLEWARE soiled by the CONSUMER—including SINGLE-SERVICE ARTICLES—except for refilling a CONSUMER’S drinking cup or container without contact between the pouring UTENSIL and the lip-contact area of the drinking cup or container.
- Self-service CONSUMERS must not be allowed to use soiled TABLEWARE—including SINGLE-SERVICE ARTICLES—to obtain additional FOOD from the display and serving EQUIPMENT except as specified in the bullet below.
- **Self-service CONSUMERS may reuse drinking cups and containers if refilling is a CONTAMINATION-free process.**

7.3.3.5 Food Storage and Preparation

This section applies to storage of candy and other FOOD items sold in candy shops, including self-service candy shops and shops where candy is served by a crew member.

7.3.3.5.1 Storage Protection (19)

FOOD must be protected from CONTAMINATION by storing it as follows:

- Covered or otherwise protected;
- In a clean, dry location;
- Where it is not exposed to splash, dust, or other CONTAMINATION; and
- At least 150 millimeters (6 inches) above the deck. FOOD in packages and working containers on pallets, skids, and racks may be 127 millimeters (5 inches) above the deck. Shelving units must be 150 millimeters (6 inches) above the deck.

7.3.3.5.2 Prohibited Storage (19)

FOOD must not be stored as follows:

- In locker rooms.
- In toilet rooms.
- In dressing rooms.
- In garbage rooms.
- In mechanical rooms.
- Under sewer lines that are not continuously sleeve welded.
- Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has

condensed.

- Under open stairwells.
- Under other sources of CONTAMINATION from nonfood items such as ice blocks, ice carvings, and flowers.
- In areas not finished in accordance with 7.7.5 and 7.7.6 for FOOD STORAGE AREAS.

7.3.3.5.3 Potentially Hazardous Food Packages in Vending Machines (19)

POTENTIALLY HAZARDOUS FOOD dispensed through a vending machine must be in the package in which it was placed in the galley or FOOD-PROCESSING PLANT at which it was prepared.

7.3.3.5.4 Preparation (19)

During preparation, unpackaged FOOD must be protected from environmental sources of CONTAMINATION such as rain.

7.3.3.6 Food Display and Service

This section applies to self-service candy shops where customers serve themselves from candy displays or dispensers.

7.3.3.6.1 Display Preparation (19)

FOOD on display must be protected from CONTAMINATION by the use of packaging; counter, service line, or salad bar FOOD guards; display cases; self-closing hinged lids; or other effective means. Install side protection for sneeze guards if the distance between exposed FOOD and where CONSUMERS are expected to stand is less than 1 meter (40 inches).

7.3.3.6.2 Condiments (19)

Condiments must be protected from CONTAMINATION by being kept in one of the following:

- Dispensers designed to provide protection.
- Protected FOOD DISPLAYS provided with the proper UTENSILS.
- Original containers designed for dispensing.
- Individual packages or portions.

Condiments at a vending machine location must be in individual packages or provided in dispensers that are filled at an APPROVED location, such as the galley that provides FOOD to the vending machine location, a FOOD-PROCESSING PLANT, or a properly equipped facility located on the site of the vending machine location.

7.3.3.6.3 Self Service (19)

CONSUMER self-service operations, such as salad bars and buffets, for unpackaged READY-TO-EAT FOODS must be

- Provided with suitable UTENSILS or effective dispensing methods that protect the FOOD from CONTAMINATION.
- Monitored by FOOD EMPLOYEES trained in safe operating procedures.

Where there is self-service of scooped frozen dessert, service must be out of shallow pans no deeper than 4 inches (100 millimeters) and no longer than 12 inches (300 millimeters).

7.3.3.6.4 Utensils, Consumer Self-service**7.3.3.6.4.1 Dispensing Utensil (19)**

A FOOD-dispensing UTENSIL must be available for each container of FOOD displayed at a CONSUMER self-service unit such as a buffet or salad bar.

7.3.3.6.4.2 Utensil Protected (19)

The FOOD contact portion of each self-service FOOD-dispensing UTENSIL must be covered or located beneath shielding during service.

Dishware, glassware, and UTENSILS out for service must be inverted or covered.

7.3.3.6.5 Food Reservice (15 C)

After being served and in the possession of a CONSUMER or being placed on a buffet service line, FOOD that is unused or returned by the CONSUMER must not be offered as FOOD for human consumption.

Exceptions:

- **A container of FOOD that is not POTENTIALLY HAZARDOUS may be transferred from one CONSUMER to another if the FOOD is dispensed so that it is protected from CONTAMINATION and the container is closed between uses (such as a narrow-neck bottle containing catsup, steak sauce, or wine) OR the FOOD (such as crackers, salt, or pepper) is in an unopened original package and is maintained in sound condition.**
- **Reservice for FOODS served to passengers from a fully enclosed display case and under strict employee monitoring, strict temperature control of hot/cold POTENTIALLY HAZARDOUS FOODS, proper cooling and reheating of hot-held POTENTIALLY**

HAZARDOUS FOODS, and complete protection from any other CONTAMINATION sources, including pests.

7.3.3.7 Other Contamination

7.3.3.7.1 Other Contaminants (19)

FOOD must be protected from CONTAMINATION that may result from a physical, chemical, biological origin.

7.3.4 Pathogen Destruction

7.3.4.1 Cooking Temperatures/Times

7.3.4.1.1 Cooking (16 C)

Raw animal FOODS such as eggs, FISH, MEAT, and POULTRY—and FOODS containing these raw animal FOODS—must be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD being cooked:

- **63°C (145°F) or above** for 15 seconds for
 - Raw shell eggs broken and prepared in response to CONSUMERS' orders and for immediate service.
 - FISH, MEAT, and pork, including GAME ANIMALS commercially raised for FOOD and GAME ANIMALS under a voluntary inspection program.
- **68°C (155°F) or above** for 15 seconds or equivalent temperature-time combination for
 - RATITES, MECHANICALLY TENDERIZED and INJECTED MEATS, and raw eggs not prepared for immediate service.
 - COMMINUTED FISH, MEAT, GAME ANIMALS commercially raised for FOOD, and GAME ANIMALS under a voluntary inspection program.
- **74°C (165°F) or above** for 15 seconds for
 - POULTRY.
 - Wild GAME ANIMALS not specified in above bullet for 68°C (155°F).
 - Stuffed FISH, MEAT, pasta, POULTRY, or RATITES.
 - Stuffing containing FISH, MEAT, POULTRY, or RATITES.

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- Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham, must be cooked as detailed in sections a and b below.

- a. Food cooked in an oven preheated to the temperature specified below for the roast's weight and oven type
AND

Oven Type	Roast Weight Less Than 4.5 kg (10 lbs)	Roast Weight 4.5 kg (10 lbs) or More
Still dry	Preheat to 177°C (350°F) or more	Preheat to 121°C (250°F) or more
Convection	Preheat to 163°C (325°F) or more	Preheat to 121°C (250°F) or more
High humidity*	Preheat to 121°C (250°F)	Preheat to 121°C (250°F)

*Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven or in a moisture-impermeable bag that provides 100% humidity.

- b. All parts of the FOOD heated to a temperature and for the holding time corresponding to that temperature:

Temperature	Time*
54.4°C (130°F)	112 minutes
55.0°C (131°F)	89 minutes
56.1°C (133°F)	56 minutes
57.2°C (135°F)	36 minutes
57.8°C (136°F)	28 minutes
58.9°C (138°F)	18 minutes
60.0°C (140°F)	12 minutes
61.1°C (142°F)	8 minutes
62.2°C (144°F)	5 minutes
62.8°C (145°F)	4 minutes
63.9°C (147°F)	134 seconds
65.0°C (149°F)	85 seconds
66.1°C (151°F)	54 seconds
67.2°C (153°F)	34 seconds
68.3°C (155°F)	22 seconds
69.4°C (157°F)	14 seconds
70.0°C (158°F)	0 seconds

*Holding time may include postoven heat rise.
Extracted from *FOOD Code*, Recommendations of the United States Public Health Service, 2013.

- **A raw or undercooked WHOLE-MUSCLE, INTACT BEEF steak may be served or offered for sale in a READY-TO-EAT form if the steak is labeled to indicate**

that it meets the definition of “WHOLE-MUSCLE, INTACT BEEF” and the steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.

- A raw animal FOOD (such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, or steak tartare) or a partially cooked FOOD (such as lightly cooked FISH, soft-cooked eggs, or rare MEAT other than WHOLE-MUSCLE, INTACT BEEF steaks) may be served or offered for sale in a READY-TO-EAT form if the CONSUMER is informed by the written CONSUMER advisory or if VSP grants a VARIANCE from the cooking recommendations based on a HACCP PLAN submitted by the vessel. The HACCP PLAN must document scientific data or other information showing that a lesser time and temperature regimen results in a safe FOOD. The HACCP PLAN must verify that EQUIPMENT and procedures for FOOD preparation and training of FOOD EMPLOYEES meet the conditions of the VARIANCE.

7.3.4.1.2 *Microwave (16 C)*

Raw animal FOODS cooked in a microwave oven must be

- Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat.
- Covered to retain surface moisture.
- Heated to a temperature of at least 74°C (165°F) in all parts of the FOOD.
- Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

7.3.4.1.3 *Fruits/Vegetables (17)*

Fruits and vegetables cooked for hot holding must be cooked to a temperature of 57°C (135°F).

7.3.4.2 Parasite Destruction

7.3.4.2.1 *Parasite Destruction (16 C)*

Before service in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH and fishery products other than MOLLUSCAN SHELLFISH must be frozen throughout to a temperature of -20°C (-4°F) or below for 168 hours (7 days) in a freezer or to -35°C (-31°F) or below for 15 hours in a BLAST CHILLER.

These FISH may be served in a raw, raw-marinated, or partially cooked READY-TO-EAT form without freezing if the

- **FISH are tuna of the species *Thunnus alalunga*, *T. albacares* (yellowfin tuna), *T. atlanticus*, *T. maccoyii* (bluefin tuna, southern), *T. obesus* (bigeye tuna), or *T. thynnus* (bluefin tuna, northern) OR**
- **Aquacultured FISH, such as salmon, are**
 - **raised in open water, net-pens, or land-based operations such as ponds or tanks and**
 - **fed formulated feed (such as pellets) that contains no live parasites infective to the aquacultured.**
- **FISH eggs have been removed from the skein and rinsed.**

If FOODS, such as gravlax, ceviche/seviche, FISH carpaccio, or sashimi, are prepared in a FOOD-PROCESSING PLANT and certified as parasite free, they may be served raw, raw-marinated, or partially cooked READY-TO-EAT without freezing the product onboard the vessel.

7.3.4.2.2 Records (17)

If raw, raw-marinated, partially cooked, or marinated partially cooked FISH are served in READY-TO-EAT form,

- The supervisor or PERSON IN CHARGE must record the freezing temperature and time to which the FISH are subjected and must retain the records on the vessel for 90 calendar days beyond the time of service or sale of the FISH; OR
- If the FISH are frozen by a supplier, a written letter from the supplier must specify the FISH species involved and both the temperature to which the FISH was frozen and the total time period at that temperature. If the supplier provides any of the same FISH species to the vessel in a fresh state, the outer packaging must designate which one is the parasite-free FISH.

For FISH exempt from freezing requirements based on section 7.3.4.2.1, a written letter from the supplier must state both the species of FISH and the conditions in which they were raised and fed.

7.3.4.3 Reheating

7.3.4.3.1 *Immediate Service*

Cooked and refrigerated FOOD prepared for immediate service in response to an individual CONSUMER order (such as a roast beef sandwich au jus) may be served at any temperature.

7.3.4.3.2 *74°C/165°F (16 C)*

POTENTIALLY HAZARDOUS FOOD that is cooked, cooled, and reheated for hot holding must be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.

7.3.4.3.3 *Microwave Heating (16 C)*

If reheated in a microwave oven for hot holding, POTENTIALLY HAZARDOUS FOOD must be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.

7.3.4.3.4 *Commercial Products (17)*

READY-TO-EAT POTENTIALLY HAZARDOUS FOOD taken from a commercially processed, HERMETICALLY SEALED CONTAINER, or from an intact package from a FOOD-PROCESSING PLANT inspected by the FOOD REGULATORY AUTHORITY that has jurisdiction over the plant, must be heated to a temperature of at least 57°C (135°F) for hot holding.

7.3.4.3.5 *Rapid Reheat (16 C)*

Reheating for hot holding must be done rapidly. The time the FOOD is between 5°C (41°F) and 74°C (165°F) must not exceed 2 hours.

7.3.4.3.6 *Reheat Roast Beef*

Remaining unsliced portions of roasts of beef cooked on the vessel may be reheated for hot holding using the oven parameters and minimum time and temperature conditions used in the original cooking process.

7.3.5 Food Holding Temperatures and Times

7.3.5.1 Frozen, Slacking, and Thawing Procedures

7.3.5.1.1 *Store Frozen Food Frozen (17)*

Stored frozen FOODS must be maintained frozen.

7.3.5.1.2 Slacking (17)

Frozen POTENTIALLY HAZARDOUS FOOD that is SLACKED to moderate the temperature must be held

- Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less; or
- At any temperature if the FOOD remains frozen.

7.3.5.1.3 Thawing (17)

POTENTIALLY HAZARDOUS FOOD must be thawed by one of the following:

- Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less.
- Completely submerged under running water at a water temperature of 21°C (70°F) or below, with sufficient water velocity to agitate and float off loose particles in an overflow, and for a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F).
- Completely submerged under running water at a water temperature of 21°C (70°F) or below with sufficient water velocity to agitate and float off loose particles in an overflow and for a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking to be above 5°C (41°F) for more than 4 hours, including
 - The time the FOOD is exposed to the running water and the time needed for preparation for cooking, OR
 - The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F).
- As part of a cooking process if the frozen FOOD is cooked or thawed in a microwave oven.

If a portion of frozen READY-TO-EAT FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order, it can be thawed using any procedure.

7.3.5.2 Food Cooling**7.3.5.2.1 Cooling Times/Temperatures (16 C)**

Cooked POTENTIALLY HAZARDOUS FOOD must be cooled

- From 57°C (135°F) to 21°C (70°F) within 2 hours and
- From 21°C (70°F) to 5°C (41°F) or less within 4 hours.

7.3.5.2.2 Cooling Prepared Food (16 C)

POTENTIALLY HAZARDOUS FOOD must be cooled within 4 hours to 5°C (41°F) or less if prepared from ingredients at ambient temperature (such as reconstituted FOODS and canned tuna).

7.3.5.2.3 Cooling Received Food (16 C)

A POTENTIALLY HAZARDOUS FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier must be cooled within 4 hours to 5°C (41°F) or less.

7.3.5.2.4 Shell Eggs

Shell eggs need not comply with the cooling time if, on receipt, they are placed immediately into refrigerated EQUIPMENT capable of maintaining FOOD at 5°C (41°F) or less.

7.3.5.2.5 Cooling Methods (17)

Cooling must be accomplished using one or more of the following methods based on the type of FOOD being cooled:

- Placing the FOOD in shallow pans.
- Separating the FOOD into smaller or thinner portions.
- Using BLAST CHILLERS, freezers, or other rapid cooling EQUIPMENT.
- Stirring the FOOD in a container placed in an ice water bath.
- Using containers that facilitate heat transfer.
- Adding ice as an ingredient.
- Using other effective methods.

When placed in cooling or cold-holding EQUIPMENT, FOOD containers in which FOOD is being cooled must be arranged in the EQUIPMENT to provide maximum heat transfer through the container walls and must be loosely covered—or uncovered if protected from overhead CONTAMINATION—during the cooling period to facilitate heat transfer from the surface of the FOOD.

7.3.5.2.6 Cooling Logs (17)

Logs documenting cooked POTENTIALLY HAZARDOUS FOOD cooling temperatures and times from the starting points designated in 7.3.5.2.1 through the control points at 2 and 6 hours must be maintained onboard the vessel for a period of 30 days from the date the FOOD was placed in a cooling process. Logs documenting cooling of POTENTIALLY HAZARDOUS FOODS prepared from ingredients at ambient temperatures, with the start time to the time

when 5°C (41°F) is reached, must also be maintained for a 30-day period beginning with the day of preparation.

7.3.5.3 Food Holding Temperatures and Times

7.3.5.3.1 Holding Temperature/Time (16 C)

Except during preparation, cooking, or cooling, or when time is used as the public health control, POTENTIALLY HAZARDOUS FOOD must be maintained at

- 57°C (135°F) or above, except that roasts may be held at a temperature of 54°C (130°F); or
- 5°C (41°F) or less.

7.3.5.3.2 RTE PHF Shelf-Life: Date Marking (16 C)

Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD

- Prepared on a vessel and held refrigerated for more than 24 hours must be clearly marked at the time of preparation to indicate the date or day by which the FOOD must be consumed (7 calendar days or fewer from the day the FOOD is prepared). The day of preparation is counted as day 1.
- Prepared and PACKAGED by a FOOD-PROCESSING PLANT and held on the vessel after opening for more than 24 hours must be clearly marked at the time the original container is opened to indicate the date by which the FOOD must be consumed (7 calendar days or fewer after the original container is opened). The day of package opening is counted as day 1.

The date marking requirement can be accomplished with a calendar date, day of the week, color-code, or other system, provided it is effective.

The date marking requirement does not apply to the following FOODS prepared and PACKAGED by a FOOD-PROCESSING PLANT inspected by a REGULATORY AUTHORITY:

- Deli salads (such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad) manufactured in accordance with 21 CFR 110.
- Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 (such as cheddar, gruyere, parmesan and reggiano, and romano).

- Semisoft cheeses containing more than 39% moisture but not more than 50% moisture, as defined in 21 CFR 133 (such as blue, edam, gorgonzola, gouda, and monterey jack).
- Cultured dairy products as defined in 21 CFR 131 (such as yogurt, sour cream, and buttermilk).
- Preserved FISH products (such as pickled herring and dried or salted cod) and other acidified FISH products defined in 21 CFR 114.
- Shelf stable, dry fermented sausages (such as pepperoni and Genoa salami) not labeled “keep refrigerated” as specified in 9 CFR 317. [Retain the original casing on the product.]
- Shelf stable salt-cured products (such as prosciutto and Parma [ham]) not labeled “keep refrigerated” as specified in 9 CFR 317.

These products are exempted from date marking even after being opened, cut, shredded, etc.

7.3.5.3.3 *Discarding RTE PHF (16 C)*

Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD must be discarded if not consumed within 7 calendar days from the date of preparation or opening.

7.3.5.3.4 *Retain Date (16 C)*

A refrigerated, potentially hazardous, READY-TO-EAT FOOD ingredient or a portion of a refrigerated, potentially hazardous, READY-TO-EAT FOOD subsequently combined with additional ingredients or portions of FOOD must retain the date marking of the earliest or first-prepared ingredient.

7.3.5.3.5 *Time as a Public Health Control (16 C)*

If time only—rather than time in conjunction with temperature—is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is displayed or held for service for immediate consumption, the FOOD

- Must have an initial temperature of 5°C (41°F) or less or 57°C (135°F) or greater before placement on time control.
- Must not be placed on temperature control again.
- Must be marked or otherwise identified to indicate the time 4 hours past the point in time when the FOOD is removed from temperature control (if the time between service set-up and closing is greater than 4 hours).

- Must be discarded within 4 hours of placement on time control.
 - If FOOD is on/in a time control unit (bain marie, cold basin, soup wells) and service is under 4 hours, a 4-hour discard label is not needed.
 - If the time control unit meant to be cold holding or hot holding is not operational or used as intended, the unit is considered a counter and the FOOD stored within it must be labeled with its 4-hour discard time.
 - Containers of POTENTIALLY HAZARDOUS FOOD under time control and placed on preparation counters must be labeled with the discard time, even if the outlet is open less than 4 hours.

EQUIPMENT that does not have cabinets or compartments does not need to be labeled as time control. Such EQUIPMENT includes bains marie, cold tops, and soup wells.

7.3.5.3.6 Time Control Plan (17)

A written time control plan(s) that ensures compliance with these guidelines must be maintained on the vessel and made available for review during inspections (Annex 13.13). A time control plan must be posted and ACCESSIBLE to all crew working at each outlet where time control is used.

The plan(s) must

- Include set-up and discard times for each outlet. Include all services and events where POTENTIALLY HAZARDOUS FOODS are kept on time control. If used, colored labels must correspond to the discard times stated in the plan.
- List all units (to include preparation counters, cabinets, compartments, and EQUIPMENT) on time control.
- Describe or show the flow of POTENTIALLY HAZARDOUS FOOD from when last in temperature control to placement in time control and discard.

7.3.6 Consumer Information

7.3.6.1 Consumer Advisory

7.3.6.1.1 Raw Shell Egg Preparations (16 C)

Raw shell egg preparations are prohibited in uncooked products as described in 7.3.3.2.3.

7.3.6.1.2 Animal Food (16 C)

If an animal FOOD such as beef, eggs, FISH, lamb, milk, pork, POULTRY, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a READY-TO-EAT form or as a raw ingredient in another READY-TO-EAT FOOD, the CONSUMER must be informed by way of disclosure as specified below using menu advisories, placards, or other easily visible written means of the significantly increased risk to certain especially vulnerable CONSUMERS eating such FOODS in raw or undercooked form. The advisory must be located at the outlets where these types of FOOD are served.

Disclosure must be made by one of the two following methods:

- On a sign describing the animal-derived FOODS (e.g., “oysters on the half-shell,” “hamburgers,” “steaks,” or “eggs”) AND that they can be cooked to order **or** may be served raw or undercooked AND a statement indicating that consuming raw or undercooked MEATS, seafood, shellfish, eggs, milk, or POULTRY may increase your risk for foodborne illness, especially if you have certain medical conditions. The advisory must be posted at the specific station where the FOOD is served raw, undercooked, or cooked to order.

OR

- On a menu using an asterisk at the animal-derived FOODS requiring disclosure and a footnote with a statement indicating that consuming raw or undercooked MEATS, seafood, shellfish, eggs, milk, or POULTRY may increase your risk for foodborne illness, especially if you have certain medical conditions.

It is acceptable to limit the list of animal-derived FOODS in the CONSUMER advisory to only the type(s) of animal-derived FOOD served raw, undercooked, or cooked to order at a specific location. For example, at a sushi counter, the CONSUMER advisory might only refer to seafood.

A CONSUMER advisory is not required for raw or undercooked WHOLE-MUSCLE, INTACT BEEF steak as specified under 7.3.2.1.4.

7.3.7 Contaminated Food

7.3.7.1 Discarding Food

7.3.7.1.1 Unsafe/Adulterated (18 C)

A FOOD that is unsafe or ADULTERATED must be discarded.

7.3.7.1.2 Unapproved Source (18 C)

FOOD that is not from an APPROVED source must be discarded.

7.3.7.1.3 Restricted or Excluded Employee (18 C)

READY-TO-EAT FOOD that may have been contaminated by an employee who has been restricted or excluded for FOOD EMPLOYEE health issues must be discarded.

7.3.7.1.4 Contaminated by Others (18 C)

FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other persons through contact with their hands, bodily discharges (such as nasal or oral discharges), or other means must be discarded.

7.4 Equipment and Utensils

7.4.1 Materials

7.4.1.1 Multiuse Characteristics and Use Limitations

7.4.1.1.1 Safe Food-Contact Materials (26 C)

Materials used in the construction of multiuse UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT must not allow the migration of deleterious substances or impart colors, odors, or tastes to FOOD and must be safe under normal use conditions.

7.4.1.1.2 Food-Contact Surfaces (20)

Materials used in the construction of multiuse UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT must be as follows:

- Durable, corrosion-resistant, and nonabsorbent.
- Sufficient in weight and thickness to withstand repeated WAREWASHING.
- Finished to have a SMOOTH, EASILY CLEANABLE surface.

- Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

7.4.1.1.3 Cast Iron (20)

Cast iron must not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT. Cast iron may be used as a surface for cooking. Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.

Cast iron FOOD DISPLAY dishes heated to a temperature of 74°C (165°F) for 15 seconds may be used for the immediate service of FOOD.

7.4.1.1.4 Lead (20)

Limitation of lead use must be as follows:

- Ceramic, china, crystal UTENSILS, and decorative UTENSILS such as hand-painted ceramic or china used in contact with FOOD must be lead-free or contain levels of lead not exceeding the limits for specific UTENSIL categories as allowed by LAW.
- Pewter alloys containing lead in excess of 0.05% must not be used as a FOOD-CONTACT SURFACE.
- Solder and flux containing lead in excess of 0.2% must not be used as a FOOD-CONTACT SURFACE.

7.4.1.1.5 Copper/Brass (26 C)

Copper and copper alloys such as brass must not be used in contact with a FOOD that has a pH below 6 (such as vinegar, fruit juice, or wine) or for a fitting or tubing installed between a BACKFLOW PREVENTION DEVICE and a carbonator.

Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

7.4.1.1.6 Galvanized (26 C)

Galvanized metal must not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

7.4.1.1.7 Wood (20)

Wood use must be limited as follows:

- Wood and wood wicker must not be used as a FOOD-CONTACT SURFACE.
- **Hard maple or an equivalently hard, close-grained wood may be used for cutting boards; cutting blocks; bakers' tables; UTENSILS such as rolling pins, doughnut dowels, serving dishes, and chopsticks; and wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.**
- **Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping container in which they were received until the fruits, vegetables, or nuts are used.**
- **If the nature of the FOOD requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw FOOD may be kept in untreated wood containers or in treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for Wood.**

7.4.1.1.8 Coatings (20)

Multiuse KITCHENWARE such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating must be used with nonscoring or nonscratching UTENSILS and cleaning aids.

7.4.1.1.9 Nonfood-Contact Surfaces (21)

NONFOOD-CONTACT SURFACES of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning must be constructed of a corrosion-resistant, nonabsorbent, and SMOOTH material.

7.4.1.2 Single-Service and Single-Use Characteristics**7.4.1.2.1 Single-Service Materials Safe (26 C)**

Materials used to make SINGLE-SERVICE and SINGLE-USE ARTICLES must not allow the migration of deleterious substances and must be safe.

7.4.1.2.2 No Colors/Odors/Taste (20)

Materials used to make SINGLE-SERVICE and SINGLE-USE ARTICLES must not impart colors, odors, or tastes to FOOD and must be clean.

7.4.2 Design and Construction

7.4.2.1 Durability and Strength

7.4.2.1.1 ***Food-Contact Durability/Strength (20)***

FOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS must be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

7.4.2.1.2 ***Nonfood-Contact Durability/Strength (21)***

NONFOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS must be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

7.4.2.1.3 ***Glass TMDs (26 C)***

FOOD TEMPERATURE-MEASURING DEVICES must not have sensors or stems constructed of glass, except for thermometers with glass sensors or stems encased in a shatterproof coating (such as candy thermometers).

7.4.2.2 Cleanability

7.4.2.2.1 ***Multiuse Food-Contact Surfaces (20)***

Multiuse FOOD-CONTACT SURFACES must be

- SMOOTH.
- Free of breaks, open SEAMS >0.8 millimeters (1/32 inch), cracks, chips, inclusions, pits, and similar imperfections.
- Free of sharp internal angles, corners, and crevices.
- Finished to have SMOOTH welds and joints.
- ACCESSIBLE for cleaning and inspection by one of the following methods [does not apply to cooking oil storage tanks, distribution lines for cooking oils, or BEVERAGE syrup lines or tubes]:
 - Without being disassembled,
 - by disassembling without the use of tools, or
 - by easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel (such as screwdrivers, pliers, open-end wrenches, and Allen wrenches).

Use low profile, nonslotted, NONCORRODING, and easy-to-clean fasteners on FOOD-CONTACT SURFACES and in splash zones. The use of exposed slotted screws, Phillips head screws, or pop rivets in these areas is prohibited.

7.4.2.2.2 CIP Equipment Design/Construction (20)

Clean-in-place EQUIPMENT must be designed and constructed so cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior FOOD-CONTACT SURFACES and so the system self drains or can be completely drained of cleaning and sanitizing solutions.

Clean-in-place EQUIPMENT not designed to be disassembled for cleaning must be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned.

7.4.2.2.3 “V” Type Threads (20)

Except for hot oil cooking or filtering EQUIPMENT, “V” type threads must not be used on FOOD-CONTACT SURFACES.

7.4.2.2.4 Oil Filtering Equipment (20)

Hot oil filtering EQUIPMENT must be READILY ACCESSIBLE for filter replacement and filter cleaning.

7.4.2.2.5 Can Openers (20)

Cutting or piercing parts of can openers must be READILY REMOVABLE for cleaning and replacement.

7.4.2.2.6 Nonfood-Contact Design (21)

NONFOOD-CONTACT SURFACES must be free of unnecessary ledges, projections, and crevices, and must be designed and constructed to allow easy cleaning and facilitate maintenance.

7.4.2.2.7 Kick Plates (21)

Kick plates must be designed so that the areas behind them are ACCESSIBLE for inspection and cleaning by being easily REMOVABLE or capable of being rotated open without unlocking EQUIPMENT doors.

7.4.2.2.8 Grease Filters (21)

If not designed to be CLEANED IN PLACE, filters or other grease-extracting EQUIPMENT must be designed to be READILY REMOVABLE for cleaning and replacement.

7.4.2.3 Food TMDs (20)

FOOD TEMPERATURE-MEASURING DEVICES must be provided and READILY ACCESSIBLE for use in ensuring attainment and maintenance of FOOD temperatures. Tip-sensitive TEMPERATURE-MEASURING DEVICES, such as a thermocouple or thermistor, must be used for measuring thin FOOD products.

7.4.2.3.1 Food TMD Accuracy (20)**FOOD TEMPERATURE-MEASURING DEVICES**

- Scaled only in Celsius or dually scaled in Celsius and Fahrenheit must be accurate to $\pm 1^{\circ}\text{C}$ ($\pm 2^{\circ}\text{F}$) in the intended range of use.
- Scaled only in Fahrenheit must be accurate to $\pm 2^{\circ}\text{F}$ in the intended range of use.

FOOD TEMPERATURE-MEASURING DEVICES must have a numerical scale, printed record, or digital readout in increments no greater than 1°C (2°F) in the intended range of use.

7.4.2.3.2 Ambient Air TMD Accuracy (21)**Ambient air TEMPERATURE-MEASURING DEVICES**

- Scaled in Celsius or dually scaled in Celsius and Fahrenheit must be designed to be easily readable and accurate to $\pm 1.5^{\circ}\text{C}$ ($\pm 3^{\circ}\text{F}$) in the intended range of use.
- Scaled only in Fahrenheit must be accurate to $\pm 3^{\circ}\text{F}$ in the intended range of use.

7.4.2.4 Functionality**7.4.2.4.1 Ventilation Hood Design (37)**

Exhaust ventilation hood systems in FOOD PREPARATION and WAREWASHING areas—including components such as hoods, fans, guards, and ducting—must be designed to prevent grease or condensation from draining or dripping onto FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.4.2.4.2 Equipment Openings, Closures, and Deflectors (20)

EQUIPMENT openings, closures, and deflectors must conform to the following:

- A cover or lid for EQUIPMENT must overlap the opening and be sloped to drain.
- An opening in the top of a unit of EQUIPMENT and designed for use with a cover or lid must be flanged upward at least 5 millimeters (2/10 of an inch).
- Fixed piping, TEMPERATURE-MEASURING DEVICES, rotary shafts, and other parts extending into EQUIPMENT must be provided with a watertight joint at the point where the item enters the EQUIPMENT.
- If a watertight joint is not provided, the piping, TEMPERATURE-MEASURING DEVICES, rotary shafts, and other parts extending through the openings must be equipped with an apron designed to deflect condensation,

drips, and dust from openings into the FOOD; the opening must be flanged at least 5 millimeters (2/10 of an inch).

7.4.2.4.3 Beverage/Ice Dispensing (20)

In EQUIPMENT that dispenses liquid FOOD or ice in unpackaged form,

- The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the FOOD must be designed in a manner (such as with barriers, baffles, or drip aprons) so that drips from condensation and splash are diverted from the opening of the container receiving the FOOD.
- The delivery tube, chute, and orifice must be protected from manual contact (such as by being recessed).
- The delivery tube or chute and orifice of EQUIPMENT used to vend liquid FOOD or ice in unpackaged form to self-service CONSUMERS must be designed so the delivery tube or chute and orifice are protected from dust, insects, rodents, and other CONTAMINATION by a self-closing door if the EQUIPMENT
 - Is in an outside area that does not otherwise afford protection against rain, windblown debris, insects, rodents, and other contaminants present in the environment OR
 - Is available for self service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE.

The dispensing EQUIPMENT actuating lever or mechanism and filling device of CONSUMER self-service BEVERAGE dispensing EQUIPMENT must be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

7.4.2.4.4 Bearings/Gears (21)

EQUIPMENT containing bearings and gears that require lubricants must be designed and constructed so the lubricant cannot leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

7.4.2.4.5 Beverage Line Cooling (20)

BEVERAGE tubing and cold-plate BEVERAGE cooling devices must not be installed in contact with stored ice. **This guidance does not apply to cold plates constructed integrally without SEAMS in an ice storage bin.**

7.4.2.4.6 Equipment Drainage (21)

EQUIPMENT compartments subject to accumulation of moisture because of conditions such as condensation, FOOD or BEVERAGE drip, or water from melting ice must be sloped to an outlet that allows complete draining.

7.4.2.4.7 Drain Lines (20)

Liquid waste drain lines must not pass through an ice machine or ice storage bin.

7.4.2.4.8 Condenser Unit (21)

If a condenser unit is an integral component of EQUIPMENT, the condenser unit must be separated from the FOOD and FOOD STORAGE space by a dustproof barrier.

7.4.2.4.9 Ambient Air TMDs (21)

TEMPERATURE-MEASURING DEVICES must conform to the following guidelines:

- In a mechanically refrigerated FOOD storage unit, the sensor of a TEMPERATURE-MEASURING DEVICE must be located to measure the air temperature in the warmest part of the unit.
- In a hot-FOOD storage unit, the sensor of a TEMPERATURE-MEASURING DEVICE must be located to measure the air temperature in the coolest part of the unit.
- Cold or hot holding EQUIPMENT used for POTENTIALLY HAZARDOUS FOOD must be designed to include and must be equipped with at least one integral or affixed TEMPERATURE-MEASURING DEVICE that is located to allow easy viewing of the device's temperature display.
- The above bullets do not apply to EQUIPMENT for which the placement of a TEMPERATURE-MEASURING DEVICE is not a practical means for measuring the ambient air surrounding the FOOD because of the design,

type, and use of the EQUIPMENT (such as calrod units, heat lamps, cold plates, bains-marie, steam tables, insulated FOOD transport containers, and salad bars).

- TEMPERATURE-MEASURING DEVICES must be easily readable.

7.4.2.5 Food Equipment Standards and Classification

7.4.2.5.1 Food-Contact Equipment Standards (20)

FOOD-CONTACT SURFACES of FOOD EQUIPMENT must comply with American National Standards Institute (ANSI), National Sanitation Foundation International (NSF International), or other internationally accredited FOOD EQUIPMENT sanitation standards for materials, design, and construction.

7.4.2.5.2 Nonfood-Contact Equipment Standards (21)

NONFOOD-CONTACT SURFACES of FOOD EQUIPMENT must comply with American National Standards Institute (ANSI), National Sanitation Foundation International (NSF International), or other internationally accredited FOOD EQUIPMENT sanitation standards for materials, design, and construction.

7.4.3 Numbers and Capacities

7.4.3.1 Cooling, Heating, and Holding Capacities

7.4.3.1.1 Cold/Hot Holding Capacity (20)

EQUIPMENT for cooling and heating FOOD and for holding cold and hot FOOD must be sufficient in number and capacity to maintain temperatures in POTENTIALLY HAZARDOUS FOOD.

7.4.3.2 Ventilation Hood Systems

7.4.3.2.1 Ventilation Hood (37)

Ventilation hood systems and devices must be sufficient in number and capacity to prevent grease or condensation from collecting on BULKHEADS and DECKHEADS.

7.4.4 Equipment Location and Installation

7.4.4.1 Fixed Equipment, Spacing or Sealing

7.4.4.1.1 Fixed Equipment Installation (21)

EQUIPMENT that is fixed because it is not EASILY MOVABLE must be installed in one of the following ways:

- Spaced to allow access for cleaning along the sides, behind, under, and above the EQUIPMENT.
- Spaced from adjoining EQUIPMENT, BULKHEAD, and DECKHEAD at a distance of not more than 0.8 millimeters or 1/32 inch.
- Sealed to adjoining EQUIPMENT or BULKHEAD (if the EQUIPMENT is exposed to spillage or seepage).

7.4.4.1.2 Table-Mounted Sealed or Elevated (21)

TABLE-MOUNTED EQUIPMENT that is not EASILY MOVABLE must be installed to allow cleaning of the EQUIPMENT and areas underneath and around the EQUIPMENT in one of the following ways:

- Sealed to the table.
- Elevated on legs.

7.4.4.2 Fixed Equipment, Elevation or Sealing

7.4.4.2.1 Deck-Mounted Sealed or Elevated (21)

Deck-mounted EQUIPMENT that is not EASILY MOVABLE must be sealed to the deck or elevated on legs that provide at least a 150-millimeter (6-inch) clearance between the deck and the EQUIPMENT.

7.4.4.2.2 Deck-Mounted Clearance

If no part of the deck under the deck-mounted EQUIPMENT is more than 150 millimeters (6 inches) from the point of cleaning access, the clearance space may be only 100 millimeters (4 inches).

7.4.4.2.3 Table-Mounted Elevated (21)

TABLE-MOUNTED EQUIPMENT that is not EASILY MOVABLE must be elevated on legs that provide at least a 100-millimeter (4-inch) clearance between the table and the EQUIPMENT.

7.4.4.2.4 Table-Mounted Clearance

The clearance space between the table and TABLE-MOUNTED EQUIPMENT may be either of the following:

- 75 millimeters (3 inches) if the horizontal distance of the table top under the EQUIPMENT is no more than 500 millimeters (20 inches) from the point of access for cleaning.
- 50 millimeters (2 inches) if the horizontal distance of the table top under the EQUIPMENT is no more than 75 millimeters (3 inches) from the point of access for cleaning.

7.4.5 Maintenance and Operation**7.4.5.1 Equipment****7.4.5.1.1 Food-Contact Equipment in Good Repair (20)**

FOOD-contact EQUIPMENT must be maintained in good repair and proper adjustment, including the following:

- EQUIPMENT must be maintained in a state of repair and condition that meets the materials, design, construction, and operation specifications of these guidelines.
- Can opener parts that cut or pierce must be kept sharp to minimize the creation of metal fragments that can contaminate FOOD when the container is opened.

7.4.5.1.2 Nonfood-Contact Equipment in Good Repair (21)

Nonfood-CONTACT EQUIPMENT must be maintained in good repair and proper adjustment, including the following:

- EQUIPMENT must be maintained in a state of repair and condition that meets the materials, design, construction, and operation specifications of these guidelines.
- EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates must be kept intact and tight and adjusted in accordance with manufacturer's specifications.

7.4.5.1.3 Cutting Boards (20)

Surfaces such as cutting blocks and boards subject to scratching and scoring must be resurfaced if they can no longer be effectively cleaned and sanitized or discarded if they cannot be resurfaced.

7.4.5.1.4 Microwave Ovens (20)

Microwave ovens must meet the safety standards specified in 21 CFR 1030.10 Microwave Ovens, or equivalent.

7.4.5.2 Good Repair and Calibration

7.4.5.2.1 *Utensils and TMDs in Good Repair and Calibration (20)*

UTENSILS and TEMPERATURE-MEASURING DEVICES must be maintained in good repair and proper adjustment, including the following:

- UTENSILS must be maintained in a state of repair or condition that meets the materials, design, and construction specifications of these guidelines or must be discarded.
- FOOD TEMPERATURE-MEASURING DEVICES must be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

7.4.5.2.2 *Ambient Air TMDs Good Repair and Calibration (21)*

Ambient air TEMPERATURE-MEASURING DEVICES must be maintained in good repair and be accurate within the intended range of use.

7.4.5.3 Single-Service and Single-Use Articles

7.4.5.3.1 *No Reuse (28)*

SINGLE-SERVICE and SINGLE-USE ARTICLES must not be reused.

7.4.5.3.2 *Bulk Milk Tubes (20)*

Bulk milk container dispensing tubes must be cut on the diagonal, leaving no more than 25 millimeters (1 inch) protruding from the chilled dispensing head.

7.4.5.3.3 *Shell Reuse (28)*

Mollusk and crustacean shells must not be used more than once as serving containers.

7.5 Warewashing

7.5.1 Warewashing Design and Construction

7.5.1.1 Warewashing Measuring Device Accuracy (22)

Provide a maximum registering TEMPERATURE-MEASURING DEVICE to verify the temperature in the warewash machines and the three-compartment sink.

7.5.1.1.1 Water TMD Accuracy (22)

Water TEMPERATURE-MEASURING DEVICES scaled

- In Celsius or dually scaled in Celsius and Fahrenheit must be designed to be accurate to $\pm 1.5^{\circ}\text{C}$ ($\pm 3^{\circ}\text{F}$) in the intended range of use.
- Only in Fahrenheit must be designed to be accurate to $\pm 3^{\circ}\text{F}$ in the intended range of use.

7.5.1.1.2 Pressure Gauge Accuracy (22)

Pressure measuring devices that display pressures in the water supply line for the fresh hot water sanitizing rinse must have increments of 7 kilopascals (1 pound per square inch or 0.07 bar) or smaller and must be accurate to ± 14 kilopascals (± 2 pounds per square inch or ± 0.14 bar) in the 100–170 kilopascals (15–25 pounds per square inch or 1.03–1.72 bars) range.

7.5.1.2 Warewashing Functionality**7.5.1.2.1 Water TMDs Readable (22)**

Water TEMPERATURE-MEASURING DEVICES must be designed to be easily readable.

7.5.1.2.2 Water TMD Scale (22)

Water TEMPERATURE-MEASURING DEVICES on WAREWASHING machines must have a numerical scale, printed record, or digital readout in increments no greater than 1°C (2°F) in the intended range of use.

7.5.1.2.3 Warewasher Data Plate (22)

A WAREWASHING machine must be provided with an easily ACCESSIBLE and readable data plate affixed to or posted adjacent to the machine that indicates the machine's design and operating specifications including the

- Wash tank, rinse tank(s) if present, and final sanitizing rinse temperatures.
- Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse.
- Conveyor speed in meters or feet per minute or minimum transit time for belt conveyor machines, minimum transit time for rack conveyor machines, and wash and final sanitizing rinse times as specified by the manufacturer for stationary rack machines.

7.5.1.2.4 Baffles/Curtains (22)

WAREWASHING machine wash and rinse tanks must be equipped with baffles, curtains, or other means to minimize internal CROSS-CONTAMINATION of the solutions in wash and rinse tanks.

7.5.1.2.5 Warewash TMDs (22)

A WAREWASHING machine must be equipped with a TEMPERATURE-MEASURING DEVICE that indicates the temperature of the water in each wash tank, in rinse tank(s) if present, and in the final sanitizing rinse manifold.

7.5.1.2.6 Pressure Gauge (22)

WAREWASHING machines that provide a fresh hot water sanitizing rinse must be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the WAREWASHING machine.

If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device must be mounted in a 6.4-millimeter (1/4-inch) iron pipe size (IPS) valve.

These guidelines do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

7.5.1.2.7 Manual Sanitizing Booster Heater (22)

If hot water is used for SANITIZATION in manual WAREWASHING operations, the sanitizing compartment of the sink must be designed with an integral heating device capable of maintaining water at a temperature not less than 77°C (171°F).

7.5.1.2.8 Self Draining (22)

Sinks and drainboards of WAREWASHING sinks and machines must be self draining.

7.5.2 Warewashing Numbers and Capacities**7.5.2.1 Three-Compartment Sinks****7.5.2.1.1 Three-Compartment Sink (22)**

A sink with at least three compartments must be provided for manually washing, rinsing, and sanitizing EQUIPMENT and UTENSILS.

7.5.2.1.2 Size (22)

Sink compartments must be large enough to accommodate immersion of the largest EQUIPMENT and UTENSILS. If EQUIPMENT or UTENSILS are too large for the WAREWASHING sink, a WAREWASHING machine or alternative EQUIPMENT, such as a three-bucket system, must be used.

7.5.2.1.3 Manual Warewashing Alternatives

Alternative manual WAREWASHING EQUIPMENT may be used when there are special cleaning needs or constraints and its use is APPROVED. Alternative manual WAREWASHING EQUIPMENT may include the following:

- **High-pressure detergent sprayers.**
- **Low- or line-pressure spray detergent foamers.**
- **Other task-specific cleaning EQUIPMENT.**
- **Brushes or other implements.**
- **Receptacles such as a three-bucket system that substitute for the compartments of a three-compartment sink.**

7.5.2.2 Drainboards**7.5.2.2.1 Soiled/Clean Storage (22)**

Drainboards, UTENSIL racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation must be provided for UTENSIL holding before cleaning and after sanitizing.

7.5.2.3 Sanitizing Solutions, Testing Devices**7.5.2.3.1 Test Kit (22)**

A test kit or other device that accurately measures the concentration in milligrams per liter (parts per million) of sanitizing solutions must be provided.

7.5.3 Warewashing Equipment Maintenance and Operation

7.5.3.1 Good Repair and Proper Adjustment

7.5.3.1.1 Warewash Equipment Repair (22)

WAREWASHING EQUIPMENT must be maintained in good repair and proper adjustment, including the following:

- WAREWASHING EQUIPMENT must be maintained in a state of repair and condition that meets the standards of the materials, design, and construction of these guidelines.
- Water pressure and water TEMPERATURE-MEASURING DEVICES must be maintained in good repair and be accurate within the intended range of use.

7.5.3.1.2 Warewash Equipment Cleaning (22)

WAREWASHING machines, drainboards, and the compartments of sinks, basins, or other receptacles used for washing and rinsing EQUIPMENT, UTENSILS, or raw FOODS, or laundering wiping cloths must be cleaned as follows:

- Before use.
- Throughout the day at a frequency necessary to prevent **recontamination and accumulation of debris** and to ensure the EQUIPMENT performs its intended function.
- At least every 24 hours (if used).

7.5.3.1.3 Warewash Equipment Operation (22)

A WAREWASHING machine and its auxiliary components must be operated in accordance with the machine's data plate and other manufacturer's instructions.

A WAREWASHING machine's conveyor speed or automatic cycle times must be maintained accurately timed in accordance with manufacturer's specifications.

7.5.3.1.4 Cleaners (22)

When used for WAREWASHING, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual WAREWASHING EQUIPMENT must contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.

7.5.3.1.5 Solution Clean (22)

The wash, rinse, and sanitize solutions must be maintained clean.

7.5.3.2 Wash Temperatures

7.5.3.2.1 **Manual Wash Temperature (23)**

The temperature of the wash solution in manual WAREWASHING EQUIPMENT must be maintained at not less than the temperature specified on the cleaning agent manufacturer's label instructions.

7.5.3.2.2 **Warewash Wash Temperatures (23)**

The temperature of the wash solution in spray type warewashers that use hot water to sanitize must not be less than

- 74°C (165°F) for a stationary-rack, single-temperature machine.
- 66°C (150°F) for a stationary-rack, dual-temperature machine.
- 71°C (160°F) for a single-tank, conveyor, dual-temperature machine.
- 66°C (150°F) for a multi-tank, conveyor, multitemperature machine.

High wash tank temperatures do not compensate for low auxiliary rinse and/or hot water final rinse sanitizing temperatures.

7.5.3.2.3 **Wash Temperatures for Chemical Machines (23)**

The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize must not be less than 49°C (120°F).

7.5.3.2.4 **Alarm (22)**

Warewash machines for vessels built to *VSP 2005 Construction Guidelines* or later or installed/replaced on existing vessels after July 2005 must be equipped with an audible or visual alarm that indicates when the sanitizing temperature or chemical SANITIZER level drops below the levels stated on the machine data plate.

7.5.4 Cleaning Equipment and Utensils

7.5.4.1 Cleaning Frequency

7.5.4.1.1 **Food-Contact Surfaces Clean (26 C)**

FOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS must be clean to sight and touch.

7.5.4.1.2 **Encrusted (26 C)**

FOOD-CONTACT SURFACES of cooking EQUIPMENT and pans must be kept free of encrusted grease deposits and other soil accumulations.

7.5.4.1.3 Nonfood-Contact Surfaces (27)

NONFOOD-CONTACT SURFACES of EQUIPMENT must be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.

7.5.4.1.4 Food-Contact Cleaning Frequency (26 C)

FOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS must be washed, rinsed, and sanitized as follows:

- Before each use with a different type of raw animal FOOD such as beef, FISH, lamb, pork, or POULTRY.
- Each time there is a change from working with raw FOODS to working with READY-TO-EAT FOODS.
- Between uses with raw fruits and vegetables and with POTENTIALLY HAZARDOUS FOOD.
- Before using or storing a FOOD TEMPERATURE-MEASURING DEVICE.
- Any time during the operation when CONTAMINATION might have occurred.

7.5.4.1.5 In-Use Food-Contact Equipment (28)

If used with POTENTIALLY HAZARDOUS FOOD, FOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS used on a continuing basis must be washed, rinsed, and sanitized at least every 4 hours.

7.5.4.1.6 Dispensing Equipment Cleaning (28)

Cleaning of EQUIPMENT such as ice bins; BEVERAGE dispensing nozzles; and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks, and distribution lines, BEVERAGE dispensing lines, and syrup dispensing lines or tubes; and coffee bean grinders must be conducted

- At a frequency specified by the manufacturer, or
- In the absence of manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

7.5.4.1.7 Cooking/Baking Equipment Cleaning (28)

Cooking and baking EQUIPMENT must be cleaned as follows:

- FOOD-CONTACT SURFACES of cooking and baking EQUIPMENT must be cleaned at least every 24 hours.
- Cavities and door seals of microwave ovens must be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

7.5.4.2 Dry Cleaning Methods

7.5.4.2.1 Dry Cleaning (28)

If dry cleaning is used, it must be conducted as follows:

- Methods such as brushing, scraping, and vacuuming must contact only surfaces soiled with dry FOOD residues that are not potentially hazardous.
- Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES must not be used for any other purpose.

7.5.4.3 Precleaning and Racking

7.5.4.3.1 Precleaning/Scrapping (23)

FOOD debris on EQUIPMENT and UTENSILS must be scrapped over a waste disposal unit, pulper, or garbage receptacle or must be removed in a WAREWASHING machine with a prewash cycle.

7.5.4.3.2 Presoak/Scrubbed (23)

If necessary for effective cleaning, EQUIPMENT and UTENSILS must be preflushed, presoaked, or scrubbed with abrasives.

7.5.4.3.3 Racking (22)

Soiled items to be cleaned in a WAREWASHING machine must be loaded into racks, trays, or baskets or onto conveyors in a position that

- Exposes the items to the unobstructed spray from all cycles and
- Allows the items to drain.

7.5.4.4 Wet Cleaning

7.5.4.4.1 Washing (23)

FOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS must be effectively washed to remove or completely loosen soils by using whatever manual or mechanical means is necessary (such as application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices).

7.5.4.4.2 Soil Specific (22)

The washing procedures selected must be based on the type and purpose of the EQUIPMENT or UTENSIL and on the type of soil to be removed.

7.5.4.5 Alternative Manual Warewashing Procedures

7.5.4.5.1 Alternative Warewashing Procedures (23)

If washing in sink compartments or a WAREWASHING machine is impractical (such as when the EQUIPMENT is fixed or the UTENSILS are too large), washing must be done by using alternative manual WAREWASHING EQUIPMENT in accordance with the following procedures:

- EQUIPMENT must be disassembled as necessary to allow access of the detergent solution to all parts.
- EQUIPMENT components and UTENSILS must be scrapped or rough-cleaned to remove FOOD particle accumulation.
- EQUIPMENT and UTENSILS must be washed.

7.5.4.5.2 Sponges Limited (22)

Sponges must not be used in contact with cleaned and sanitized or in-use FOOD-CONTACT SURFACES.

7.5.4.6 Rinsing Procedures

7.5.4.6.1 Rinsing (23)

Washed EQUIPMENT and UTENSILS must be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted with water by using one of the following procedures:

- Use of a distinct, separate water rinse after washing and before sanitizing (if using a three-compartment sink, alternative manual WAREWASHING EQUIPMENT equivalent to a three-compartment sink, or a three-step washing, rinsing, and sanitizing procedure in a WAREWASHING system for CIP EQUIPMENT).
- Use of a nondistinct water rinse integrated in the application of the sanitizing solution and wasted immediately after each application (if using a WAREWASHING machine that does not recycle the sanitizing solution or if using alternative manual WAREWASHING EQUIPMENT such as sprayers).
- Use of a nondistinct water rinse integrated in the application of the sanitizing solution (if using a WAREWASHING machine that recycles the sanitizing solution for use in the next wash cycle).

7.5.5 Sanitizing

7.5.5.1 Food-Contact Surfaces (24 C)

FOOD-CONTACT SURFACES of EQUIPMENT and UTENSILS must be sanitized.

7.5.5.2 Sanitizing Temperatures

7.5.5.2.1 *Manual Hot-Water Sanitizing (24 C)*

In a manual operation, if immersion in hot water is used for sanitizing,

- The temperature of the water must be maintained at 77°C (171°F) or above and
- The FOOD-CONTACT SURFACE must be immersed for at least 30 seconds.

7.5.5.2.2 *Warewasher Hot-Water Sanitizing (24 C)*

In a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold must not be more than 90°C (194°F) or less than

- 74°C (165°F) for a stationary rack, single-temperature machine.
- 82°C (180°F) for all other machines.

The UTENSIL surface temperature must not be less than 71°C (160°F) as measured by an irreversible registering temperature indicator.

The maximum temperature of 90°C (194°F) does not apply to the high pressure and temperature systems with wand-type, hand-held spraying devices used for in-place cleaning and sanitizing of EQUIPMENT such as MEAT saws.

7.5.5.2.3 *Warewasher Hot-Water Sanitizing Pressure (22)*

The flow pressure of the fresh hot water sanitizing rinse in a WAREWASHING machine must not be less than 34.5 kilopascals (5 pounds per square inch or 0.34 bars) or more than 207 kilopascals (30 pounds per square inch or 2.07 bars) as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve.

7.5.5.3 Sanitizing Concentrations**7.5.5.3.1 Chemical Sanitizing Solutions (24 C)**

A chemical SANITIZER used in a sanitizing solution for a manual or mechanical operation must be listed in 40 CFR 180.940 Sanitizing Solutions.

7.5.5.3.2 Chemical Sanitizing Exposure (24 C)

A chemical SANITIZER must be used in accordance with the EPA-APPROVED manufacturer's label use instructions at a minimum temperature of 24°C (75°F) with an exposure time of 7 seconds for a chlorine solution and 30 seconds for other chemical SANITIZERS.

7.5.5.3.3 Chemical Sanitizing Concentration (24 C)

Sanitizing solutions must be used with the following concentrations:

- A chlorine solution must have a concentration between 50 MG/L (ppm) and 200 MG/L (ppm).
- An iodine solution must have a pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective AND a concentration between 12.5 MG/L (ppm) and 25 MG/L (ppm).
- A quaternary ammonium compound solution must have a concentration as specified in 40 CFR 180.940 Sanitizing Solutions AND as indicated by the manufacturer's use directions included in the labeling.

If another solution concentration or pH of a chlorine, iodine, or quaternary ammonium compound is used, the vessel must demonstrate to VSP that the solution achieves SANITIZATION and the use of the solution must be APPROVED.

If a chemical SANITIZER other than a chlorine, iodine, or quaternary ammonium compound is used, it must be applied in accordance with the manufacturer's use directions included in the labeling.

7.5.5.3.4 Sanitizer Concentration Testing (22)

Concentration of the sanitizing solution must be accurately determined by using a test kit or other device.

7.5.6 Protection of Clean Items

7.5.6.1 Drying

7.5.6.1.1 *Air Dried/Drained (28)*

After cleaning and sanitizing, EQUIPMENT and UTENSILS must be air dried or ADEQUATELY drained before contact with FOOD. Cleaned, sanitized, and air-dried dishware, glassware, and **UTENSILS may be polished with a clean, dry, lint-free cloth that is maintained clean and dry.**

7.5.6.2 Lubricating and Reassembling

7.5.6.2.1 *Lubricating (28)*

Lubricants must be applied to FOOD-CONTACT SURFACES that require lubrication in a manner that does not contaminate FOOD-CONTACT SURFACES.

7.5.6.2.2 *Assembling (28)*

EQUIPMENT must be reassembled so that FOOD-CONTACT SURFACES are not contaminated.

7.5.6.3 Storing Equipment, Utensils, Linens, and Single-Service and Single-Use Articles

7.5.6.3.1 *Storing Protected (28)*

Cleaned EQUIPMENT and UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES must be stored

- In a clean, dry location.
- In a location where they are not exposed to splash, dust, or other CONTAMINATION.
- At least 150 millimeters (6 inches) above the deck unless in packages on pallets, skids, or racks, which may be 127 millimeters (5 inches) above the deck.

EQUIPMENT can be stored in unfinished lockers or rooms in sealed or resealed original packaging, plastic boxes with complete coverage (plastic wrap if needed), and/or wrapped in plastic. EQUIPMENT must be off the deck (rack/deck stand/pallet) and the deck must be clean.

EQUIPMENT and shelving in unfinished lockers or rooms must be kept clean. Shelving does not need to meet EASILY CLEANABLE standard.

No SINGLE-SERVICE/SINGLE-USE ITEMS or chemicals should be stored in unfinished lockers or rooms.

Exposed GREY WATER and BLACK WATER lines must not be in unfinished EQUIPMENT lockers if they are push-fit or coupled. These lines can be solid pipe, butt-welded, or sleeve-welded. If plastic pipe, the lines can be heat fused or chemically welded.

7.5.6.3.2 Storing Inverted (28)

Clean EQUIPMENT and UTENSILS must be stored

- In a self-draining position that allows air drying.
- Covered or inverted.

7.5.6.3.3 Preset Tableware (28)

TABLEWARE preset longer than 4 hours before the beginning of service must be protected from CONTAMINATION by being wrapped, covered, or inverted.

When TABLEWARE is preset, exposed unused settings must be

- removed at the time a CONSUMER is seated or
- washed, rinsed, and sanitized before further use if the settings are not removed when a CONSUMER is seated.

7.5.6.3.4 Original Package (28)

SINGLE-SERVICE and SINGLE-USE ARTICLES must be kept in the original protective package or stored by using other means that afford protection from CONTAMINATION until used.

7.5.6.3.5 Utensil Dispensing (28)

Eating UTENSILS dispensed at a CONSUMER self-service unit such as a buffet or salad bar must be protected from CONTAMINATION.

7.5.7 Laundering

7.5.7.1 Laundry Facilities

7.5.7.1.1 Laundry Equipment (28)

If LINENS used in FOOD AREAS are laundered on the vessel, a mechanical clothes washer and dryer must be provided and used.

7.5.7.1.2 Laundry Operations Location (28)

Laundry operations must be located to protect operations from CONTAMINATION and only located where there are none of the following: Exposed FOOD; clean EQUIPMENT, UTENSILS, and

LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.5.7.2 Laundry Procedures

7.5.7.2.1 Laundry Frequency (28)

LINENS that do not come in direct contact with FOOD must be laundered between operations if they become wet, sticky, or visibly soiled.

7.5.7.2.2 Cloth Gloves (28)

Cloth gloves must be laundered before being used with a different type of raw animal FOOD such as beef, lamb, pork, and FISH.

7.5.7.2.3 Linens/Napkins (28)

LINENS and napkins used to line FOOD-service containers and cloth napkins must be laundered between each use.

7.5.7.2.4 Wet Wiping Cloths (28)

Wet wiping cloths must be laundered daily.

7.5.7.2.5 Dry Wiping Cloths (28)

Dry wiping cloths must be laundered as necessary to prevent CONTAMINATION of FOOD and clean serving UTENSILS.

7.5.7.2.6 Laundry Procedures (28)

Soiled LINENS must be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent CONTAMINATION of FOOD, clean EQUIPMENT, clean UTENSILS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.5.7.2.7 Washing (28)

LINENS must be mechanically washed.

7.6 Poisonous and Toxic Materials

7.6.1 Identification

7.6.1.1 Labeling

7.6.1.1.1 Manufacturer Label (31 C)

Original containers of POISONOUS OR TOXIC MATERIALS and PERSONAL-CARE ITEMS must bear a legible manufacturer's label.

7.6.1.1.2 Working Containers (31 C)

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and SANITIZERS taken from bulk supplies must be clearly and individually identified with the common name of the material.

7.6.2 Operational Supplies and Applications**7.6.2.1 Storage****7.6.2.1.1 Pesticide/Rodenticide Locker (31 C)**

PESTICIDES, insecticides, and rodenticides must be stored in a locked area of the vessel that is not in a FOOD AREA.

7.6.2.1.2 Cleaning Materials Locker (31 C)

POISONOUS OR TOXIC MATERIALS used in the cleaning and maintenance of FOOD AREAS must be stored in a cleaning materials locker so they cannot contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.6.2.1.3 Exemptions

This guideline does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent CONTAMINATION of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.6.2.2 Use**7.6.2.2.1 Necessary Materials (31 C)**

Only POISONOUS OR TOXIC MATERIALS required for the operation and maintenance of a FOOD AREA of the vessel—such as for cleaning and sanitizing EQUIPMENT and UTENSILS and controlling insects and rodents—are allowed in the FOOD AREAS of the vessel.

7.6.2.2.2 Use Conditions (31 C)

POISONOUS OR TOXIC MATERIALS must be used according to the following:

- LAW and these guidelines.
- Manufacturer's use directions included in labeling (and, for a PESTICIDE, manufacturer's label instructions stating that use is allowed in a FOOD AREA).

- Conditions of certification (if certification is required) for use of the pest-control materials.

7.6.2.2.3 Application (31 C)

POISONOUS OR TOXIC MATERIALS must be applied in a manner that prevents

- A HAZARD to employees or other persons.
- CONTAMINATION including toxic residues resulting from drip, drain, fog, splash, or spray on FOOD; EQUIPMENT; UTENSILS; LINENS; and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.6.2.2.4 Restricted-Use Applications (31 C)

When a RESTRICTED-USE PESTICIDE is applied, FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES must be removed; covered with impermeable covers; or other precautions taken.

7.6.2.2.5 Restricted-Use Applicator (31 C)

A RESTRICTED-USE PESTICIDE must be applied only by an applicator certified as defined in 7 USC 136(e) Certified Applicator of the Federal Insecticide, Fungicide, and Rodenticide Act or a person under the direct supervision of a certified applicator.

7.6.2.2.6 Equipment Cleaning and Sanitizing (31 C)

FOOD EQUIPMENT and UTENSILS in the area treated must be cleaned and sanitized after the application.

7.6.2.2.7 Containers (31 C)

A container previously used to store cleanser, chemicals, or POISONOUS OR TOXIC MATERIALS must not be used to store, transport, or dispense FOOD. Additionally, FOOD containers must not be used to store, transport, or dispense cleanser, chemicals, or POISONOUS OR TOXIC MATERIALS.

7.6.2.3 Sanitizers and Other Food Area Chemicals**7.6.2.3.1 Sanitizers (31 C)**

Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES must meet the requirements specified in 21 CFR 178.1010 Sanitizing Solutions.

7.6.2.3.2 Fruit/Vegetable Wash (31 C)

Chemicals used to wash or peel raw whole fruits and vegetables must meet the requirements specified in 21 CFR 173.315

Chemicals Used in Washing or to Assist in the Peeling of Fruits and Vegetables (Annex 13.12).

7.6.2.3.3 *Boiler Water Additives (31 C)*

Chemicals used as boiler water ADDITIVES for culinary steam or other FOOD AREA purposes must meet the requirements specified in 21 CFR 173.310 Boiler Water ADDITIVES.

7.6.2.3.4 *Drying Agents (31 C)*

Drying agents used in conjunction with SANITIZATION must contain only components listed as one of the following:

- Generally recognized as safe for use in FOOD as specified in 21 CFR 182 Substances Generally Recognized as Safe or in 21 CFR 184 Direct FOOD Substances Affirmed as Generally Recognized as Safe.
- Generally recognized as safe for the intended use as specified in 21 CFR 186 Indirect FOOD Substances Affirmed as Generally Recognized as Safe.
- APPROVED for use as a drying agent under a prior sanction specified in 21 CFR 181 Prior-Sanctioned FOOD Ingredients.
- Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 175-178.
- APPROVED for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of Regulation for Substances Used in FOOD-Contact Articles.

7.6.2.3.5 *Approved for Use with Chemical Sanitizers (31 C)*

When used with chemical SANITIZATION, drying agents must be specifically APPROVED for use with chemical sanitizing solutions.

7.6.2.3.6 *Lubricants (31 C)*

Lubricants must meet the requirements specified in 21 CFR 178.3570 Lubricants with Incidental FOOD CONTACT if they are used on FOOD-CONTACT SURFACES; on bearings and gears on or within FOOD-CONTACT SURFACES; or on bearings and gears located so that lubricants may leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

7.6.2.4 Pesticides and Rodenticides

7.6.2.4.1 *Restricted-Use Pesticides (31 C)*

RESTRICTED-USE PESTICIDES used in FOOD AREAS must meet the requirements specified in 40 CFR 152 Subpart I Classification of PESTICIDES.

7.6.2.4.2 *Rodent Bait (31 C)*

Rodent bait used in FOOD AREAS must be contained in a covered, tamper-resistant bait station.

7.6.2.4.3 *Tracking Powder Pesticides (31 C)*

A tracking powder PESTICIDE must not be used in a FOOD AREA.

7.6.2.4.4 *Nontoxic Tracking Powders (19)*

A nontoxic tracking powder such as talcum or flour, if used, must not contaminate FOOD.

7.6.2.4.5 *Prevent Contamination (28)*

If a nontoxic tracking powder such as talcum or flour is used, it must not contaminate EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.6.3 Medicines

7.6.3.1 Restriction and Storage

7.6.3.1.1 *Necessary Medicines (31 C)*

Only medicines necessary for the health of the FOOD EMPLOYEES are allowed in a FOOD AREA.

7.6.3.1.2 *Medicine Labeling/Separation (31 C)*

Medicines in a FOOD AREA for FOOD EMPLOYEES' use must be labeled and be located in an area such as the chef's office to prevent the CONTAMINATION of FOOD, EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.6.3.1.3 *First Aid Supplies (31 C)*

First aid supplies in a FOOD AREA for FOOD EMPLOYEES' use must be labeled and stored in a kit or a container in a location that prevents the CONTAMINATION of FOOD, EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.7 Facilities

7.7.1 Handwashing and Toilet Facilities for **Food Employees**

This applies to toilet facilities for galley personnel even if those facilities are ACCESSIBLE to other crew members.

7.7.1.1 Handwashing Facility Installation

7.7.1.1.1 *Convenient (29 C)*

Each FOOD PREPARATION AREA, bar, WAREWASHING area, and garbage-processing area must have at least one handwashing facility in it.

This applies to self-service and served candy shops where employees serve candy, refill self-service containers, etc.

7.7.1.1.2 *8 Meters/26 Feet (29 C)*

The handwashing facility must be within 8 meters (26 feet) of all parts of the area and should not be located in an adjacent area that requires passage through a closed door where users make hand contact with the door.

Handwash sinks must be at least 750 millimeters (30 inches) above the deck so users do not have to reach excessively to wash their hands.

Counter-mounted handwash sinks may be installed a minimum of 600 millimeters (24 inches) above the deck, as measured at the counter level.

7.7.1.1.3 *Tempered Water (29 C)*

A handwashing sink must be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. For handwash sinks with electronic sensors and other types of handwash sinks where users cannot make temperature adjustments, the temperature after the mixing valve must not exceed 49°C (120°F).

7.7.1.1.4 *Metered Faucet (30)*

A self-closing, slow-closing, or metering faucet must provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

7.7.1.1.5 *Automatic Systems (30)*

An automatic handwashing facility must be installed in accordance with manufacturer's instructions.

7.7.1.1.6 Dispenser/Receptacle (30)

A handwashing facility must include a sink, soap dispenser, single-use towel dispenser, and waste receptacle.

7.7.1.1.7 Sign (30)

A sign stating “wash hands often,” “wash hands frequently,” or similar wording in a language that the FOOD EMPLOYEES understand must be posted over handwashing sinks.

7.7.1.2 Toilet Facility Installation**7.7.1.2.1 Convenient (29 C)**

Toilet rooms must be provided and conveniently located.

7.7.1.2.2 Handwashing Facilities (29 C)

Handwashing facilities must be in or immediately adjacent to toilet rooms or vestibules.

7.7.1.2.3 Sign (30)

A sign must be conspicuously posted on the BULKHEAD adjacent to the door of the toilet or on the back of the door. The sign must state “WASH HANDS AFTER USING TOILET” in a language the FOOD EMPLOYEES understand.

A sign must be posted advising users of toilet facilities to use hand towel, paper towel, or tissue to open the door unless the exit is hands free.

A pictogram that illustrates the correct use and disposal of paper towels may be used in lieu of a sign.

Toilet facilities must be equipped so persons exiting the toilet room are not required to touch the door handle with bare hands.

Where toilet stalls include handwashing facilities, the bare-hands-free contact must begin in the toilet stall. Toilet facilities with multiple exits must have bare-hands-free contact at each exit.

Bare-hands-free contact may be accomplished by methods such as locating paper towel dispensers at sinks and waste containers near the room door, installing mechanically operated doors, or using other effective means.

7.7.1.2.4 Enclosed/Doors (30)

Toilet rooms must be completely enclosed and must have tight-fitting, self-closing doors that must be kept closed except during cleaning or maintenance.

7.7.1.2.5 Waste Receptacle (30)

EASILY CLEANABLE receptacles must be provided for waste materials.

7.7.1.2.6 Unlocked (29 C)

Toilet facilities intended for use by galley personnel must not be locked when the galley is in service.

7.7.1.3 Handwashing and Toilet Facility Maintenance**7.7.1.3.1 Accessible (29 C)**

Handwashing facilities must be used for no other purpose and must be ACCESSIBLE at all times.

7.7.1.3.2 Facilities Clean/Good Repair (30)

Handwashing facilities must be kept clean and in good repair.

7.7.1.3.3 Soap/Towels (30)

Each handwashing facility must have a supply of hand-cleansing soap or detergent and a supply of SINGLE-SERVICE paper towels available.

7.7.1.3.4 Toilets Clean/Good Repair (30)

Toilet fixtures must be kept clean and in good repair.

7.7.1.3.5 Toilet Tissue (30)

A supply of toilet tissue must be provided at each toilet at all times.

7.7.2 Passenger Self-Service Buffet Handwashing Stations (30)**7.7.2.1 Installation Date**

The following section applies to all vessels with a keel laid date of June 1, 2018 or later and any FOOD self-service areas that have been modified since June 1, 2018, including replacement, relocation, or addition of buffet self-service counter(s) or self-service EQUIPMENT.

7.7.2.2 Number

Provide one obvious handwashing station per 100-passenger seating or fraction thereof. Stations should be equally distributed between the major passenger entry points to the buffet area and must be separate from a toilet room.

7.7.2.3 Passenger Entries

Provide handwashing stations at each minor passenger entry to the main buffet areas proportional to the passenger flow, with at least one per entry. These handwash stations can count toward the requirement of one station per 100 passengers.

7.7.2.4 Self-Service Stations Outside the Main Buffet

Provide at least one handwashing station at the passenger entrance of each self-service station outside of the main buffet. BEVERAGE stations are excluded.

7.7.2.5 Equipment and Supplies

The handwashing station must include a handwash sink with hot and cold water, soap dispenser, and SINGLE-USE paper towel dispenser. Electric hand dryers can be installed in addition to paper towel dispensers. Each handwashing station must have a supply of hand-cleansing soap or detergent and a supply of SINGLE-SERVICE paper towels available. Waste receptacles must be provided in close proximity to the handwash sink and sized to accommodate the quantity of paper towel waste generated. The handwashing station may be decorative but must be nonabsorbent, durable, and EASILY CLEANABLE.

7.7.2.6 Automatic Handwashing System

An automatic handwashing system in lieu of a handwash sink is acceptable.

7.7.2.7 Sign

Each handwashing station must have a sign advising passengers to wash hands before eating. A pictogram can be used in lieu of words on the sign.

7.7.2.8 Location

Stations can be installed just outside of the entry. Position the handwashing stations along the passenger flow to the buffets.

7.7.2.9 Lighting

The light intensity must be at least 110 lux (10 foot candles) at passenger

7.7.3 Solid Waste**7.7.3.1 Receptacles and Containers****7.7.3.1.1 Containers (32)**

Receptacles and waste-handling containers for REFUSE and recyclables and for use with materials containing FOOD residue must be durable, nonabsorbent, EASILY CLEANABLE, and

leakproof.

7.7.3.1.2 Insect/Rodent Resistant (32)

Receptacles and waste-handling containers for REFUSE and recyclables and for use with materials containing FOOD residue must be insect and rodent resistant and must have tight-fitting lids.

7.7.3.1.3 Covered/Provided (32)

Receptacles and waste-handling containers must be kept covered when not in continuous use and after they are filled.

7.7.3.1.4 Location (32)

A receptacle or waste-handling container must be provided in each area of the vessel or premise where REFUSE is generated or commonly discarded or where recyclables are placed.

7.7.3.1.5 Wash Facilities (32)

Facilities suitable for washing receptacles and waste-handling containers must be provided separate from FOOD EQUIPMENT and UTENSIL storage areas or FOOD PREPARATION AREAS.

7.7.3.1.6 Design/Supplies (32)

The designated container wash area must be EASILY CLEANABLE and must have tempered water, access to detergent, and suitable drainage.

7.7.3.1.7 Cleaned (32)

Receptacles and waste-handling containers must be cleaned when emptied.

7.7.3.2 Garbage and Refuse Storage Room

7.7.3.2.1 Easily Cleanable/Durable (32)

The dry and refrigerated garbage and REFUSE storage room must be constructed of EASILY CLEANABLE, corrosion-resistant, nonabsorbent, and durable materials.

7.7.3.2.2 Size (32)

The garbage and REFUSE storage room must be large enough to store and process the garbage and REFUSE.

7.7.3.2.3 Prevent Contamination (32)

The garbage and REFUSE storage room must be located so as to prevent CONTAMINATION in FOOD PREPARATION, FOOD STORAGE, and UTENSIL washing areas.

7.7.3.2.4 Good Repair/Clean (32)

The garbage and REFUSE storage room must be maintained in good repair and kept clean.

7.7.4 Liquid Waste Disposal and Plumbing**7.7.4.1 Drain Lines****7.7.4.1.1 Drain Lines (19)**

Drain lines from all fixtures; sinks; appliances; compartments; refrigeration units; or devices used, designed for, or intended to be used in the a) preparation, b) processing, c) storage, or d) handling of FOOD, ice, or drinks must be indirectly connected to appropriate waste systems by means of an AIR GAP or AIR-BREAK.

Drain lines from handwashing and mop sinks may be directly connected to the appropriate waste system.

7.7.4.1.2 Overhead (19)

Drain lines carrying SEWAGE or other liquid waste must not pass directly overhead or horizontally through spaces used for preparing, serving, or storing FOOD or for washing or storing UTENSILS and EQUIPMENT. Drain lines that are unavoidable in these FOOD AREAS must be sleeve-welded and must not have mechanical couplings.

7.7.4.1.3 Warewash Sink/Machine Drains (28)

All drain lines from WAREWASHING sinks or machines must drain through an AIR GAP or AIR-BREAK to a drain or SCUPPER.

7.7.4.2 Liquid Waste Disposal**7.7.4.2.1 Discharge (35)**

BLACK and GRAY WATER must be discharged to the vessel's wastewater disposal system and must not pool on the deck.

7.7.4.2.2 Leakage (35)

Leakage of SEWAGE tanks or discharge of SEWAGE into the bilge or other areas on the vessel is prohibited.

7.7.4.3 Plumbing

7.7.4.3.1 Good Repair (34)

A PLUMBING SYSTEM in a FOOD AREA must be maintained in good repair.

7.7.5 Decks, Bulkheads, and Deckheads

This applies to self-service and served candy shops where employees serve candy and refill self-service containers and CONSUMERS serve themselves.

7.7.5.1 Design and Construction

7.7.5.1.1 Cleanable (33)

Decks, BULKHEADS, and DECKHEADS in FOOD preparation, WAREWASHING, pantries, bars, and FOOD and EQUIPMENT storage areas must be constructed and maintained for easy cleaning.

Decks may be of nonskid construction provided they are EASILY CLEANABLE. Carpet is not considered EASILY CLEANABLE and should not be used in these areas.

EQUIPMENT can be stored in unfinished lockers or rooms in sealed or resealed original packaging, plastic boxes with complete coverage (plastic wrap if needed), and/or wrapped in plastic. EQUIPMENT must be off the deck (rack/deck stand/pallet) and the deck must be clean.

EQUIPMENT and shelving in unfinished lockers or rooms must be kept clean. Shelving does not need to meet EASILY CLEANABLE standard.

No SINGLE-SERVICE/SINGLE-USE ITEMS or chemicals should be stored in unfinished lockers or rooms.

Exposed GREY WATER and BLACK WATER lines must not be in unfinished EQUIPMENT lockers if they are push-fit or coupled. These lines can be solid pipe, butt-welded, or sleeve-welded. If plastic pipe, the lines can be heat fused or chemically welded.

7.7.5.1.2 Coving (33)

BULKHEAD/deck, EQUIPMENT/deck, cabinet/deck, and DECK SINK coaming/deck junctures must have COVING (including galleys, pantries, buffets, bars, waiter stations, dining room work counters, provisions, FOOD STORAGE ROOMS,

EQUIPMENT/UTENSIL storage rooms, and toilet rooms intended for use by galley personnel).

7.7.5.1.3 Finishes (33)

BULKHEADS and DECKHEADS must have SMOOTH, hard finishes and light-colored surfaces.

7.7.5.1.4 Corrosion Resistant (33)

Decks, BULKHEADS, and DECKHEADS in FOOD PREPARATION, WAREWASHING, pantries, and storage areas must be corrosion resistant.

7.7.5.1.5 Attached Equipment (33)

Light fixtures, vent covers, and similar EQUIPMENT attached to the BULKHEADS or DECKHEADS must be EASILY CLEANABLE.

7.7.5.1.6 Exposed Lines (33)

Exposed utility service lines and pipes, including lines for fire detection and protection systems, must be installed so they do not obstruct or prevent cleaning.

7.7.5.1.7 Cleanable Surfaces (33)

Surfaces subject to routine splashes, spillage, or other soiling during normal use must have EASILY CLEANABLE features.

7.7.5.1.8 Deck Mats (33)

Mats must be designed to be REMOVABLE and EASILY CLEANABLE.

7.7.5.2 Maintenance

7.7.5.2.1 Clean (33)

Decks, BULKHEADS, DECKHEADS, and attached EQUIPMENT in FOOD PREPARATION, WAREWASHING, pantries, and storage areas must be cleaned as often as necessary.

7.7.5.2.2 Timing (33)

Cleaning must be done during periods when the least amount of FOOD is exposed.

7.7.5.2.3 Good Repair (33)

Decks, BULKHEADS, and DECKHEADS in FOOD PREPARATION, WAREWASHING, pantries, and storage areas must be maintained in good repair.

7.7.5.2.4 Ventilation (33)

Slots for supply ventilation over the void space (plenum) are not allowed directly over FOOD preparation areas, FOOD STORAGE areas, or clean EQUIPMENT storage.

This section applies to vessels built or renovated in accordance with the *2011 VSP Construction Guidelines* or later.

7.7.6 Lighting

This section applies to self-service and served candy shops where employees serve candy and refill self-service containers and CONSUMERS serve themselves.

7.7.6.1 Intensity**7.7.6.1.1 220 Lux/20 Foot Candles (36)**

The light intensity must be at least 220 lux (20 foot candles) on FOOD preparation surfaces.

The light intensity must be at least 220 lux (20 foot candles) as measured 75 centimeters (30 inches) above the deck in FOOD PREPARATION AREAS, handwashing facilities, WAREWASHING areas, EQUIPMENT, and UTENSIL storage, pantries, toilet rooms, and CONSUMER self-service areas.

7.7.6.1.2 110 Lux/10 Foot Candles (36)

When lights are in use, the light intensity must be at least 110 lux (10 foot candles) at a distance of 75 centimeters (30 inches) above the deck in walk-in refrigerator units and DRY STORAGE AREAS and in other areas and rooms during cleaning operations.

The light intensity must be at least 110 lux (10 foot candles) behind and around mounted EQUIPMENT, including counter-mounted EQUIPMENT.

7.7.6.1.3 Bars and Waiter Stations (36)

The light intensity must be at least 110 lux (10 foot candles) at handwashing stations in bars. In bars and dining room waiter stations, provide 220 lux (20 foot candles) light intensity during cleaning operations.

7.7.6.2 Protected**7.7.6.2.1 Shielded/Shatter Resistant (36)**

Light bulbs must be shielded, coated, or otherwise shatter resistant in areas with exposed FOOD; clean EQUIPMENT, UTENSILS,

and LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.7.6.2.2 Heat Lamps (36)

An infrared or other heat lamp must be protected against breakage by a shield surrounding and extending beyond the bulb so only the face of the bulb is exposed.

7.7.7 Ventilation

7.7.7.1 Design and Operation

7.7.7.1.1 Sufficient (37)

All FOOD preparation, WAREWASHING, and toilet rooms must have sufficient ventilation to keep them free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.

7.7.7.1.2 Effective (37)

Ventilation hood systems and devices must operate effectively to prevent grease and condensate from collecting on the BULKHEADS and DECKHEADS and to remove contaminants generated by EQUIPMENT located under them.

7.7.7.1.3 No Contamination (37)

Heating, ventilating, and air conditioning systems must be designed and installed so that make-up air intake and exhaust vents do not cause CONTAMINATION of FOOD, FOOD-CONTACT SURFACES, EQUIPMENT, or UTENSILS.

7.7.7.2 Maintenance

7.7.7.2.1 Filters (37)

Filters and other grease-extracting EQUIPMENT must be designed to be READILY REMOVABLE for cleaning and replacement if not designed to be CLEANED IN PLACE. Intake and exhaust air ducts must be cleaned and filters changed so they are not a source of CONTAMINATION by dust, dirt, and other materials.

7.7.8 Cleaning Equipment and Unnecessary Articles

7.7.8.1 Storage

7.7.8.1.1 Necessary Articles (38)

Only articles necessary for the FOOD service operation must be stored in FOOD PREPARATION, FOOD STORAGE, and WAREWASHING areas.

7.7.8.1.2 *Cleaning Locker (38)*

Maintenance tools such as mops, brooms, and similar items must be stored in a designated locker so they do not contaminate FOOD, FOOD-CONTACT SURFACES of UTENSILS and EQUIPMENT, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES.

7.7.8.1.3 *Labeled (38)*

The locker must be labeled “CLEANING MATERIALS ONLY.”

7.7.8.1.4 *Orderly Manner (38)*

Maintenance tools such as mops, brooms, and similar items must be stored in an orderly manner that facilitates cleaning of the area used for storing the maintenance tools.

7.7.8.1.5 *Mop Drying (38)*

After use, mops must be placed in a position that allows them to air dry without soiling walls, EQUIPMENT, or supplies.

7.7.8.1.6 *Bucket Storage (38)*

Wash, rinse, and sanitizing buckets or other containers may be stored with maintenance tools as long as they are stored inverted and nested.

8.0 Integrated Pest Management (IPM)

This section includes the following subsections:

- 8.1 Plan Development, Evaluation, and Use of Pesticides
- 8.2 Pest Control
- 8.3 Knowledge

References for 8.0 Integrated Pest Management (IPM) can be found in Annex 14.8.

8.1 Plan Development, Evaluation, and Use of Pesticides

8.1.1 IPM Plans

8.1.1.1 IPM Plan (40)

Each vessel must have an IPM plan to implement effective monitoring and control strategies for pests aboard the vessel.

8.1.1.2 Monitoring (40)

The IPM plan must set a schedule for periodic active monitoring inspections, including some at night or during periods of no or minimal activity.

8.1.1.3 Logs (40)

The IPM plan must include provisions for logs for active monitoring of pest sightings in operational areas of the vessel. The IPM plan also must include provisions for training of crew members in charge of log completion. The time of the active monitoring inspections must be recorded in the log.

8.1.1.4 Passive Surveillance (40)

The IPM plan must include passive surveillance procedures such as glue traps or other passive monitoring devices and must include the location of each. A passive device monitoring log must be maintained.

8.1.1.5 Action and Follow Up (40)

When pests are observed during an inspection, the log must include action taken as well as follow-up inspection results.

8.1.2 Plan Evaluation

8.1.2.1 Evaluation (40)

The vessel's IPM plan must be evaluated for effectiveness periodically or whenever there is a significant change in the vessel's operation or structure (e.g., renovation).

Evaluation may be required more frequently in areas where pest infestations cannot be controlled.

8.1.2.2 Reviews (40)

IPM plan evaluations and changes must be documented in the IPM plan.

8.1.2.3 Inspections (40)

The IPM plan, monitoring records, and other documentation must be available for review during inspections.

8.1.3 IPM and Pesticide Use

8.1.3.1 Pesticide Application

8.1.3.1.1 Pesticide Record (40)

The IPM plan must include a record of **GENERAL-USE and RESTRICTED-USE PESTICIDES** used to control pests and vectors. The record must include all **GENERAL-USE and RESTRICTED-USE PESTICIDES** currently onboard the vessel and those used in the previous 12 months.

8.1.3.1.2 Restricted Use (39 C)

A RESTRICTED-USE PESTICIDE must be applied only by a certified applicator or a person with training and testing equivalent to that of a certified applicator.

8.1.3.1.3 Applicator Training (40)

Training of the pest-control personnel must be documented.

8.1.3.1.4 Safety (40)

The IPM plan must establish health and safety procedures to protect the passengers and crew.

8.2 Pest Control

8.2.1 Exclusion

8.2.1.1 Food Areas

8.2.1.1.1 Effective Control (39 C)

The presence of insects, rodents, and other pests must be effectively controlled to minimize their presence in the FOOD STORAGE, preparation, and service areas and WAREWASHING and UTENSIL storage areas aboard a vessel.

8.2.1.1.2 Exclusion (40)

Entry points where pests may enter the FOOD AREAS must be protected.

Rat guards must be made of a durable and nonchewable material. Single-line, multiple-line, or conical shape rat guards should be used according to the manufacturer's specifications.

Rat guards must be on all lines that go ashore on arrival and until 1 hour before the ship leaves port. Each line must have at least one rat guard placed either as far as practicable from the pier or as far as practicable from the ship but still close enough for any openings to be stuffed with nonchewable material. Rat guards must not be staggered on adjacent lines, and a group of lines must not be merged onto one rat guard.

8.2.1.1.3 Incoming Food and Other Supplies (40)

Incoming shipments of FOOD and all other supplies must be routinely inspected for evidence of insects, rodents, and other pests. A record of these inspections must be maintained onboard the vessel and must be available for review during inspections.

8.2.1.1.4 IPM Inspections (40)

All FOOD AREAS must be inspected at a frequency that can quickly detect the evidence of pests, harborage conditions, cleanliness, and protection of outer openings.

Nonfood Areas

Reasonable care must be given to conduct inspections in nonfood areas for the presence of insects, rodents, and other pests.

The garbage handling areas of the vessel must be inspected at least weekly for the presence of insects, rodents, and other pests. The results of these inspections must be maintained in a log. **These results may be included in the log of the FOOD AREA inspections.**

8.2.2 Control Measures**8.2.2.1 Chemical****8.2.2.1.1 Chemical Controls (39 C)**

Chemical control measures must conform to products and application procedures specifically allowed in the FOOD safety section of these guidelines and the vessel's IPM plan.

8.2.2.2 Physical**8.2.2.2.1 *Insect-Control Devices (40)***

Insect-control devices that electrocute or stun flying insects are not permitted in FOOD AREAS.

8.2.2.2.2 *Food Protection (19)*

Insect control devices such as insect light traps must not be located over FOOD STORAGE, FOOD PREPARATION AREAS, FOOD SERVICE stations, or clean EQUIPMENT. Dead insects and insect fragments must be prevented from falling on exposed FOOD.

8.2.2.2.3 *Utensil Protection (28)*

Insect-control devices must not be located over WAREWASHING, UTENSIL storage areas, EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES. Dead insects and insect fragments must be prevented from falling on clean items.

8.2.2.2.4 *Cleaning (40)*

Dead or trapped insects, rodents, and other pests must be removed from control devices and the vessel at a frequency that prevents their accumulation or decomposition or the attraction of other pests.

8.3 Integrated Pest Management Knowledge**8.3.1 Demonstration of Knowledge (44)**

The supervisor or PERSON IN CHARGE of IPM operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of IPM operations. The supervisor or PERSON IN CHARGE must demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector's questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of IPM operations on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

9.0 Housekeeping

This section includes the following subsections:

- 9.1 OUTBREAK Prevention and Management Procedures
- 9.2 Knowledge

References for 9.0 Housekeeping can be found in Annex 14.9.

9.1 Outbreak Prevention and Management Procedures

9.1.1 Disinfection

9.1.1.1 Public Areas

9.1.1.1.1 Continuous Disinfection (41)

When the cumulative proportion of cases of AGE among passengers or crew members is $\geq 2\%$, the OUTBREAK management response must include cleaning and disinfecting all public areas, including handrails and restrooms, on a continuous basis while passengers and/or crew are circulating in those areas.

This process involves DISINFECTION of hand-contact surfaces of all public areas, including restrooms and handrails, throughout the ship and identified in the OPRP. Workers disinfect these surfaces without interruption along a logical route by deck, venue, and area when people are present or circulating in these areas.

9.1.1.1.2 Cabin Cleaning (41)

Cabins that house passengers or crew with AGE must be cleaned and disinfected daily while the occupants are ill.

9.1.1.1.3 Precautionary Measures (41)

Precautionary measures by housekeeping personnel must be taken in consultation with the vessel's medical staff to prevent the spread of AGE from cabin to cabin.

9.1.1.1.4 Example

Precautionary measures by the housekeeping personnel may include using disposable personal protection EQUIPMENT, including gloves that are changed after each cabin; cleaning cabins with ill passengers or crew after all other cabins; or having specific crew members only clean cabins of ill passengers or crew.

9.1.1.1.5 Written OPRP (41)

Each vessel must have a written OUTBREAK Prevention and Response Plan (OPRP) that details standard procedures and policies to specifically address AGE onboard. The written OPRP must include the following at a minimum:

- Duties and responsibilities of each department and their staff for all passenger and crew public areas.
- Steps in OUTBREAK management and control and the trigger required for action at each step.

At a minimum, triggers must address a graduated approach to OUTBREAK management in response to increasing case counts. **Additionally, triggers may be based on events, such as reports of public vomiting/diarrhea, increased room service requests, meal or excursion cancellations, missed events, or others.**

Cruise ship AGE surveillance data has shown that a 0.45% daily ATTACK RATE is indicative of a pending OUTBREAK.

- DISINFECTANT products or systems used, including the surfaces or items the DISINFECTANTS will be applied to, concentrations, and required contact times. The DISINFECTANT products or systems must be effective against human norovirus or an acceptable surrogate (e.g., caliciviruses).
- Procedures for informing passengers and crew members of the OUTBREAK. This section should address the procedures for notification of passengers embarking the vessel after an OUTBREAK voyage. In the case of an extended voyage separated into segments, such as a world cruise, this requirement applies to passengers embarking for the segment after an OUTBREAK segment.
- Procedures for returning the vessel to normal operating conditions after an OUTBREAK.
- Procedures to protect the passengers and crew from exposure to DISINFECTANTS, if not already included in the vessel's safety management system. At a minimum, this must include the following:
 - Material safety data sheets (MSDSs).

- Personal protective EQUIPMENT for crew.
- Health and safety procedures to minimize respiratory and dermal exposures to both passengers and crew.

9.1.1.1.6 Public Toilet Facilities (41)

Passenger and crew public toilets (not including FOOD-area toilets) must be provided with a handwashing station that includes the following:

- Hot and cold running water.
- Soap.
- A method to dry hands (e.g., sanitary hand-drying device, paper towels).
- A sign advising users to wash hands (pictograms are acceptable).

9.1.1.1.7 Hands-Free Exit (41)

Passenger and crew public toilet facilities must be equipped so persons exiting the toilet room are not required to touch the door handle with bare hands.

Where toilet stalls include handwashing facilities, the bare-hands-free contact must begin in the toilet stall. Toilet facilities with multiple exits, such as spa dressing rooms, must have bare-hands-free contact at each exit.

Bare-hands-free contact may be accomplished by methods such as locating paper towel dispensers at sinks and waste containers near the room door, installing mechanically operated doors, removing doors, or using other effective means.

9.1.1.1.8 Sign (41)

A sign must be posted advising users of toilet facilities to use hand towel, paper towel, or tissue to open the door unless the exit is hands free.

A pictogram that illustrates the correct use and disposal of paper towels may be used in lieu of a sign.

9.2 Housekeeping Knowledge

9.2.1 Demonstration of Knowledge (44)

The supervisor or PERSON IN CHARGE of housekeeping operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of housekeeping operations. The supervisor or PERSON IN CHARGE must

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demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector's questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of housekeeping operations on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

10.0 Child Activity Centers

This section includes the following subsections:

- 10.1 Diaper Changing
- 10.2 Toilets and Handwashing
- 10.3 Cleaning and DISINFECTION
- 10.4 Exclusions
- 10.5 Knowledge

References for 10.0 Child Activity Centers can be found in Annex 14.10.

10.1 Diaper Changing

10.1.1 Diaper-Changing Facilities

10.1.1.1 Design

10.1.1.1.1 *Diaper Changing (42)*

If children who wear diapers are accepted in the CHILD ACTIVITY CENTER, diaper-changing stations and disposal facilities must be provided.

10.1.1.1.2 *Diaper-Changing Stations (42)*

Each station must include the following:

- A changing table that is nonabsorbent, nontoxic, SMOOTH, durable, EASILY CLEANABLE, and designed for diaper changing.
- A supply of disposable diapers, gloves, wipes, table cleanser, and DISINFECTANT.
- An airtight soiled-diaper receptacle.
- An adjacent handwashing station.

10.1.1.1.3 *Signs (42)*

Signs must be posted in the diaper changing area advising handwashing after each diaper change.

10.2 Toilets and Handwashing

10.2.1 Employee Handwashing (42)

Vessels constructed to the *VSP 2005 Construction Guidelines* or later must have at least one handwashing station separate from the toilet room(s). The handwashing station must be maintained clean and available at all times.

10.2.2 Facilities

Sections 9.1.1.1.6–9.1.1.1.8 also apply to this section, except that the sign advising users to wash hands (section 9.1.1.1.8) is not required.

10.2.2.1 Design**10.2.2.1.1 Child-Size Toilet (42)**

If toilet rooms are located in a CHILD ACTIVITY CENTER, CHILD-SIZE TOILET(s) or child-ACCESSIBLE toilet(s) (child-size seat and step stool) and handwashing facilities must be provided.

CHILD-SIZE TOILETS (to include the toilet seat) must have a maximum height of 280 millimeters (11 inches) and a toilet seat opening no greater than 203 millimeters (8 inches). Handwashing sinks must have a maximum height of 560 millimeters (22 inches) above the deck or a step stool must be provided.

10.2.2.1.2 Toilet Supplies (42)

Each child's toilet facility must be provided with a supply of toilet tissue, disposable gloves, and sanitary wipes.

10.2.2.1.3 Waste Receptacle (42)

An airtight, washable waste receptacle must be conveniently located to dispose of excrement, soiled sanitary wipes, and soiled gloves. Waste materials must be removed from the CHILD ACTIVITY CENTER each day.

10.2.2.1.4 Handwashing Supplies (42)

Soap, paper towels or air dryers, and a waste towel receptacle must be located at handwashing stations.

10.2.2.1.5 Signs (42)

Signs must be posted in children's toilet room advising providers to wash their hands and the children's hands after assisting children with using the toilet.

10.2.2.1.6 Assistance (42)

Children under 6 years old must be assisted in washing their hands in the CHILD ACTIVITY CENTER after using the toilet room, before eating, and after otherwise contaminating their hands.

10.2.2.1.7 Separate (42)

Separate toilet facilities must be provided for CHILD ACTIVITY CENTER staff. CHILD ACTIVITY CENTER staff must not use the children's toilet facilities. Public toilet facilities are acceptable.

10.2.2.1.8 Exiting (41)

Toilet rooms must be equipped so that persons exiting the toilet room are not required to handle the door with bare hands.

10.2.2.2.9 Temperature (42)

The maximum water temperature for a handwashing station must not exceed 43°C (110°F).

10.2.2.2.10 Outside Toilet Rooms (42)

Handwashing stations designated for children and located outside toilet rooms must meet the requirements in sections 10.2.2.1.1 and 10.2.2.1.9.

10.3 Cleaning and Disinfection**10.3.1 Employee Handwashing****10.3.1.1 When to Wash Hands (12 C)**

Child care providers must wash their hands before giving FOOD or BEVERAGES to children.

10.3.2 Furnishings and Toys**10.3.2.1 Construction****10.3.2.1.1 Cleanable (42)**

Surfaces of tables, chairs, and other furnishings that children touch with their hands must be cleanable.

10.3.2.1.2 Condition (42)

Toys used in the CHILD ACTIVITY CENTER must be maintained in a clean condition.

10.3.2.2 Procedures**10.3.2.2.1 Hard Surfaces (42)**

Surfaces that children touch with their hands must be cleaned and disinfected daily with products labeled by the manufacturer for that purpose.

10.3.2.2.2 Toy Cleaning/Ball Pits (42)

Toys used in the CHILD ACTIVITY CENTER must be cleaned and disinfected daily.

Balls used in ball pits/pens must be cleaned when contaminated or at least once per week.

If a CHEMICAL DISINFECTANT is used, toys must be air dried before use.

10.3.2.2.3 Tables/High Chairs (42)

Tables and high chair trays must be cleaned and disinfected before and after they are used for eating.

10.3.2.2.4 Decks (42)

Carpeting must be vacuumed daily and must be periodically cleaned when it becomes visibly soiled. Decks must be washed and disinfected when soiled or at least daily.

10.3.2.2.5 Facility Cleaning/Disinfecting (42)

Diaper changing stations, handwashing facilities, and toilet rooms must be cleaned and disinfected daily and when soiled during use.

10.3.2.2.6 Linens Laundered (42)

LINENS such as blankets, sheets, and pillow cases must be laundered between each use.

10.3.2.2.7 Costumes (42)

Costumes worn by children—including clothing items, masks, and hats—must be laundered, cleaned and disinfected, discarded, retained by the guest, or dry cleaned between each use.

10.4 Exclusions

10.4.1 Children with Infectious Illness

10.4.1.1 Procedures

10.4.1.1.1 Written Guidance (42)

Written guidance on symptoms of common childhood infectious illnesses must be posted at the entrance of the CHILD ACTIVITY CENTER.

10.4.1.1.2 Exclusion Policy (42)

The CHILD ACTIVITY CENTER must have a written exclusion policy on procedures to be followed when a child develops symptoms of an infectious illness while at the center.

The policy must include a requirement for written clearance from the medical staff before a child with symptoms of infectious illness can be allowed in the CHILD ACTIVITY CENTER.

This policy must be posted at the entrance of the CHILD ACTIVITY CENTER.

10.4.1.1.3 Infectious Illness (42)

Children with infectious illness must not be allowed in the CHILD ACTIVITY CENTER without written permission from the vessel's medical staff.

10.5 Child Activity Center Knowledge

10.5.1 Demonstration of Knowledge (44)

The supervisor or PERSON IN CHARGE of CHILD ACTIVITY CENTER operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of CHILD ACTIVITY CENTER operations. The supervisor or PERSON IN CHARGE must demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector's questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of CHILD ACTIVITY CENTER operations on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

11.0 Heating, Ventilation, and Air Conditioning (HVAC) Systems, Fountains, Misting Systems, Humidifiers, and Showers

This section includes the following subsections:

- 11.1 HVAC Construction and Maintenance
- 11.2 Fountains, Humidifiers, Misting Systems, and Showers
- 11.3 Knowledge

References for 11.0 Heating, Ventilation, and Air Conditioning (HVAC) Systems, Fountains, Misting Systems, Humidifiers, and Showers can be found in Annex 14.11.

11.1 HVAC Construction and Maintenance

11.1.1 Construction

11.1.1.1 Condensate Pans (43)

Air handling unit condensate drain pans and collection systems must be able to be accessed for inspection, maintenance, and cleaning. Installation of sight windows or other effective methods for full inspection of condensate collection pans must be used when original EQUIPMENT access makes evaluation during operational inspections impractical.

11.1.1.2 Self Draining (43)

Condensation collection pans must be self draining.

11.1.1.3 Potable Water (43)

Only POTABLE WATER can be used for cleaning the HVAC distribution system.

11.1.2 Maintenance

11.1.2.1 Air Handling Units (43)

Air handling units must be kept clean.

11.1.2.2 Condensers (43)

Evaporative condensers must be inspected at least annually and cleaned as necessary to remove scale and sediment. Cooling coils and condensate pans must be cleaned as necessary to remove dirt and organic material.

11.1.2.3 Inspection and Maintenance Plan (43)

Vessels must have a plan to inspect and maintain HVAC systems in accordance with the manufacturer's recommendations and industry standards. The written inspection, cleaning, and maintenance plan for the HVAC system must be maintained on the vessel and available for review during inspections.

Documentation of the inspection, cleaning, and maintenance plan must be available for review during inspections.

An electronic maintenance tracking system is acceptable for both the plan and the documentation if the work description and action completed are available.

11.2 Fountains, Humidifiers, Misting Systems, and Showers

11.2.1 Fountains, Humidifiers, and Misting Systems

11.2.1.1 Water Source

11.2.1.1.1 Sprays (43)

Only POTABLE WATER can be used for water sprays, decorative fountains, humidifiers, and misting systems. The water must be further treated to avoid microbial buildup in the operation of water sprays, fountains, humidifiers, and misting systems.

11.2.1.2 Fountains and Misting Systems

11.2.1.2.1 Clean (43)

Decorative fountains and misting systems must be maintained free of *Mycobacterium*, *Legionella*, algae, and mold growth.

For systems installed after the adoption of the *VSP 2011 Operations Manual*,

- Provide an automated treatment system (halogenation, UV, or other effective DISINFECTANT) to prevent the growth of *Mycobacterium* and *Legionella* in any decorative fountain, misting system, or similar facility.
- Ensure that nozzles are REMOVABLE for cleaning and DISINFECTION.
- Ensure that pipes and reservoirs can be drained when the fountain/system is not in use.

PORTABLE units must be maintained clean.

11.2.1.2.2 Shock Treatment (43)

For misting systems and similar facilities, ensure that these systems can also be manually disinfected (halogenation, heat, etc.).

If heat is used as a DISINFECTANT, ensure that the water temperature, as measured at the misting nozzle, can be maintained at 65°C (149°F) for a minimum of 10 minutes.

11.2.2 Hot-Water System and Showers

11.2.2.1 Maintenance

11.2.2.1.1 Hot-Water System (43)

The potable hot-water system—including shower heads—must be maintained to preclude growth of *Mycobacterium* or *Legionella*.

11.2.2.1.2 Showers (43)

Shower heads must be cleaned and disinfected every 6 months. DISINFECTION must be accomplished with an appropriate HALOGEN-based DISINFECTANT at 10 ppm for 60 minutes, or an equivalent CT VALUE.

Shower head cleaning and DISINFECTION must be recorded in a log and maintained on the vessel.

11.3 HVAC Systems, Fountains, Misting Systems, Humidifiers, and Showers Knowledge

11.3.1 Demonstration of Knowledge (44)

The supervisor or PERSON IN CHARGE of HVAC operations on the vessel must demonstrate to VSP—on request during inspections—knowledge of HVAC systems, fountains, misting systems, humidifiers, and showers operations. The supervisor or PERSON IN CHARGE must demonstrate this knowledge by compliance with this section of these guidelines or by responding correctly to the inspector's questions as they relate to the specific operation. In addition, the supervisor or PERSON IN CHARGE of HVAC systems, fountains, misting systems, humidifiers, and showers operations on the vessel must ensure that employees are properly trained to comply with this section of the guidelines in this manual as it relates to their assigned duties.

12.0 Administrative Guidelines

This section includes the following subsections:

- 12.1 Inspections
- 12.2 Inspection Report
- 12.3 Risk-based Scoring and Correction Priority
- 12.4 Closing Conference
- 12.5 Inspection Review
- 12.6 Corrective Action Statement
- 12.7 Correction Affidavit
- 12.8 Inspection Publication
- 12.9 Recommendation That the Vessel Not Sail
- 12.10 Reinspections and Follow-up Inspections
- 12.11 Construction/Renovation Inspections
- 12.12 Other Environmental Investigations
- 12.13 VARIANCES

References for 12.0 Administrative Guidelines can be found in Annex 14.12.

12.1 Inspections

12.1.1 Inspection Procedures

12.1.1.1 Routine Inspections

An unannounced, complete sanitation inspection by VSP Environmental Health Officers (EHOs) will be done twice each federal fiscal year if the vessel is available.

12.1.1.2 IHR Ship Sanitation Inspections

The Vessel Sanitation Program will conduct International Health Regulations (IHR) ship sanitation inspections during unannounced routine operational inspections of cruise ships using the final APPROVED IHR inspection manual from the World Health Organization (WHO). The IHR inspection will only be conducted if there is sufficient time to do both inspections while the ship is in port. There will be no additional fee charged for a dual inspection. The IHR inspection will not be conducted if the cruise line involved has invoices from other ship inspections unpaid for more than 60 days from receipt of those invoices.

VSP will also provide extensions to existing ship sanitation control exemption certificates. Because the standard for the IHR inspections is set by WHO, the ship will be issued the certificate appropriate to the findings of the inspection. The findings specific to the IHR will be so designated in the inspection report narrative.

12.1.1.3 Inspectors

VSP EHOs will be trained in the interpretation and application of the current *VSP Operations Manual*.

12.1.1.4 Boarding

The VSP EHO or EHOs will board the vessel and immediately inform the master of the vessel or a designated agent that a vessel sanitation inspection is to be conducted.

12.1.1.5 Sequence

The VSP EHO or EHOs will then conduct the inspection in a logical sequence until all areas identified in this manual have been inspected.

12.1.1.6 Imminent Health Hazard Detection

The VSP EHO or EHOs will contact the master of the vessel or a designated agent and the VSP Chief immediately during an inspection about a possible recommendation that the vessel not sail

- If an IMMINENT HEALTH HAZARD as specified in section 12.9.1 is found to exist on the vessel AND
- If these deficiencies possibly cannot be corrected before the inspection is completed.

12.1.1.7 Incomplete Inspections

Once an inspection has begun, it will be completed in that same visit. If the inspection cannot be completed, the results of an incomplete inspection will be discussed with the vessel's staff. A complete inspection will be conducted at a later date.

12.2 Inspection Report**12.2.1 Draft Report****12.2.1.1 Provided**

The VSP EHO or EHOs will provide a draft inspection report to the master of the vessel, or a designated agent, at the conclusion of the inspection.

12.2.1.2 Information

The draft inspection report will provide administrative information, AGE log review details, and inspection score.

12.2.1.3 Deficiency Descriptions

The draft inspection report will provide a written description of the items found deficient and where the deficiency was observed.

12.2.2 Final Report

12.2.2.1 Report Form

The VSP EHO or EHOs will use the Vessel Sanitation Inspection Report (Annex 13.17) to summarize the inspection score. The inspection report will contain the elements in 12.2.2.2 through 12.2.2.5.

12.2.2.2 Administrative

The inspection report includes administrative information that identifies the vessel and its master or designee. It also includes the inspection report score, which is calculated by subtracting credit point values for all observed deficiencies from 100.

12.2.2.3 Deviations

The item number and the credit point value for that item number will be indicated if the vessel does not meet the current *VSP Operations Manual* standard for that item.

12.2.2.4 Medical Review

The medical documentation (e.g., GI logs, medical logs, special reports, etc.) will be available for review by VSP for accuracy and timeliness of reporting.

12.2.2.5 Report Detail

A written description of the items found deficient will be included. The deficiencies will be itemized with references to the section of the current *VSP Operations Manual*. The description will include the deficiency location and citation of the appropriate *VSP Operations Manual* section.

12.3 Risk-Based Scoring and Correction Priority

12.3.1 Scoring System

12.3.1.1 Weighted Items

The inspection report scoring system is based on inspection items with a total value of 100 points.

12.3.1.2 Risk Based

Inspection items are weighted according to their probability of increasing the risk for an AGE OUTBREAK.

12.3.1.3 Critical Items

CRITICAL ITEMS are those with a weight of 3 to 5 credit point values on the inspection report.

12.3.1.4 Critical Designation

CRITICAL ITEMS are designated in this *VSP Operations Manual* in bold red underlined text. In addition, the text **CRITICAL ITEM** appears in parentheses after the section number and keywords; for example, **7.5.5.1 Food-Contact Surfaces (24 C)**. The section numbers of the CRITICAL ITEMS in this manual are also provided in red text.

12.3.1.5 Noncritical Items

Noncritical items are those with a weight of 1 to 2 credit point values on the inspection report.

12.3.1.6 Scoring

Each weighted deficiency found on an inspection will be deducted from 100 possible credit points.

12.3.2 Risk-Based Correction Priority**12.3.2.1 Critical Correction Time Frame**

At the time of inspection, a vessel will correct a critical deficiency as defined in the current *VSP Operations Manual* and implement a corrective-action plan for monitoring the CRITICAL ITEM for continued compliance.

12.3.2.2 Extension

Considering the nature of the potential HAZARD involved and the complexity of the corrective action needed, VSP may agree to, or specify, a longer time frame (not to exceed 10 calendar days after the inspection) for the vessel to correct critical deficiencies.

12.4 Closing Conference**12.4.1 Procedures****12.4.1.1 Closing Conference**

The results of the inspection will be explained to the master or a designee before the VSP EHO or EHOs leave the vessel.

12.4.1.2 Report Copy

The VSP EHO or EHOs will leave a copy of the draft inspection report with the master or designee. The report will be reviewed in detail and opportunity provided for discussions of the findings. The draft report is provided so vessel personnel can begin correcting deficiencies immediately.

12.4.1.3 Invoice

The VSP EHO or EHOs will provide the master or a designee with a payment invoice for signature. The VSP EHO or EHOs will provide one copy of the signed invoice to the master or designee and will forward one copy to the vessel's company office along with the final inspection report.

12.4.1.4 Fee Schedule

The fee for inspections is based on the existing fee schedule for routine inspections of passenger cruise vessels. The schedule is published annually in the *Federal Register*.

12.5 Inspection Review**12.5.1 Inspection Report Review Requests****12.5.1.1 Contested Results**

The vessel owner or operator must notify VSP within 72 hours of the inspection closing conference of their intent to contest results of the inspection. After the initial notification and within 2 weeks of the inspection, the vessel owner or operator must provide VSP with the specific reference and facts concerning the contested deficiencies documented by the VSP EHO or EHOs during the inspection.

12.5.1.2 Interim Report

At the request of the owner or operator, the VSP EHO or EHOs will complete an interim report if an inspection is under review. The interim report will indicate the item(s) under review. VSP will modify the final inspection report, as necessary, after the review by the VSP Chief.

12.5.1.3 Report Remarks

After receiving a request for review, the VSP EHO or EHOs will mark the vessel's inspection report as under review at the request of the vessel owner or operator.

12.5.1.4 Address

Send written requests to the following:
Chief, Vessel Sanitation Program
National Center for Environmental Health
Centers for Disease Control and Prevention
4770 Buford Hwy NE, Mailstop F59
Atlanta, GA 30341-3717 USA

12.5.2 Inspection Report Review Procedures

12.5.2.1 Review

The VSP Chief will review the matter and respond within 2 weeks of receiving the request for a review. In the response, the VSP Chief will state whether the inspection report will be changed.

12.5.2.2 No Score

No numerical score will be published before the VSP Chief makes a final determination on the review. Publication of inspection results will indicate the vessel's status as under review at the request of the vessel owner or operator.

12.5.2.3 Report Copies

Copies of the contested inspection results released before the VSP Chief makes a final determination on the review will have each contested deficiency clearly marked as under review at the request of the vessel owner or operator.

12.5.2.4 Final Report

The interim report will be issued as a final report if the written request for review is not received within 2 weeks of the inspection.

12.5.2.5 Appeal

If the ship owner does not agree with the review and decision of the VSP Chief, he or she may appeal the decision to the Director, Division of Emergency and Environmental Health Services, National Center for Environmental Health.

12.5.3 Other Recommendations Review

12.5.3.1 Review

A vessel owner or operator has the right to request a review of recommendations made during a technical consultation or inspection if the owner or operator believes VSP officials have imposed requirements inconsistent with or beyond the scope of this manual.

12.5.3.2 Written Request

The owner or operator must send a written statement explaining the problem in detail to the VSP Chief within 30 days of the date the recommendation was made.

12.5.3.3 Review

The VSP Chief will review the issue and respond within 2 weeks of receiving the statement, advising whether the recommendation will be revised.

12.5.3.4 Appeal

If the ship owner does not agree with the review and decision of the VSP Chief, he or she may appeal the decision to the Director, Division of Emergency and Environmental Health Services, National Center for Environmental Health.

12.6 Corrective Action Statement**12.6.1 Procedures****12.6.1.1 Corrective Actions**

Signed corrective-action statements (Annex 13.18) must be submitted to the VSP Chief by the master, owner, or operator. Corrective-action statements must detail each deficiency identified during the inspection and the corrective action taken.

Corrective-action statements (Annex 13.18) must be submitted to the VSP Chief by the master, owner, or operator within 2 weeks of receiving the final inspection report.

12.6.1.2 Critical-Item Corrective Actions

Critical-item deficiencies must also include standard operating procedures and monitoring procedures implemented to prevent the recurrence of the critical deficiency.

12.6.1.3 Clarification Requests

The corrective-action statement may contain requests for clarification of items noted on the inspection report. The request for clarification must be included in the cover letter from the vessel's master, owner, or operator. Clarification of these items will be provided in writing to the requestor by the VSP Chief or the EHO or EHOs who conducted the inspection in question.

12.6.1.4 Public Distribution

The corrective-action statement will be appended to the final inspection report for future reference and, if requested, made available for public distribution.

12.6.1.5 Same Score

A corrective-action statement will not affect the inspection score.

12.7 Correction Affidavit

12.7.1 Procedures

12.7.7.1 Procedures

An affidavit of correction from the owner or operator, certifying that corrective action has been completed, may be submitted to the VSP Chief. The procedure may be used only one time for an item. The item must be structure- or EQUIPMENT-related and must be corrected within a reasonable period.

12.7.1.2 Conditions

At least one of the following conditions must apply for an item to qualify for an affidavit of correction. The item must be a

- Longstanding deficiency that has not been identified during previous inspections OR
- Deficiency in which the function of the EQUIPMENT is being accomplished by an alternative method.

12.7.1.3 Requested at Inspection

After the inspection, but before the VSP EHO or EHOs leave the vessel, the vessel's master or a representative must provide notification of the intent to submit an affidavit of correction. This notice must specify the deficiency or deficiencies to be corrected and the corrective action to be taken. The draft inspection report will include a notation of the items to be corrected.

12.7.1.4 Final Inspection Score

After acceptance of the affidavit, the final inspection score will be recalculated to include credit for the items corrected.

12.8 Inspection Publication

12.8.1 Methods

12.8.1.1 Report Availability on Website

CDC publishes inspection reports and scores (the Green Sheet report) on the VSP website (www.cdc.gov/nceh/vsp).

12.8.1.2 Data

The website will include, at a minimum, the names of the vessels in the inspection program, the dates of their most recent inspections, and the numerical score achieved by each vessel.

12.8.1.3 Public Record

Reports, including corrective-action statements, are available on the VSP website. Paper copies are available to the public on request.

12.9 Recommendation That the Vessel Not Sail**12.9.1 Imminent Health Hazards****12.9.1.1 Imminent Health Hazard**

An IMMINENT HEALTH HAZARD will be determined to be, but not limited to, one of the following situations:

- Free HALOGEN residual in the POTABLE WATER distribution system is less than 0.2 MG/L (ppm) and this deficiency is not corrected before the inspection ends.
- Inadequate facilities for maintaining safe temperatures for POTENTIALLY HAZARDOUS FOOD.
- Inadequate facilities for cleaning and sanitizing EQUIPMENT.
- Continuous problems with liquid and solid waste disposal, such as inoperative or overflowing toilets or shower stalls in passenger and crew member cabins.
- Infectious disease OUTBREAK among passengers or crew, and where it is suspected that continuing normal operations may subject newly arriving passengers to disease.

12.9.2 Procedures**12.9.2.1 Notify VSP Chief**

The VSP EHO or EHOs will immediately notify the VSP Chief when any of these IMMINENT HEALTH HAZARDS or similar imminent threats to public health are found aboard a vessel.

12.9.2.2 No Sail

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. Such a recommendation will be signed by the VSP Chief, with concurrence of the Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry or the Director's designee.

12.10 Reinspection and Follow-up Inspections

12.10.1 Reinspection Procedures

12.10.1.1 Failing Vessels Reinspections

A reinspection is a complete sanitation inspection performed on vessels that did not score at least 86 on the previous inspection.

12.10.1.2 Reasonable Time

Vessels that fail a routine inspection will be reinspected within a reasonable time, depending on vessel schedules and receipt of the corrective-action statement from the vessel's management.

12.10.1.3 Unannounced

Reinspections will be unannounced.

12.10.1.4 No-Sail Reinspections

If a no-sail recommendation is made, a follow-up inspection will be conducted as soon as requested.

12.10.1.5 Scheduling Priority

In scheduling inspections, VSP will give priority to the reinspection of vessels that failed routine inspections.

12.10.1.6 One Reinspection

Vessels that fail a routine inspection will undergo only one reinspection.

12.10.1.7 Written Requests

Exceptions to 12.10.1.6 may be made when the owner or operator submits a written request for an additional reinspection to the VSP Chief stating why the additional reinspection is warranted.

12.10.1.8 Unannounced/Inspection Fee

Additional reinspections are unannounced and the vessel will be charged the standard inspection fee.

12.10.2 Followup Inspection Procedures

12.10.2.1 Follow Up

A follow-up inspection is a partial inspection to review the status of deficiencies identified during the previous periodic inspection or reinspection.

12.10.2.2 Not Periodic or Reinspection

A follow-up inspection cannot be a substitute for a periodic inspection or reinspection.

12.10.2.3 Followup Reasons

Follow-up inspections may be conducted to resolve a contested inspection or to inspect IMMINENT HEALTH HAZARDS that resulted in a recommendation to prohibit the vessel from sailing.

12.10.2.4 Next Arrival

These inspections will be conducted as soon as possible after the routine inspection or reinspection, preferably the next time the vessel arrives at a U.S. port.

12.10.2.5 Limited

Follow-up inspections will be limited to inspection of deficiencies in question. For example, if an item under the refrigerator section of the inspection was a deficiency and was the only item contested, only refrigeration would be checked during the follow-up inspection.

12.10.2.6 Other Items

Any other problems noted during the follow-up inspection will be brought to the attention of the vessel's master or designee so the deficiencies can be corrected.

12.10.2.7 No Score

No inspection score will be provided and no fee will be charged for follow-up inspections.

12.11 Construction/Renovation Inspections**12.11.1 Procedures****12.11.1.1 Construction**

Whenever possible, VSP staff will conduct inspections of vessels being constructed or undergoing major retrofits on request of the vessel owner or operator.

12.11.1.2 Requesting Inspection

An official written request will be submitted to the VSP Chief requesting a voluntary construction renovation inspection. CDC's ability to honor these requests will be based on the availability of the VSP staff.

12.11.1.3 Time Frame

Construction/renovation inspections are normally conducted at the shipyard 4 to 6 weeks before completion. An additional inspection may also be conducted on completion of the work and before the vessel enters operational status.

12.11.1.4 Construction Compliance

Construction/renovation inspections will document the vessel's compliance with CDC's *VSP Construction Guidelines*, which provide a framework for consistency in the sanitary design, construction, and construction inspections of cruise vessels.

12.11.1.5 New Vessels

The CDC *VSP 2018 Construction Guidelines* will apply to all new vessels in which the keel is laid after **June 1, 2018**.

12.11.1.6 Major Renovations

The construction guidelines will also apply to major renovations planned after **June 1, 2018**. A major renovation is a renovation where a new FOOD AREA (e.g., galley, bar, buffet) is installed, a new facility (e.g., recreational water, CHILD ACTIVITY CENTER) is installed, or an existing FOOD AREA or facility is changed by size or EQUIPMENT by 30% or more from the original. It also includes the addition of or change to an area/facility or a technical system (e.g., POTABLE WATER, wastewater, air systems) through the introduction of new technology.

12.11.1.7 Minor Renovations

These guidelines will not apply to minor renovations.

12.11.1.8 Fee Schedule

The fee for construction/renovation inspections is based on the existing fee schedule for routine inspections.

12.11.2 Construction/Renovation Inspection Reports**12.11.2.1 Report**

A written report will be issued by VSP after a construction/renovation inspection. These reports will summarize any changes recommended to ensure conformity with CDC guidelines.

12.11.2.2 Guides

The reports prepared by VSP personnel in the shipyards during construction will be used as guides if VSP conducts a final construction/renovation inspection on the vessel before the vessel enters operational service.

12.11.2.3 No Score

There is no score for construction/renovation inspections.

12.12 Other Environmental Investigations

12.12.1 Procedures

12.12.1.1 Environmental Investigations

VSP may conduct or coordinate other activities such as investigating disease OUTBREAKS, checking a specific condition such as HALOGEN residual in the POTABLE WATER distribution system, or investigating complaints of unsanitary conditions on a vessel.

12.12.1.2 Problems Noted

Public health problems noted during other environmental investigations will be brought to the attention of the vessel's master or designee when these investigations are performed.

12.12.1.3 No Score

No inspection score will be provided and no fee will be charged for other environmental investigations.

12.13 Variances

12.13.1 Procedures

12.13.1.1 Variance Procedures

VSP may grant a VARIANCE by modifying or waiving the requirements of this *VSP 2018 Operations Manual* if VSP determines that a HEALTH HAZARD or nuisance will not result from the VARIANCE.

12.13.1.2 VSP Records

If a VARIANCE is granted, VSP will retain the information in its records for the vessel or, if applicable, multiple vessels.

12.13.1.3 Vessel Records

If a VARIANCE is granted, the vessel using the VARIANCE must retain the information in its records for ready reference.

12.13.1.4 Existing Variances

If changes are submitted for an existing APPROVED VARIANCE, the entire VARIANCE will be reviewed. If a new vessel is added to an existing APPROVED VARIANCE, the VARIANCE will be reviewed for that vessel.

If new technology or science has been developed since approval of a VARIANCE, that section of the VARIANCE where the new technology or science was developed will be reviewed.

12.13.2 Documentation

12.13.2.1 Detailed Justification

Before a VARIANCE from a requirement of the *VSP 2018 Operations Manual* is APPROVED, the person requesting the VARIANCE must provide the following, which will be retained in VSP's file on the vessel or vessels:

- A statement of the proposed VARIANCE from the *VSP 2018 Operations Manual* requirement including relevant section number citations.
- An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant *VSP 2018 Operations Manual* requirement will be alternatively addressed by the proposed VARIANCE.
- If required, a HACCP PLAN, standard operating procedures, training plan, and monitoring plan that includes all the information as it is relevant to the VARIANCE requested.
- Additional scientific data or other information as required to support the determination that public health will not be compromised by the proposal.

12.13.3 Conformance

12.13.3.1 Conformance

If VSP grants a VARIANCE, the vessel must

- Comply with the HACCP PLANS, standard operating procedures, training plan, and monitoring plan submitted and APPROVED as a basis for the modification or waiver.
- Maintain and provide to VSP, on request, records to demonstrate that
 - procedures monitoring CRITICAL CONTROL POINTS are effective,
 - monitoring of the CRITICAL CONTROL POINT are routinely used,
 - necessary corrective actions are taken if there is failure at a CRITICAL CONTROL POINT, and
 - effectiveness of the operation or process in protection of public health is periodically verified.

12.13.3.2 Rescinding Variance

VARIANCE approval may be rescinded at any time for noncompliance with these conditions or if it is determined that public health could be compromised.

12.13.3.3 Areas Not Identified (44)

Procedures, systems, EQUIPMENT, technology, processes, or activities not identified in the scope of this manual must not be tested or introduced operationally onboard any vessel until the concept is submitted in writing to the VSP Chief for review. If the review determines the concept is within the scope of the *VSP Operations Manual*, written procedures, control measures, or a complete VARIANCE submission may be required.

13.0 Annexes

This section includes the following subsections:

- 13.1 Authority
- 13.2 ACUTE GASTROENTERITIS Surveillance System
- 13.3 ACUTE GASTROENTERITIS Surveillance System Reporting
- 13.4 ACUTE GASTROENTERITIS OUTBREAK Investigation
- 13.5 DISINFECTION Calculations for Water and EQUIPMENT
- 13.6 Potable Water Pipe and System Disinfection Method Examples
- 13.7 Sample CROSS-CONNECTION Control Program Guideline
- 13.8 BABY-ONLY WATER FACILITY
- 13.9 Fecal, Vomit, and Blood Accident Response for RWFs
- 13.10 Cartridge Filter Cleaning Procedures
- 13.11 FOOD Cooking Temperature Alternatives
- 13.12 Chemicals Used in Washing or to Assist in the Peeling of Fruits and Vegetables
- 13.13 TIME-CONTROL Plan Examples
- 13.14 List of Some Hard and Semisoft Cheeses Exempt from Datemarking
- 13.15 CONSUMER Advisory Examples
- 13.16 WAREWASHING Evaluation
- 13.17 Inspection Report
- 13.18 Corrective-Action Statement
- 13.19 Summary of Sanitation Inspections of International Cruise Ships

13.1 Authority

13.1.1 Public Health Service Act

CHAPTER 6A--PUBLIC HEALTH SERVICE SUBCHAPTER II--GENERAL POWERS AND DUTIES

Part G--Quarantine and Inspection

Sec. 264. Regulations to control communicable diseases

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General.

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d) of this section, regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) Apprehension and examination of persons reasonably believed to be infected

On recommendation of the National Advisory Health Council, regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage and (1) to be moving or about to move from a State to another State; or (2) to be a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

(July 1, 1944, ch. 373, title III, Sec. 361, 58 Stat. 703; 1953 Reorg. Plan No. 1, Secs. 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub. L. 86-624, Sec. 29(c), 74 Stat. 419; June 23, 1976, Pub. L. 94-317, title III, Sec. 301(b)(1), 90 Stat. 707.)

Sec. 269. Bills of Health

(a) Detail of medical officer; conditions precedent to issuance; consular officer to receive fees

Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c) of this section. Before granting such duplicate bill of health, such consular or medical officer shall be satisfied that the matters and things therein stated are true. The consular officer shall be entitled to demand and receive the fees for bills of health and such fees shall be established by regulation.

(b) Collectors of customs to receive originals; duplicate copies as part of ship's papers

Original bills of health shall be delivered to the collectors of customs at the port of entry. Duplicate copies of such bills of health shall be delivered at the time of inspection to quarantine officers at such port. The bills of health herein prescribed shall be considered as part of the ship's papers, and when duly certified to by the proper consular or other officer of the United States, over his official signature and seal, shall be accepted as evidence of the statements therein contained in any court of the United States.

(c) Regulations to secure sanitary conditions of vessels

The Surgeon General shall from time to time prescribe regulations, applicable to vessels referred to in subsection (a) of this section for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews. Such regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station.

(d) Vessels from ports near frontier

The provisions of subsections (a) and (b) of this section shall not apply to vessels plying between such foreign ports on or near the frontiers of the United States and ports of the United States as are designated by treaty.

(e) Compliance with regulations

It shall be unlawful for any vessel to enter any port in any State or possession of the United States to discharge its cargo, or land its passengers, except upon a certificate of the quarantine officer that regulations prescribed under subsection (c) of this section have in all respects been complied with by such officer, the vessel, and its master. The master of every such vessel shall deliver such certificate to the collector of customs at the port of entry, together with the original bill of health and other papers of the vessel. The certificate required by this subsection shall be procurable from the quarantine officer, upon arrival of the vessel at the quarantine station and satisfactory inspection thereof, at any time within which quarantine services are performed at such station.

(July 1, 1944, ch. 373, title III, Sec. 366, 58 Stat. 705.)

Sec. 271. Penalties for violation of quarantine laws**(a) Penalties for persons violating quarantine laws**

Any person who violates any regulation prescribed under sections 264 to 266 of this title, or any provision of section 269 of this title or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than \$1,000 or

by imprisonment for not more than one year, or both.

(b) Penalties for vessels violating quarantine laws

Any vessel which violates section 269 of this title, or any regulations thereunder or under section 267 of this title, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than \$5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

(c) Remittance or mitigation of forfeitures

With the approval of the Secretary, the Surgeon General may, upon application therefore, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

(July 1, 1944, ch. 373, title III, Sec. 368, 58 Stat. 706; June 25, 1948, ch. 646, Sec. 1, 62 Stat. 909; 1953 Reorg. Plan No. 1, Secs. 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

13.1.2 Title 42 Code of Federal Regulations

TITLE 42--PUBLIC HEALTH

CHAPTER I--PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 71--FOREIGN QUARANTINE

Subpart C--Notice of Communicable Disease Prior to Arrival

71.21 Radio report of death or illness.

(a) The master of a ship destined for a U.S. port shall report immediately to the quarantine station at or nearest the port at which the ship will arrive, the occurrence, on board, of any death or any ill person among passengers or crew (including those who have disembarked or have been removed) during the 15-day period preceding the date of expected arrival or during the period since departure from a U.S. port (whichever period of time is shorter).

(b) The commander of an aircraft destined for a U.S. airport shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew.

(c) In addition to paragraph (a) of this section, the master of a ship carrying 13 or more passengers must report by radio 24 hours before arrival the number of cases (including zero) of diarrhea in passengers and crew recorded in the ship's medical log during the current cruise. All cases of diarrhea that occur after the 24 hour report must also be reported not less than 4 hours before arrival.

(Approved by the Office of Management and Budget under control number 0920-0134)

Subpart D--Health Measures at U.S. Ports: Communicable Diseases
Sec. 71.31 General provisions.

(a) Upon arrival at a U.S. port, a carrier will not undergo inspection unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States, as may exist when the carrier has on board individual(s) reportable in accordance with Sec. 71.21 or meets the circumstances described in Sec. 71.42. Carriers not subject to inspection under this section will be subject to sanitary inspection under Sec. 71.41 of this part.

(b) The Director may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease. The Director may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

Sec. 71.32 Persons, carriers, and things.

(a) Whenever the Director has reason to believe that any arriving person is infected with or has been exposed to any of the communicable diseases listed in paragraph (b) of this section, he/she may detain, isolate, or place the person under surveillance and may order disinfection or disinfestation as he/she considers necessary to prevent the introduction, transmission, or spread of the listed communicable diseases.

(b) The communicable diseases authorizing the application of sanitary, detention, and/or isolation measures under paragraph (a) of this section are: cholera or suspected cholera, diphtheria, infectious tuberculosis, plague, suspected smallpox, yellow fever, or suspected viral hemorrhagic fevers (Lassa, Marburg, Ebola, Congo-Crimean, and others not yet isolated or named).

(c) Whenever the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease, he/she may require detention, disinsection, disinfection, disinfestation, fumigation, or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases.

Sec. 71.33 Persons: Isolation and surveillance.

(a) Persons held in isolation under this subpart may be held in facilities suitable for isolation and treatment.

(b) The Director may require isolation where surveillance is authorized in this subpart whenever the Director considers the risk of transmission of infection to be exceptionally serious.

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(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and report, in person or by telephone, to the local health officer having jurisdiction over the areas to be visited, and report for medical examinations as may be required;

(2) Upon arrival at any address other than that stated as the intended destination when placed under surveillance, or prior to departure from the United States, inform, in person or by telephone, the health officer serving the health jurisdiction from which he/she is departing.

(d) From time to time the Director may, in accordance with section 322 of the Public Health Service Act, enter into agreements with public or private medical or hospital facilities for providing care and treatment for persons detained under this part.

(Approved by the Office of Management and Budget under control number 0920-0134) [50 FR 1519, Jan. 11, 1985; 50 FR 3910, Jan. 29, 1985]

Sec. 71.34 Carriers of U.S. military services.

(a) Carriers belonging to or operated by the military services of the United States may be exempted from inspection if the Director is satisfied that they have complied with regulations of the military services which also meet the requirements of the regulations in this part. (For applicable regulations of the military services, see Army Regulation No. 40-12, Air Force Regulation No. 161-4, Secretary of the Navy Instruction 6210.2, and Coast Guard Commandant Instruction 6210.2).

(b) Notwithstanding exemption from inspection of carriers under this section, animals or articles on board shall be required to comply with the applicable requirements of subpart F of this part.

Sec. 71.35 Report of death or illness on carrier during stay in port.

The master of any carrier at a U.S. port shall report immediately to the quarantine station at or nearest the port the occurrence, on board, of any death or any ill person among passengers or crew.

(Approved by the Office of Management and Budget under control number 0920-0134)

Subpart E--Requirements Upon Arrival at U.S. Ports: Sanitary Inspection

Sec. 71.41 General provisions.

Carriers arriving at a U.S. port from a foreign area shall be subject to a sanitary inspection to determine whether there exists rodent, insect, or other vermin infestation, contaminated FOOD or water, or other insanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable disease.

Sec. 71.45 FOOD, potable water, and waste: U.S. seaports and airports.

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(a) Every seaport and airport shall be provided with a supply of potable water from a watering point approved by the Commissioner of FOOD and Drugs, FOOD and Drug Administration, in accordance with standards established in title 21, Code of Federal Regulations, parts 1240 and 1250.

(b) All FOOD and potable water taken on board a ship or aircraft at any seaport or airport intended for human consumption thereon shall be obtained from sources approved in accordance with regulations cited in paragraph (a) of this section.

(c) Aircraft inbound or outbound on an international voyage shall not discharge over the United States any excrement, or waste water or other polluting materials. Arriving aircraft shall discharge such matter only at servicing areas approved under regulations cited in paragraph (a) of this section.

Sec. 71.48 Carriers in intercoastal and interstate traffic.

Carriers, on an international voyage, which are in traffic between U.S. ports, shall be subject to inspection as described in Secs. 71.31 and 71.41 when there occurs on board, among passengers or crew, any death, or any ill person, or when illness is suspected to be caused by insanitary conditions.

13.2 Acute Gastroenteritis Surveillance System

13.2.1 Introduction

The following three forms are provided as guides to standardize the collection of information required to assess the patterns of AGE and monitor for OUTBREAKS aboard vessels:

- Vessel Sanitation Program - ACUTE GASTROENTERITIS (AGE) Surveillance Log
- AGE Surveillance System Questionnaire
- Meals and Activities Aboard Vessel Prior to Illness

13.2.2 Forms

[illegible]

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Acute Gastroenteritis Surveillance System Questionnaire



(To be completed if you experienced acute gastroenteritis)

Vessel Name:		Voyage No. :		Date:	
Last Name:		First Name:			
Date of Birth:	(mm/dd/yyyy)	Age:	(in years)	Sex M / F	
Cabin Number:		Total Number of People in Cabin:			
Dining Seating:		Dining Table Number:			
Symptoms Started Date:	(mm/dd/yyyy)	Time:	(hh:mm)	AM / PM	
Do you know other people ill with the same symptoms?					Yes / No
If yes, please list their names:					
Did you stay overnight or longer in a boarding city before you joined the vessel?					Yes / No
If yes, where?	City:	State:	Country:		
Was the overnight stay in a hotel/motel/commercial residence?					Yes / No
If yes, what was the name and address of the hotel, motel/commercial residence					
Name:					
Address:					
City:		State:		Country:	
How did you travel to the city where you boarded the ship for this cruise? Select all that apply.					
☐	Airplane	Airlines:	Flight No.:		
☐	Automobile				
☐	Bus/Motorcoach				
☐	Train				
☐	Other Please specify:				
Are you a member of a tour group?					Yes / No
Prior to boarding the ship, did you participate in a pre-embarkation tour/package?					Yes / No
If yes, which tour(s)/package(s) did you participate in? (list all)					
Prior you your illness, did you go ashore at any of the ports of call?					Yes / No
If yes, please list the ports of call where you went ashore					
Did participate in any shore excursions at any port of call?					Yes / No
If yes, which shore excursions did you participate in? (list all)					
Did you eat anything while you were ashore at any port of call?					Yes / No
Did you drink anything (including drinks with ice) while ashore at any port of call?					Yes / No
What did you think is the cause of your illness?:					

PLEASE TURN THIS FORM OVER TO PROVIDE FOOD AND SHIPBOARD ACTIVITIES HISTORY

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Last Name _____ First Name _____

Meals and Activities Aboard Vessel Prior to IllnessPlease list the *specific* vessel locations of the meals you consumed and the vessel activities you participated in before you became ill.

Day of illness onset Give Date:	Day before illness onset	Two days before illness onset	Three days before illness onset
Breakfast Place: _____ Time: _____ Items eaten/drunk _____	Breakfast Place: _____ Time: _____ Items eaten/drunk _____	Breakfast Place: _____ Time: _____ Items eaten/drunk _____	Breakfast Place: _____ Time: _____ Items eaten/drunk _____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Lunch Place: _____ Time: _____ Items eaten/drunk _____	Lunch Place: _____ Time: _____ Items eaten/drunk _____	Lunch Place: _____ Time: _____ Items eaten/drunk _____	Lunch Place: _____ Time: _____ Items eaten/drunk _____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Dinner Place: _____ Time: _____ Items eaten/drunk _____	Dinner Place: _____ Time: _____ Items eaten/drunk _____	Dinner Place: _____ Time: _____ Items eaten/drunk _____	Dinner Place: _____ Time: _____ Items eaten/drunk _____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Snack Place: _____ Time: _____ Items eaten/drunk _____	Snack Place: _____ Time: _____ Items eaten/drunk _____	Snack Place: _____ Time: _____ Items eaten/drunk _____	Snack Place: _____ Time: _____ Items eaten/drunk _____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Activities	Activities	Activities	Activities
AM PM	AM PM	AM PM	AM PM
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

13.3 Acute Gastroenteritis Surveillance System Reporting

13.3.1 Introduction

13.3.1.1 Operations Manual

Details of the AGE surveillance data collection and notification system are contained in section 4.0 of this manual (ACUTE GASTROENTERITIS Surveillance).

Following are some sample itineraries of vessels that may call upon a U.S. port. The ports where the routine AGE surveillance report is required at least 24 hours before arrival, but not more than 36 hours, are marked with .

13.3.1.2 Sample Itineraries

Itinerary A

Port Everglades, FL
at Sea
at Sea
St. Thomas, U.S. VI
Philipsburg, St. Maarten
at Sea
Nassau, Bahamas **Port**
Everglades, FL 

Itinerary C* Barcelona,
Spain
at Sea
at Sea
at Sea
St. Thomas, U.S. VI 
at Sea
Port Everglades, FL

Itinerary B

Vancouver, BC
at Sea
Juneau, AK  Ketchikan,
AK
Sitka, AK
at Sea
Seward, AK
Vancouver, BC

Itinerary D

Miami, FL
at Sea
St. Barthélemy, French W.I.
San Juan, PR 
St. Thomas, U.S. VI
at Sea
Freeport, Bahamas
Miami, FL 

*Note: The report in Itinerary C includes passengers and crew members during the 15 days before arrival in St. Thomas, U.S. VI.

13.3.2 Submission Procedures

13.3.2.1 Mechanism

Routine AGE surveillance reports may be submitted as follows:

- Telephone: 800-323-2132 or 954-356-6650,
- Fax: 954-356-6671,
- Email: vsp-report@cdc.gov, or
- Website (user ID and password required):
<https://wwwn.cdc.gov/midrs/gilogin.aspx>

13.3.2.2 Telephone Call Required

A telephone notification to VSP at the telephone numbers listed above must accompany a special 2% report required when the vessel is within 15 days of expected arrival at a U.S. port, even when the special 2% report is submitted via fax, electronic mail, or website.

13.4 Acute Gastroenteritis Outbreak Investigation

13.4.1 Introduction

13.4.1.1 Introduction

OUTBREAKS of AGE aboard cruise ships are relatively infrequent occurrences. Since implementation of the cooperative program between the cruise industry and VSP, the OUTBREAK rate on vessels has steadily declined each year.

13.4.1.2 Vigilance

Ongoing vigilance and rapid OUTBREAK detection and response are still warranted. Because so many people share the same environment, meals, and water, disease can often spread quickly to passengers and crew members on the vessel and overwhelm the vessel's medical system. The infection can also continue unabated between cruises if proper interventions are not instituted.

13.4.1.3 Consultation

An OUTBREAK of AGE occurs aboard a vessel when the number of cases is in excess of expected levels for a given time period. When the cumulative proportion of REPORTABLE CASES of AGE reaches 2% among passengers or 2% among crew and the vessel is within 15 days of arrival at a U.S. port, the vessel must submit a special report to VSP. This provides an early opportunity for consultation to potentially avert more illness among passengers and crew members.

13.4.1.4 Monitoring

In most instances, a 2% proportion of illness will not lead to an investigation aboard the vessel but will provide the opportunity to discuss and monitor illness patterns and collaboratively develop intervention strategies. VSP staff members are always available to discuss disease TRANSMISSION and intervention questions.

13.4.1.5 Investigation

OUTBREAKS of AGE aboard cruise ships are relatively infrequent occurrences. If the proportion of illness in either passenger or crew populations crests VSP's 3% OUTBREAK threshold or for subsequent voyages that crest the 2% or 3% thresholds, an onboard investigation may occur.

13.4.1.6 Special Circumstances

Under special circumstances, when an unusual AGE pattern or disease characteristic is found, an investigation may be conducted when the proportion of cases is less than 3%. These special circumstances may

include a high incidence of illness in successive cruises, unusual severity of illnesses or complications, or a large number of persons reporting the illness over a brief period of time.

13.4.1.7 Rapid Response

Conducting an OUTBREAK investigation aboard a vessel demands a rapid, organized, and comprehensive response. Because of the TURNOVER of passengers, and sometimes crew members, the investigation must be rapid in order to collect data needed to identify the cause.

13.4.1.8 Collaboration

The investigation is a collaborative effort of the cruise line, passengers and crew members aboard the vessel, and VSP. Therefore, an organized plan drafted between the organizations and individuals involved is crucial in conducting a successful investigation—a comprehensive effort that includes epidemiologic, environmental, and laboratory studies. Recommendations based on the success of the investigation can then be implemented to prevent a recurrence on the following cruise.

13.4.2 Objectives

The objectives of an investigation are to

- Determine the extent of the AGE among passengers and crew.
- Identify the agent causing the illness.
- Identify risk factors associated with the illness.
- Formulate control measures to prevent the spread of the illness.

13.4.3 Outbreak Investigation Procedures

13.4.3.1 Contingency Plan

The early stages of an investigation are usually coordinated aboard the vessel by the vessel's medical staff in cooperation with engineering and hotel staff. It is important to have a coordinated contingency plan in place on board the vessel before implementation is needed. All staff with a potential for involvement in an investigation should be familiar with the contingency plan.

13.4.3.2 Periodic Review

This preliminary preparation will assist the vessel with the necessary rapid implementation of investigation and response measures before the arrival of the VSP team. The OUTBREAK contingency plan should be periodically reviewed to ensure it will still meet the vessel's needs in dealing with an OUTBREAK.

13.4.3.3 Specimens and Samples

Timely collection of medical specimens and FOOD and water samples is important in the disease investigative process. The proper materials and techniques for collection and preservation are a part of the planning. It is important to periodically review these to make sure they are on hand and ready to use in the event they are needed.

13.4.3.4 Ready to Use

A list of recommended medical specimen and FOOD sample collection supplies for investigating AGE OUTBREAKS can be found in sections 13.4.5 and 13.4.6 of this annex.

Vessels with no medical staff aboard may choose to stock only the starred items in 13.4.5.1 unless a qualified staff member aboard is capable of performing venipuncture for collection of serum specimens.

13.4.3.5 Useful Information

To assist in the rapid evaluation of the extent of illness among passengers and crew and identify the causative pathogen and associated risk factors, VSP may request the following items:

- AGE OUTBREAK Action Plan for turnaround day.
- General OUTBREAK Prevention and Response Plan.
- AGE surveillance logs (previous and current voyages).
- AGE 72-hour questionnaires.
- Vessel's itinerary (previous and current voyages).
- List of shore excursions, including lunch and BEVERAGE menus.
- Public vomiting/diarrhea logs (previous and current voyages).
- POTABLE WATER bunkering, production, and distribution logs.
- POTABLE WATER bacteriological testing records.
- POTABLE WATER maintenance records.
- Recreational water logs, including information about fecal and vomit accidents.
- Vessel map of cabins with AGE CASES.
- Dining room seating maps with AGE passenger cases indicated.
- Dining room seating maps with AGE waiter and assistant waiter stations indicated.
- All menus.
- Cooling logs for POTENTIALLY HAZARDOUS FOOD.
- Vessel daily newsletters indicating guest activities.
- Letter for passengers embarking on turnaround day.
- Manifests for all groups of ≥ 15 people (groups traveling together).
- Manifests for shore excursions within 48 hours of first peak of cases.
- Security gangway records for AGE CASES within 48 hours of illness onset.

13.4.3.6 Survey

VSP may also request distribution of a survey to all passengers and crew members. VSP will provide this survey to the vessel. Completed surveys should be held in the infirmary until collection by VSP staff for epidemiologic analysis.

13.4.3.7 Interviews

Interviews with cases may also be useful for identifying the etiology and associated risk factors of an OUTBREAK. When distributing the surveys, medical staff should advise cases that interviews may be requested when VSP arrives at the vessel.

13.4.4 Report**13.4.4.1 Preliminary Report**

After an OUTBREAK investigation, a preliminary report of findings based on available clinical and epidemiologic information, environmental inspection reports of the investigation, and interim recommendations will be presented to the master of the vessel. Based on preliminary findings, additional materials (including additional passenger and crew information) may be requested from the cruise line or the vessel and follow-up studies may be undertaken to address specific suspicions or concerns.

13.4.4.2 Final Report

The report presented to the master of the vessel will remain preliminary until completion of more-extensive epidemiologic and laboratory studies and distribution of a final report containing summary recommendations.

13.4.5 AGE Specimens**13.4.5.1 AGE Specimen Supplies**

Supplies recommended for specimen collection include the following:

- *20–50 wide-mouth plastic jars or specimen cups with screw caps for stool specimens.
- *20 plastic bags for storing specimen cups.
- *Disposable medical gloves.
- *Plastic disposable spoons for collecting stool.
- *20 sterile bottles or tubes containing bacterial preservative and transport medium (e.g., Cary-Blair).
- *Sterile swabs.
- *Rectal swabs.
- Stool preservative medium for parasites.
- *A large commercial roll of plastic wrap.
- Sterile phlebotomy supplies for obtaining serum specimens (needles, syringes, swabs).

- Sterile pipettes.
- 20 serum separator tubes (containing no anticoagulant [red tops]).
- 20 nunc tubes for serum separation.
- Shipping containers (for diagnostic specimens).
- Shipping container labels and markings (as required by current shipping regulations for diagnostic specimens).

As noted in Annex 13.4.3.4, vessels with no medical staff aboard may choose to stock only the *starred items unless a qualified staff member aboard is capable of performing venipuncture for collection of serum specimens.

13.4.5.2 Specimen Collection

13.4.5.2.1 Request Procedures

It may be advisable to collect clinical specimens of stool, vomitus, or serum from passengers and crew members with REPORTABLE CASES of AGE. Timely notification of the vessel as to what samples and information will be required is essential. Collection of specimens for analysis for viruses, bacteria, or parasites may be recommended depending on the likely etiology of illness.

It is recommended that specimens be requested from patients during clinical evaluation in the infirmary or after infirmary visits by direct contact with or a letter from medical staff. Each individual asked to provide specimens should be given disposable gloves, two specimen cups, a disposable spoon, and plastic wrap.

Following are

- Suggested language for a passenger letter requesting stool specimens.
- Instructions to passengers and crew for collection of stool.

Request to Passengers for Stool Specimens

The [U.S. Public Health Service/Name of Cruise Line/Medical Department] is requesting stool specimens from some people who became ill with AGE on this cruise. Please give one cup to a friend who has recently become ill and use the other cup for yourself. Put your next bowel movement into the cup and return the cup to the vessel's medical center as soon possible so it can be refrigerated.

Patient Instructions

1. Urinate into the toilet (if you feel the need).
2. Wash and dry your hands.
3. Lift the toilet seat.

4. Place sheets of plastic wrap over the toilet bowl, leaving a slight dip in the center.
5. Put the toilet seat down.
6. Pass some stool onto the plastic wrap. Do not let urine or water touch the stool specimen, if possible.
7. Using the spoon given to you, place bloody, slimy, or whitish areas of the stool into the container first. Fill the cup at least 2/3 full, if possible.
8. Tighten the cap.
9. Wash your hands.
10. Label the specimen jar with your name, the date, and your cabin number.

13.4.5.2.2 Medical Staff Instructions

Specimen Labeling

Please ensure that each specimen is properly labeled with the following:

- Date of collection.
- Unique identifying number. (A separate log containing unique identifying number linked to case name must be kept on the ship.)
- Notation on use of antidiarrheal or antibiotic medication.

Collection, Storage, and Transport

Complete guidelines for collection and storage of specimens for viral, bacterial, and parasite analysis are listed below, although it may not be necessary to implement all procedures during each investigation. Transport of specimens will be arranged in collaboration with VSP.

13.4.5.3 Guidelines for Collecting Fecal Specimens for Viral Diagnosis

(Modified from *MMWR*, 1990; 39[RR-5];19.)

13.4.5.3.1 Stool for Viral Diagnosis

1. Collect stool specimens in the first 48 hours. Specimen collection should not await the results of epidemiologic and other investigations because delay will almost certainly preclude a viral diagnosis. If information gathered subsequently indicates that a viral etiology is unlikely, the specimens can be discarded.
2. Collect 10 diarrhea bulk specimens, if possible. Bulk specimens, enough to fill a large stool cup, are preferred. Serial specimens from persons with acute, frequent, high-volume diarrhea are particularly useful. The smaller the specimen and the more formed the stool, the lower the

diagnostic yield. Rectal swabs are of little or no value in viral detection. Specimens from at least 10 ill persons should be collected to maximize the chance that a diagnosis can be made. The diagnostic yield is low when specimens from fewer than 10 persons are submitted.

3. Store specimens at 4°C (40°F). Freezing may destroy the characteristic viral morphology that permits a diagnosis by electron microscopy.
4. Take special care to prevent cross-CONTAMINATION of specimens during collection and transport because new amplification techniques are exquisitely sensitive.

13.4.5.3.2 Paired Serum Specimens for Viral Diagnosis

1. Collect acute-period serum specimens during the first 5 days of symptoms. The convalescent-period serum specimen should be collected during the third to sixth week after illness.
2. Collect 10 pairs from ill persons (the same persons submitting stool specimens) and 10 pairs from well persons. Serum specimens from adults should be 10 mL and serum specimens from children should be 3 mL.
3. Use storage tubes containing no anticoagulant (tubes with red tops) for collection.
4. If a centrifuge is available, centrifuge the specimen for 10 minutes and remove the serum using a pipette. If no centrifuge is available, the blood specimens can sit in a refrigerator until a clot has formed; remove the serum using pipettes, as above.
5. Place the serum into an empty nunc tube, label, then refrigerate. Do not freeze.

13.4.5.3.3 Other Specimens for Viral Diagnosis

Water, FOOD, and Environmental Samples

Viruses causing AGE are not routinely detected in water or FOOD, but may be detectable on surfaces with environmental swabbing. Swabbing may be completed under the guidance of VSP staff or the CDC National Calicivirus Laboratory.

Viruses have been successfully detected in vomitus specimens. These should be collected and sent using same methodology as for

stool specimens.

13.4.5.4 Guidelines for Collecting Fecal Specimens for Bacteriologic Diagnosis

Before use, the transport media should be stored in a refrigerator or at room temperature. If the transport media is stored at room temperature, it should normally be chilled for 1 to 2 hours by refrigeration before use.

At least two rectal swabs or swabs of fresh stools should normally be collected for bacterial analysis and placed in refrigerated Cary-Blair transport media.

It is recommended that the swabs be inserted initially into the transport media to moisten, then inserted about 1 to 1-1/2 inches (approximately 25 to 38 millimeters) into the rectum, gently rotated, and removed for insertion individually into the same tube of transport media.

If possible, there should be visible fecal material on the swabs.

Both swabs should be inserted into the same tube of media and the swabs pushed completely to the bottom of the tube.

The top portion of the stick touching the fingers should be broken off and discarded.

Refrigeration during transport may be accomplished by shipping in an insulated box with frozen refrigerant packs. The specimens must never be frozen during storage or transport.

13.4.5.5 Guidelines for Collecting Fecal Specimens for Parasite Diagnosis

13.4.5.5.1 *Parasite Specimens*

In the event a disease of parasitic etiology is suspected, arrangements will be made for shipment of appropriate specimen containers containing 10% formalin and PVA (polyvinyl alcohol).

A summary table with instructions for collecting clinical specimens during OUTBREAKS to test for bacteria, viruses, and parasites is available at

www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/specimen-collection.html.

13.4.6 Food and Water Samples

13.4.6.1 Food and Water Sample Collection Kit

A recommended FOOD and water sampling kit includes the following:

- Sterile sampling containers (15 or more sealable plastic bags and wide-mouth screw top jars; 15 water sample bottles with sodium thiosulfate solution to provide concentration of 100 mg per mL of sample volume; foil or heavy wrapping paper).
- Sterile specimen collection devices (spoons, tongs, scoop, knife, scissors, swabs, and pipettes).
- DISINFECTION agents (sanitizing solution, 95% ethyl alcohol, and propane torch).
- Support EQUIPMENT (plastic gloves, plastic container liners for iced samples, waterproof marking pen for sample identification, roll of adhesive or masking tape, labels, waterproof cardboard tags with ties, insulated ice chests, and frozen refrigerant packs).

13.4.6.2 Food and Water Sampling Procedures

13.4.6.2.1 Sample Plan

Environmental sampling should be directed toward suspect FOOD and sources identified by the preliminary epidemiologic investigation.

13.4.6.2.2 Aseptic Techniques

FOOD and water samples should be collected using aseptic techniques. Washed and gloved hands and sterile sampling UTENSILS and containers protect the integrity of the sample during collection. Taps used for water collection should be sterilized with heat or chemicals. The sample should be collected after 1 minute of flow time.

13.4.6.2.3 Sample Amount

Approximately 200 grams or 200 mL of sample will usually suffice for the laboratory analytical requirements. Carefully squeeze most of the air out of the bag before sealing FOOD samples.

13.4.6.2.4 Sample Identification

Sample numbers should be assigned on each collection container and recorded on a sample log that will accompany samples to the laboratory. Record information that identifies the date, time, and location of collection; product information; codes; storage

conditions and temperatures for each sample on the sample log. Include contact information for the PERSON IN CHARGE of collecting the samples on the vessel.

13.4.6.2.5 Sample Temperatures

FOOD and water samples should be held below 5°C (41°F) but not frozen. Sufficient frozen refrigerant packs should be used to maintain cold sample temperatures during transport to the laboratory.

13.5 Disinfection Calculations for Water and Equipment

13.5.1 Introduction

POTABLE WATER systems and EQUIPMENT, SWIMMING POOLS, and WHIRLPOOL SPAS on a vessel may need to be disinfected when there is a possibility of CONTAMINATION and as a routine part of maintenance.

This annex provides tables for calculating the amount of chlorine to be used in emergency chlorination of POTABLE WATER and for the routine DISINFECTION of POTABLE WATER systems and EQUIPMENT, SWIMMING POOLS, and WHIRLPOOL SPAS.

13.5.2 Water Chlorination

Tables 1 and 2 (Annex 13.5.4) are for calculating the amount of chlorine to be used in the DISINFECTION of POTABLE WATER systems, SWIMMING POOLS, and EQUIPMENT.

Amounts of chlorine compound shown in Table 1 are in GRAMS.

Amounts of chlorine compound shown in Table 2 are in KILOGRAMS.

The chlorine compound column in Tables 1 and 2 refers to the amount of available chlorine in the compound as stated on the product label. Requirements varying from those shown in the table—for example: metric tons of water, available chlorine compounds, or final chlorine concentrations—may be extrapolated.

For example, POTABLE WATER TANKS or fresh water tanks must be superchlorinated to at least 50 MG/L (ppm) available chlorine when samples taken from these tanks indicate potential CONTAMINATION with fecal coliform bacteria.

The total amount of 70% chlorine compound required to obtain 50 MG/L (ppm) in 166 metric tons of water is calculated in Example 1, which illustrates how to use the tables.

Example 1. The capacity of a potable tank from which a coliform-positive sample was obtained is 166 metric tons. The vessel has a compound on board containing 70% available chlorine.

The amount of chlorine required for 50 ppm is determined as follows:

- Use the 70% chlorine compound columns in Table 1.
- Find the 70% row that corresponds to 100 metric tons of water.
- Follow this 70%/100 ton row across until you reach the “50 ppm” column (7,150 grams).
- Do the same using the 50, 10, 5, and 1 metric ton columns to

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determine the totals for 166 metric tons.

- Total each column as shown in the calculation table below.

Calculation Table for Example 1

Metric Tons of Water	Grams Required, 70% Available Chlorine Solution
100	7,150.0
50	3,575.0
10	715.0
5	357.5
1	71.5
166 Total Weight of Water	11,869.0 grams or 11.87 kilograms

In this example, the amount of 70% chlorine compound required for 166 tons of water at 50 parts per million is 11,869.0 grams or 11.87 kilograms.

13.5.3 Equipment Disinfection

The Available Chlorine in Compounds table lists the various chlorine compounds and the amount of the compound required in grams per liter of water to produce a solution containing 100 ppm of chlorine. The 100-ppm chlorine solution should be applied as outlined in this manual.

Available Chlorine in Compounds

Grams per Liter of Available Chlorine	Grams per Liter for 100 ppm
70%	0.143
65%	0.154
25%	0.4
15%	0.7
10%	1.0
5%	2.0

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13.5.4 Tables**Table 1. Amount of Chlorine Required in GRAMS to Produce Desired Parts per Million (ppm) (MG/L)**

Chlorine Compound	Metric Tons of Water	1 ppm	2 ppm	5 ppm	10 ppm	50 ppm	100 ppm
70%	1	1.43	2.86	7.15	14.30	71.50	143.00
70%	5	7.15	14.30	35.75	71.50	357.50	715.00
70%	10	14.30	28.60	71.50	143.00	715.00	1,430.00
70%	50	71.50	143.00	357.50	715.00	3,575.00	7,150.00
70%	100	143.00	286.00	715.00	1,430.00	7,150.00	14,300.00
65%	1	1.54	3.08	7.70	15.40	77.00	154.00
65%	5	7.70	15.40	38.50	77.00	385.00	770.00
65%	10	15.40	30.80	77.00	154.00	770.00	1,540.00
65%	50	77.00	154.00	385.00	770.00	3,850.00	7,700.00
65%	100	154.00	308.00	770.00	1,540.00	7,700.00	15,400.00
25%	1	4.00	8.00	20.00	40.00	200.00	400.00
25%	5	20.00	40.00	100.00	200.00	1,000.00	2,000.00
25%	10	40.00	80.00	200.00	400.00	2,000.00	4,000.00
25%	50	200.00	400.00	1,000.00	2,000.00	10,000.00	20,000.00
25%	100	400.00	800.00	2,000.00	4,000.00	20,000.00	40,000.00

Table 2. Amount of Chlorine Required in KILOGRAMS to Produce Desired Parts per Million (ppm) (MG/L)

Chlorine Compound	Metric Tons of Water	1 ppm	2 ppm	5 ppm	10 ppm	50 ppm	100 ppm
15%	1	0.007	0.01	0.03	0.07	0.34	0.70
15%	5	0.035	0.07	0.17	0.35	1.70	3.50
15%	10	0.070	0.13	0.34	0.70	3.40	7.00
15%	50	0.350	0.65	1.70	3.50	17.00	35.00
15%	100	0.70	1.30	3.40	7.00	34.00	70.00
10%	1	0.01	0.02	0.05	0.10	0.50	1.00
10%	5	0.05	0.10	0.25	0.50	2.50	5.00
10%	10	0.10	0.20	0.50	1.00	5.00	10.00
10%	50	0.50	1.00	2.50	5.00	25.00	50.00
10%	100	1.00	2.00	5.00	10.00	50.00	100.00
5%	1	0.02	0.04	0.10	0.20	1.00	2.00
5%	5	0.10	0.20	0.50	1.00	5.00	10.00
5%	10	0.20	0.40	1.00	2.00	10.00	20.00
5%	50	1.00	2.00	5.00	10.00	50.00	100.00
5%	100	2.00	4.00	10.00	20.00	100.00	200.00

13.6 Potable Water Pipe and System Disinfection Method Examples (Nonemergency)

Examples in this section relate to nonemergency situations. In an emergency, see section 5.3.4.1.4 for concentration and contact time.

To achieve the proper DISINFECTION of a section of pipe being replaced,

- Fill the pipe with 50 MG/L (ppm) of free residual HALOGEN, cap on both ends, and let it sit for 4 hours **OR** Place small sections of pipes in a large container filled with 50 MG/L (ppm) of free residual HALOGEN for 4 hours.
- Drain and flush disinfected parts of the system with POTABLE WATER.

To achieve the proper DISINFECTION of a section of pipe already installed on part of the distribution system,

1. Install temporary shut-off valves at each end of the new section.
2. Close the valves.
3. Inject 50 MG/L (ppm) of free residual HALOGEN through a temporary injection port.
4. Let it stand for 4 hours.
5. Drain and flush disinfected parts of the system with POTABLE WATER.

13.7 Sample Cross-Connection Control Program Guideline

13.7.1 Background

Unprotected CROSS-CONNECTIONS to the POTABLE WATER system can result in mild changes to the aesthetic quality of the water affecting taste, odor, and color or severe changes that can result in illness or death. The purpose of a CROSS-CONNECTION control program is to identify these connections and provide appropriate protection.

13.7.2 Introduction

Use this outline to either develop a comprehensive CROSS-CONNECTION control program or update and maintain an existing program.

13.7.3 Cross-Connection Survey

One of the first steps in developing a CROSS-CONNECTION control program is to conduct a thorough survey of the POTABLE WATER system to identify all actual or potential CROSS-CONNECTIONS. Although an initial survey of the vessel can be time consuming, it is essential to ensure that all connections are identified so that appropriate protection can be decided on.

Protection of POTABLE WATER can take two forms—containment or complete protection. Although the former may be the objective for a water supplier and requires less time and detail, the latter is the objective for this guidance.

Example: A surveyor enters a structure and identifies numerous connections to the POTABLE WATER—both nonhealth-HAZARD and health-HAZARD connections. For containment purposes, an RP ASSEMBLY on the exterior supply line downstream of the water meter would contain all of the HAZARDS within the structure but would do nothing to protect the individual connections within the facility. If complete protection is the goal, each CROSS-CONNECTION in the structure must be identified and a decision made as to the appropriate BACKFLOW PREVENTION METHOD to be used. For vessels under VSP, the goal is complete protection.

Surveyors should be

- Knowledgeable in basic plumbing.
- Knowledgeable in the principles of BACKFLOW, including BACKSIPHONAGE and BACKPRESSURE.
- Able to identify both potential and actual CROSS-CONNECTIONS.
- Familiar with the level of HAZARD posed by each connection.

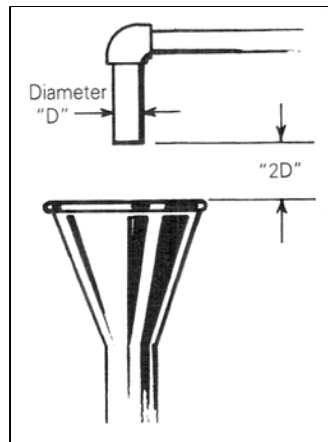
Surveyors should physically inspect all areas of the vessel supplied with POTABLE WATER. The best approach for this may be to go deck by deck, starting with the decks with connections that pose the greatest risk to health.

This may require starting with the engine room deck. As each connection is identified, it is added to a listing. All information related to this connection should also be added to the listing. An example of required information can be found in section 13.7.5.1. Unprotected or inadequately protected connections must be addressed as quickly as possible, especially if the connection is a health HAZARD.

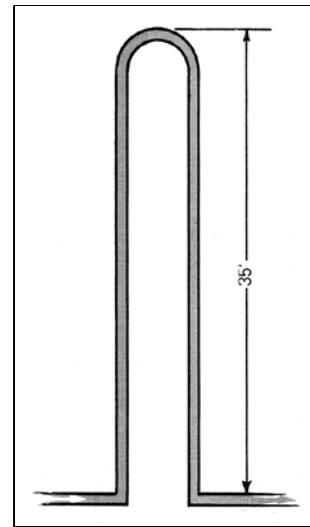
13.7.4 Backflow Protection Methods

All figures in this section are provided courtesy of the U.S. Environmental Protection Agency (EPA).

13.7.4.1 Nonmechanical Backflow Protection

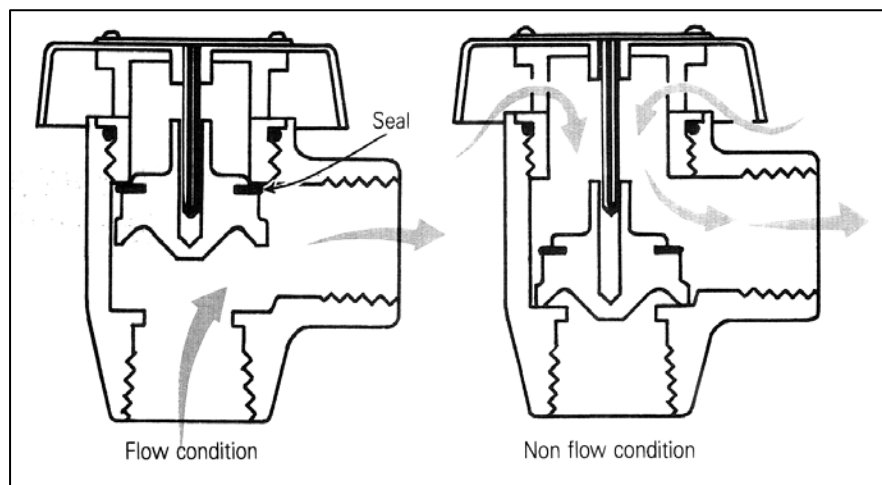


AIR GAP



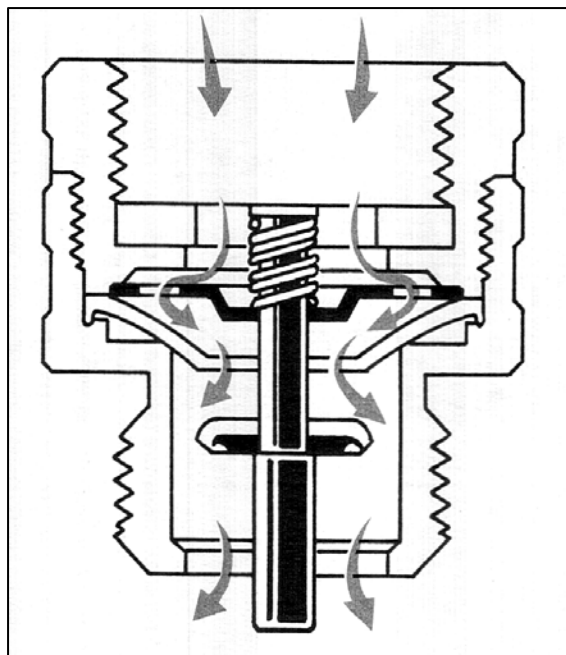
Antisiphon loop

13.7.4.2 Mechanical Backflow Protection

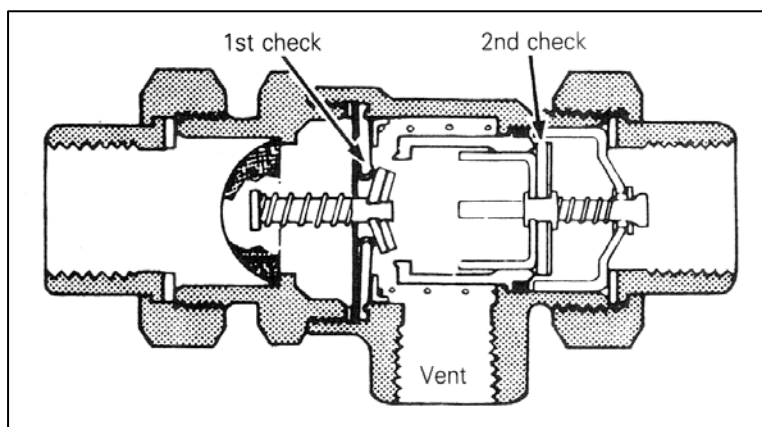


ATMOSPHERIC VACUUM BREAKER

VSP 2018 Operations Manual

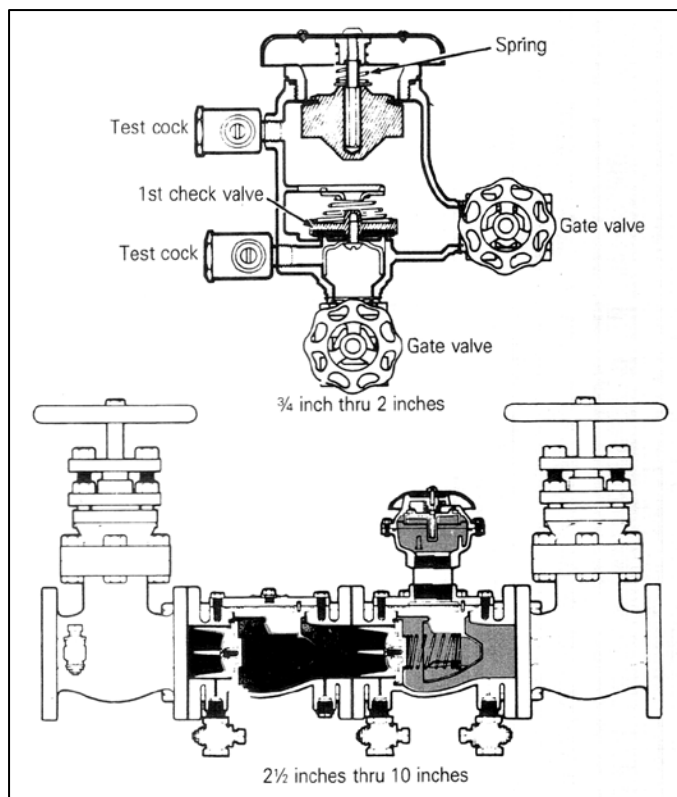
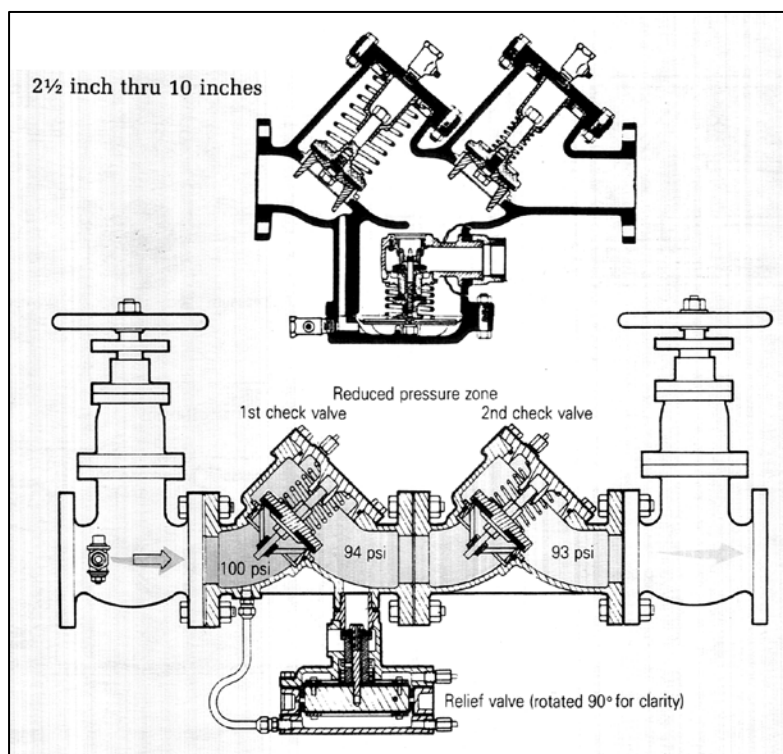


HOSE-BIB VACUUM BREAKER



DUAL CHECK VALVE WITH ATMOSPHERIC VENT

VSP 2018 Operations Manual

**PRESSURE VACUUM BREAKER****REDUCED PRESSURE PRINCIPLE ASSEMBLY**

13.7.5 Cross-Connections on Vessels

13.7.5.1 List of Connections Requiring Backflow Prevention on Vessels

A log listing of all CROSS-CONNECTIONS on the vessel must be developed. At a minimum the log should contain the data elements in numbers 2, 3, 6, 7, and 8. Inclusion of the additional data in numbers 1, 4, and 5 is recommended.

1. Deck (A, B, C, 1, 2, 3...).
2. Location (of connection and of device, if different).
3. Connection description (e.g., hose, chemical tank, coffee machine, detergent dispenser).
4. Connection subjected to CONTINUOUS PRESSURE (CP) or noncontinuous pressure (NCP).
5. Connection subjected to [*BACKSIPHONAGE only* or *BACKSIPHONAGE and BACKPRESSURE*].
6. Protection used (AIR GAP or manufacturer name and designation for device).
7. Inspection date.
8. Inspection results (passed, replaced, psi results).

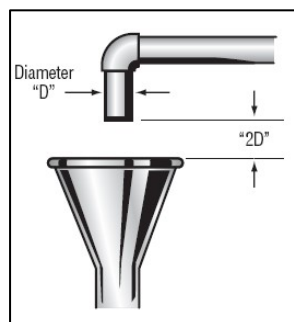
13.7.5.2 Specific Backflow Protection Choices on Vessels: Air Gaps and Backflow Prevention Devices

Use this section to provide information to vessel staff on the specific BACKFLOW PREVENTION DEVICES used on the vessel. For each device, a copy of the specification sheets or technical sheets as well as the manufacturer's installation recommendations should be included in the program documentation file. Generally these documents are available online from the websites of each device manufacturer.

AIR GAPS

Vessel-designed AIR GAPS

- See definitions



Manufactured AIR GAPS

- Manufacturer's specification sheets
- Manufacturer's installation recommendations

Noncontinuous Pressure Devices

ATMOSPHERIC VACUUM BREAKER

- Manufacturer's specification sheets
- Manufacturer's installation recommendations

Hose Vacuum Breaker

- Manufacturer's specification sheets
- Manufacturer's installation recommendations

Select DUAL-CHECK VALVE with intermediate vents (such as Watts NLF9)

- Manufacturer's specification sheets
- Manufacturer's installation recommendations

CONTINUOUS PRESSURE devices

Select DUAL CHECK VALVE with intermediate vent (such as Watts N9)

- Manufacturer's specification sheets
- Manufacturer's installation recommendations

PRESSURE VACUUM BREAKER

- Manufacturer's specification sheets
- Manufacturer's installation recommendations
- Test kit and instructions

REDUCED PRESSURE PRINCIPLE ASSEMBLY

- Manufacturer's specification sheets
- Manufacturer's installation recommendations
- Test kit and instructions

References

- EPA CROSS-CONNECTION Control Manual
- Device manufacturer list (based on devices used on vessel)
- Manual of CROSS-CONNECTION Control, 9th edition (University of Southern California)

13.8 Baby-Only Water Facility

For use by children who are in diapers or who are not completely toilet trained.

13.8.1 Introduction

VSP recognizes the increased desire of passengers to allow children who are in diapers or who are not completely toilet trained to use RWFs. With that in mind, following are requirements for operating a RWF for the sole use by children who are in diapers or who are not completely toilet trained. Each cruise line is required to submit a VARIANCE request to operate this type of facility.

Administrative Note: This section does not apply to vessels that have an APPROVED VARIANCE from section 6.9.1 at the time of issuance of the *VSP 2018 Operations Manual*. Those vessels must continue to comply with all of the requirements of the VARIANCE.

13.8.2 Design and Construction

Facilities must be designed and constructed in accordance with the latest version of the *VSP Construction Guidelines*, regardless of the date the keel was laid.

Before new construction or remodeling of an existing RWF, all plans must be submitted for review and approval by VSP. Once APPROVED, no parts of the system or its operation may be changed without prior written approval from VSP. For maintenance purposes, system components of at least equal performance specifications may be changed without prior approval.

13.8.3 Water Source

13.8.3.1 Recirculation

The water source for this facility must only be POTABLE WATER for recirculation systems.

13.8.3.2 Flow-Through

Seawater or POTABLE WATER may be used for a flow-through system.

13.8.3.3 Operation

The system must be designed to operate in flow-through only or recirculation only.

13.8.3.3.1 Flow-Through

At Sea

A flow-through seawater supply system must be used only while the vessel is MAKING WAY and at sea beyond 20 kilometers (12 miles) from nearest land or any point of land discharge.

In Port

Before arriving to a port or HARBOR, the seawater supply system must be shut down and the facility closed for use before the vessel reaches the 20-kilometer (12-mile) mark or any point of land-based discharge. The system must remain empty while in port or at anchor or the flow-through supply must be switched to POTABLE WATER.

Recirculation

Fill water must be provided only to the compensation tank and not directly to the BABY-ONLY WATER FACILITY.

TURNOVER Rate

The entire volume of water must pass through all parts of the system to include filtration, secondary UV DISINFECTION, and halogenation at least once per half hour.

The filtration, UV DISINFECTION, and HALOGEN and pH control systems must be operated 24 hours a day. This is required even when the facilities are not in use. The systems may only be shut down for required maintenance or cleaning of system components.

13.8.3.4 Filtration

BABY-ONLY WATER FACILITY water must be filtered.

At least one replacement cartridge or canister-type filter must be available.

Cartridge or canister-type filters must be inspected weekly for cracks, breaks, damaged components, and accumulation of excessive organic material.

Granular filters must be backwashed daily. Backwashing must be repeated until the water viewed through the sight glass or discharge point is clean flowing.

The granular filters must be opened monthly and examined for channeling, mounds, or holes in the filter media. **Inspection method: Drain the water from the filter housing and inspect the granular filter for cracks, mounds, or holes.**

A core sample must be examined monthly for accumulation of excessive organic material. **Core sample method:**

1. **Take a sand sample from the filter core after inspection and place it in a clear container. A core sample can be taken by inserting a rigid hollow tube or pipe in to the filter media.**

2. **Add clean water to the clear container, cover, and shake.**
3. **Allow the container to rest undisturbed for 30 minutes.**
4. **Evaluate sample. If, after 30 minutes of settling, a measurable layer of sediment is within or on top of the filter media or fine, colored particles are suspended in the water, the organic loading may be excessive. Consider media replacement.**
5. **Record results of filter inspection and sedimentation test in a log.**

Cartridge filters must be replaced based on inspection results or manufacturer's recommendations, whichever is sooner.

The granular filter media must be replaced at least every 6 months. Before the new filter media is placed in the filter housing, the housing must be scrubbed with an appropriate cleanser, rinsed, and disinfected. DISINFECTION must be accomplished with an appropriate HALOGEN-based DISINFECTANT at 1 ppm for 50 minutes, or an equivalent CT VALUE. Record the filter replacement date and cleaning and DISINFECTION of the filter housing in a log. The log must include the DISINFECTANT residual and contact time or CT VALUE.

Filter pressure gauges and valves must be replaced when they are defective.

The operating manuals for all components such as filters, pumps, HALOGEN and pH control EQUIPMENT, and UV DISINFECTION systems must be maintained aboard the vessel in a location ACCESSIBLE to crew members who are responsible for the operation and maintenance of these facilities.

13.8.3.5 Halogen and pH Control

Automated HALOGEN dosing and pH control systems must be installed and maintained.

Halogenation must be by use of chlorine or bromine. A free residual of HALOGEN must be maintained between 3.0-10.0 ppm for chlorine and 4.0-10.0 ppm for bromine.

The pH levels must be maintained between 7.2 and 7.6.

13.8.3.6 UV Disinfection

A UV DISINFECTION system must be installed after filtration and before HALOGEN-based DISINFECTION.

The UV DISINFECTION system must be maintained at an intensity that inactivates *Cryptosporidium parvum* and *Giardia*.

The UV DISINFECTION system must be maintained and operated in accordance with the manufacturer's recommendation. At least one spare UV lamp must be available.

13.8.3.7 System Shutdown

An automatic shutdown must be maintained whereby any failure in maintaining the required free residual HALOGEN level, pH level, or UV lamp intensity must cause the water to completely divert from the BABY-ONLY WATER FACILITY and instead loop back to the compensation tank. Additionally, this system must be equipped with an audible alarm that sounds in a continuously manned space, such as the bridge or engine control room.

13.8.3.8 Shutdown and Alarm Testing

The emergency shutdown and alarms systems must be tested monthly. Testing procedures and results must be recorded.

13.8.4 System Cleaning and Disinfection

13.8.4.1 Daily Cleaning of Spray Pad Surface

Every 24 hours, the SPRAY PAD surface and any associated features must be cleaned with an appropriate cleaner. The surface must be rinsed and disinfected at 50-ppm free residual HALOGEN for 1 minute, or the equivalent CT VALUE. Ensure that the liquid waste from this process is not directed to the compensation tank.

At least every 72 hours, the facility must be shut down and these procedures must be followed:

1. The entire volume of water within the system must be discharged. This includes the BABY-ONLY WATER FACILITY, compensation tank, filter housing, and all associated piping.
2. The BABY-ONLY WATER FACILITY, compensation tank, and filter housing (cartridge filter) must be cleaned with an appropriate cleanser, rinsed, and disinfected (chlorine or bromine). DISINFECTION must be accomplished with a solution of at least 50 MG/L (ppm) free residual HALOGEN for 1 minute, or the equivalent CT VALUE.

13.8.5 Monitoring and Record Keeping

An automated analyzer-chart recorder capable of recording free residual HALOGEN levels in MG/L (ppm) and pH levels must be installed.

The system must be checked for calibration before opening the facility for use, and then every 3 hours thereafter with a test kit accurate to within 0.2 MG/L

(ppm) free residual HALOGEN and 0.2 pH.

- Charts must be reviewed and signed daily by trained supervisory staff.
- Charts must be dated and changed daily.
- Records must be retained for 12 months.

In the event of a failure in the automated analyzer-chart recorder, manual tests must be conducted and recorded for each required parameter on an hourly basis. A maximum of 72 hours will be allowed for manual tests while repairs are under way. If more than 72 hours pass, the facilities must be shut down until repairs are completed.

A log must be kept to detail all maintenance activities, including the following:

- Filter changes including filter housing cleaning and DISINFECTION (including ppm and contact time).
- Backwashing time.
- Fecal accidents.
- Injury accidents.
- Facility opening and closing times.

One test must be conducted at the end of each day for the presence of *Escherichia coli* (*E. coli*) using a test in accordance with the latest edition of *Standard Methods for the Examination of Water and Wastewater*. Test kits, incubators, and associated EQUIPMENT must be operated and maintained in accordance with the manufacturers' specifications.

For positive *E. coli* tests, follow this procedure:

- Discharge the entire volume of water within the system. This includes the BABY-ONLY WATER FACILITY, compensation tank, filter housing, and all associated piping.
- Use an appropriate cleaner on the BABY-ONLY WATER FACILITY, compensation tank, and filter housing (cartridge filter), then rinse and disinfect them (chlorine or bromine). DISINFECTION must be accomplished with a solution of at least 50 MG/L (ppm) for 1 minute, or the equivalent CT VALUE.
- Conduct follow-up testing. The facility must not be put back in operation unless follow-up test results are negative for the presence of *E. coli*.

A record of the test results must be maintained onboard the vessel and must be available for review during inspections. Retain records for 12 months.

The maintenance logs, records, and charts must be kept for 12 months.

13.8.6 Training

At least one person trained in the maintenance and operation of RWFs must be on the vessel and available at all times the facility is open for use. Such training includes the requirements of this manual, prevention of recreational water

illnesses and injuries, HALOGEN and pH control chemicals, UV DISINFECTION systems, recreational water safety, and using test kits for HALOGEN-based DISINFECTANTS and pH. A record must be kept with the names of all trained individuals.

13.8.9 Monitor

At least one individual must be available in the immediate area of the facility when it is open for use. This individual must monitor the area to ensure all of the following:

- Children are wearing swim diapers.
- Diapers are changed at suitable diaper-changing stations and not at the facility.
- All children are under adult supervision.
- FOOD, BEVERAGES, and glass are not used near the facility.
- There is no running or boisterous play near the facility.
- Children who are ill are prohibited from using the facility.

13.8.8 Safety

13.8.8.1 Eye Damage

Ensure that water sprays are designed with pressures and directional flow controls to prevent eye damage to users.

13.8.8.2 Safety Sign

A safety sign must be posted by the facility with letters at least 26 millimeters (1 inch) high at each entrance to the BABY-ONLY WATER FACILITY feature that states, at a minimum, the following:

- This facility is only for use by children in diapers or who are not completely toilet trained.
- Children who have a medical condition which may put them at increased risk for illness should not use these facilities.
- Children who are experiencing symptoms such as vomiting, fever, or diarrhea are prohibited from using these facilities.
- Children must be accompanied by an adult at all times.
- Children must wear a clean swim diaper before using these facilities. Frequent swim diaper changes are recommended.
- Do not change diapers in the area of the BABY-ONLY WATER FACILITY. A diaper changing station has been provided (exact location) for your convenience.

The letters on the sign heading must be at least 26 millimeters (1 inch) high, but all other lettering must be at least 13 millimeters (1/2 inch) high.

Pictograms may replace words as appropriate or available.

This information may be included on multiple signs, as long as they are posted at the entrances to the facility.

13.8.9 Swim Diapers

Swim diapers in a variety of sizes must be available in close proximity to this facility.

13.9 Fecal, Vomit, and Blood Accident Response for RWFs

13.9.1 Fecal and Vomit Accident Response for RWFs

This annex includes a sample fecal accident plan and sample fecal accident log required data elements. The sample fecal accident plan is based in part on recommendations found on CDC's Healthy Swimming website (www.cdc.gov/healthywater/swimming).

In the sample plan (13.9.1.1), two tables address chlorine residuals and contact times to be used for DISINFECTION after an accident involving fecal material or vomitus. Each table has chlorine residuals and contact times that reduce the risk for recreational water illness based on the pathogenic organisms that might be present as a result of a fecal or vomit accident.

- The Residual and Contact Time for Loose Stool table shows chlorine residuals and contact times to address loose stools. The primary pathogenic organism of concern in loose stool is *Cryptosporidium*. This organism is highly chlorine resistant; to destroy it, a CT VALUE of 15,300 is required. This means that when the chlorine residual in ppm is multiplied by the contact time in minutes, a minimum of 15,300 is required.
 - $\text{Concentration (ppm)} \times \text{Contact Time (minutes)} \geq 15,300$
- The Residual and Contact Time for Formed Stool or Vomitus table shows chlorine residuals and contact times to address accidents involving formed stools or vomitus. The disease-causing organisms of primary concern are *Giardia*, *E. coli* 0157:H7, and *Shigella*. To destroy the more highly chlorine resistant of these organisms (*Giardia*), a CT VALUE of 45 is required. This means that when the chlorine residual in ppm is multiplied by the contact time in minutes, a minimum of 45 is required.
 - $\text{Concentration (ppm)} \times \text{Contact Time (minutes)} \geq 45$

To determine the appropriate chlorine residual and contact time, operators should observe the nature of the accident.

- If the fecal accident is loose (diarrhea), the loose-stool table should be used for DISINFECTION.
- If the fecal material is solid or formed or if the accident involves vomitus, the formed stool or vomitus table should be used for DISINFECTION.

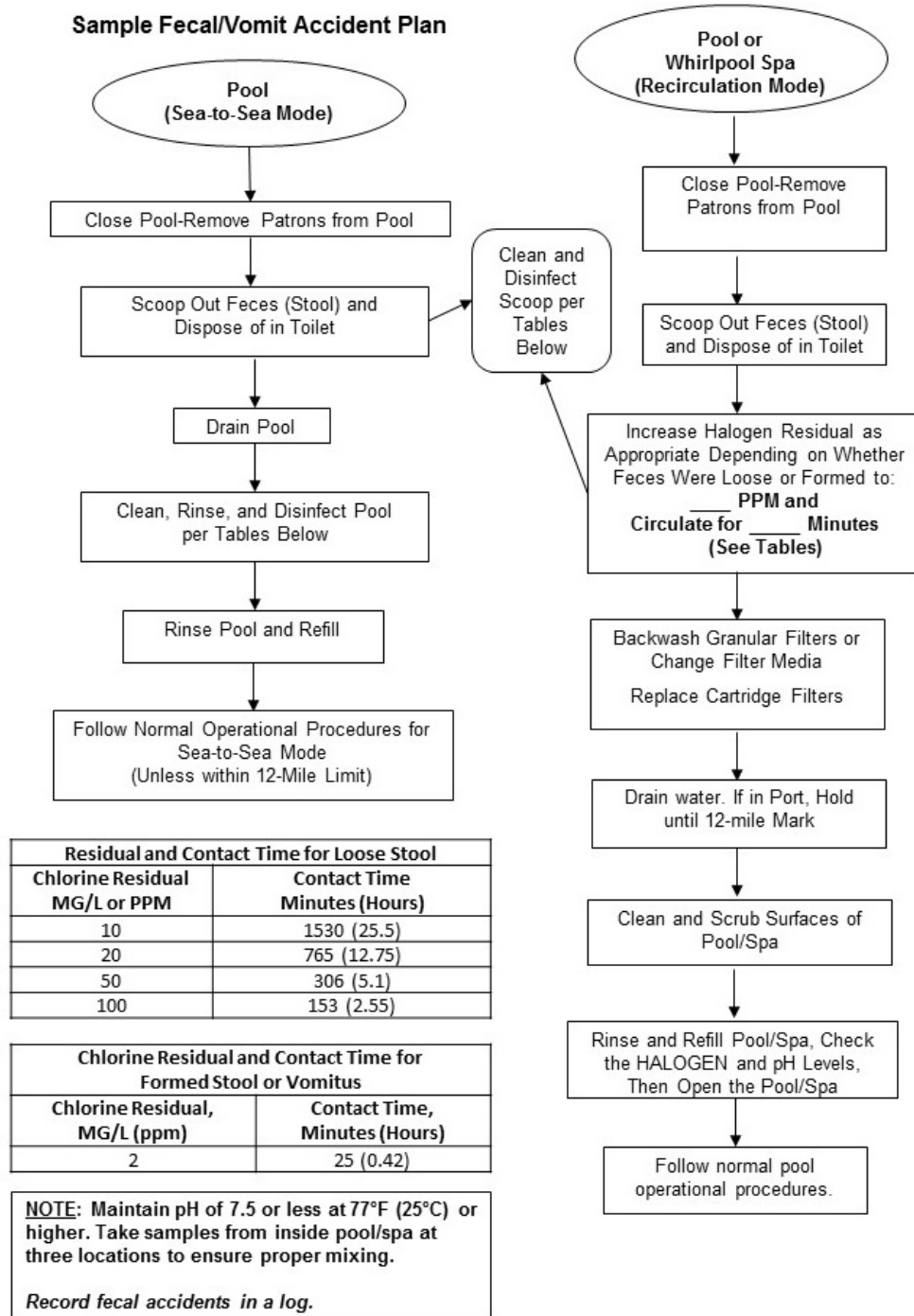
It is important to remember that the DISINFECTION capabilities of chlorine diminish as pH increases. Operators should ensure that pH levels are maintained 7.5 or less at 77°F (25°C) or higher during this DISINFECTION process.

Record all fecal/vomit accidents in a log with all of the following information:

- Name of RWF.
- Date of event.
- Time of event.
- Number of bathers.
- Formed stool, loose stool, or vomitus.
- Chlorine residual for DISINFECTION.
- Contact time for DISINFECTION.
- pH level for DISINFECTION.
- Chlorine residual for reopening.
- pH for reopening.

13.9.1.1 Fecal/Vomit Accident Plan

VSP 2018 Operations Manual

Sample Fecal/Vomit Accident Plan

13.9.2 Blood Response Q and A

Excerpt from www.cdc.gov/healthywater/swimming/pools/vomit-blood-contamination.html.

13.9.2.1 Blood in Pool Water

Germs (for example, Hepatitis B virus or HIV) found in blood are spread when infected blood or certain body fluids get into the body and bloodstream (for example, by sharing needles and by sexual contact). Chlorine kills germs found in blood and CDC is not aware of any instances in which a person has become infected with these germs after being exposed to a blood spill in a pool.

Q: Does chlorine kill the germs in blood?

A: Yes. These germs do not survive long when diluted into properly chlorinated pool water.

Q: Swimmers want something to be done after a blood spill. Should the pool be closed for a short period of time?

A: There is no public health reason to recommend closing the pool after a blood spill. However, some pool staff choose to do so temporarily to satisfy patrons.

13.10 Cartridge Filter Cleaning Procedures

Cartridges should be cleaned in accordance with manufacturer's instructions where available and complete. In the absence of instructions, clean filters when the gauge pressure differential is 10 psi (68.9 KPa).

Cleaning EQUIPMENT should include a soaking container properly sized to immerse the filter elements, a rinsing area with proper drainage, and a drying area protected from CONTAMINATION (e.g., birds and insects).

New filters do not regain 100% of their capacity. Perhaps only about 80% of the capacity is recoverable, regardless of the treatment. If the recommended design flow rate exceeds 80% of the maximum flow allowed on the filter, the filter may be undersized.

Facilities with cartridge filters are recommended to have EQUIPMENT on-site to clean the cartridges. This includes a basin or tub large enough to immerse the entire cartridge. Water from the cleaning and soaking process must be discharged to the sanitary sewer. Proper cleaning is critical. Failure to clean the cartridge properly can lead to disease OUTBREAKS.

How to Clean Cartridge Filters:

1. Rinse Thoroughly: Rinse the cartridge of as much dirt and debris as possible by washing inside and out with a garden hose and spray nozzle.

DO NOT use a pressure washer. High flow/pressure can drive dirt into the interior and permanently damage the cartridge. It can also aerosolize pathogens in the filter.

2. Degrease: Cartridge filters need to be degreased each time they are cleaned. Body oil, suntan oil, cosmetics, hair products, and/or algae and biofilms can form a greasy coating on the filter pleats, which will clog the pores and reduce the filter capacity.

Soak the cartridge overnight in one of the following:

- Filter cleaner/degreaser OR
- A solution of water with 1 cup (236.6 g) of TSP (trisodium phosphate) OR
- One cup (236.6 g) of automatic dishwashing detergent per 5 gallons (3.8 L) of water.

Never use muriatic acid or products with acid in them before degreasing. Acid may permanently set the grease and ruin the cartridge.

Rinse thoroughly.

3. Sanitize: To remove or prevent biofilms, algae, and bacteria growing on the cartridge, add 1 quart (0.95 L) of household bleach per 5 gallons (19 L) of clean water and soak 1 hour before rinsing.

4. Rinse: Remove the clean cartridge from the SANITIZATION soak water and rinse thoroughly with a hose.

5. Dry: After the filter is cleaned and degreased, it should be allowed to dry completely. Some bacteria (for example, *Legionella* spp.) that survive the cleaning process can be killed by drying. Do not allow the filter to become contaminated with dirt or soil after it is cleaned. Put the cartridges in a clean plastic trash bag if they are to be transported and the original boxes are not available.

Acid Wash (Only if Necessary): Excessive calcium or mineral deposits on the filter media can be cleaned with a 1:20 solution of clean water and muriatic acid. Put a few drops of muriatic acid on the filter. If it foams, it might need to be acid washed. Very few filters need to be acid washed.

13.11 Food Cooking Temperature Alternatives

13.11.1 Introduction

To be effective in eliminating pathogens, cooking must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the FOOD, and the FOOD's bulk, which affects the time to achieve the needed internal product temperature. Other factors to be considered include postcooking heat rise and the time the FOOD must be held at a specified internal temperature.

To kill microorganisms, FOOD must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous TIME/TEMPERATURE combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 63°C (145°F).

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

FOOD characteristics also affect the lethality of cooking temperatures. Heat penetrates different FOODS at different rates. High fat content in FOOD reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of FOOD aids thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in FOOD, cooking must bring *all* parts of the FOOD up to the required temperatures for the correct length of time.

The TEMPERATURE AND TIME COMBINATION CRITERIA specified in Annex 13.11.2 are based on the destruction of *Salmonellae*. This section includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°C (145°F), a time span of 15 seconds will provide a 3D reduction of *Salmonella enteritidis* in eggs. This organism, if present in raw shell eggs, is generally found in relatively low numbers.

Other FOODS, FISH, and MEATS that have not been ground or minced—including commercially raised GAME ANIMAL MEAT specified as acceptable

for cooking at this temperature and time parameter—are expected to have a low level of internal CONTAMINATION. The parameters are expected to provide destruction of the surface contaminants on these FOODS.

13.11.2 Temperature-Time Alternatives

Chart 1. Alternative Temperature Times for 68°C (155°F)

Minimum Temperature	Time
63°C (145°F)	3 minutes
66°C (150°F)	1 minute
70°C (158°F)	<1 second (instantaneous)

Chart 2. Cooking Exemptions

FOOD	Provisions
Beef steak: WHOLE-MUSCLE, INTACT	Steak is cooked on top and bottom to a surface temperature of 63°C (145°F) or above and color change is achieved on all surfaces.
Eggs, FISH, MOLLUSCAN SHELLFISH, and other MEATs	CONSUMER information is provided as specified in section 7.3.6.1.2 or a VARIANCE is granted as specified in section 12.13 of the <i>VSP 2018 Operations Manual</i> .

Extracted from *FOOD Code*, Recommendations of the United States Public Health Service, 2013.

13.12 Chemicals Used in Washing or to Assist in the Peeling of Fruits and Vegetables

[Excerpted from 21 CFR 173.315]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)**PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION--Table of Contents****Subpart D--Specific Usage ADDITIVES**

Sec. 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables.

Chemicals may be safely used to wash or to assist in the peeling of fruits and vegetables in accordance with the following conditions:

(a) The chemicals consist of one or more of the following:

(1) Substances generally recognized as safe in FOOD or covered by prior sanctions for use in washing fruits and vegetables.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Adduct Mixture

Substance: A mixture of alkylene oxide adducts of alkyl alcohols and phosphate esters of alkylene oxide adducts of alkyl alcohols consisting of: [alpha]-alkyl (C₁₂- C₁₈)-omega-hydroxy-poly (oxyethylene) (7.5-8.5 moles)/poly (oxypropylene) block copolymer having an average molecular weight of 810; [alpha]-alkyl (C₁₂-C₁₈)- omega-hydroxy- poly (oxyethylene) (3.3-3.7 moles) polymer having an average molecular weight of 380, and subsequently esterified with 1.25 moles phosphoric anhydride; and [alpha]-alkyl (C₁₀-C₁₂)- omega-hydroxypoly (oxyethylene) (11.9-12.9 moles)/poly (oxypropylene) copolymer, having an average molecular copolymer, having an average molecular weight of 810, and subsequently esterified with 1.25 moles phosphoric anhydride.

Limitations: May be used at a level not to exceed 0.2 percent in lye-peeling solution to assist in the lye peeling of fruit and vegetables.

Aliphatic Acid Mixture

Substance: Aliphatic acid mixture consisting of valeric, caproic, enanthic, caprylic, and pelargonic acids.

Limitations: May be used at a level not to exceed 1 percent in lye peeling solution to assist in the lye peeling of fruits and vegetables.

Polyacrylamide

Substance: Polyacrylamide

Limitations: Not to exceed 10 parts per million in wash water.

Contains not more than 0.2 percent acrylamide monomer. May be used in the washing of fruits and vegetables.

Potassium Bromide

Substance: Potassium bromide

Limitations: May be used in the washing or to assist in the lye peeling of fruits and vegetables.

Sodium n-alkylbenzene-sulfonate

Substance: Sodium n-alkylbenzene-sulfonate (alkyl group predominantly C₁₂ and C₁₃ and not less than 95 percent C₁₀ to C₁₆).

Limitations: Not to exceed 0.2 percent in wash water. May be used in washing or to assist in the lye peeling of fruits and vegetables.

Sodium Dodecylbenzene-sulfonate

Substance: Sodium dodecylbenzene-sulfonate (alkyl predominantly C₁₂ and not less than 95 percent C₁₀ to C₁₆).

Limitations: Not to exceed 0.2 percent in wash water. May be used in washing or to assist in the lye peeling of fruits and vegetables.

Sodium 2 Ethyl-hexyl Sulfate

Substance: Sodium 2 ethyl-hexyl sulfate

Limitations: Not to exceed 0.2 percent in wash water. May be used in washing or to assist in the lye peeling of fruits and vegetables.

Sodium Hypochlorite

Substance: Sodium hypochlorite

Limitations: May be used in the washing or to assist in the lye peeling of fruits and vegetables.

Sodium Mono- and Dimethyl Naphthalene Sulfonates

Substance: Sodium mono- and dimethyl naphthalene sulfonates (mol. wt. 245-260)

Limitations: Not to exceed 0.2 percent in wash water. May be used in the washing or to assist in the lye peeling of fruits and vegetables.

(3) Sodium mono- and dimethyl naphthalene sulfonates (mol. wt. 245-260) may be used in the steam/scald vacuum peeling of tomatoes at a level not to exceed 0.2 percent in the condensate or scald water.

(4) Substances identified in this paragraph (a)(4) for use in flume water for washing sugar beets prior to the slicing operation and subject to the limitations as are provided for the level of the substances in the flume water:

[alpha]-Alkyl-omega-hydroxypoly-(oxyethylene)

Substance: [alpha]-Alkyl-omega-hydroxypoly-(oxyethylene) produced by condensation of 1 mole of C₁₁-C₄₈ 63₁₅ straight chain randomly substituted secondary alcohols with an average of 9 moles of ethylene oxide.

Limitations: Not to exceed 3 ppm.

Linear Undecylbenzenesulfonic Acid

Substance: Linear undecylbenzenesulfonic acid

Limitations: Not to exceed 3 ppm.

Dialkanolamide

Substance: Dialkanolamide produced by condensing 1 mole of methyl laurate with 1.05 moles of diethanolamine.

Limitations: Not to exceed 2 ppm.

Triethanolamine

Substance: Triethanolamine

Limitations: Not to exceed 2 ppm.

Ethylene Glycol Monobutyl Ether

Substance: Ethylene glycol monobutyl ether

Limitations: Not to exceed 1 ppm.

Oleic Acid

Substance: Oleic acid conforming with Sec. 172.860 of this chapter.

Limitations: Not to exceed 1 ppm.

Tetrapotassium Pyrophosphate

Substance: Tetrapotassium pyrophosphate

Limitations: Not to exceed 0.3 ppm.

Monoethanolamine

Substance: Monoethanolamine

Limitations: Not to exceed 0.3 ppm.

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Ethylene Dichloride

Substance: Ethylene dichloride

Limitations: Not to exceed 0.2 ppm.

Tetrasodium ethylenediaminetetraacetate

Substance: Tetrasodium ethylenediaminetetraacetate

Limitations: Not to exceed 0.1 ppm.

(5) Substances identified in this paragraph (a)(5) for use on fruits and vegetables that are not raw agricultural commodities and subject to the limitations provided:

Hydrogen Peroxide

Substance: Hydrogen peroxide

Limitations: Used in combination with acetic acid to form peroxyacetic acid. Not to exceed 59 ppm in wash water.

1-Hydroxyethylidene-1,1-diphosphonic Acid

Substance: 1-Hydroxyethylidene-1,1-diphosphonic acid

Limitations: May be used only with peroxyacetic acid. Not to exceed 4.8 ppm in wash water.

Peroxyacetic Acid

Substance: Peroxyacetic acid

Limitations: Prepared by reacting acetic acid with hydrogen peroxide. Not to exceed 80 ppm in wash water.

(b) The chemicals are used in amounts not in excess of the minimum required to accomplish their intended effect.

(c) The use of the chemicals listed under paragraphs (a)(1), (a)(2), and (a)(4) is followed by rinsing with POTABLE WATER to remove, to the extent possible, residues of the chemicals.

(d) To assure safe use of the ADDITIVE:

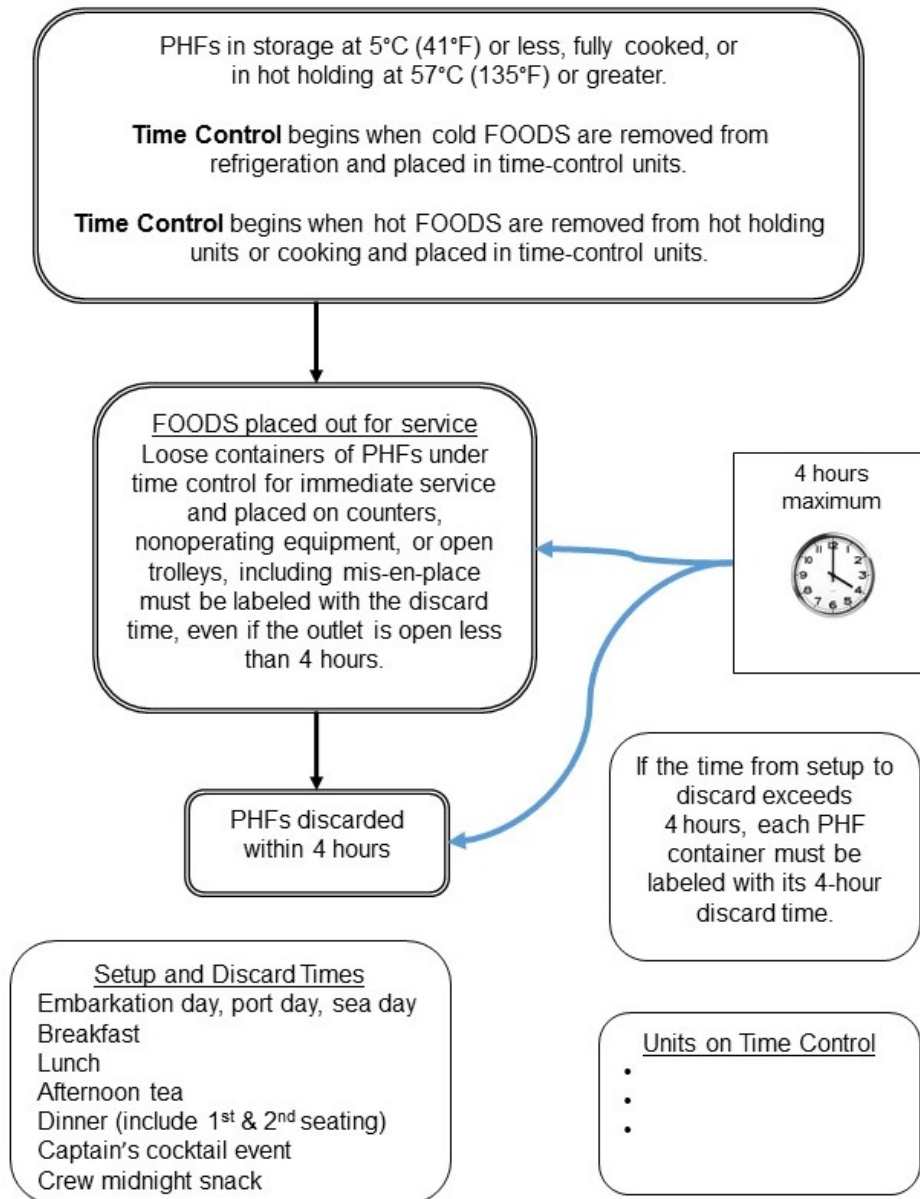
(1) The label and labeling of the ADDITIVE container shall bear, in addition to the other information required by the act, the name of the ADDITIVE or a statement of its composition.

(2) The label or labeling of the ADDITIVE container shall bear ADEQUATE use directions to assure use in compliance with all provisions of this section.

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13.13 Time-Control Plan Examples**Sample Time-Control Plan for POTENTIALLY HAZARDOUS FOODS (PHFs)**

Location: _____



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Time-Control Plan

Location: _____

Operation Hours:

Breakfast:

Embarkation Day – 5:30 hours–9:30
hoursPort/Sea Days – 6:30 hours–10:30
hours

Lunch: 11:30 hours–14:00 hours

Dinner 1st: 17:30 hours–19:45 hours

Dinner 2nd: 20:00 hours–21:45 hours

Units on Time Control:Roll-in refrigerators: 104, 105,
106, 325, and 326Cold soup well port/starboard
146A and 147BAll bains marie including soup
line

All FOOD preparation counters

POTENTIALLY HAZARDOUS FOODS are stored at
5°C (41°F) or below or
57°C (135°F) or above

All PHFs, including
mis-en-place on the FOOD
preparation counters, are on
time control.

Containers of PHFs are
labeled with the start time
and 4-hour discard time.



Time Control begins when cold FOODS are removed from
refrigeration and placed in time-control units.

Time Control begins when hot FOODS are removed from hot
holding units or cooking and placed in time-control units.



All PHFs are discarded at the end of the service period.

13.14 List of Some Hard and Semisoft Cheeses Exempt from Datemarking

The cheeses listed below are exempted from 7-day datemarking:

Abertam	Limburger
Appenzeller	Lorraine
Asadero	Manchego
Asiago medium or old	Milano
Asiago soft	Monterey
Battelmatt	Muenster
Bellelay (blue veined)	Oaxaca
Blue	Oka
Bra Brick	Parmesan
Camosum	Pecorino
Chantelle	Port du Salut
Cheddar	Provolone
Christalinna	Queso Anejo
Colby	Queso Chihuahua
Coon	Queso de Bola
Cotija	Queso de la Tierra
Cotija Anejo	Queso de Prensa
Derby	Reggiano
Edam	Robbiole
Emmentaler	Romanello
English Dairy	Romano
Fontina	Roquefort (blue veined)
Gex (blue veined)	Samsoe
Gjetost	Sapsago
Gloucester	Sassenage (blue veined)
Gorgonzola (blue veined)	Stilton (blue veined)
Gouda	Swiss
Gruyere	Tignard (blue veined)
Havarti	Tilsiter
Herve	Trappist
Konigskase	Vize
‘Lapland	Wenssleydale (blue veined)

13.15 Consumer Advisory Examples

13.15.1 Menu Example

*Hamburgers
Chicken
Potato Salad
*Seared Tuna
French Fries
House Salad

*Public Health Advisory: Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or eggs may increase your risk for foodborne illness, especially if you have certain medical conditions.

13.15.2 Point-of-Service Examples

13.15.2.1 At an Omelet Station

Eggs can be cooked to order.

Public Health Advisory: Consuming raw or undercooked eggs may increase your risk for foodborne illness, especially if you have certain medical conditions.

13.15.2.2 At a Hamburger Grill

Hamburgers and cheeseburgers can be cooked to order.

Public Health Advisory: Consuming raw or undercooked MEATS may increase your risk for foodborne illness, especially if you have certain medical conditions.

13.15.2.3 At a Buffet Station

Cold Smoked Salmon is served undercooked.

Public Health Advisory: Consuming raw or undercooked seafood may increase your risk for foodborne illness, especially if you have certain medical conditions.

13.16 Warewashing Evaluation

13.16.1 Introduction

13.16.1.1 Methodology Source

The following WAREWASHING machine evaluation procedure was compiled from the NSF International (NSF) brochure *FOOD Service: Recommended Field Evaluation Procedures for Spray-type Dishwashing Machines* (1991), and *FOOD Code* (2013).

ANSI/NSF 3-2017, *Commercial Spray-type Dishwashing and Glasswashing Machines*, and the *VSP 2018 Operations Manual* should be consulted for recommended construction and operational parameters.

13.16.1.2 Recommended Evaluation Equipment

The following EQUIPMENT to conduct WAREWASHING evaluations is recommended:

- Thermocouple or thermistor TEMPERATURE-MEASURING DEVICE for warewasher operational temperatures.
- Maximum registering TEMPERATURE-MEASURING DEVICE or temperature-sensitive tapes for verifying hot water warewasher final rinse temperature, 73°C (160°F).
- Optional: Calibrated melting temperature wax crayons with melt points set at 82°C (180°F) and another at 91°C (195°F).
- Pressure gauge, as applicable, for determining in-line pressure of hot water at injection point of warewasher in the range of 100-170 kilopascals (15-25 pounds per square inch).
- Chemical test kits for different chemical SANITIZER types used on the vessel.
- Flashlight.
- Tape measure.
- Watch or stopwatch.

13.16.1.2.1 Calibration

Calibrate TEMPERATURE-MEASURING DEVICES and pressure gauges against standards to ensure reliable warewasher evaluations.

Maintain chemical test kits and temperature sensitive tapes as specified by their manufacturers to ensure accuracy.

13.16.1.2.2 Mercury Spills

Use mercury-filled maximum registering TEMPERATURE-MEASURING DEVICES carefully during the evaluations; these devices are subject to breakage. If they break, clean up thoroughly before WAREWASHING operations resume.

13.16.2 Machines Data Plates**13.16.2.1 Data Plate Required**

Review the required manufacturer's data plate for correct operating parameters.

- If the data plate indicates a flow pressure, the machine must have a gauge or a gauge valve to measure it.
- If the data plate does not indicate a flow pressure, the machine is not required to have a gauge or a gauge valve.

13.16.2.2 Temperature Requirements

Temperatures stated on the warewash machine data plate are considered minimums unless a specified range is given.

13.16.2.3 Conform to ANSI/NSF 3-1996

The warewash machine temperatures must conform to those specified in these guidelines for the specific type of machine. For those manufactured to different temperature standards, evidence must be furnished that they at least conform to the minimum equivalent standards of ANSI/NSF 3-2008, *Commercial Spray-type Dishwashing and Glasswashing Machines*.

13.16.3 Evaluation Procedures**13.16.3.1 Operational Evaluation**

The VSP EHO will evaluate the WAREWASHING as follows:

- Dishes properly prescraped and racked.
- Machine prewash scrap trays clear of excessive soil and debris.
- Curtains and baffles on conveyor type machines intact and in their proper position.
- Conveyor speed and cycle times set according to manufacturer's specifications.
- Overflow standpipe installed and not blocked or leaking.
- Wash and rinse nozzles properly aligned and providing a uniform spray pattern.
- Wash and rinse nozzles clear of obstructions.
- Wash and rinse manifolds in good repair, properly installed in the machine, and end caps installed.
- Heating elements used in tanks free of mineral or other deposits.
- Rinse supply line strainer clear of debris.

- Wash and rinse tanks and final rinse manifold TEMPERATURE-MEASURING DEVICES accurate to ± 1.5 °C (± 3 °F).
- Pressure regulator functioning properly.
- Flow pressure within the range specified on the data plate and between 34.5-207 kilopascals (5-30 pounds per square inch).

13.16.3.2 Temperature Evaluation

13.16.3.2.1 *Manufacturer's Instructions*

Install and operate the machine in accordance to the manufacturer's instructions.

13.16.3.2.2 *Warmup*

Run the machine through at least two complete cycles before testing unless it has been operating just before the evaluation. On conveyor machines, run at least two racks through the machine.

13.16.3.2.3 *Additional Warmup*

When minimum temperatures are not indicated on machine-mounted TEMPERATURE-MEASURING DEVICES, additional pre-evaluation cycles may be run to determine if higher temperatures are possible.

13.16.3.2.4 *Tank Thermometer Calibration*

Take temperatures of the wash water and pumped rinse directly from the tanks of the machines and compare them against the machine-mounted TEMPERATURE-MEASURING DEVICES. If possible, place the evaluation TEMPERATURE-MEASURING DEVICE probe in the tank near the machine-mounted TEMPERATURE-MEASURING DEVICE probe.

13.16.3.2.5 *Sanitizing Rinse TMDs*

Use a maximum registering TEMPERATURE-MEASURING DEVICE, remote sensing thermocouple, or nonreversible thermolabels such as paper TEMPERATURE-MEASURING DEVICES that turn from silver to black or similar device to confirm the effectiveness of heat SANITIZATION.

13.16.3.2.6 *Rinse Exposure*

Attach the maximum registering TEMPERATURE-MEASURING DEVICE in a vertical position in a rack that is exposed to the final sanitizing rinse spray at the approximate level of a plate. Attach nonreversible thermolabels to the center of a dry ceramic plate.

13.16.3.2.7 High Wash/Rinse Temperature Factor

Factor the effect of the temperatures of the wash water and pumped rinse into the evaluation if tank thermometers indicate they are above 71°C (160°F).

If the wash and or rinse tank temperatures are greater than or equal to 71°C (160°F), verify the final sanitizing rinse temperature using one of the methods in section 13.16.3.2.9 or another ISOLATION method where a rapid response TEMPERATURE-MEASURING DEVICE is held at plate level in the final sanitizing rinse spray for at least 8 seconds. The maximum-registering TEMPERATURE-MEASURING DEVICE may also be checked at the end of each part of the cycle to verify that the wash and rinse temperatures have not been in excess of 71°C (160°F).

13.16.3.2.8 Effective Sanitation

Evaluate effective SANITIZATION by noting that in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold must not be more than 90°C (194°F) or less than

- 74°C (165°F) for a stationary rack, single-temperature machine.
- 82°C (180°F) for all other machines.
- 71°C (160°F) at the UTENSIL surface, as measured by an irreversible registering temperature indicator.

13.16.3.2.9 Indirect Methods

The final rinse spray temperature may be indirectly evaluated by using a nonreversible thermolabel attached to the manifold or final rinse spray arm near the hub or by using calibrated melting temperature wax crayons. Make a mark on a dry portion of the final sanitizing rinse manifold or supply line with a crayon that melts at 82°C (180°F) and another that melts at 91°C (195°F).

Another acceptable test to establish the final sanitizing rinse temperature (manifold) is to dry the final sanitizing rinse spray arm as near to the manifold entry into the machine as possible and affix an 82°C (180°F) thermolabel. The thermolabel should be left in place through one full warewash cycle. There may be slight temperature decreases at positions distant from the manifold entry into the machine.

A third method is to attach a maximum registering thermometer to the end of a rod and hold the thermometer in the final rinse spray at plate level for 8 seconds.

After any of the three of the indirect method tests above, assess the spray pattern from the final rinse spray arm to ensure that the spray pattern is effective.

For a stationary rack machine, the final rinse temperature can be evaluated by running the machine with a maximum registering thermometer at plate level. Stop the machine at the end of the wash cycle to check the temperature, and again at the end of the final rinse cycle.

13.16.3.3 Chemical Sanitizing Evaluation

Obtain sample at the end of the final chemical sanitizing rinse cycle and use a SANITIZER test kit to confirm the SANITIZER level is at the minimum specified on machine data plate and in these guidelines.

13.16.4 Routine Monitoring

13.16.4.1 Periodic Detailed Evaluations

Proper WAREWASHING is critical to protecting the health of a vessel's passengers. The procedures provided in this annex may assist the vessel crew in periodically verifying the proper operation of its WAREWASHING machines. Following the manufacturer's recommendations for maintenance and operation will ensure the WAREWASHING machines continue to meet the criteria of these guidelines and standards of ANSI/NSF 3-1996, *Commercial Spray-type Dishwashing and Glasswashing Machines*.

13.16.4.2 Startup Evaluations

During each WAREWASHING machine's startup, the proper setup and operation of the EQUIPMENT should be verified with basic checks. These include checks of the tank, manifold, and curtain assemblies to ensure they are properly installed. Proper operating temperatures should be verified to meet the minimum required temperatures during the start-up.

13.16.4.3 Routine Operation Evaluations

Periodic operation and temperature checks by the WAREWASHING crew during the WAREWASHING time should detect problems soon after they occur. The person removing the clean and sanitized ware must examine each piece to determine if it is clean. Periodic management checks of the WAREWASHING process during operation verify that the machines are operating properly and the UTENSILS processed are indeed clean and sanitized.

13.16.4.4 Simple Records

Simple records can assist in the warewash machine monitoring process. A review of these records can ensure proper monitoring is being conducted and assist in determining a gradual or severe malfunction of the machine.

13.17 Inspection Report

13.17.1 Report Form

A copy of the VSP Inspection Report form follows on the next page.

During the implementation of the *VSP 2018 Operations Manual*, an electronic version of this form will also be used. Copies of the electronic version will be returned to the cruise line by email.

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VESSEL SANITATION INSPECTION REPORT



Vessel Name		Inspection Date		Port		Results Presented to		Score:
Cruise Line		No. Pax.	No. Crew	Inspection Type		Inspected by		

Item No. / Point Value / Description			Bold = Critical Item
DISEASE REPORTING			
01	4	Disease reporting	
02	1	Medical logs maintenance	
POTABLE WATER			
03	5	Bunker / production source; Halogen residual	
04	5	Distribution system halogen residual	
05	2	Distribution system halogen analyzer calibrated	
06	2	Halogen analyzer chart recorder maintenance, operation, records; Micro sampling, records	
07	3	System protection cross-connections, backflow; Disinfection	
08	1	Filling hoses, caps, connections, procedures; Sample records, valves; System construction, maintenance	
RECREATIONAL WATER FACILITIES			
09	3	RWF halogen residuals	
10	2	RWF maintenance, safety equipment	
FOOD SAFETY			
PERSONNEL			
11	5	Food handlers infections, communicable diseases	
12	4	Hands washed; Hygienic practices	
13	3	Management, knowledge, monitoring	
14	1	Outer clothing clean; Jewelry, hair, hand sanitizers	
FOOD			
15	5	Food source, sound condition; Food reservice	
16	5	Potentially hazardous food temperatures	
17	2	Temperature practices; Thawing	
18	3	Cross-contamination	
19	2	Food protection; Original containers; labeling; In-use food dispensing, preparation utensils	
MEDICAL LOG REVIEW			
Cruise – Start / End / Port / PAX / ILL / CREW / ILL			
1.			
2.			
3.			
4.			
5.			

Item No. / Point Value / Description			Bold = Critical Item
EQUIPMENT			
20	2	PHF temperature maintenance facilities; Food-contact surfaces; Food TMDs	
21	1	Nonfood-contact surfaces; Ambient TMDs	
22	2	Warewashing facilities; TMDs; Test kits	
23	2	Prewash; Wash and rinse solutions	
24	3	Sanitizing rinse	
25	1	Wiping cloths / chef's towels	
26	3	Food-contact surfaces equipment / utensils clean; Safe materials	
27	1	Nonfood-contact surfaces equipment / utensils clean	
28	2	Equipment / utensil / linen / single / service storage handling dispensing; Cleaning frequency	
TOILET AND HANDWASHING FACILITIES			
29	3	Facilities convenient, accessible, design, installation	
30	1	Hand cleanser, sanitary towels, waste receptacles; Handwashing signs; Maintenance	
TOXIC SUBSTANCES			
31	3	Toxic items	
FACILITIES			
32	1	Solid waste containers	
33	1	Decks / bulkheads / deckheads	
34	1	Plumbing fixtures / supply lines / drain lines / drains	
35	2	Liquid waste disposal	
36	1	Lighting	
37	1	Rooms / equipment venting	
38	1	Unnecessary articles, cleaning equipment; Unauthorized personnel	
ENVIRONMENTAL HEALTH			
39	3	IPM program effective; Approved pesticide application	
40	1	IPM procedures; Outer openings protection	
41	2	Housekeeping	
42	1	Child activity centers	
43	1	Ventilation	
KNOWLEDGE			
44	2	Person in charge, Knowledge	

13.18 Corrective-Action Statement

13.18.1 Introduction

13.18.1.1 Purpose

VSP established a procedure for postinspection reporting of corrective actions to encourage the correction of deficiencies noted during an inspection. A signed corrective action statement will not affect the inspection score.

13.18.1.2 Critical Item Monitoring

The corrective-action statement, particularly for CRITICAL ITEMS, should include a management monitoring plan to ensure that the procedure or process that was out of control will be monitored and controlled in the future. The public health goal of the inspection is to prevent the recurrence of the critical deficiency in the specific instance where it was found and generally in future similar operations aboard the vessel.

13.18.1.3 Publicly Available

The corrective-action statement will be appended to the final inspection report for future reference and public distribution via the VSP website.

13.18.1.4 Email Submission

The corrective action statement may be submitted to VSP by electronic mail. Please send the statement to vsp@cdc.gov; include the vessel name, corrective-action statement, and inspection date in the message subject line. Submission as an attached word processing format file is preferable.

13.18.1.5 Mail Submission

The corrective-action statement may also be mailed to the following:

CDC/Vessel Sanitation Program
1850 Eller Drive, Suite 101
Ft. Lauderdale, FL 33316
USA

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13.18.2 Format

Example Statement

Date

CDC/Vessel Sanitation Program

1850 Eller Drive, Suite 101

Ft. Lauderdale, FL 33316

USA

Dear Sir:

The following actions have been taken to correct each of the deficiencies noted during the inspection of (Name of Vessel) on (Date) at (Port).

Item Number	Deficiency/Corrective Action

1.	

2.	

3.	

(Continue until all violations have been listed.)

Sincerely,

(Signature)

Name

Title

Company

13.19 Summary of Sanitation Inspections of International Cruise Ships

13.19.1 Introduction

Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly inspections and, when necessary, to reinspection by the Centers for Disease Control and Prevention's VSP. To ensure a clean and healthful environment, cruise ships must meet the criteria established by VSP.

The score and the complete report for each inspection are published on the VSP website (www.cdc.gov/nceh/vsp).

The ship's level of sanitation is acceptable to VSP if its score on the inspection is 86 or higher.

13.19.2 Online Information

The VSP website has a searchable database of inspection report summaries and lists. The complete inspection report information is also retrievable.

Lists available on the VSP website include the following:

- Advanced Cruise Ship Inspection Search.
- Green Sheet Report.
- Cruise Ship Inspection Score 100.
- VARIANCES by Section.

These lists show the data by

- Ship name.
- Cruise line.
- Inspection date.
- Score (all scores, scores of 86 or higher [satisfactory scores], and scores of 85 or lower [unsatisfactory scores]).

Further information can be obtained on a particular ship, including all scores for that ship and an inspection report preview.

The VSP website also provides the Inspection Detail Report for each ship inspection. This report provides a categorical review of the deficiencies noted along with the number of points deducted for that category and the numerical score for the inspection of a particular ship. Details of the inspection with the specific deficiencies and recommendations are also available from this page.

Inspection report data are also searchable from the VSP database for the following search categories:

- Ship name.
- Cruise line.
- Inspection date.

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- Most recent date.
- All dates.
- Range of dates.
- Score (all scores, scores of 86 or higher [satisfactory scores], and scores of 85 or lower [unsatisfactory scores]).

13.19.3 Contact Information

Further information on VSP, inspection results, and vessels' corrective action statements may be obtained

- On the VSP website (www.cdc.gov/nceh/vsp).
- Through email (vsp@cdc.gov).
- By telephone (800-323-2132).
- By fax (770-488-4127).

14.0 Bibliography

This section includes the following subsections:

- 14.1 Introduction
- 14.2 Authority
- 14.3 Definitions
- 14.4 ACUTE GASTROENTERITIS Surveillance
- 14.5 POTABLE WATER
- 14.6 RECREATIONAL WATER FACILITIES
- 14.7 FOOD Safety
- 14.8 INTEGRATED PEST MANAGEMENT
- 14.9 Housekeeping
- 14.10 CHILD ACTIVITY CENTERS
- 14.11 HVAC Systems, Fountains, Misting Systems, Humidifiers, and Showers
- 14.12 Administrative Guidelines

14.1 Introduction

Centers for Disease Control and Prevention, NCEH. 1999. Vessel Sanitation Program: Charting a Healthier Course.

Centers for Disease Control and Prevention, NCEH. 1999. www.cdc.gov/nceh/vsp.

Centers for Disease Control and Prevention, NCEH. 1989, 2000, 2005, 2011. Vessel Sanitation Program operations manual.

14.2 Authority

Code of Federal Regulations 42 CFR 71.31. Health Measures at U.S. Ports: Communicable Diseases. General provisions.

Code of Federal Regulations 42 CFR 71.32. Health Measures at U.S. Ports: Communicable Diseases. Persons, carriers, and things.

Code of Federal Regulations 42 CFR Section 71.41. General Provisions. Foreign Quarantine - Requirements Upon Arrival at U.S. Ports: Sanitary Inspection.

The Public Health Service Act, 42 U.S.C. Section 264. Quarantine and Inspection—Regulations to control communicable diseases.

The Public Health Service Act, 42 U.S.C. Section 269. Quarantine and Inspection—Bills of health.

14.3 Definitions

Food and Drug Administration. 2017. Food Code, Recommendations of the United States Public Health Service.

Centers for Disease Control and Prevention. 2016. Model Aquatic Health Code (MAHC): A National Model Swimming Pool and Spa Code. 2nd edition.

14.4 Acute Gastroenteritis Surveillance

Addiss DG, Yashuk JC, Clapp DE, Blake PA. 1989. Outbreaks of diarrhoeal illness on passenger cruise ships, 1975–85. *Epidemiol Infect.* 103(1):63–72.

Centers for Disease Control and Prevention. 1990. Recommendations for collection of laboratory specimens associated with outbreaks of gastroenteritis. *MMWR.* 39RR-14.

Centers for Disease Control and Prevention, NCEH. 1999. Disease Surveillance and Outbreak Investigation. www.cdc.gov/nceh/vsp/pub/biblio/biblio.htm

Cramer EH, Blanton C, Browne L, Vaughan G, Bopp C, Forney D. 2006. Epidemiology of gastroenteritis on cruise ships, 2001–2004: the impact of noroviruses. *Am J Prev Med.* 30(3):252–7.

Cramer EH, Gu DX, Durbin RE, Vessel Sanitation Program Environmental Health Inspection Team. 2003. Diarrheal disease on cruise ships, 1990–2000: the impact of environmental health programs. *Am J Prev Med.* 24(3):227–33.

Dalton C, Mintz ED, Wells JG, Bopp CA, Tauxe RV. 1999. Outbreaks of enterotoxigenic *Escherichia coli* infection in American adults: a clinical and epidemiologic profile. *Epidemiol Infect.* 123:9–16.

Daniels NA, Neimann J, Karpati A, Parashar UD, Greene KD, Wells JG, et al. 2000. Traveler's diarrhea at sea: three outbreaks of waterborne enterotoxigenic *Escherichia coli* on cruise ships. *J Infect Dis.* 181:1491–5.

Dannenberg AL, Yashuk JC, Feldman RA. 1982. Gastrointestinal illness on passenger cruise ships, 1975–1978. *Am J Publ Health.* 72:484–8.

Davies JW, Cox KG, Simon WR, Bowmer EJ, Mallory A. 1972. Typhoid at sea: epidemic aboard an ocean liner. *Can Med Assoc J.* 106:877–83.

Freedom of Information Act. 5 U.S.C. Section 552. Administrative Procedure—Public information; agency rules, opinions, orders, records, and proceedings.

Freedom of Information Act. 5 U.S.C. Section 552a. Privacy Act—Records maintained on individuals.

Freeland AL, Vaughan GH Jr, Banerjee SN. 2016. Acute gastroenteritis on cruise ships—United States, 2008–2014. *MMWR.* 65(1):1–5.

Gunn RA, Terranova WA, Greenberg HB, Yashuk J, Gary GW, Wells JG, et al. 1980. Norwalk virus gastroenteritis aboard a cruise ship: an outbreak of five consecutive cruises. *Am J Epidemiol.* 1122:820–7.

Hall AJ, Vinjé J, Lopman B, Park GW, Yen C, Gregoricus N, et al. 2011. Updated norovirus outbreak management and disease prevention guidelines. *MMWR.* 60(RR03);1-15.

Herwaldt BL, Lew JF, Moe CL, Lewis DC, Humphrey CD, Monroe SS, et al. 1994. Characterization of a variant strain of Norwalk virus from a food-borne outbreak of gastroenteritis on a cruise ship in Hawaii. *J Clin Microbiol.* 4:861–6.

Ho MS, Glass RI, Monroe SS, Madore HP, Stine S, Pinsky PF, et al. 1989. Viral gastroenteritis aboard a cruise ship. *Lancet.* 2(8669):961–5.

IAMFES. 2016. Procedures to Investigate Waterborne Illness, 3rd Edition. Des Moines, IA.

IAMFES. 2011. Procedures to Investigate Foodborne Illness, 6th Edition. Des Moines, IA.

Khan AS, Moe CL, Glass RI, Monroe SS, Estes MK, Chapman LK, et al. 1994. Norwalk virus-associated gastroenteritis traced to ice consumption aboard a cruise ship in Hawaii: comparison and application of molecular method-based assays. *J Clin Microbiol.* 2:318– 22.

Koo D, Maloney K, Tauxe R. 1996. Epidemiology of diarrheal disease outbreaks on cruise ships, 1986 through 1993. *JAMA.* 7:545–7.

Lew JF, Swerdlow DL, Dance ME, Griffin PM, Bopp CA, Gillenwater MJ, et al. 1991. An outbreak of shigellosis aboard a cruise ship caused by a multiple-antibiotic-resistant strain of *Shigella flexneri*. *Am J Epidemiol.* 134(4):413–20.

Marks PJ, Vipond IB, Carlisle D, Deakin D, Fey RE, Caul EO. 2000. Evidence for airborne transmission of Norwalk-like virus (NLV) in a hotel restaurant. *Epidemiol. Infect.* 124: 481-487.

Merson MH, Hughes JM, Lawrence DN, Wells JG, D’Agnese JJ, Yashuk JC. 1976. Food- and waterborne disease outbreaks on passenger cruise vessels and aircraft. *J Milk Food Technol.* 39:285–8.

Merson MH, Hughes JM, Wood BT, Yashuk JC, Wells JG. 1987. Gastrointestinal illness on passenger cruise ships. *JAMA.* 231:723–7.

Merson MH, Tenney JH, Meyers JD, Wood BT, Wells JG, Rymzo W, et al., 1975. Shigellosis at sea: an outbreak aboard a passenger cruise ship. *Am J Epidemiol.* 101:165– 75.

Nguyen CH, Qualls NL, O’Toole TE, 1989. A cost-effectiveness analysis of the Vessel Sanitation Program. Centers for Disease Control and Prevention, U.S. Public Health Service; Atlanta, GA.

Park GW, Lee D, Treffiletti A, Hrsak M, Shugart J, Vinjé J. 2015. Evaluation of a new environmental sampling protocol for detection of human norovirus on inanimate surfaces. *Appl Environ Microbiol* 81(17):5987-92.

Sawyer LA, Murphy JJ, Kaplan JE, Pinsky PF, Chacon D, Walmsley S, et al. 1988. 25- to 30-nm virus particle associated with a hospital outbreak of acute gastroenteritis with evidence for airborne transmission. *Am J Epidemiol.* 127:1261–71.

Wikswa ME, Cortes J, Hall AJ, Vaughan G, Howard C, Gregoricus N, Cramer EH. 2011. Disease transmission and passenger behaviors during a high morbidity norovirus outbreak on a cruise ship, January 2009. *Clin Infect Dis.* 52(9):1116-22.

14.5 Potable Water

American Public Health Association. 2017. Standard methods for the examination of water and wastewater. 23rd ed. Washington, DC.

American Society of Sanitary Engineering. 2004. ASSE #1032—2004, Dual check valve type backflow preventers. Westlake, OH.

American Society of Sanitary Engineering. 2008. ANSI/ASSE #1004—20081990, Commercial dishwashing machines. Westlake, OH.

American Society of Sanitary Engineering. 2005. ASSE #1014—2005, Hand-held showers. Westlake, OH.

VSP 2018 Operations Manual

- American Society of Sanitary Engineering. 2011. ASSE #1013—2011, Reduced pressure principle backflow preventers. Westlake, OH.
- American Society of Sanitary Engineering. 2011. ASSE #1015—2011, Double check backflow prevention assembly. Westlake, OH.
- American Society of Sanitary Engineering. 2016. ANSI/ASSE #1052—2016, Hose connection backflow preventers. Westlake, OH.
- American Society of Sanitary Engineering. 1990. ANSI/ASSE #1009—1990, Commercial food waste grinder units. Westlake, OH.
- American Society of Sanitary Engineering. 2011. ANSI/ASSE #1047—2011, Reduced pressure detector backflow preventer. Westlake, OH.
- American Society of Sanitary Engineering. 2011. ANSI/ASSE #1048—2011, Double check detector assembly backflow preventer. Westlake, OH.
- American Society of Sanitary Engineering. 2013. ANSI/ASSE #1056—2013, Performance requirements for spill resistant vacuum breaker assemblies. Westlake, OH.
- American Society of Sanitary Engineering. 2016. ASSE#1055—2016, Chemical dispensing systems. Westlake, OH.
- American Society of Sanitary Engineering. 2004. ANSI/ASSE #1024—2004, Dual check valve type backflow preventers, Westlake, OH.
- American Society of Sanitary Engineering. 2004. ASSE #1020—2004, Pressure vacuum breaker assembly. Westlake, OH.
- American Society of Sanitary Engineering. 2004. ANSI/ASSE #1011—2004, Hose connection vacuum breakers. Westlake, OH. American Society of Sanitary Engineering, 1995.
- American Society of Sanitary Engineering. 2008. ANSI/ASSE #1001—2008, Atmospheric type vacuum breakers. Westlake, OH.
- American Water Works Association. 2006. Water chlorination and chloramination principles and practices, 2nd edition. Denver, CO.
- American Water Works Association. 2015. Recommended practice for backflow prevention and cross-connection control, 4th edition. Denver, CO.
- American Water Works Association. 1992. ANSI/AWWA C651-92: Disinfecting water mains. Denver, CO.
- American Water Works Association. 2011. ANSI/AWWA C652-11: Disinfection of water-storage facilities. Denver, CO.
- American Water Works Association. 2001. Emergency planning for water utility management, 4th edition. Denver, CO. American Water Works Association. 1995. Electrodialysis and electrodialysis reversal. Denver, CO.
- American Water Works Association. 1997. ANSI/AWWA C653-97: Disinfection of water treatment plants. Denver, CO.
- American Water Works Association. 2016. Simplified procedures for water examination, 6th edition. Denver, CO.

VSP 2018 Operations Manual

American Water Works Association. 2007. Reverse osmosis and nanofiltration, 2nd edition. Denver, CO.

American Water Works Association. 2013. Water distribution operator training handbook, 4th edition. Denver, CO.

ANSI/ASSE.2008. #1012—2008, Backflow preventers with intermediate atmospheric vent. Westlake, OH.

ANSI/ASSE. 2017. #1022—2017, Backflow preventer for carbonated beverage machines. Westlake, OH.

Clesceri LS, Greenberg AE, Eaton AD, eds. 2012. Standard methods for the examination of water and wastewater. 22nd edition. American Public Health Association, American Water Works Association and Water Environment Federation, Washington, DC.

Code of Federal Regulations, Title 40 Section 141 National Primary Drinking Water Regulations.

Foundation for Cross-Connection Control and Hydraulic Research. Manual of cross-connection control, 10th edition. Los Angeles, CA: University of Southern California.

NSF International. 2013. ANSI/NSF Standard 60-2013 drinking water treatment chemicals—health effects. Ann Arbor, MI.

NSF International.2013. ANSI/NSF Standard 61-2013 drinking water system components—health effects. Ann Arbor, MI.

U.S. Environmental Protection Agency. 1989. Cross-connection control manual.

World Health Organization. 2011. Guidelines for drinking-water quality, volume 1: recommendations. 4th edition. Geneva, Switzerland.

World Health Organization. 1996. Guidelines for drinking-water quality, volume 2: health criteria and other supporting information. 2nd edition. Geneva, Switzerland.

World Health Organization. 1997. Guidelines for Drinking-water quality, world health organization, volume 3: surveillance and control of community water supplies. 2nd edition. Geneva, Switzerland.

World Health Organization. 2017. Guidelines for drinking-water quality, 4th edition, addendum to volume 1: recommendations. Geneva, Switzerland.

World Health Organization. 2002. Guidelines for drinking-water quality, second edition, addendum to volume 2: health criteria and other supporting information. Geneva, Switzerland.

14.6 Recreational Water Facilities

American National Standards Institute/National Spa & Pool Institute. 2016. NSF/ANSI 50-2016. Standard for public swimming pools and standard for public spas, standard 50: circulation system components and related materials for swimming pools, spas/hot tubs. Ann Arbor, MI: NSF International. <http://www.nsf.org/>.

ASME International. 1987. ASME/ANSI A112.19.8M Suction fittings for use in swimming pools, wading pools, spas, hot tubs, and whirlpool bathtub appliances (Reaffirmed 1996). New York.

California Code of Regulations, Title 22 Chapter 20.

VSP 2018 Operations Manual

- Centers for Disease Control and Prevention. 2016. Model Aquatic Health Code (MAHC): A National Model Swimming Pool and Spa Code. 2nd edition.
- Centers for Disease Control and Prevention. 2001. Notice to Readers: Responding to fecal accidents in disinfected swimming venues. MMWR. 50(20):416–7.
- Centers for Disease Control and Prevention. 1997. Final recommendations to minimize transmission of Legionnaires’ disease from whirlpool spas on cruise ships.
- Centers for Disease Control and Prevention, Division of Parasitic Diseases. 1999. Information for swimming pool operators: prevention of cryptosporidiosis.
- Code of Federal Regulations, Title 16, Part 1450. Virginia Graeme Baker Pool and Spa Safety Act.
- Environmental Protection Agency. 2003. Ultraviolet disinfection manual. EPA-D-03-007.
- Environmental Protection Agency. 1986. Disinfection with ultra violet light—design, construct and operate for success. Cincinnati, OH.
- Environmental Protection Agency. 1988. Ultra violet disinfection: special evaluation project. EPA Region 5, Chicago, IL.
- Florida Administrative Code. Chapter 64E-9. Public swimming pools and bathing places.
- Gallagher TE. 1996. Comprehensive water quality testing of high-use public spas. J Environ Health. 58;7:11.
- Kebabjian R. 1995. Disinfection of public pools and management of fecal accidents. J Environ Health. 58;1:8.
- Lemmon JM, McAnulty JM, Bawden-Smith J. 1996. Outbreak of cryptosporidiosis linked to an indoor swimming pool. Med J Australia. 165:613.
- National Pool and Spa Institute. 2003. ANSI/NSPI-1 2003 standard for public swimming pools. Alexandria, VA.
- National Pool and Spa Institute. 1996. Symposium on water chemistry and disinfection 1996. Alexandria, VA.
- National Pool and Spa Institute. 1997. Chemical dynamics within the pool and spa environment 1997. Alexandria, VA.
- National Pool and Spa Institute. 1999. ANSI/NSPI-2 1999 standard for public spas. Alexandria, VA.
- National Swimming Pool Foundation. 2017. Pool and spa operator handbook.
- New York Codes, Rules and Regulations, Title 10, Chapter 1, Part 6. Swimming pools, bathing beaches and recreational aquatic spray grounds.
- NSF International. 2016. ANSI/NSF Standard 50-2016. Equipment for swimming pools, spas, hot tubs and other recreational water facilities. Ann Arbor, MI.
- NSF International. 2016. ANSI/NSF Standard 14-2016. Plastics piping system components and related materials. Ann Arbor, MI.
- NSF International. 2013. ANSI/NSF Standard 60-2013. Drinking water treatment chemicals—health effects. Ann Arbor, MI.

NSF International. 2013. ANSI/NSF Standard 61-2013. Drinking water system components—health effects. Ann Arbor, MI.

Ormecci B, Ishida GA, Linden KG, 2005. UV disinfection of chlorinated water: impact on chlorine concentration and UV dose delivery. *J Water Suppl Res Technol.* 54(3):189–99.

Rennell DS, ed. 1992. Basic pool and spa technology, 2nd edition. National Spa & Pool Institute. Alexandria, VA.

Rowley W. Entrapment and evisceration study. National Swimming Pool Foundation. Merrick, NY.

Shin GA, Linden KG, Arrowood MJ, Sobsey MD. 2001. Low-pressure UV inactivation and DNA repair potential of cryptosporidium parvum oocysts. *Appl Environ Microbiol.* 67(7):3029–32.

U.S. Army, CHPPM. 1996. Controlling contamination from fecal accidents in swimming pools.

Vogt RL, Hudson PJ, Orciari L, Heun EM, Woods TC. 1987. Legionnaires' disease and a whirlpool spa (Letter). *Ann Intern Med.* 107:596.

Wisconsin Administrative Code, Chapter ATCP 76. Safety, maintenance, and operation of public pools and water attractions.

14.7 Food Safety

Food and Drug Administration. 2013. Food code, recommendations of the United States Public Health Service.

Additional Chapter 7.0 Food Safety References

Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C, et al. 1999. Food-related illness and death in the United States. *Emerg Infect Dis.* 5(5).

Food and Drug Administration, Center for Food Safety and Applied Nutrition. 2012. Foodborne pathogenic microorganisms and natural toxins handbook: the “bad bug book.” 2nd edition.

Guzewich J, Ross MP. 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. Food and Drug Administration.

Food and Drug Administration, Center for Food Safety and Applied Nutrition. 2000. CFP 2000 backgrounder: no bare hand contact.

Larson E, 1995. APIC guidelines for handwashing and hand antisepsis in healthcare settings. *Am J Infect Control.* 23:251–69.

NSF International. 1983. NSF C2-1983, Special equipment and/or devices (food service equipment). Ann Arbor, MI.

NSF International. 2015. ANSI/NSF 2-2015, Food equipment. Ann Arbor, MI.

NSF International. 2017. ANSI/NSF 3-2017, Commercial spray-type dishwashing and glasswashing machines. Ann Arbor, MI.

NSF International. 2016. ANSI/NSF 4-2016, Commercial cooking, rethermalization, and powered hot food holding and transport equipment. Ann Arbor, MI.

VSP 2018 Operations Manual

- NSF International. 2016. NSF 5-2016, Water heaters, hot water supply boilers, and heat recovery equipment. Ann Arbor, MI.
- NSF International. 2016. ANSI/NSF 6-2016, Dispensing freezers (for dairy dessert-type products). Ann Arbor, MI.
- NSF International. 2016. ANSI/NSF 7-2016, Commercial refrigerators and storage freezers. Ann Arbor, MI.
- NSF International. 2017. ANSI/NSF 8-2017, Commercial powered food preparation equipment. Ann Arbor, MI.
- NSF International. 2017. ANSI/NSF 12-2017, Automatic ice making equipment. Ann Arbor, MI.
- NSF International. 2017. ANSI/NSF 13-2017, Refuse compactors and compactor systems. Ann Arbor, MI.
- NSF International. 2016. ANSI/NSF 18-2016, Manual food and BEVERAGE dispensing equipment. Ann Arbor, MI.
- NSF International. 2016. ANSI/NSF 20-2016, Commercial bulk milk dispensing equipment. Ann Arbor, MI.
- NSF International. 2015. ANSI/NSF 21-2015, Thermoplastic refuse containers. Ann Arbor, MI.
- NSF International. 2012. ANSI/NSF 25-2012, Vending machines for food and BEVERAGES. Ann Arbor, MI.
- NSF International. 1980. NSF 26-1980, Pot, pan, and utensil commercial spray-type washing machines. Ann Arbor, MI.
- NSF International. 2017. ANSI/NSF 29-2017, Detergent and chemical feeders for commercial spray-type dishwashing machines. Ann Arbor, MI.
- NSF International. 2012. ANSI/NSF 35-2012, Laminated plastics for surfacing food service equipment. Ann Arbor, MI.
- NSF International. 2012. ANSI/NSF 36-2012, Dinnerware. Ann Arbor, MI.
- NSF International. 2017. ANSI/NSF 37-2017, Air curtains for entranceways in food and food service establishments. Ann Arbor, MI.
- NSF International. 2014. ANSI/NSF 51-2014, Food equipment materials. Ann Arbor, MI.
- NSF International. 2017. ANSI/NSF 52-2017, Supplemental flooring. Ann Arbor, MI.
- NSF International. 2012. ANSI/NSF 59-2012, Mobile food carts. Ann Arbor, MI.
- Standard specification for factory assembled anodeless risers and transition fittings in polyethylene (PE) fuel gas distribution systems, ASTM Designation: F 1973-99.

14.8 Integrated Pest Management

- Armed Forces Pest Management Board. 1994. Technical Information Memorandum No.
29. Integrated pest management in and around buildings. Defense Pest Management Information Analysis Center. Washington, DC.

ASTM International. 2011. F1099M-98(2011), Standard Specification for Rat Guards, Ship's (Metric). West Conshohocken, PA.

Code of Federal Regulations, Title 40, Parts 152-186. Federal Insecticide, Fungicide, and Rodenticide Act.

D'Agnese JJ. 2008. Integrated pest management system guide for cruise ships. 7th edition. Cruise Ship Consultation Service, Fernandina Beach, FL.

Educational Foundation of the National Restaurant Association. 1992. Applied Foodservice Sanitation. 4th edition. John Wiley & Sons, New York.

National Restaurant Association. Pest management in restaurants. Washington, DC.

ServSafe. 1999. The educational foundation of the National Restaurant Association, Chicago, IL.

U.S. Army. 1996. Cockroach IPM: installation integrated pest management program for German cockroach control.

U.S. Navy. 1999. LT Christian's little blue book: an unofficial guide for US Navy shipboard medical officers.

U.S. Navy. 2009. Shipboard pest management pocket guide.

14.9 Housekeeping

APIC. 2002. Handbook of infection control. 3rd edition. Association for Professionals in Infection Control and Epidemiology. Mosby, St. Louis, MO.

Black JG. 1995. Microbiology: principles and application. 3rd edition. Prentice Hall, Upper Saddle River, NJ.

Block SS. 2001. Disinfection, sterilization & preservation. 5th edition. Williams & Wilkins, Philadelphia, PA.

Centers for Disease Control and Prevention. 1997. Final recommendations to minimize transmission of Legionnaires' disease from whirlpool spas on cruise ships.

Centers for Disease Control and Prevention. 2011. Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings. Available from URL: <https://www.cdc.gov/infectioncontrol/guidelines/norovirus/index.html>.

Collins CH, ed. 1981. Disinfectants: their use and evaluation of effectiveness. Technical Series No 16. Society for Applied Bacteriology. Academic Press, San Diego, CA.

Freije MR, Barbaree JM, ed. 1996. Legionellae control in health care facilities: minimizing risk. HC Information Resources, Indianapolis, IN.

Marks PJ, Vipond IB, Carlisle D, Deakin D, Fey RE, Caul EO. 2000. Evidence for airborne transmission of Norwalk-like virus (NLV) in a hotel restaurant. Epidemiol. Infect. 124: 481-487.

Nester E, Nester M. 2015. Microbiology: a human perspective. 8th edition. McGraw Hill, New York, NY.

Robinson M. 1997. Housekeeping. Bantam Books, New York, NY.

Rutala RW. 1996. APIC guidelines for selection and use of disinfectants. Am J Infect Control. 24:13-42.

Tortora G. 2016. Microbiology: an introduction. 12th edition. Addison-Wesley, Reading, MA.

14.10 Child Activity Centers

American Academy of Pediatrics and American Public Health Association Staff. 1992. Caring for our children: national health & safety performance standards. Washington, DC.

National Resource Center for Health & Safety in Child Care, <http://nrckids.org/>.

Rutala RW. 1996. APIC guidelines for selection and use of disinfectants. Am J Infect Control. 24:13–42.

Young FE. 1989. In day-care centers, cleanliness is a must. FDA Consumer. U.S. Food and Drug Administration. Washington, DC.

14.11 HVAC Systems, Fountains, Misting Systems, Humidifiers, and Showers

ASHRAE. Guideline 12-2000, Minimizing the Risk of Legionellosis Associated with Building Water Systems.

ASHRAE. Guideline 180-2012, Standard Practice for Inspection and Maintenance of Commercial Building HVAC Systems.

ASHRAE. Guidelines 188-2015, Legionellosis: Risk Management for Building Water Systems.

Bollin GE, Plouffe JF, Para MF, Hackman B. 1985. Aerosols containing “Legionella pneumophila” generated by shower heads and hot-water faucets. Appl Environ Microbiol. 50(5):1128–31.

Breiman R, Fields B, Volmer L, et al. 1989. Definitive association of shower use with Legionnaires’ disease: possible role of amoebae (Abstract). In: Program and abstracts of the 89th Annual Meeting of the American Society for Microbiology. American Society for Microbiology, Washington, DC; 126.

Freije MR. 1998. Minimizing the risk of Legionella in cooling towers and other HVAC equipment. HC Information Resources, Indianapolis, IN.

14.12 Administrative Guidelines

Centers for Disease Control and Prevention. 2001. Recommended shipbuilding construction guidelines for passenger vessels destined to call on U.S. ports.

Centers for Disease Control and Prevention, NCEH. 2011. Vessel Sanitation Program Construction Guidelines.

Centers for Disease Control and Prevention, NCEH. 2005. Vessel Sanitation Program Construction Guidelines.

Centers for Disease Control and Prevention. Summary of sanitation inspections of international cruise ships. www.cdc.gov/nceh/vsp.

DEPARTMENT OF HEALTH AND HUMAN SERVICES**42 CFR Parts 70 and 71****[CDC Docket No. CDC–2016–0068]****RIN 0920–AA63****Control of Communicable Diseases**

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this final rule (FR) to amend its regulations governing its domestic (interstate) and foreign quarantine regulations to best protect the public health of the United States. These amendments have been made to aid public health responses to outbreaks of new or re-emerging communicable diseases and to accord due process to individuals subject to Federal public health orders. In response to public comment received, the updated provisions in this final rule clarify various safeguards to prevent the importation and spread of communicable diseases affecting human health into the United States and interstate.

DATES: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Director, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E03, Atlanta, GA 30329, or email dgmqpolicyoffice@cdc.gov.

SUPPLEMENTARY INFORMATION: Based on public comment received to the Notice of Proposed Rulemaking (NPRM) (81 FR 54230) this final rule, among other things: Withdraws a provision regarding “Agreements” as proposed in the NPRM, requires CDC to issue a federal order within 72 hours after apprehending an individual, increases the threshold for those who may be considered “indigent” to 200% of the applicable poverty guideline, adds a definition for “Secretary,” adds a requirement for CDC to provide legal counsel for isolated or quarantined individuals qualifying as indigent who request a medical review, modifies the definition of “non-invasive,” includes “known or possible exposure” in the list of information that may be collected during a public health risk assessment, and strengthens due process protections by ensuring that CDC will arrange for translation or interpretation services for

public health orders and medical reviews as needed. In implementing quarantine, isolation, or other public health measures under this Final Rule, HHS/CDC will seek to use the least restrictive means necessary to prevent the spread of communicable disease.

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I. Executive Summary**A. Purpose of the Action**

HHS/CDC has statutory authority (42 U.S.C. 264, 265) to promulgate regulations that protect U.S. public health from communicable diseases, including quarantinable communicable diseases as specified in an Executive Order of the President. *See* Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 (July 31, 2014). The need for this rulemaking was reinforced during HHS/CDC’s response to the largest outbreak of Ebola virus disease (Ebola) on record, followed by the recent outbreak of Middle East Respiratory Syndrome (MERS), both quarantinable communicable diseases, and repeated outbreaks and responses to measles, a non-quarantinable communicable disease of public health concern. This

final rule will enhance HHS/CDC's ability to prevent the introduction, transmission, and spread of communicable diseases into the United States and interstate by clarifying and providing greater transparency regarding its response capabilities and practices.

B. Summary of Major Provisions

Both the domestic and foreign portions of this regulation include new proposed public health definitions; new regulatory language implementing HHS/CDC's activities concerning non-invasive public health prevention measures (*i.e.*, traveler health screening) at U.S. ports of entry and other U.S. locations (*i.e.*, railway stations, bus terminals); and provisions affording due process to persons served with a Federal public health order (*e.g.*, isolation, quarantine), including requiring that HHS/CDC explain the reasons for issuing the order, administrative processes for appealing the order, and a mandatory reassessment of the order.

The domestic portion of this final rule includes a requirement that commercial passenger flights report deaths or illnesses to the CDC. It also includes a provision requiring that individuals apply for a travel permit if they are under a Federal quarantine, isolation, or conditional release order (unless the specific travel is authorized by the Federal conditional release order) or if a State or local public health department requests CDC assistance in enforcing a State or local quarantine or isolation order. Additionally, the domestic portion of this final rule includes new regulatory language clarifying when an individual who is moving between U.S. states is "reasonably believed to be infected" with a quarantinable communicable disease in a "qualifying stage." These determinations are made when the CDC considers the need to apprehend or examine an individual for potential infection with a quarantinable communicable disease. The foreign portion of this final rule includes new regulatory authority permitting the CDC Director to prohibit the importation of animals or products that pose a threat to public health.

HHS/CDC has also changed the text of the regulation to reflect modern terminology, technology, and plain language used by private industry, public health partners, and the public. The final rule also authorizes public health monitoring through electronic or internet-based means of communication for individuals under a Federal conditional release order who are reasonably believed to be exposed to or

infected with a quarantinable communicable disease. This would include communication through email and webcam application tools. Finally, while neither modifying nor authorizing additional criminal penalties for violations of quarantine rules and regulations, this final rule updates regulatory language to align with existing criminal penalties set forth in statute.

C. Summary of Costs and Benefits

The regulatory impact analysis quantitatively addresses the costs and benefits associated with this final rule. The economic impact analysis of this final rule is subdivided into two sections.

The first analysis summarizes the economic impact of changes to 42 CFR 70.1, 42 CFR 71.1/71.4/71.5 for which the primary costs for submitting passenger and crew information to HHS/CDC are incurred by airlines and vessel operators and the primary benefit is improved public health responsiveness to assess and offer post-exposure prophylaxis to travelers potentially exposed to communicable diseases of public health concern. The most likely estimates of annual costs to airlines, vessel operators, the United States government, and public health departments are low (\$32,622, range \$10,959 to \$430,839) because the final rule primarily codifies existing practice or improves alignment between existing regulatory text and the International Civil Aviation Organization (ICAO)'s guidelines for symptoms to report. The cost estimates in this final rule are based on (1) an anticipated small increase in the number of illness reports delivered by airlines and processed by HHS/CDC and (2) increased costs for airlines and vessel operators to comply with HHS/CDC orders for traveler and crew contact data, to the extent that such information is readily available and already maintained, and not already transmitted to the U.S. Customs and Border Protection (CBP). The cost estimate also includes an increase in costs for public health departments to contact more exposed travelers due to the availability of improved contact data.

The best estimate of the annual quantified benefits of the final rule are \$110,045 (range \$26,337 to \$297,393) and mostly result from increased efficiencies for HHS/CDC and State and local public health departments to conduct contact investigations among travelers on an aircraft exposed to communicable diseases of public health concern, especially for measles and tuberculosis. To the extent that improved responsiveness of airlines to

HHS/CDC traveler data orders may result from the implementation of the provisions in this final rule, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety associated with quarantinable communicable disease outbreaks initiated by international travelers (such as have been observed during outbreak of severe acute respiratory syndrome in Canada or Middle East respiratory syndrome in South Korea), and (4) reduce the amount of personnel labor time to conduct large-scale contact investigations in response to a new infectious disease or one with larger scale public health and medical consequences like Ebola.

The second analysis in this final rule is of a number of provisions that aim to improve transparency of how HHS/CDC uses its regulatory authorities to protect public health. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way.

II. Public Participation

On August 15, 2016, HHS/CDC published a notice of proposed rulemaking (NPRM) (81 FR 54299) to amend 42 CFR part 70 (interstate) and 42 CFR part 71 (foreign) quarantine regulations. The public was invited to comment on these amendments. The comment period ended October 14, 2016. In the NPRM, HHS/CDC specifically requested public comment on the following:

- Whether the use of the standard definition of "indigent" is an appropriate threshold to determine whether an individual cannot afford representation and therefore should be appointed a medical representative at the government's expense and whether the public believes that there may be non-indigent individuals, as defined in the NPRM, who may have difficulty affording a representative;
- The definition of *public health emergency* and its utility in identifying communicable diseases that "would be likely to cause a public health emergency if transmitted to other individuals" under 42 U.S.C. 264(d)(2)(B);

- Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release; specifically, on whether stakeholders

have concerns regarding the requirement imposed on conveyance operators to not “knowingly” transport individuals under a Federal order and the feasibility of this requirement and the application of this provision to individuals under State/local order as well as individuals traveling entirely within a State.

- Public health prevention measures and whether the public has any concerns regarding the mandatory health screening of passengers using non-invasive means as defined in the proposal or the collection of personal information from screened individuals for the purposes of contact tracing;
- Payment for care and treatment, and whether there are any concerns that all third party payments be exhausted prior to the Federal reimbursement of medical care or treatment for individuals placed under a Federal order for quarantine, isolation, or conditional surveillance;
- The application of requirements relating to issuance of a Federal order for quarantine, isolation or conditional release as it applies to groups and whether this provision sufficiently informs the public of the important details concerning circumstances during which HHS/CDC would issue to groups or individuals Federal orders for quarantine, isolation, and conditional release and the duration and conditions of such orders;
- Whether 72 hours is the necessary amount of time to conduct a reassessment after a Federal order is first issued, or if the reassessment should take place earlier or later;
- Whether or not the public sees a role for the Federal government to ensure that basic living conditions, amenities, and standards are satisfactory when placing individuals under Federal orders;
- Whether the definition of “non-invasive” aligns with common perceptions of what constitutes non-invasive procedures that may be conducted outside of a traditional clinical setting;
- Whether the penalties proposed, and the circumstances under which such penalties may be imposed, were clearly explained;
- The applicability of the December 13, 2007 system of records notice (SORN) to the activities proposed (72 FR 70867), and whether the SORN sufficiently addresses the public’s concerns related to maintenance and protection of the data elements proposed;
- The request for a passenger and crew manifest within 24 hours and whether the provision grants operators

of airlines sufficient time for operators to respond to manifests orders;

- The likelihood that the passenger and crew data elements requested are already collected and maintained by airline operators for transmission to CDC;
- Any industry concerns regarding whether proposed section 71.63 sufficiently details the circumstances under which HHS/CDC may impose an embargo on the importation of animals, articles, or things, including how such an embargo would be implemented, as well as any concerns regarding coordination with other Federal agencies.

The public comment period for the proposed rule ended on October 14, 2016 and HHS/CDC received 15,800 comments from individuals, stakeholders, and groups. A summary of those comments and responses to those comments are found at Section IV, below.

II. Background

A. Legal Authority

The primary legal authorities supporting this rulemaking are sections 361 and 362¹ of the Public Health Service Act (42 U.S.C. 264, 265). HHS/CDC also believes that the following Public Health Service Act sections are relevant with respect to this rulemaking: section 311 (42 U.S.C. 243), section 321 (42 U.S.C. 248), section 322 (42 U.S.C. 249), section 365 (42 U.S.C. 268), and sections 367–69 (42 U.S.C. 270–72). A detailed explanation of these legal authorities was provided in the NPRM published at 81 FR 54230 (Aug. 15, 2016).

B. Regulatory History

On August 15, 2016, HHS/CDC published a Notice of Proposed Rulemaking to update 42 CFR 70 (domestic) and 42 CFR 71 (foreign) quarantine regulations. These amendments were proposed to aid public health responses to outbreaks of communicable disease, such as the largest outbreak of Ebola virus disease (Ebola) on record, Middle East Respiratory Syndrome (MERS), both quarantinable communicable diseases, and repeated outbreaks of measles in the United States, a non-quarantinable communicable disease of public health concern. (81 FR 54299). Communicable diseases of public health concern are those diseases that because of their

potential for spread, particularly during travel, may require a public health intervention. The provisions contained within the proposal were designed to enhance HHS/CDC’s ability to prevent the further importation and spread of communicable diseases into the United States and interstate by clarifying HHS/CDC’s response capabilities, practices, and making them more transparent.

III. Summary of the Final Rule

Upon consideration of public comment, the following is a section-by-section summary of the changes from the proposed text that HHS/CDC made to parts 70 and 71:

A. General References to “CDC” and “Director” in Parts 70 and 71

Throughout the regulatory text in parts 70 and 71, references to “CDC” or “HHS/CDC” have been replaced with “Director.” This is in keeping with the common practice that federal agencies act through employees and officials to whom the authority involved has been delegated. *Director* is currently defined in sections 70.1 and 71.1 to mean “the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.” Where it is necessary to exclude CDC employees or officials from undertaking certain functions this has been indicated by use of parenthesis, e.g., “Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order).” This is a stylistic change from the NPRM, but does not result in a substantive change in the final rule.

B. Definitions (Sections 70.1 and 71.1(b))

- The definition of *Agreements* has been removed.
- The definition of *Electronic or internet-based monitoring* has been modified to include “communication through” these means and “audio” conference.
- The definition of *Indigent* has been modified to increase the threshold to 200% of the applicable poverty guidelines.
- The definition of *Ill person* under section 71.1 has been modified to include a person who “Has a fever that has persisted for more than 48 hours” or “Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-

¹ Section 3 of Executive Order 13295 (April 4, 2003) states that the functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the HHS Secretary.

hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38°C] or greater)." This language was quoted verbatim in the preamble of the NPRM at 81 FR 54305 but was inadvertently omitted from the proposed regulatory text.

- The definition of *Medical Examination* has been modified to indicate that the health worker conducting the assessment must be "licensed."
- The definition of *Medical Representative* has been changed to *Representatives* and now includes for an indigent individual the additional appointment of "an attorney who is knowledgeable of public health practices" if the indigent individual requests a medical review.
- The definition of *Non-invasive* has been modified to: (1) Replace "physical examination" with "visual examination;" (2) specify that the individual performing the assessment must be a "public health worker (*i.e.*, an individual with education and training in the field of public health)"; and (3) remove "auscultation, external palpation, external measurement of blood pressure."
- A definition for *Secretary* has been added. *Secretary* means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated. We note that while the NPRM did not propose this definition, the NPRM referenced the *Secretary* in defining *Public Health Emergency*. Thus, HHS/CDC considers it useful to also define the term *Secretary*.

C. Apprehension and Detention of Persons With Quarantinable Communicable Diseases (Section 70.6)

This provision has been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section. HHS/CDC has also added a requirement that the Director arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication, for individuals who are apprehended or held in quarantine or isolation. Similar language has been added to an analogous provision at Section 71.33(a).

D. Medical Examinations (Sections 70.12 and 71.36)

These provisions are finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section. HHS/CDC has also added a requirement

that the Director, as part of the Federal order, advise the individual that the medical examination shall be conducted by an authorized and licensed health worker with prior informed consent.

E. Requirements Relating to the Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.14 and 71.37)

Paragraphs (a)(5) and (a)(4) of these provisions have been modified, respectively, to require that the Federal order include an explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense. Paragraph (b) of these provisions has been modified to require that a Federal public health order be served within 72 hours of an individual's apprehension. Paragraph (c) has been modified to require that the Director arrange for translation or interpretation services of the Federal order as needed. References to CDC have been replaced with Director throughout this section.

F. Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.15 and 71.38)

These provisions have been modified to include paragraph (g) which states that the Director shall arrange for translation or interpretation services of the Federal order as needed. References to CDC have been replaced with Director throughout this section.

G. Medical Review of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.16 and 71.39)

Paragraph (f) of these provisions has been modified to reference "Representatives," consistent with the change in definition. Paragraph (f) of these provisions has also been modified to remove, "and cannot afford a medical representative" because this language is duplicative and unnecessary if the individual has already qualified as indigent. Paragraph (k) of these provisions has been modified to state: "The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under

quarantine, isolation, or conditional release to participate in the medical review." These provisions have also been modified to include paragraph (q) which states that the Director shall arrange for translation or interpretation services as needed for purposes of this section. References to CDC have been replaced with Director throughout this section.

H. Administrative Records Relating to a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.17 and 71.29)

These sections have been modified to remove paragraphs (5) regarding agreements between CDC and the individual.

I. Payment for Care and Treatment (§§ 70.13 and 71.30)

These provisions have been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section.

J. Agreements (§§ 70.18 and 71.40)

These provisions have been removed.

K. Penalties (§§ 70.18 and 71.2)

The content of these provisions has been finalized as proposed. Proposed § 70.19 *Penalties* has been moved to § 70.18, since proposed § 70.18 *Agreements* has been removed from this final rule.

L. Public Health Prevention Measures To Detect Communicable Disease (§§ 70.10 and 71.20)

Paragraph (b) has been modified to include "known or possible exposure" information to the list of information that may be collected. References to CDC have been replaced with Director throughout this section.

M. Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release (Section 70.5)

Paragraph (a), (a)(4), (b)(1), (b)(2), and (c) of this provision have been modified to remove "agreements." Paragraph (d) has been modified to add "to individuals traveling entirely intrastate and to conveyances that may transport such individuals." The language in paragraph (d) was discussed in the NPRM at 81 FR 54243 and public comment concerning intrastate application of this provision was explicitly solicited. The language, however, was inadvertently omitted from the regulatory text. References to CDC have also been replaced with Director throughout this section. In response to public comments, HHS/CDC

has included a requirement that the Director respond to a request for a travel permit within five (5) business days and to an appeal under this section within three (3) business days. Public comments concerning this provision are addressed below.

N. Report of Death or Illness Onboard Aircraft Operated by an Airline (§ 70.11)

This provision has been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section.

O. Requirements Relating to Transmission of Airline and Vessel Passenger, Crew, and Flight and Voyage Information for Public Health Purposes (§ 71.4 and 71.5)

These provisions have been finalized as proposed, with the exception that the title has been modified to remove references to collection and storage of information to more accurately reflect the requirements under this section and references to CDC have been replaced with Director throughout this section.

P. Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States (§ 71.63)

This provision has been finalized as proposed with the exception that references to CDC have been replaced with Director throughout this section.

Q. Report of Death or Illness (§ 71.21)

The title of this provision has been finalized as proposed, to remove the word “Radio.”

V. Overview of Public Comments to the 2016 NPRM

On August 15, 2016 HHS/CDC published a Notice of Proposed Rulemaking proposing to amend the current interstate (domestic) and foreign quarantine regulations for the control of communicable diseases. The NPRM included a 60-day public comment period and during this time, HHS/CDC received 15,800 comments from individuals, groups, organizations, industry, and unions. Comments were both in support of and in opposition to the regulation. Many public comments expressed concern that these updated regulations sought to compel medical treatment or vaccination without patient consent. One association stated its strong objection “to the coercive imposition of treatment, including vaccination, without the genuine consent of the patient.”

HHS/CDC begins this section by stating that these regulations do not compel vaccination or involuntary

medical treatment. In keeping with current practice, HHS/CDC will continue to recommend care and treatment, including post-exposure prophylaxis when indicated, to individuals who are either sick with or at risk of disease following exposure to a communicable disease of public health concern.

HHS/CDC also received comments relating to immigration policy and regulations, issues of citizenship, border security, religion, personal testimony regarding adverse vaccine events, and requests to apply these regulations only to individuals who are not citizens of the United States. These comments are beyond the scope of this final rule and have not been included in this discussion. However, HHS/CDC notes that it will continue to apply communicable disease control and prevention measures uniformly to all individuals in the United States, regardless of citizenship, religion, race, or country of residency.

HHS/CDC also received public comment regarding disinsection (*i.e.*, measures to control or kill insect vectors of disease) and fumigation procedures, citing HHS/CDC’s statutory authorities relating to inspection, fumigation, and pest extermination. We note that while HHS/CDC maintains regulations at 42 CFR 70.2 and 71.32(b) implementing this statutory authority, such comments are outside of the scope of this final rule, which did not include proposed changes to these regulatory provisions.

The following is a discussion of public comments received that are applicable and within the scope of the regulation. Topics including: Accountability, Administrative Records, Agreements, Apprehension, Authority (including Scope), Conditional Release, Constitutional Issues (including Amendments, Court Cases, and Habeas Corpus), Data Collection, Definitions, Detention, Due Process, Economic Impact, Electronic Monitoring, Exposure, Informed Consent, Least Restrictive Means, Minors, Medical Assessments, Examination, Notice, Penalties, Privacy, Qualifying Stage, Quarantine, Quarantinable Communicable Diseases List, and others are discussed.

A summary of comments and a response to those comments are found below, organized by general and specific comments that apply to both parts 70 and 71, comments that only apply to part 70 (interstate), and comments that only apply to part 71 (foreign).

A. Provisions Applicable to Both Parts 70 and 71

a. General Comments

Since posting the proposed regulation on August 15, 2016, HHS/CDC received 15,800 public comments. HHS/CDC received several comments from individuals, groups, or industry requesting to extend the 60-day comment period. In light of the number of comments submitted, HHS/CDC has determined that a 60-day comment period was both fair and sufficient to adequately inform the public of the contents of this rulemaking, allow the public to carefully consider the rulemaking, and receive informed public feedback. Thus, HHS/CDC declines to reopen the comment period.

Several commenters requested that HHS/CDC withdraw the NPRM in its entirety. A non-profit organization stated that the “NPRM would be, if adopted, a direct and onerous infringement of the personal liberties of Americans and an unnecessary aggressive method of assisting in the control of communicable disease.” Another commenter said that the “NPRM is premature.” HHS/CDC disagrees and declines to withdraw the proposal in its entirety because it contains important measures that will aid the public health response to prevent the introduction, transmission, and spread of communicable diseases into and within the United States. Moreover, in the spirit of transparency, these measures, which are largely current practice, are being published and codified to make the public aware of their use.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that it should promulgate a separate rule guaranteeing humane conditions of confinement. HHS/CDC disagrees that such a separate rule is needed and believes that the current final rule adequately addresses these concerns, as discussed in detail below.

HHS/CDC received a comment that the proposed rule does not comply with Executive Order 12866 because there is no public need for the rule and it did not adequately assess the costs and benefits of the rule, including the alternative of not regulating. HHS/CDC disagrees. As discussed in detail below, this rule describes the public health measures that may be used in response to outbreaks of communicable diseases, such as the recent largest recorded outbreak of Ebola. The economic impact analysis has been clarified to more clearly differentiate quarantinable and non-quarantinable diseases. The

economic impact analysis also examines the costs and benefits of the Final Rule measured against current practices (*i.e.*, a status quo baseline). Both the costs and benefits of this Final Rule are small because the provisions set forth are primarily a codification of current practices, based on existing regulatory authorities.

A public health research center commented that there is no evidence that measures employed at points of entry were effective during the response to the 2014–2016 Ebola outbreak and that HHS/CDC is attempting to codify these ineffective practices for use in future disease outbreaks. They further noted that despite greater than 99% complete monitoring, zero cases of Ebola were detected among those monitored. HHS/CDC appreciates this comment and recognizes the challenges presented by measuring the benefits of prevention in public health.

HHS/CDC disagrees that the measures employed in response to the 2014–16 Ebola outbreak were ineffective and that it is seeking to codify ineffective measures. HHS/CDC considers more than 99% complete monitoring a successful effort in State and Federal cooperation in response to an unprecedented outbreak of Ebola. Second, rather than the number of cases detected, HHS/CDC considers the key metrics of effectiveness to be the number of people who were able to continue to travel safely without fear of disease spread and the ability to facilitate rapid isolation and evaluation of the approximately 1400 individuals who developed illness compatible with Ebola during the 21-day monitoring period. Finally, we note that this commenter limited his or her statement to HHS/CDC measures put into place at U.S. ports of entry during the Ebola response.

The enhanced public health risk assessment protocol put into place at U.S. ports of entry in response to the Ebola outbreak was one part of a layered risk mitigation program to prevent the importation and spread of Ebola within the United States, which included exit screening in the affected countries as recommended by the World Health Organization (WHO) (see Statement on the 1st meeting of the International Health Regulations [IHR] Emergency Committee on the 2014 Ebola outbreak in West Africa 8/8/2014) and a reliance on air industry partners for detection and reporting of potentially ill travelers prior to arrival.

The enhanced entry risk assessment process was instituted after an individual infected with Ebola entered the United States and transmitted the

disease. This case demonstrated that the processes then in place to prevent departure of individuals exposed to or infected with Ebola in affected West African countries could not detect persons who were exposed but were unaware of or denied such exposure and were potentially incubating the infection. To further reduce the risk of introduction and spread, HHS/CDC recommended monitoring of all potentially exposed individuals by a public health authority through the 21-day risk period after potential exposure, rather than relying on previously recommended self-monitoring. Monitoring was viewed as the least restrictive alternative to widespread quarantine and travel bans demanded by some members of the public that would ultimately have hampered the response efforts in West Africa and domestically. HHS/CDC, along with its Federal and State partners, implemented an entry process by which individuals identified as having recently traveled to, from, or through an affected country entered through five ports of entry where public health staff and partners were stationed, submitted accurate and complete contact information, were checked for symptoms, and were provided answers to Ebola risk assessment questions.

This was done for several reasons:

- To ensure that any individual entering the United States who could have been exposed to or infected with Ebola in a country experiencing an Ebola outbreak was identified and reported to the State and local health department of final destination so that, if the individual became ill, State or local health departments could rapidly notify healthcare providers prior to the individual's arriving at a hospital. This process was designed specifically to prevent unknowing individuals from exposing others such as occurred in Texas when a patient exposed two healthcare workers.

- While HHS/CDC acknowledges that a public health worker may be unlikely to encounter someone with symptoms at the moment of entry because of the 21-day incubation period, individuals coming from the outbreak countries frequently traveled for well over 24 hours and in many cases had itineraries that involved interstate movement within the United States. The odds of developing symptoms during that travel, and potential onward travel, were considered non-trivial, and public health measures to detect symptoms upon entry were considered warranted given the serious morbidity and costs associated with Ebola.

- The risk assessment at the limited ports of entry provided an important opportunity for HHS/CDC to stratify the risk of developing Ebola for every individual who entered from the affected countries. It allowed HHS/CDC to work with State and local health departments in implementing the least restrictive means of monitoring individuals for development of symptoms. HHS/CDC notes that there were no Federal quarantine orders issued because of the availability of monitoring options provided by State and local authorities under the *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*.

- The encounter also provided an opportunity to provide travelers with educational materials, orientate them to the monitoring program (Check and Report Ebola (CARE)), and facilitate reporting of the traveler's health status to State and local health departments.

The enhanced entry risk assessment and monitoring process described above was developed in response to the epidemiological profile of Ebola and the complexities of a 21-day incubation period. However, in the event of an outbreak of a different communicable disease requiring enhanced assessment or monitoring of travelers (whether quarantinable or non-quarantinable), HHS/CDC, in concert with Federal and State partners, may implement a different system of risk assessment and monitoring. HHS/CDC would tailor the program in accordance with the scientific evidence of the situation and the utility and feasibility of the program given the availability of resources.

The same public health research center commented that employing non-evidence-based measures is contrary to the United States' international legal agreements, specifically mentioning the public health measures implemented during the response to Ebola as they pertain to the International Health Regulations (IHR 2005). The commenter further stated that given the absence of evidence to support the use of travel monitoring and quarantine, HHS/CDC should proceed cautiously before employing these measures in the future.

Having addressed the commenter's concern regarding the evidence of the effectiveness of public health measures at ports of entry above, HHS/CDC concurs with the commenter that the use of quarantine and travel restrictions, in the absence of evidence of their utility, is detrimental to efforts to combat the spread of communicable disease. However, HHS/CDC disagrees that it used non-evidence based measures in contravention of the IHR.

To the contrary, HHS/CDC used the best available science and risk assessment procedures in designing a port of entry risk assessment and management program that took into account available resources, circumstances in the countries with Ebola outbreaks, and principles of least restrictive means to successfully ensure that measures to ban travel between the United States and the affected countries were unnecessary. These measures would have negatively impacted the efforts to combat Ebola in the region and would have had dramatic negative implications for travelers and industry.

Furthermore, the measures did not unduly affect travel or trade beyond the voluntary changes made by industry and travelers. HHS/CDC believes that CDC's entry risk assessment and management program was appropriate, commensurate with the risk, and consistent with the following WHO recommendation: "[Member] States should be prepared to detect, investigate, and manage Ebola cases; this should include assured access to a qualified diagnostic laboratory for Ebola and, where appropriate, the capacity to manage travelers originating from known Ebola-infected areas who arrive at international airports or major land crossing points with unexplained febrile illness." *WHO Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa* (Aug. 8, 2014). Travelers were assessed for risk on an individual basis upon entry; and any individual who met the pre-defined symptom threshold (based on exposure level) was medically evaluated and referred to care as needed. No Federal quarantine orders were issued for the duration of the response because HHS/CDC in coordination with State and local public health authorities was able to tailor its interventions to allow onward travel.

Future outbreaks may necessitate a different combination of public health measures at ports of entry. In those circumstances, HHS/CDC will use the best available science to assess the risk of importation and spread within the United States.

One commenter suggested that if HHS/CDC were to apply the "Precautionary Principle," it would not promulgate these regulations. HHS/CDC notes first that the "precautionary principle," often described as the avoidance of harm when there is scientific uncertainty about risks, originated in environmental contexts and remains largely associated with environmental issues. Invoking the precautionary principle in an environmental context, for instance,

places the onus on those considering a potentially harmful action, such as drilling or mining near a watershed, to prove its safety in advance. The principle may be used by policy makers to justify discretionary decisions in situations where there is the possibility of harm from making a certain decision (e.g. taking a particular course of action) when extensive scientific knowledge on the matter is lacking.

HHS/CDC disagrees that this regulation will have harmful effect or that these measures lack a scientific basis for protecting public health. In fact, as described above regarding the response efforts to the 2014–2016 Ebola response, HHS/CDC has successfully employed the measures outlined in this regulation for many years. Again, the provisions outlined through this regulation are not new practices, nor new authorities, but a codification of HHS/CDC practice to protect public health.

One commenter suggested that education on healthy practices would be more effective than regulatory provisions. Another commenter stated that our immune systems would ward off communicable disease if we encourage clean water, adequate shelter, effective sewage treatment, and nutritious food. HHS/CDC agrees that these necessities are important to public health, and we rely on health communication often to educate the public on how to protect themselves and others from certain communicable diseases. For example, HHS/CDC routinely advises people with seasonal influenza to stay home from work and school, to cover their coughs and sneezes, and to wash their hands. HHS/CDC also works with State, local, and airport authorities in posting health education materials for the public. However, in certain circumstances, when a communicable disease poses a severe health threat to others, additional measures may be needed to protect the public's health. This is particularly important in situations when the infectious individual has disregarded public health recommendations by, for example, refusing to take prescribed medications to treat infectious tuberculosis or traveling while infectious. In such situations, it may be necessary to use public health authorities to require the individual to remain in isolation or to prevent travel to protect the public's health.

HHS/CDC received a few comments suggesting that publication of the NPRM in the **Federal Register** was not sufficient to inform the public of these proposed updates. One comment questioned why the proposed

regulations were not more widely disseminated through media outlets. In response, HHS/CDC notes that Federal courts have long recognized that publication in the **Federal Register** is legally sufficient for giving affected persons notice of proposed rulemaking. *See Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 385 (1947) ("Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents."). The **Federal Register**, within the National Archives and Records Administration, is the official publication for all Federal agency rules, proposed rules, and notices of Federal agencies and organizations, as well as for Executive Orders and certain other presidential documents. Individuals interested in obtaining more information regarding HHS/CDC's regulatory processes, including input provided by persons and organizations, may examine the regulatory docket or submit a request through the Freedom of Information Act.

HHS/CDC received a comment stating that HHS/CDC should, by regulation, provide sufficient public health justification for screening practices to support its proposed public health prevention measures at ports of entry. While HHS/CDC agrees that it should provide sufficient public health justification for large-scale screening practices, HHS/CDC disagrees that this justification should be formalized in regulations. During the 2014–2016 Ebola epidemic, HHS/CDC issued *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure* to assist HHS/CDC staff and public health partners engaged in the response. The guidance provided public health authorities and partners with recommendations for monitoring people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when necessary. From August 2014–December 2015, the guidance was accessed online approximately 334,000 times, with more than 88,000 views during the first 4 days after the October 2014 update that added recommendations for active monitoring and clarified travel and movement restriction recommendations. Updates to the guidance to accommodate new information and changes in the outbreak situation continued through 2015. The guidance was retired on February 19, 2016, when more than 45 days had passed since Guinea was declared free of Ebola virus transmission, signaling widespread human-to-human transmission in the

affected countries was at an end. Formalizing this guidance in regulation would have deprived HHS/CDC of the needed flexibility to respond to public health events as they occurred, would have proved administratively burdensome and unnecessary, and would have potentially delayed prevention measures therefore resulting in a less effective response. HHS/CDC will consider the need for similar guidance during future outbreaks taking into account the extent of the outbreak and the risk of importation and spread of disease into the United States.

HHS/CDC received several comments suggesting that the proposed regulations were not written in plain language and were therefore difficult to understand. One commenter also noted errors in the document such as hyperlinks, references, and footnotes. This commenter also reviewed the NPRM for inconsistencies, conflicts, missing definitions, misleading language, and ambiguities. HHS/CDC thanks these commenters for the input. We have developed communication materials and published them to our Web site to help facilitate the review and comprehension of these documents. Interested persons should see <http://www.cdc.gov/quarantine/notice-proposed-rulemaking-control-communicable-diseases.html>.

One commenter opposed the rule because of a perceived negative social impact upon individuals placed under a public health order. We respond that one compelling reason for the publication of this final rule is to make the public aware of these measures so that the words, purposes, and meanings of “quarantine” and “isolation” become more familiar and less likely to cause public anxiety and stigmatization.

HHS/CDC received comments suggesting that, to best prevent the introduction of communicable diseases into the U.S., individuals who travel to or originate in countries with high risk of communicable disease should not be allowed to enter (or return to) the United States. On March 27, 2015, HHS/CDC published a Notice in the **Federal Register** titled *Criteria for Recommending Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers*. See 80 FR 16400 (Mar. 27, 2015). The Notice describes the tools the Federal government has to ensure that people who pose a public health risk do not board flights or enter the United States without a public health evaluation. See 80 FR 16400 (Mar. 27, 2015). It is the policy of HHS/CDC to work with the Department of State, and any other relevant Federal and State agencies to

ensure infected U.S. citizens seeking to return to the U.S. do so in a manner that does not place the public at risk.

A few commenters expressed concern, as parents or guardians, about their rights with respect to children or minors. Specifically, these commenters wondered whether children/minors would be separated from parents/guardians during a public health risk assessment. HHS/CDC thanks the commenters for these questions and appreciates the opportunity to respond. In response, HHS/CDC notes that these regulations do not limit the rights that parents or guardians may have over minor children, including the right to make medical decisions. Notwithstanding, children are included in the definition of “individuals” as used in these regulations and thus minor children may be subject to apprehension, detention, examination, and conditional release for quarantinable communicable diseases to the same extent as adults. In such rare circumstances, HHS/CDC will work with the child’s parent or guardian to ensure that the rights accorded to any individual subject to Federal isolation or quarantine, such as the opportunity for an administrative medical review, are adequately protected.

In addition, and in keeping with standard public health practice, parents or guardians while in the presence of infected minor children may be required to adhere to infection control precautions for their own protection. Such protections may include wearing personal protective equipment (such as a mask) while in close proximity to the child/minor to avoid further transmission of the illness. In extremely rare circumstances, such as a child infected with Ebola, the risk may be too great to allow a parent to remain with a child; however, every effort will be made to facilitate communication between a parent and a minor child through the least restrictive means, for example, through the use of technology.

One commenter asked about HHS/CDC obtaining the consent of a parent or legal guardian prior to the medical examination, quarantine, or treatment of minors. We respond that HHS/CDC will adhere to all applicable laws regarding the medical examination or treatment of minors. If minors are traveling unaccompanied by a parent or legal guardian and are believed to be infected with or exposed to a quarantinable communicable disease, HHS/CDC will use its best efforts to contact a parent or guardian to obtain consent prior to medical examination. In addition, HHS/CDC will not restrict a minor’s ability to communicate with family or legal

counsel hired by the minor’s parent or legal guardian. As explained further below, HHS/CDC will appoint representatives, including a medical representative and an attorney, if the individual (including a minor’s parent or legal guardian) is indigent and requests a medical review. HHS/CDC clarifies, however, that the public health measures included in this final rule, including apprehension, examination, quarantine, and isolation, do not require a parent or legal guardian’s consent as a prerequisite to their application. However, in response to concerns about informed consent, HHS/CDC has added regulatory language requiring that the Director advise the individual that if a medical examination is required as part of a Federal order that the examination will be conducted by an authorized and licensed health worker with prior informed consent.

b. Scope and Authority

HHS/CDC received comments from the public questioning whether HHS/CDC is a part of the Federal government and has the authority to propose and promulgate regulations, or whether the Agency is a private entity. The “Communicable Disease Center” became part of the U.S. Public Health Service on July 1, 1946 and is an Agency within the U.S. Department of Health and Human Services. For more information on the history of CDC, please see <http://www.cdc.gov/museum/timeline/index.html>.

HHS/CDC received numerous comments from the public seeking clarity on the scope of authority the Agency has to take actions described in this regulation. Specifically, HHS/CDC received comments questioning whether the authority to detain an individual may be exercised by a Federal agency of government, instead of the U.S. President or Congress. Several commenters specifically questioned whether the wording of the regulation was too “general” and expressed concern over its potential for abuse. A public health organization recommended that HHS/CDC’s authority should be limited only to those diseases listed by Executive Order as quarantinable communicable diseases. An association suggested that the proposed rule would vastly increase the authority of HHS/CDC. One individual stated that this regulation is an attempt by HHS/CDC to evade Congress. One organization speculated that HHS/CDC plans to request that the list of quarantinable communicable diseases be expanded “to include measles and other vaccine targeted diseases for the purpose of

apprehending and quarantining travelers entering the US or traveling between States, who have not been vaccinated with MMR (measles-mumps-rubella vaccine) and other Federally recommended vaccines.”

In response, HHS/CDC first notes that it cannot—and will not—act beyond the scope of authority granted by Congress in statute; HHS/CDC offers the following clarifications. Under section 361(a) of the Public Health Service Act (42 U.S.C. 264(a)), the HHS Secretary is authorized to make and enforce regulations as in the Secretary’s judgment are necessary to prevent the introduction, transmission, or spread of all communicable diseases from foreign countries into the States or possessions of the United States and from one State or possession into any other State or possession. Under section 361(b)(42 U.S.C. 264(b)), the authority to issue regulations authorizing the apprehension, examination, detention, and conditional release of individuals is limited to those communicable diseases specified in an Executive Order of the President, *i.e.*, “quarantinable communicable diseases.” The authority for carrying out these regulations has been delegated from the HHS Secretary to the CDC Director, who in turn delegated these authorities to HHS/CDC’s Division of Global Migration & Quarantine (DGMQ). These quarantinable communicable diseases are currently limited to cholera, diphtheria, infectious tuberculosis (TB), plague, smallpox, yellow fever, and viral hemorrhagic fevers (such as Marburg, Ebola, Lassa fever, and Crimean-Congo), severe acute respiratory syndromes, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. *See* Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 (July 31, 2014). Changes to the list of quarantinable communicable diseases are beyond the scope of this regulation. And again, we reemphasize that HHS/CDC does not intend, through these regulations, to mandate vaccination or compulsory medical treatment of individuals.

One commenter supported the international proposals (part 71), but urged HHS/CDC to remove the domestic portion (part 70) of this regulation. We disagree. HHS/CDC’s authorities apply to all travelers in the United States, regardless of citizenship or residency, and are intended to complement State authorities within their jurisdictions by providing a mechanism to prevent importation of communicable disease

from other countries as well as spread of communicable disease between States and between States and territories. Thus, HHS/CDC’s and States’ authorities together create a comprehensive system to protect the public from communicable disease threats including in situations such as interstate travel when a single State’s authorities may be inadequate to address the communicable disease threat.

Several commenters suggested that HHS/CDC has the authority to unilaterally change or update the list of quarantinable communicable diseases. Other commenters requested that the list be narrowed to only those diseases with a “high mortality rate.” HHS/CDC reemphasizes that, as prescribed by statute, the list of quarantinable communicable diseases may only be changed by Executive Order of the President and that such suggestions are beyond the scope of this final rule.

HHS/CDC received several comments on the Agency’s accountability system, encouraging that a “strong system of checks and balances” should be in place for this regulation to be implemented. HHS/CDC agrees that there should be accountability and oversight regarding the agency’s activities. We note that these regulations do not affect the ability of Congress to conduct its oversight activities or affect the jurisdiction of federal courts to review federal agency actions under the Administrative Procedure Act (5 U.S.C. 704).

HHS/CDC received a comment that there is no court supervision of HHS/CDC activities. We disagree. These regulations do not affect the jurisdiction of the Federal courts or the statutory rights of individuals to obtain judicial review of CDC’s actions and decisions through appropriate mechanisms such as the habeas corpus statute (28 U.S.C. 2241) or the Administrative Procedure Act (5 U.S.C. 704).

Some commenters questioned the need for HHS/CDC to use its authorities if the threat of death is minimal compared with the size of the population, listing illnesses such as chickenpox, pertussis, Zika, the common cold and flu, and leprosy. One organization suggested that, through the language of the NPRM, HHS/CDC was “equating” non-quarantinable diseases with quarantinable diseases. Another commenter suggested that HHS/CDC’s authority to act should be based on the mortality of the illness, rather than whether or not it appears on the list of quarantinable communicable diseases. HHS/CDC thanks the commenters for

consideration of the proposal as well as the input provided.

First, we note that HHS/CDC only has authority to quarantine or isolate individuals who have illnesses that are listed by Executive Order of the President as quarantinable communicable diseases. HHS/CDC does not have the ability or authority to unilaterally modify the list of quarantinable communicable diseases. Second, because HHS/CDC also has statutory authority to prevent the “introduction, transmission, and spread” of communicable diseases, HHS/CDC may take actions other than quarantine or isolation to protect the public’s health. These other actions may include contact tracing investigations to notify individuals to seek proper treatment if they have been exposed to a communicable disease, even if the disease is not listed by Executive Order as quarantinable. HHS/CDC does not seek to compel vaccination or medical treatment. In keeping with current practice, HHS/CDC recommends certain vaccines for post-exposure prophylaxis and individuals may choose to follow these recommendations as they deem appropriate.

Other commenters questioned why diseases such as Ebola, measles, and Zika—three very different diseases with three very different effects on individuals—are used to support the same regulatory provisions. One organization quoted the NPRM, citing correctly that while measles is not a quarantinable communicable disease, it was used in the NPRM to support the need for this updated regulation. HHS/CDC welcomes the opportunity to provide further clarification.

The proposed rule provides HHS/CDC with a number of options for public health interventions based on a public health risk assessment of the communicable disease in question and the situation at hand. These interventions could include conducting a contact investigation on an airplane or vessel if a person with a serious communicable disease was known to have traveled on the airplane or vessel. These contact investigations are similar to those conducted by health departments in community settings. In addition to these interventions, for the nine communicable diseases currently designated by Executive Order as quarantinable communicable diseases, HHS/CDC may apprehend, detain, examine, quarantine, isolate, or conditionally release individuals for purposes of preventing communicable disease spread. Ebola and infectious tuberculosis are examples of quarantinable communicable diseases.

HHS/CDC also provides the public with recommendations to address other communicable diseases of public health concern. Zika is a good example of a disease of public health concern because of the ways it can be spread, e.g., through mosquitoes, sexual transmission, and maternal-fetal transmission. Therefore, HHS/CDC has recommended avoiding mosquito bites, protecting against sexual transmission, and for pregnant women to avoid travel to areas where Zika is spreading. Another example is seasonal influenza, which is very contagious but also very common; therefore, HHS/CDC makes recommendations for people sick with flu-like symptoms to stay home from work or school and take basic precautions such as covering their coughs and sneezes and washing their hands. In all situations, HHS/CDC considers how common and severe the communicable disease is, how it is transmitted, and what interventions are available and appropriate before making recommendations or taking action to protect the health of the public.

One commenter questioned why HHS/CDC was not able to currently control all communicable diseases, specifically leprosy. While HHS/CDC works regularly and continuously with other Federal, State, local and tribal health departments to eliminate the introduction, transmission and spread of all communicable disease, outbreaks can and do still occur. HHS/CDC staff have experienced first-hand the impact of globalization on public health. The rapid speed and tremendous volume of international and transcontinental travel, commerce, and human migration enable microbial threats to disperse worldwide in 24 hours—less time than the incubation period of most communicable diseases. These and other forces intrinsic to modern technology and ways of life favor the emergence of new communicable diseases and the reemergence or increased transmission of known communicable diseases.

HHS/CDC received many comments regarding measles and the need to apply public health measures to prevent the transmission and spread of the disease. We note also that while measles may be transmissible during travel, it is not one of the quarantinable communicable diseases listed by Executive Order of the President. Therefore, while HHS/CDC may recommend post-exposure prophylaxis, or other ways to manage and prevent spread, we do not have the authority to apprehend, examine, detain, or conditionally release individuals who may have measles, nor those who may have been exposed. See

80 FR 16,400 (Mar. 27, 2015)(describing air travel restrictions that may be applicable to a passenger who would represent a threat to public health).

HHS/CDC believes that requesting that DHS restrict the air travel of persons with measles is warranted because measles is a serious and highly contagious communicable disease that would pose a public health threat during travel. People exposed to measles who are not immune to the infection and have not been vaccinated following the exposure are advised to delay their travel voluntarily until they are no longer at risk of becoming infectious.

A number of commenters suggested that the proposed regulations are unconstitutional or in violation of the “Nuremberg Code,” the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Universal Declaration on Bioethics and Human Rights, the Geneva Convention, human rights in general, and/or civil liberties in general because they ostensibly authorize compulsory medical treatment without informed consent. Commenters also cited numerous Supreme Court cases purportedly in support of these claims, such as *Mills v. Rogers*, 457 U.S. 291 (1982), (curtailing the involuntary administration of anti-psychotic drugs to mental patients); *Vacco v. Quill*, 521 U.S. 793 (1997) (constitutionality of an assisted suicide ban); *Washington v. Harper*, 494 U.S. 210 (1990) (involuntary administration of anti-psychotic drugs to prison inmates); *Sell v. United States*, 539 U.S. 166 (2003)(upholding certain strict due process protections before any involuntary administration of anti-psychotic drugs to incarcerated prisoners can be made); and *Canterbury v. Spence*, 409 U.S. 1064 (1972)(duty of doctors to obtain informed consent). HHS/CDC disagrees and re-asserts that this final rule does not authorize compulsory medical treatment, including compulsory vaccination, without informed consent.

These regulations do not violate or take away any recognized rights guaranteed by the U.S. Constitution or applicable international agreements. While HHS/CDC has successfully responded to outbreaks of communicable diseases, such as Ebola, these regulations will improve HHS/CDC’s future ability to prevent the introduction, transmission, and spread of communicable diseases, through such mechanisms as improved reporting of illnesses and public health prevention measures at airports. While many of these activities have been carried out in the past through internal operating

procedures, these regulations improve the public’s awareness and understanding of HHS/CDC’s activities to protect the public’s health.

One commenter expressed concerns about religious exemptions for mandatory vaccination or treatment. In response, HHS/CDC notes that these regulations do not authorize compulsory vaccinations or medical treatment. While HHS/CDC will implement these regulations in a manner consistent with respecting the religious rights of individuals, religion is not a basis for exempting individuals from the provisions of these regulations, including those provisions relating to quarantine and isolation.

One commenter raised similar concerns that the regulations may lead to apprehensions based on factors unrelated to public health such as wearing of religious garb or reading of certain newspapers. HHS/CDC agrees that public health actions should not be taken based on factors unrelated to protecting the public’s health and these regulations do not authorize such actions. Additionally, these regulations strike the appropriate balance between individual liberties and public health protection.

Several commenters questioned whether quarantine and isolation may be carried out consistent with the Fourth Amendment to the U.S. Constitution. One commenter also suggested that implementation of public health prevention measures at airports would lead to “unreasonable searches and seizures” under the Fourth Amendment. HHS/CDC disagrees with these assertions. The Fourth Amendment protects the rights of persons to be free in their persons, houses, papers, and effects, against unreasonable government searches and seizures. HHS/CDC notes that at ports of entry, routine apprehensions and examinations related to quarantine and isolation may fall under the border-search doctrine, which provides that, in general, searches conducted by CBP officers at the border are not subject to the requirements of first establishing probable cause or obtaining a warrant. See *United States v. Roberts*, 274 F.3d 1007, 1011 (5th Cir. 2001); see also *United States v. Bravo*, 295 F.3d 1002, 1006 (9th Cir. 2002) (noting that only in circumstances involving extended detentions or intrusive medical examinations have courts required that border searches be premised upon reasonable suspicion). Similarly, apprehensions and examination of persons traveling interstate under this rule are authorized under the special-needs doctrine articulated by the

Supreme Court in *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989) because of the "special need" in preventing communicable disease spread. Furthermore, to the extent that "probable cause," rather than "special needs," would be the applicable Fourth Amendment standard, HHS/CDC contends that meeting the requirements of 42 U.S.C. 264 satisfies this standard. See *Villanova v. Abrams*, 972 F.2d 792, 795 (7th Cir.1992)(noting that probable cause for emergency civil commitment exists where "there are reasonable grounds for believing that the person seized is subject to the governing legal standard."). HHS/CDC further acknowledges that any searches and seizures of individuals must be reasonable under the circumstances. HHS/CDC reiterates that this final rule does not authorize compulsory medical treatment, including vaccination, without informed consent.

HHS/CDC received a comment citing *Missouri v. McNeely*, where the U.S. Supreme Court ruled that police must generally obtain a warrant before subjecting a drunken-driving suspect to a blood test, and that the natural metabolism of blood alcohol does not establish a *per se* exigency that would justify a blood draw without consent. In response, HHS/CDC notes that courts have recognized that while the requirements for probable cause and a warrant generally apply in a criminal context, these standards do not apply when the government is conducting a non-law enforcement related activity. See *Nat'l Treasury Employees Union v. Von Raab*, 489 U.S. 665 (1989) (reaffirming the general principle that a government search may be conducted without probable cause and a warrant when there is a special governmental need, beyond the normal need for law enforcement). HHS/CDC reiterates that the special-needs doctrine articulated by the Supreme Court in *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989) provides the appropriate legal standard under the Fourth Amendment for apprehensions and detentions under this final rule.

Several commenters also questioned whether the regulations are consistent with the requirements of the Fifth and Sixth Amendments to the U.S. Constitution. We note at the outset that the Sixth Amendment only applies to criminal proceedings and thus would be inapplicable to isolation and quarantine decisions which are public health protection measures unrelated to the normal needs of law enforcement. Furthermore, HHS/CDC asserts that this final rule is consistent with the requirements of due process embodied

in the Fifth Amendment to the U.S. Constitution. Specifically, procedural safeguards contained in the final rule include: (1) A requirement for written orders of quarantine, isolation, or conditional release, including translation or interpretation services as needed; (2) mandatory review of the Federal order after the first 72 hours; (3) notifying individuals through the written order of their right to request a medical review; (4) an opportunity at the medical review for the detained individual to be heard through an attorney or other advocate hired at their own expense, present experts or other witnesses, submit documentary or other evidence; and confront and cross-examine any government witnesses; (5) a decision-maker independent of those who authorized the original isolation, quarantine, or conditional release; (6) a written statement by the fact-finder of the evidence relied upon and the reasons for the decision; (7) appointment of representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review; and (8) timely notice of the preceding rights. See *Vitek v. Jones*, 445 U.S. 480 (1980); *Mathews v. Eldridge*, 424 U.S. 319 (1976).

HHS/CDC also received a comment that quarantine violates the guarantees of substantive due process under the 5th Amendment to the U.S. Constitution. HHS/CDC disagrees. In addition to a guarantee of fair procedures, the U.S. Supreme Court has interpreted the Fifth Amendment's Due Process Clause as containing a substantive component barring certain arbitrary, wrongful government actions regardless of the fairness of the procedures used to implement them. See *Zinermon v. Burch*, 494 U.S. 113, 125 (1990). HHS/CDC notes that the quarantine of individuals who have been exposed to a communicable disease, but are not yet capable of transmission is a well-known and accepted public health strategy of long standing. See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (recognizing the power of States to issue "quarantine laws and health laws of every description"); *Compagnie Francaise de Navigation a Vapeur v. State Bd. of Health, Louisiana*, 186 U.S. 380, 396 (1902) (discussing the 1893 Federal quarantine statute). The restrictions on individuals authorized under this regulation are justified by the benefits to the public health.

HHS/CDC received a comment that quarantine and isolation are State police powers that should not be exercised at the Federal level. While HHS/CDC acknowledges that the States have

primary authority for quarantine and isolation within their borders, the Federal government has an important and longstanding role in preventing communicable disease spread at ports of entry and interstate. This authority is reflected in 42 U.S.C. 264 and consistent with principles of Federalism.

HHS/CDC received one comment stating that it should conduct a Federalism analysis because implementing the rule will require working with State health officials and resources. Under Executive Order 13132, a Federalism analysis is required if a rulemaking has federalism implications, would limit or preempt State or local law, or imposes substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. While HHS/CDC acknowledges that portions of this rule may involve HHS/CDC "working with State health officials" to better coordinate public health responses, the rule is consistent with 42 U.S.C. 264(e) and there are no provisions that impose direct compliance costs on State and local governments. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

HHS/CDC received several questions asking who would be responsible for the enforcement of these regulations. One commenter questioned whether HHS/CDC would use "militarized police or create [an] armed Federal police force to carry out these actions." As explained elsewhere, in keeping with current practice and existing law, law enforcement support for quarantine or isolation orders will generally be provided by U.S. Customs and Border Protection, U.S. Coast Guard, or other Federal law enforcement programs, but

HHS/CDC may also accept voluntary State and local assistance in enforcing its Federal orders. HHS/CDC will also continue to enforce its regulations in a manner consistent with the Fourth Amendment and other provisions of the U.S. Constitution.

c. Definitions

Agreements

HHS/CDC received many comments on the definition of *Agreement*, largely expressing confusion and concern that such agreements would not be truly voluntary. The intent of this provision was to provide HHS/CDC with an additional tool to facilitate cooperation from individuals in regard to recommended public health actions. In response to public comments, however, HHS/CDC has withdrawn this definition and will not issue the proposed provisions on “Agreements.”

Airline

HHS/CDC did not receive public comment on the proposed definition of *Airline*. However, consistent with HHS/CDC’s intent that this definition apply to common air carriers, to improve clarity, we have removed the phrase “including scheduled or public charter passenger operations operating in air commerce within the United States” and removed the reference to 49 U.S.C. 40102(a)(3).

Apprehension

HHS/CDC received many comments on the proposed definition and provision regarding *Apprehension*; a discussion of these comments is in the section below titled, “Apprehension and Detention of Persons with Quarantinable Communicable Diseases.” The definition is finalized as proposed.

Commander

HHS/CDC did not receive public comment on the proposed definition of *Commander*. Therefore, this definition is finalized as proposed.

Communicable Stage

HHS/CDC received a comment seeking clarity regarding the definition of *Communicable Stage*. The commenter stated that the definition for *communicable stage* may unnecessarily restrict social distancing powers because it appears limited to human-to-human transmission and does not include human transmission via an intermediate vector, such as mosquitoes or flea bites. HHS/CDC disagrees. The definition of communicable stage includes transmission of an infectious agent either “directly or indirectly from

an infected individual to another individual.” Thus, HHS/CDC clarifies that indirect transmission of an infectious agent may include transmission via an insect vector as described by the commenter. This definition is finalized as proposed.

Conditional Release

HHS/CDC received many comments on the proposed definition and provision regarding *Conditional Release*; a substantive discussion of these comments is presented in the section below titled *Requirements Relating to Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release*.

HHS/CDC is modifying the definition of *Conditional Release* under section 70.1 to remove the cross-reference to the definition of surveillance as that term appears in current section 71.1. The definition of *Conditional Release* under section 70.1 tracks the definition of surveillance under section 71.1 and means “the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or internet-based monitoring.” HHS/CDC is making this change to improve clarity and remove the need for the public to cross-reference the definition of surveillance to understand the definition of *Conditional Release* as used in section 70.1.

This definition of *Conditional Release* under section 71.1 is finalized as proposed.

Contaminated Environment

HHS/CDC did not receive public comment on the proposed definition of *Contaminated Environment*. Therefore, this definition is finalized as proposed.

Conveyance

HHS/CDC did not receive public comment on the proposed definition of *Conveyance*. Therefore, this definition is finalized as proposed.

Electronic or Internet-Based Monitoring

HHS/CDC received many comments on the proposed definition and provision regarding *Electronic or Internet-based monitoring*. We have modified this definition as follows: “mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail,

SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, or entry of information into a web-based forum; wearable tracking technologies; and other mechanisms or technologies as determined by the Director or supervising State or local health authority.”

Several commenters expressed privacy concerns because conditional release of exposed or ill individuals may be accomplished over the internet or through electronic monitoring. Other commenters expressed concerns about privacy, having misunderstood the proposed rule as authorizing HHS/CDC to conduct invasive surveillance of personal communications such as emails, text messages, and telephone calls. Commenters also expressed concerns related to the use of webcams and wearable tracking technologies as an option for monitoring of exposed people. One association viewed this proposed provision as an expansion of CDC’s “electronic monitoring of personal information, under the guise of protecting the public against rare, isolated outbreaks of disease.”

HHS/CDC appreciates the opportunity to address these concerns. CDC’s intent was to describe mechanisms that HHS/CDC or other public health authorities can use to communicate with individuals for the purpose of conducting monitoring following exposure to a quarantinable communicable disease. These mechanisms are intended as alternatives to in-person interviews because of the inconvenience and logistical problems that may arise when meeting in-person.

During the 2014–2016 Ebola response, HHS/CDC recommended “active monitoring” defined as daily communication between public health authorities and the individuals being monitored. HHS/CDC did not specify how this communication should occur, and health departments used a variety of electronic technologies for this purpose including those listed in the regulation. HHS/CDC also recommended “direct active monitoring” for people with certain higher levels of exposure. This involved having a public health official check in with the person through direct observation rather than relying on phone calls or electronic communications. Webcams were used by some health departments as an alternative to in-person visits to observe the person taking his or her temperature. The webcam was only operational during this scheduled public health “visit.” The use of webcams proved convenient for both

the health departments and the people being monitored, especially if the people lived in remote areas. Webcams are also used routinely by health departments for “directly observed therapy” for diseases like tuberculosis (TB), in order to watch patients take their TB medications. HHS/CDC has clarified the regulatory text to state that these technologies will be used for communicating with the individual and not as a means of monitoring the individual’s personal communications.

One commenter asked whether HHS/CDC would “assist with payment for internet services” if webcam communications was required. In keeping with current practice, if an individual does not have access to internet services, HHS/CDC may use alternative methods to assist with communication, such as the issuance of a cellular phone. Some organizations also expressed concerns about the use of technologies such as cellular phones or wearable tracking technologies for the purpose of electronic monitoring. HHS/CDC acknowledges that the use of wearable tracking technology may be necessary in rare situations when a person does not comply with the required monitoring or when it is necessary to know the physical whereabouts of the person to ensure that they are not in a public place. While HHS/CDC acknowledges that public health surveillance of ill or exposed individuals through electronic monitoring may raise some privacy concerns, HHS/CDC believes that protecting the public’s health outweighs these concerns.

HHS/CDC is committed to protecting the privacy of personally identifiable information collected and maintained under the Privacy Act of 1974. As detailed in the preamble of the proposed rule, on December 13, 2007, HHS/CDC published a notice of a new system of records under the Privacy Act of 1974 for its conduct of activities under this final rule (72 FR 70867). HHS/CDC accepted public comment on its proposed new system of records at that time. As required under the Privacy Act, HHS/CDC described in its notice the proposed system of records, the purpose for the collection of the system data, the proposed routine uses (*i.e.*, disclosures of system data that are compatible to the purpose for the data collection), the benefits and need for the routine use of this data, our agency’s policies, procedures, and restrictions on the routine use disclosure of this information, and, most importantly, our safeguards to prevent its unauthorized use.

Under this system of records, CDC will only release data collected under this rule and subject to the Privacy Act to authorized users as legally permitted. HHS/CDC will take precautionary measures including implementing the necessary administrative, technical and physical controls to minimize the risks of unauthorized access to medical and other private records. In addition, HHS/CDC will make disclosures from the system only with the consent of the subject individual or, in accordance with the routine uses published at 72 FR 70867, or as allowed under an exception to the Privacy Act. Furthermore, HHS/CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality. Finally, such records will be stored and maintained in keeping with the official Records Control Schedule as set forth by the National Archives and Records Administration. For more information, please see <https://www.archives.gov/records-mgmt/rcs>.

Ill Person

We have modified the definition of *Ill person* under 71.1 to include a person who “(b)(2) Has a fever that has persisted for more than 48 hours; or (b)(3) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater).” This language was quoted verbatim in the preamble of the NPRM at 81 FR 54305 but was inadvertently omitted from the proposed regulatory text.

HHS/CDC received comments regarding the updated definition of *Ill person* which flight crews use to report to the CDC occurrences of illnesses in passengers or crew during travel. Specifically, commenters expressed concern that “non-medical personnel” such as flight attendants would report such observations; others questioned whether the definition is too broad and may result in over-reporting of non-threatening illnesses; others worried that it could lead to unnecessary apprehensions of individuals. One commenter claimed to be “chemical sensitive,” and worried that he or she may be penalized for having a reaction from sitting next to someone on a plane wearing a “strong fragrance.” HHS/CDC thanks the commenters for considering the proposal and providing feedback.

HHS/CDC clarifies that the purpose of the *ill person* definition is to align with current global and accepted detection and reporting practices so that onboard deaths and illnesses are reported by airlines and, where necessary, investigated by HHS/CDC. We note that the *ill person* definition in this final rule is consistent with the internationally recognized and accepted illness reporting guidelines published by the International Civil Aviation Organization (ICAO). This practice is not new, but has been used successfully for many years by aircraft and vessel crews to assist public health officials in preventing further transmission and spread of communicable disease.

HHS/CDC also does not intend to apprehend individuals based solely on their meeting the definition of an *ill person*. The purpose of an illness report is to allow trained HHS/CDC public health and medical officers to determine whether an illness occurring onboard a flight or voyage necessitates a public health response. In contrast, an apprehension of an individual is based on a variety of criteria in addition to an illness report including: Clinical manifestations, contact or suspected contact with infected individuals, host susceptibility, travel to affected countries or places, or other evidence of exposure to or infection with a quarantinable communicable disease. Thus, HHS/CDC disagrees that the *ill person* definition will lead to unnecessary apprehensions of individuals.

Several commenters noted that the symptoms listed in HHS/CDC’s definition of an *ill person* are common symptoms of many non-threatening conditions, and thus questioned their inclusion in the definition. HHS/CDC appreciates the opportunity to respond to these concerns. The symptoms listed in HHS/CDC’s *ill person* definition are provided for airlines and vessels to report to HHS/CDC so that HHS/CDC can make a public health risk assessment; *the symptoms alone would not result in issuance of a public health order*. In making such an assessment, HHS/CDC medical and public health officers consider the symptoms as well as the medical history of the person and any possible exposures that could indicate that the person may be infected with a quarantinable communicable disease.

A few commenters stated that the definition of *ill person* appears to expand the scope of HHS/CDC’s authority beyond the list of quarantinable communicable diseases specified through an Executive Order of the President. HHS/CDC disagrees. The

purpose of the ill person definition is to help facilitate the identification, particularly by flight crews, of communicable diseases of public health concern. Thus, HHS/CDC has defined *ill person* in such a way that the term may be understood by non-medically trained crewmembers. While the reporting of an ill person onboard a flight may trigger a public health evaluation by a trained quarantine officer in consultation with an HHS/CDC medical officer, such reporting does not expand the basis upon which an ill person may be subject to apprehension, detention, or conditional release. As noted by the commenter, such public health actions are limited to those quarantinable communicable diseases specified through an Executive Order of the President (e.g., cholera, diphtheria, infectious tuberculosis, yellow fever, viral hemorrhagic fevers, Severe Acute Respiratory Syndromes, and pandemic influenza).

A public health association suggested that any changes to the list of signs and symptoms within the definition of *ill person* should be made available for public comment. HHS/CDC assumes this comment is in reference to section (3) of the definition which provides for reporting of “symptoms or other indications of communicable disease, as the HHS/CDC may announce through posting of a notice in the **Federal Register**.” HHS/CDC appreciates the opportunity to clarify the purpose of this section. Section (3) of the *ill person* definition is intended to apply only to new, emerging, and imminent threats to public health. We expect it will only be relied on in emergency situations where a quick response is required to protect the public. Other circumstances, where the list of signs and symptoms may change due to evolving science or technology, will be made available for public comment, through a similar process as this rulemaking—Notices in the **Federal Register**—and may also request input from the public.

A number of commenters noted that symptoms listed in HHS/CDC’s definition of an *ill person* are common symptoms of many conditions, particularly “appears obviously unwell” which many commenters requested be removed from the definition. HHS/CDC appreciates the opportunity to clarify that, with the exception of acute gastroenteritis on vessels, HHS/CDC only requires reporting of an ill traveler on an aircraft or vessel if fever “accompanied by one or more of the following” other symptoms listed are present. Therefore, as an example, headache alone would not be sufficient to require reporting, but rather fever

plus headache, fever plus cough, fever plus persistent vomiting, fever plus persistent diarrhea, etc. These symptoms combined with fever are frequently seen in communicable diseases that could pose a public health risk to others during travel. Because a person with fever who also appears obviously unwell could have a serious communicable disease, HHS/CDC feels it is appropriate to retain this symptom, and further notes that its inclusion better aligns with Note 1 to the guidelines set forth by the International Civil Aviation Organization in paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation.

One public health organization commented that the definition of *ill person* was broad and would be better issued through agency guidance rather than a rule. In response, HHS/CDC notes that the existing regulation contains an outdated and overly narrow definition of *ill person* that does not reflect current knowledge of communicable diseases, and that the reporting of ill travelers has been managed through a combination of regulation and agency guidance. This combination of “required” and “requested” reporting has proven confusing to some airline and vessel employees and this rule seeks to mitigate such confusion by including all relevant symptom clusters in the rule. Further, HHS/CDC notes that the change in the *ill person* definition better aligns with guidelines set forth by the International Civil Aviation Organization and is supported in comments received from the airline industry.

One public health organization commented on the different definitions of *ill person* for aircraft and vessels and recommended that the definitions be combined and not depend on the mode of transport. In response, HHS/CDC wishes to point out three crucial differences between aircraft and vessels which HHS/CDC feels justify the different definitions. One difference, additionally noted by the commenting organization, is the difference in time that a traveler spends on an aircraft and a vessel which makes the time frame (24 hours) specified in the definition of acute gastroenteritis for vessels relevant and minimizes the reporting of travelers with a single episode of loose stool that subsequently resolves, a common occurrence. The second is the high risk of spread of gastrointestinal infections onboard vessels that is unlikely to occur on aircraft; for this reason, reporting of diarrheal illnesses on aircraft includes the presence of fever which is more likely to indicate a serious

communicable disease, whereas the definition on vessels includes diarrheal illness without fever to allow for the reporting of viral gastrointestinal illnesses that typically do not cause fever but have been known to cause large outbreaks on cruise vessels. The third difference is the presence onboard cruise vessels of medical facilities capable of making a diagnosis of pneumonia which allows the inclusion of pneumonia in the vessel definition. In all other respects, the definitions are the same. HHS/CDC adds that combining the definitions would be confusing to industry professionals responsible for conducting this reporting.

One public health organization provided a recommendation to modify the description of the “rash” component in the definition of ill person to ensure that the term fully encompassed the range of potential skin rash symptoms. The organization’s recommendation for revisions was as follows: “The individual has areas on the skin that are red or purple, flat or bumps; with multiple red bumps; red, flat spots; or blister-like bumps filled with fluid or pus that are intact, draining, or partly crusted over; or dry and scaling patches. The rash may be discrete or run together, and may include one area of the body, such as the face, or more than one area.”

HHS/CDC responds that it will not change the regulatory text of the ill person definition with this language because we are concerned that this might add too much complexity to the regulatory definition. However, consistent with the regulatory definition of “ill person,” HHS/CDC will update its reporting guidance for aircraft and vessels to include this revised description. Current guidance may be found at: <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>.

An air industry commenter suggested another change to the ill person definition. The proposed definition included “headache with stiff neck,” and the commenter suggested that this be modified to “severe headache of recent onset with stiff neck.” While HHS/CDC will not change the regulatory definition of ill person to accommodate this change, HHS/CDC believes this is a useful modification to make in ill person reporting guidance to aircraft and vessels.

Incubation Period

HHS/CDC did not receive any comments on the proposed definition of *Incubation period*. However, upon a

review of the definition, we have decided that the definition should more closely track the definition of *Precommunicable stage*. For quarantinable communicable diseases, the *Incubation period* is defined as the *Precommunicable stage* of the disease. Thus, we have determined that the two definitions should more closely align. A substantive discussion of comments received concerning the definition of *Precommunicable stage* appears below.

Accordingly, we have modified the definition of *Incubation period* to add “or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear.” Other aspects of this definition are finalized as proposed.

Indigent

HHS/CDC received comments relating to the proposed definition of *Indigent* which is used to determine whether a detained individual qualifies for appointment at government expense of representatives to assist him/her during a medical review. One comment from a public health department suggested raising the threshold for indigent status to at least 200% of the applicable poverty guideline. HHS/CDC agrees and has made this change in the final regulation.

One commenter opposed including a definition for indigents and indicated that HHS/CDC should assume all costs whenever an individual is placed into Federal isolation or quarantine. HHS/CDC disagrees that assuming such costs without regard to indigence is necessary or appropriate.

Other substantive comments relating to the appointment at government expense of representatives to assist detained indigent individuals during a medical review are discussed below.

Master or Operator

HHS/CDC did not receive any comments on the definition of *Master or operator*. Accordingly, this definition is finalized as proposed.

Medical Examination

In response to comments received regarding medical examinations under sections 70.12 and 71.36, we have modified the definition of *Medical Examination* to indicate that the health worker conducting the assessment must be “licensed.” Comments regarding sections 70.12 and 71.36 are addressed below.

HHS/CDC received a comment regarding the definition of *Medical Examination*. The commenter stated that the definition of medical examination should include a mental

health assessment because a mental health condition may impact an individual’s appreciation of his or her public health risk to others. While HHS/CDC acknowledges that a mental health assessment may be useful as part of an individual’s medical care and treatment and that such an assessment may be ordered as needed by a treating clinician, HHS/CDC declines to make such assessments a formal part of the medical examination process. Specifically, because a mental health assessment is not generally needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease, HHS/CDC disagrees that it is necessary or appropriate to require such an assessment as part of a Federal public health order.

Medical Representative

HHS/CDC received several comments relating to the proposed definitions of *Medical Representative* and *Medical Reviewer* as well as the potential use of HHS/CDC employees as representatives or medical reviewers. One commenter suggested that it would be less problematic for HHS/CDC to allow and pay for outside participants to serve in these capacities. First, HHS/CDC notes that the definition of *Medical representative* has been changed to *Representatives* and revised as detailed below. HHS/CDC disagrees with this comment and notes that the definition of both *Representatives* and *Medical reviewer* would in fact allow for the appointment of non-HHS/CDC employees in these capacities as suggested by the commenter. For this reason, both *Representatives* and *Medical reviewer* are broadly defined in terms of the occupational qualifications of these individuals. HHS/CDC also does not consider it problematic to rely on internal reviewers and notes that it is not unusual, for instance, for hospitals to rely on internal decision-makers when determining whether to commit a mental health patient on an emergency basis.

HHS/CDC received a comment that the “definition of medical exemption is not apparent.” In response, HHS/CDC notes that no clarification of what is meant by “medical exemption” is provided by the commenter and that HHS/CDC did not propose adding such a definition. While these regulations do not authorize compulsory vaccination or medical treatment, there is no recognized “medical exemption” from quarantine, isolation, or conditional release and HHS/CDC declines to create one.

Non-Invasive

HHS/CDC received several comments concerning the definition of *Non-invasive*, including support from a public health association regarding the definition. However, several individuals disagreed with the proposed definition. In response to public comment that the definition of “non-invasive” allowed too much physical contact between the individual and public health officer, HHS/CDC has replaced “physical” with “visual” and removed “auscultation; external palpation; external measurement of blood pressure” from the definition. While HHS/CDC continues to believe that these procedures qualify as *Non-invasive* under the definition, after considering public comment and a review of standard operating procedures, HHS/CDC finds such procedures to be unlikely to be conducted during a public health risk assessment. Such procedures may be conducted at a port of entry by emergency medical service personnel as part of a medical assessment to determine the need for emergency medical care. We also modified the definition to clarify that the individual conducting the public health risk assessment will be a “public health worker.” Public health workers are individuals who have education and training in the field of public health.

One commenter mentioned that the new definition of *Non-invasive* states that the HHS/CDC could order laboratory testing under certain conditions. The commenter further asserted that forced laboratory testing, without the option of quarantine instead, is an invasive measure, and questioned how this could be in line with the concept of non-invasive. HHS/CDC responds that the definition of non-invasive applies to procedures conducted during a public health risk assessment at a port of entry and that this definition does not authorize forcible or invasive procedures to extract human biological samples for laboratory testing. Should laboratory testing be needed for a person reasonably believed to be infected with a quarantinable communicable disease, such testing would be done as part of a medical examination conducted at a healthcare facility and performed with the patient’s informed consent. HHS/CDC has added language to the regulatory text requiring that the Director advise individuals of their right to have medical testing and examination conducted by an authorized and licensed health worker and with prior informed consent. While this regulation does not authorize forcible testing,

HHS/CDC may require laboratory test results demonstrating that a symptomatic individual is no longer infectious prior to rescinding a Federal isolation order.

Precommunicable Stage

HHS/CDC received comments relating to the definition of *Precommunicable stage*. One commenter suggested that persons in the “precommunicable stage” of a quarantinable communicable disease pose no direct threat to the public’s health. A public health organization also stated that this definition should not apply to non-symptomatic people who have been exposed to Ebola. HHS/CDC disagrees with both comments. For instance, a patient diagnosed with multidrug-resistant or extensively drug-resistant tuberculosis who is not currently infectious, but who has not been adequately treated and is thus at high risk for relapse would be considered to be in the “precommunicable stage” of the disease and pose a direct threat to the public’s health. Similarly, an individual who is reasonably believed to have been exposed to Ebola poses a direct threat.

Several public health organizations additionally expressed concerns regarding the use of the “precommunicable stage” definition to justify quarantine of healthcare workers caring for patients with quarantinable communicable diseases such as Ebola or severe acute respiratory syndromes, including healthcare workers providing care in the United States or in other countries. One such organization further requested clarification of whether the rule provides for the needs and protection of healthcare workers who voluntarily self-quarantine while providing care for patients with the quarantinable communicable diseases noted above.

In response, HHS/CDC states that it does not recommend quarantine or occupational restrictions of healthcare workers who follow recommended infection control precautions while providing care for patients with quarantinable communicable diseases. Healthcare workers who do not follow infection control precautions or who have had unprotected exposures to patients with a quarantinable communicable disease may be subject to quarantine or occupational restrictions; these individuals would be afforded the same due process protections as other exposed individuals.

Several commenters also questioned CDC’s proposed definition for *Precommunicable stage* stating that it may result in an apprehension of an

individual who displays no symptoms of a communicable illness. In response, HHS/CDC states that it has defined *Precommunicable stage* consistent with the public health practice of quarantine. Quarantine refers to the public health practice of separating and restricting the movement of individuals who are reasonably believed to have been exposed to a communicable disease, but are not yet ill. In contrast, isolation refers to the public health practice of separating and restricting the movement of individuals who have been exposed to a communicable disease and are symptomatic from those who are not sick.

The definition of *Precommunicable stage* is finalized as proposed.

Public Health Emergency

HHS/CDC received several comments relating to the definition of *Public health emergency*. One commenter stated that use of the term is duplicative and unnecessary because the term is used elsewhere in the Public Health Service Act (42 U.S.C. 247d) and appears in State-based legislation based on the Model State Emergency Health Powers Act. This commenter suggested that to avoid confusion the term should be renamed “Public Health Exigency.” HHS/CDC disagrees. Section 361(d) of the Public Health Service Act (42 U.S.C. 264(d)(1)) authorizes the apprehension and examination of individuals traveling interstate who are in the “precommunicable stage” of a quarantinable communicable disease, but only if the disease “would be likely to cause a public health emergency if transmitted to other individuals.” Thus, section 361(d) is unique and differs from how the term public health emergency is used in other statutes or provisions of the Public Health Service Act because it authorizes application of specific public health measures (apprehension and examination) to specific individuals (those in the precommunicable stage of a quarantinable communicable disease), but only if the disease would be likely to cause a public health emergency. Thus, HHS/CDC considers it essential to define public health emergency because the existence of such an emergency is a necessary prerequisite to the apprehension and examination of individuals in the precommunicable stage of a quarantinable communicable disease.

This commenter also suggested that the definition of public health emergency contains an oversight because it does not mention the potential for an infectious condition being highly likely to cause “short- or

long-term disability.” HHS/CDC disagrees because the definition includes infectious diseases that are highly likely to cause “serious illness” if not properly controlled. HHS/CDC clarifies that “short- or long-term disability” caused by an infectious agent would be considered a “serious illness.”

This commenter further suggested that in addition to referencing a public health emergency declaration by the HHS Secretary, the definition should also include similar declarations by the President under the Stafford Act or under the National Emergencies Act. HHS/CDC disagrees. We note first that the definition of public health emergency is not limited to those emergencies declared by the HHS Secretary. Second, in the event of a man-made or natural disaster that also affects public health, the HHS Secretary may issue a separate declaration under the Public Health Service Act as was done in response to the terrorist attacks of September 11, 2001 and in response to Hurricane Katrina. Thus, HHS/CDC does not see a need to also reference Presidential declarations as suggested by the commenter.

This commenter also requested clarification concerning whether the World Health Organization’s (WHO) declaration of a Public Health Emergency of International Concern (PHEIC) could continue to serve as the basis for a “public health emergency” if the President or HHS Secretary disagreed with the declaration of a PHEIC on legal, epidemiologic, or policy grounds. In response, HHS/CDC notes that the scenario proposed by the commenter is unlikely, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

HHS/CDC also received a comment objecting to referencing the WHO’s declaration of a Public Health Emergency of International Concern (PHEIC) in the definition of “public health emergency” because this ostensibly relinquishes U.S. sovereignty. HHS/CDC disagrees. By including references to a PHEIC, HHS/CDC is not constraining its actions or making its actions subject to the dictates of the WHO. Rather, the declaration or notification of a PHEIC is only one way for HHS/CDC to define when the precommunicable stage of a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. While HHS/CDC will give consideration to the WHO’s declaration of a PHEIC or the circumstances under which a PHEIC may be notified to the

WHO, HHS/CDC will continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. Thus, HHS/CDC disagrees that referencing the WHO determination of a PHEIC results in any relinquishment of U.S. sovereignty.

The International Health Regulations are an international legal instrument that sets out the roles of WHO and State parties in identifying, responding to, and sharing information about public health emergencies of international concern. HHS/CDC believes that it would be unlikely for the United States to formally object to the WHO's declaration of a PHEIC, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

Also regarding the definition of "public health emergency," one public health association expressed concern that *any* disease considered to be a public health emergency may qualify it as quarantinable. Another commenter noted that some PHEICs "most certainly do not qualify as public health emergencies" under the proposed definition. HHS/CDC appreciates the opportunity to clarify. Only those communicable diseases listed by Executive Order of the President may qualify as quarantinable communicable diseases. For example, Zika virus infection, which although the current epidemic was declared a PHEIC by WHO, is not a quarantinable communicable disease. The definition of *Public health emergency* is finalized as proposed.

Public Health Prevention Measures

HHS/CDC received one comment relating to the definition of *Public health prevention measures*. The commenter stated that the second use of "and other non-invasive means" should be deleted from the definition of *public health prevention measures* as redundant. HHS/CDC disagrees because "observation, questioning, review of travel documents, and records review" as cited in the definition appears to materially differ from "other non-invasive means" that may be used as a part of public health prevention measures such as temperature checks, visual observation, or visual examination of the ear, nose, or mouth. Accordingly, HHS/CDC believes that the updated definition provides greater clarity as written. Further information, including a discussion regarding comments received on these proposed

provisions, is discussed in the section below titled *Public Health Prevention Measures to Detect Communicable Disease*. The definition is finalized as proposed.

Qualifying Stage

HHS/CDC received several comments relating to *Qualifying stage*. Several commenters, including one public health organization, expressed concern that the definition was either too vague, too broad, or too confusing. One commenter suggested that the definition for *Qualifying stage* is confusing because it splits communicable diseases into a "precommunicable stage" and a "communicable stage" and that a communicable disease would not be on the list of Federal quarantinable communicable diseases if its spread did not already have some potential to cause a public health emergency. In response, HHS/CDC notes that the term "qualifying stage" is defined under 42 U.S.C. 264(d)(2) to include both a "precommunicable stage" and a "communicable stage" and that this definition explicitly references diseases "likely to cause a public health emergency." Thus, while HHS/CDC may clarify and explain statutory terms through regulation, it has no authority to change the language of the statute.

One public health organization recommended that HHS/CDC policy implementing the *Qualifying stage* definition acknowledge that a one-size fits all protocol is not appropriate because different diseases have different transmission patterns and the need for isolation and quarantine may differ. HHS/CDC agrees that the need for isolation and quarantine may differ based on the disease and adds that it conducts a public health risk assessment before issuing Federal public health orders. For example, HHS/CDC does not typically issue Federal public health orders for cholera, a quarantinable communicable disease as defined by Executive Order because the sanitation infrastructure in the United States makes cholera transmission unlikely. HHS/CDC further notes that it typically conducts the public health risk assessment in coordination with the State or local health department of jurisdiction before issuing a Federal public health order.

Public health organizations and other commenters cautioned against apprehending individuals or issuing public health orders when the risk of communicable disease spread during the precommunicable period is low. HHS/CDC agrees and further adds that it will typically conduct a public health risk assessment in coordination with

State and local public health officials to ensure that any restrictions imposed on an individual are commensurate with the degree of risk and using the least restrictive means available.

The definition of *Qualifying stage* is finalized as proposed.

Reasonably Believed To Be Infected, as Applied to Individuals

HHS/CDC received several comments regarding the definition of *Reasonably believed to be infected, as applied to an individual*. Several public health organizations expressed concern there could be undue burden placed on healthcare facilities or health departments by greatly expanding the number of individuals requiring health screening, medical examination and testing, or placed under Federal isolation of quarantine orders. HHS/CDC disagrees. This rule represents a codification of current practice and decisions regarding the need for medical examination of individuals suspected of being infected with a quarantinable communicable disease, including during an outbreak or public health emergency, will generally be based on published disease-specific case definitions for PUIs (persons under investigation) that incorporate clinical and epidemiologic factors. Furthermore, decisions regarding the issuance of Federal public health orders or medical examination for a suspected quarantinable communicable disease would typically be made in coordination with a State or local health department of jurisdiction. Therefore, HHS/CDC does not anticipate placing an undue burden on healthcare facilities or health departments as a result of these definitions.

One commenter stated that the *Reasonably believed to be infected, as applied to an individual* definition allows for apprehension, quarantine, or isolation based solely on reasonable inferences that the person was exposed somehow or in some way to infectious agents. HHS/CDC disagrees because as stated in the definition reasonable inferences may only be drawn from "specific articulable facts" that an individual has been exposed to an infectious agent such as through "contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector." Thus, HHS/CDC disagrees that this standard does not comport with standard public health practice.

HHS/CDC received a comment from a public health agency expressing concern that travel to other countries where transmission of a quarantinable

communicable disease has likely occurred would be the sole basis upon which HHS/CDC would form a reasonable belief that an individual may be infected with a quarantinable communicable disease. In response, HHS/CDC clarifies that travel to other countries was simply used as an illustrative example. The decision to place an individual into isolation or quarantine will ordinarily be based on several factors, including travel, contact with an infected person or an infected person's bodily fluids, host susceptibility, and clinical manifestations. HHS/CDC believes that this definition is clear and that no further changes are necessary.

The definition of *Reasonably believed to be infected as applied to an individual* is finalized as proposed.

Secretary

HHS/CDC has added a definition for *Secretary* meaning the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated. We note that while the NPRM did not propose this definition, the NPRM referenced the *Secretary* in defining *Public Health Emergency*. Thus, HHS/CDC considers it useful to also define the term *Secretary*.

After consideration of comments regarding *Definitions*, HHS/CDC has made the following changes in the final rule:

- The definition of *Agreements* has been withdrawn.
- The definition of *Conditional Release* under section 70.1 has been modified to remove the internal cross-reference to the definition of surveillance under section 71.1. The definition of *Conditional Release* under section 70.1 has been further modified to align with the definition of surveillance under section 71.1 and means “the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or internet-based monitoring.”
- The definition of *Electronic or internet-based monitoring* has been modified to indicate “communication through” such means, and include “audio” conference.
- The definition of *Incubation period* has been modified to add “or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear.” This

aligns the definition with the *Precommunicable stage* definition.

- The definition of *Indigent* has been modified to increase the threshold to 200% of the applicable poverty guidelines.
- The definition of *Medical Examination* has been modified to indicate that the health worker conducting the assessment must be “licensed.”
- The definition of *Medical Representative* has been changed to *Representatives* and now includes in addition to the appointment of a medical professional, the appointment of “an attorney who is knowledgeable of public health practices.”
- The definition of *Non-invasive* has been modified to (1) replace “physical examination” with “visual examination,” (2) specify that the individual performing the assessment must be a “public health worker (*i.e.*, an individual with education and training in the field of public health)” and (3) remove “auscultation, external palpation, external measurement of blood pressure.”
- A definition for *Secretary* has been added and means “the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.”

d. Public Health Prevention Measures To Detect Communicable Disease

HHS/CDC received support from commenters on screening individuals entering the U.S. from parts of the world where highly infectious diseases are common. One such commenter requested to know the criteria HHS/CDC uses when deciding whether to detain an individual. Another commenter stated that travel history “should be a prerequisite for Federal orders to quarantine” and “medical exam should be a prerequisite for Federal orders to isolate.” HHS/CDC thanks these commenters and welcomes the opportunity to explain this process.

HHS/CDC's decision to detain an individual is based on several criteria, including: Clinical manifestations: Signs and symptoms consistent with those of a quarantinable communicable disease; known or suspected contact with cases, *i.e.*, patients either confirmed or suspected to be infected with a quarantinable communicable disease; epidemiologic information/evidence (travel history, exposure to animals); other documentary or physical evidence in the individual's possession, such as a physician's note documenting infection with or medication for treatment of a quarantinable disease;

and/or public health authorities having notified HHS/CDC that the individual is known or suspected to be infected with a quarantinable communicable disease and likely non-adherent with public health recommendations.

HHS/CDC has modified paragraph (b) of the provisions relating to public health prevention measures to detect communicable disease (§§ 70.10 and 71.20) to include information about “known or possible exposure,” in response to comments requesting further clarity of CDC's criteria.

One organization from the airline industry was generally supportive of 70.10 and 71.20, *public health prevention measures to detect communicable disease*, and requested that any measures, such as screening, occur prior to individuals boarding an aircraft, and preferably prior to arrival at the gate. HHS/CDC thanks these commenters for their support. In response, while an operational plan for each location has not yet been finalized, HHS/CDC expects such measures to occur prior to the boarding of an aircraft, and to the extent possible, prior to arrival at the gate. One airline organization insisted that airline operators should not be financially responsible for any costs associated with screening. HHS/CDC responds that it does not expect airlines and airline operators to assume direct costs associated with public health screening, such as providing additional personnel to conduct the screening. However, indirect costs such as missed flights of passengers who are detained may occur.

Another airline organization requested that HHS/CDC ensure wait-times in lines are not impacted by screening, and encouraged HHS/CDC to take into account the needs of all stakeholders. HHS/CDC feels strongly that in these rare circumstances, which would only occur should a threat to public health exist, preventing airline employees and other passengers from being exposed to a detained or delayed individual provides a greater benefit than the monetary loss of airfare. In keeping with current practice, HHS/CDC will work together with public health partners, carriers, and all who have equities, to ensure insofar as possible that the least restrictive and time-consuming measures are implemented. Finally, commenters requested that individuals who refuse to undergo a public health risk assessment prior to travel be denied boarding of an aircraft. In response, HHS/CDC notes that individuals may be denied boarding for public health reasons pursuant to the criteria published at 80 FR 16,400 (Mar. 27, 2015) titled *Criteria for Requesting*

Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers.

HHS/CDC received a comment expressing concern about conducting public health prevention measures at “other locations” besides U.S. ports of entry because the commenter found this language vague. HHS/CDC clarifies that this term is meant to include all locations where individuals may enter the United States from a foreign country (i.e., border crossings) or gather for the purposes of engaging in interstate travel (e.g., airports, seaports, railway stations, bus terminals), regardless of whether such places are formally designated as such.

One public health organization requested clarification regarding what information or event would justify triggering the screening of travelers. CDC’s response is that, while specific triggers cannot be defined at this time, screening of travelers may generally be conducted during a public health emergency if HHS/CDC determined that monitoring of potentially exposed travelers was needed to protect the public’s health.

One public health organization and many individual commenters asserted that people exposed to measles should not be “tracked” through the use of Federal public health orders. First, we reiterate that because measles is not a quarantinable communicable disease, HHS/CDC does not have the authority to issue a public health order for this illness. Second, it is not HHS/CDC’s policy to monitor people following measles exposures. Rather, HHS/CDC notifies State or local health departments regarding people in their jurisdictions who may have been exposed to measles. The State or local health departments, in turn, choose to notify people regarding their measles exposure, assess their immunity to measles and, if they are not immune, offer vaccination with MMR vaccine to prevent infection. State or local health authorities may choose to monitor people following exposures to measles based on their own criteria.

One commenter asked whether mandatory health screenings at airports would be conducted privately, whether processes would comply with HIPAA, and how data would be protected at airports. In response, HHS/CDC states that, in all situations, HHS/CDC strives to protect the privacy of individuals subject to screening, collection of information, or the issuance of Federal public health orders under HHS/CDC’s authority. While some aspects of the entry risk assessment process conducted during the 2014–2016 Ebola epidemic

were performed in areas of the airport that are not considered private, these were limited to collection of contact information, noncontact temperature measurement, observation for visible signs of illness, and superficial screening questions that did not collect sensitive information. Any more detailed public health assessment would be done in a private area.

HHS/CDC is bound by the Privacy Act to protect personally identifiable data collected and maintained in accordance with that Act. Furthermore, HHS/CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality. Personally identifiable data collected by HHS/CDC at airports are maintained in a secure database and shared only for official purposes on a need to know basis using secure methods as described in CDC’s System of Records Notice published at 72 FR 70867. HHS is also a hybrid entity under HIPAA, but only those parts of HHS that have been determined to be health care components are subject to the HIPAA Privacy Rule. CDC is generally not a health care component treated as a “covered entity” under the HIPAA Privacy Rule. However, certain specific offices of HHS, CDC, and the National Institute for Occupational Safety and Health (NIOSH) performing activities related to the World Trade Center Health Program are considered health care components of HHS and must comply with HIPAA and the Privacy Rule.

One public health organization recommended that the rulemaking specify that individuals undergoing a public health risk assessment only be asked to provide contact tracing information if the risk assessment leads to a reasonable belief that the individual may become infected. It is CDC’s policy to conduct conveyance-related contact investigations for confirmed cases of communicable diseases. In instances when confirmation cannot be obtained, HHS/CDC may investigate contacts based on reasonable belief of infection following a public health risk assessment which is typically conducted in coordination with the State or local health department of jurisdiction. Such operational details are generally defined in internal protocols. State or local authorities may conduct community-based contact investigations within their jurisdictions based on their own criteria.

After consideration of these comments, HHS/CDC has modified paragraph (b) the provisions relating to *Public Health Prevention Measures to Detect Communicable Disease* (§§ 70.10 and 71.20) to include information about

“known or possible exposure” in the list of information that may be collected.

e. Apprehension and Detention of Persons With Quarantinable Communicable Diseases

HHS/CDC received several comments relating to the “apprehension” of an individual. One public health association and a public health department suggested that HHS/CDC not use the term “apprehension” because this may create social stigma. HHS/CDC uses this term in these regulations to align with the statutory terminology used in 42 U.S.C. 264(b) which authorizes the “apprehension, detention, or conditional release” of individuals coming into a State or possession from a foreign country or possession for purposes of preventing the introduction, transmission, and spread of quarantinable diseases. Similarly, 42 U.S.C. 264(d) authorizes the “apprehension and examination” of any individual in the qualifying stage of a quarantinable communicable disease who is moving or about to move between States or constitutes a probable source of infection to individuals moving between States. While HHS/CDC can clarify and explain this term, only Congress has the authority to change statutory language. In addition to being a term specifically used in statute under 42 U.S.C. 264, HHS/CDC has determined that this term best conveys that HHS/CDC may, based on public health grounds, assume physical custody of individuals. Furthermore, using alternative terminology, may reduce public understanding and transparency regarding HHS/CDC’s legal authorities.

One commenter stated that not every social distancing technique needs to involve taking physical custody of individuals and that using more voluntary-based options would be advisable. HHS/CDC agrees that attempting to obtain voluntary compliance with public health measures is more advisable than assuming legal custody, but believes that maintaining the authority to apprehend individuals who may pose a public health risk is a necessary tool to protect the public’s health. HHS/CDC received a comment regarding the “burden of proof” for an apprehension. In response, HHS/CDC notes that the applicable standard for an apprehension of an interstate traveler is “reason to believe” that the individual is in the qualifying stage of a quarantinable communicable disease. HHS/CDC notes that *Reasonably believed to be infected as applied to an individual* is defined under this final rule.

Several commenters expressed concern that because the “apprehension” period is not explicitly time-limited, that HHS/CDC may “apprehend” an individual indefinitely without providing the individual with a written public health order or a medical review. One commenter noted that HHS/CDC used the term “generally” in the preamble of the NPRM and felt it was too vague, stating “setting a firm timeframe is vital.” A partnership of public health legal scholars and organizations stated that because HHS/CDC did not explicitly limit how long an individual could remain apprehended that such apprehensions could turn into the functional equivalent of a quarantine thus potentially raising Fourth and Fifth Amendment concerns. In response to these concerns, HHS/CDC has added language requiring that it serve an apprehended individual with a public health order within 72 hours of that individual’s apprehension.

HHS/CDC received several other comments relating to the sections authorizing the apprehension and detention of persons with quarantinable communicable diseases. A partnership of public health legal scholars and organizations suggested two public health frameworks for apprehension and detention, one for implementation during non-exigent circumstances and a second for exigent circumstances. As described, the primary distinction between the non-exigent and exigent framework, is that in the former HHS/CDC would be required to hold a due process hearing prior to the imposition of an isolation or quarantine, while in the latter HHS/CDC may briefly detain the individual prior to holding a hearing. While HHS/CDC appreciates the input provided by this partnership, HHS/CDC declines to adopt this suggestion. Importantly, unlike State and local public health authorities who have primary responsibility for the imposition of public health measures occurring within their jurisdictions, HHS/CDC acts in time-sensitive circumstances to prevent communicable disease spread, such as at ports of entry, upon the request of a State or local public health authority of jurisdiction, or when State or local control is inadequate. Furthermore, unlike State and local public health authorities who generally have broad police-power authority to protect the public’s health, HHS/CDC’s statutory authority with respect to isolation and quarantine is limited to only those small, subset of communicable diseases specified through an Executive Order of the

President as quarantinable. Accordingly, HHS/CDC does not foresee sufficient “non-exigent” circumstances where it would be necessary for it to issue a Federal isolation or quarantine order and thus declines to establish the suggested alternative framework on this basis.

The circumstances under which HHS/CDC may apprehend and detain individuals is limited by the terms of 42 U.S.C. 264. HHS/CDC may only isolate, quarantine, or conditionally release an individual if it reasonably believes that the individual is infected with a quarantinable communicable disease and the individual is either arriving into the U.S. from a foreign country, moving between States, or constitutes a probable source of infection to others who may then move between States.

Accordingly, the circumstances under which CDC is would issue a quarantine or isolation order are “exigent” because the individual constitutes a communicable disease risk and is actively engaged in travel or constitutes a source of infection to others engaged in travel. It is thus unnecessary and impractical to provide a “pre-deprivation” hearing prior to quarantining or isolating the individual because he/she if released from custody may be lost to public health follow-up and may expose others. HHS/CDC would not quarantine or isolate an arriving traveler from a foreign country where a single case of a communicable disease such as Ebola exists unless it reasonably believes that the traveler arriving into the U.S. is infected with a quarantinable communicable disease.

Commenters stated that individuals must receive notice of their suspected exposure and be permitted to speak with legal counsel or have legal counsel appointed to them. HHS/CDC agrees that individuals should be adequately notified of the basis for their detention and directs this commenter to sections 70.14 and 71.37, which detail the specific factual content that must be included in a Federal order for quarantine, isolation, or conditional release. We have also modified these sections to explicitly require that the federal order include an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense.

As previously stated, consistent with principles of preventing communicable disease spread, HHS/CDC will also take

measures (such as ensuring phone access) to allow apprehended individuals to have contact with family or legal counsel whom they hire at their own expense. As explained further below, HHS/CDC will also appoint representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review. Individuals who do not qualify as indigent may also choose to be represented at the medical review by an advocate (e.g., an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense. HHS/CDC, however, rejects as impractical the notion that indigent individuals should have representatives appointed to them *at the moment of apprehension* because most illnesses of public health concern can be ruled out based on a short interview with a quarantine officer involving an assessment of symptoms and travel history. Thus, the expected length of an apprehension will be very short and not justify the appointment of representatives.

This commenter also requested clarity on what legal recourse may be available to apprehended individuals. While HHS/CDC does not express an opinion regarding what form of legal action an aggrieved individual should pursue, we note that these regulations do not impact the constitutional or statutory rights of individuals to seek judicial redress for detention.

HHS/CDC received comments from the public regarding HHS/CDC’s authority to “arrest” individuals. One commenter stated that individuals should only be detained when a crime has been committed. One association objected to HHS/CDC’s “power to detain an individual for 72 hours and longer without any Federal court order.” Some commenters also worried that any person showing signs of a “common cold” may be held. To be clear, HHS/CDC is not a law enforcement agency, it has no legal authority to “arrest” individuals, but rather has been granted the authority by Congress to “apprehend and detain” individuals for the purposes of preventing the introduction, transmission and spread of quarantinable communicable disease as specified in an Executive Order of the President. 42 U.S.C. 264(b). This provision further provides that “regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary.” 42 U.S.C. 264(d)(1). HHS/CDC strongly believes that these

authorities may be implemented in a manner consistent with the U.S. Constitution. Furthermore, during the period of apprehension, HHS/CDC will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication.

HHS/CDC received comments from the public inquiring about the criteria that HHS/CDC uses to determine whether an individual should be detained and assessed. As provided for in the regulation, HHS/CDC may apprehend, examine, isolate, and quarantine such individuals to protect the public's health. In determining whether an individual poses a threat to public health, HHS/CDC has developed and uses the following criteria: Clinical manifestations: Signs and symptoms consistent with those of a quarantinable disease; known or suspected contact with a case, *i.e.*, patients either confirmed or suspected to be infected with a quarantinable disease; epidemiologic information/evidence (travel history, exposure to animals); other documentary or physical evidence in the individual's possession, such as a physician's note documenting infection with or medication for treatment of a quarantinable communicable disease; and/or public health authorities have notified HHS/CDC that the individual is known or suspected to be infected with a quarantinable communicable disease and non-adherent with public health recommendations. This determination is typically made in consultation and coordination with State and local public health authorities, as well as the treating health care physician (when available). One public health association agreed that travel history (entering the U.S. from a country where quarantinable diseases occur) made sense for screening, but not for a quarantine or isolation order. HHS/CDC responds that the criteria listed above, as well as those within the NPRM, are examples of factors that HHS/CDC takes into consideration when determining the totality of the circumstances—not one criterion does, should, or will, decide if the individual requires a public health order.

One commenter questioned whether, regarding the list of quarantinable communicable diseases listed by Executive Order of the President, a “common cold” would qualify as a “severe acute respiratory syndrome” and therefore subject the ill individual to a public health order. In response, we note that Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and

Executive Order 13674 (July 31, 2014), explicitly excludes “influenza” from the definition of severe acute respiratory syndrome.

HHS/CDC received several comments from a flight attendant union relating to apprehension and detention of a flight crew. These comments include that the flight attendant's employer should be made aware of the apprehension, that HHS/CDC should limit the personal health information that is shared with the employer, that the employer should treat this information as confidential, and that those apprehended should be able to notify families and their union. In response, HHS/CDC notes that it works closely with the airline industry regarding potential occupational exposures to communicable diseases. Furthermore, HHS/CDC notes that personally identifiable health information collected and maintained under the Privacy Act will be disclosed only with the consent of the subject individual, in accordance with the routine uses published in HHS/CDC's system of records notice (72 FR 70867), or under an applicable exception to the Privacy Act. While these regulations do not mandate how employers should treat the personal health information of their employees, HHS/CDC agrees that such information should be treated as confidential. Lastly, consistent with principles of preventing communicable disease spread, HHS/CDC will allow persons detained in accordance with these regulations to communicate with family, union representatives, legal counsel whom they hire at their own expense, and others of their choosing. HHS/CDC will also appoint representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review.

One commenter asked about provisions for people detained under HHS/CDC's authority who require emergency medical care, and whether the need to conduct a public health assessment could impede such care resulting in harm to the individual. In response, HHS/CDC states that public health officers at ports of entry work closely with emergency medical service (EMS) personnel and that emergency medical care takes precedence over the public health risk assessment. When an individual suspected of being infected with a quarantinable communicable disease requires emergency care, the individual would be transported immediately by EMS to a medical facility, using appropriate infection control precautions. The public health risk assessment would be completed subsequently using information

provided by the examining health care provider in coordination with the health department of jurisdiction.

After consideration of these comments, HHS/CDC has finalized the *Apprehension and Detention of Persons With Quarantinable Communicable Diseases* (§ 70.6) provision as proposed, with the exception that Federal public health orders must be served on the individual within 72 hours of an apprehension. As further detailed below, the 72-hour period was determined based on public comment from health departments familiar with the process, as well as CDC's previous experience of the time necessary to conduct a medical examination, collect and package laboratory specimens, transport the specimens to an appropriate laboratory (when necessary), and conduct the testing.

f. Medical Examinations

HHS/CDC received several comments relating to medical examinations. HHS/CDC received a comment from a public health agency stating that when an individual agrees to submit to a medical examination, it may be more appropriate to medically examine the patient during the “apprehension” period. In response, HHS/CDC notes that these regulations do not prohibit voluntary compliance with public health recommendations in the absence of a public health order. Notwithstanding, HHS/CDC believes that the ability to order a medical examination as part of an order for isolation, quarantine, or conditional release is an important tool to protect the public's health. This agency also stated that the definitions of “health status” and “public health risk” should be modified to ensure that the medical examination contains the minimum requirements needed to assess the communicable disease of public health concern. In response, HHS/CDC clarifies that its sole purpose in ordering a medical examination would be to determine the presence, absence, or extent of infection with a quarantinable communicable disease. HHS/CDC notes, however, that the medical examination is conducted by clinical staff who have primary responsibility for the patient's medical care and treatment and that a medical examination would thus ordinarily include the taking of a medical history and physical examination. HHS/CDC believes that this definition is clear and that no further modifications are needed.

HHS/CDC received a comment expressing concern that an individual would not be able to choose his or her own clinical healthcare provider if

ordered to undergo a medical examination. One commenter raised concerns about the possibility of medical examinations being conducted by “unqualified” or “non-medical personnel.” In response, HHS/CDC clarifies that, in keeping with current practice, any medical evaluation required by HHS/CDC would be conducted at a healthcare facility by a licensed healthcare practitioner. Furthermore, HHS/CDC has determined that it would be impractical to allow individuals to choose their own medical examiners. HHS/CDC notes that among other considerations, it must ensure that the healthcare facility where the medical examination will be conducted has appropriate containment facilities, that necessary laboratory samples will be properly collected, and that it is HHS/CDC’s practice to coordinate closely with State and local public health authorities in the choosing of clinical healthcare providers. Accordingly, we have concluded that the public interest is best served by having HHS/CDC, in coordination with the local health authority and EMS, choose the healthcare facility where the medical examination will be conducted and not the detained individual.

One commenter expressed concern that nonmedical personnel may be allowed to make a determination of illness resulting in actions being taken based on potential misdiagnosis. HHS/CDC appreciates the opportunity to clarify this point. Decisions to issue Federal public health orders are based on the assessment of qualified and licensed physicians. These decisions are based on all available evidence, including clinical presentation, medical and exposure history, and the results of medical evaluation and laboratory testing. Treatment decisions are made by the individual’s treating physician with guidance from public health subject-matter experts.

One commenter suggested that medical examinations should be conducted only with the informed consent of the individual and should not “forcibly” be required. HHS/CDC clarifies that it may require a medical examination under 42 U.S.C. 264(d) because this section, among other things, authorizes the “apprehension and examination” of individuals reasonably believed to be infected with quarantinable communicable diseases in a qualifying stage. CDC, however, agrees that medical examinations may not be conducted “forcibly.” Furthermore, because medical examinations will typically occur in a hospital setting and be performed by clinical staff, it will be incumbent upon clinical staff to obtain

the patient’s informed consent consistent with established standards of medical practice.

Public health organizations provided several comments regarding medical examinations, including that they be performed promptly so as not to curtail liberty, include only minimal components necessary to establish the diagnosis of or rule out the quarantinable communicable disease of concern, and that specimens obtained during such examinations not be used for purposes other than diagnostic testing without informed consent. In response, HHS/CDC states that it agrees with all of these points and that CDC, in keeping with current practice, has a commitment to upholding the highest ethical standards for both medical care and research.

One public health organization asked for clarification of whether hospital staff would be involved in obtaining consent for medical examinations authorized under this rule. In response, HHS/CDC states that, while a public health order authorizes that a medical examination be conducted, should any invasive procedures be determined by the treating clinician to be necessary for diagnostic or treatment purposes, consent for such procedures should be obtained by medical staff in accordance with established standards.

One organization asked for clarification of the location where medical examinations would be conducted, including whether inpatient or ambulatory-care facilities would be included. HHS/CDC responds that it will coordinate with State or local health departments of jurisdiction concerning such operational details as the exact locations where medical examinations may be conducted.

Several public health organizations commented on whether the issuance of public health orders is needed prior to medical examination if individuals agree voluntarily to such examinations, noting that a requirement for the issuance of orders could impede or delay the medical examination and that the examination, itself, could determine whether such orders are needed. In response, HHS/CDC notes that it may choose not to exercise its authority to issue public health orders if an individual complies voluntarily with HHS/CDC’s requirements, including the requirement of a medical examination. However, HHS/CDC retains the right to issue an order requiring a medical examination should an individual not comply voluntarily. Of note, one public health organization supported the use of Federal public health orders in requiring medical examinations, stating

that such orders had been used effectively in the past to facilitate timely examination.

One public health organization requested that language be added to the rule stating that medical examinations will be performed with proper adherence to worker safety and health policies and protocols. HHS/CDC responds that such occupational health protections are beyond the scope of this regulation and are covered by regulations of the Occupational Safety and Health Administration (OSHA).

HHS/CDC received several comments from a flight attendant union relating to medical examinations. This organization stated that the regulations should mandate that an employer pay a flight attendant’s salary and per diem and that no flight attendant should incur discipline as a result of being absent from work. This organization further commented that any changes in the employer-employee relationship should be addressed through joint guidance between government and industry groups. This group also commented that “promptly” should be defined in terms of the length of time that may be needed to arrange for a medical exam and that no more than five hours would be reasonable. This group further stated that “reasonably believed” should be defined to require specific, articulable facts that a trained medical professional can articulate.

HHS/CDC responds that these regulations do not alter, define, or mandate the employer-employee relationship between flight attendants and their employers. In regard to the timeframe for arranging a medical examination, HHS/CDC rejects a specific 5-hour timeframe as too prescriptive, but agrees that the medical examination should be arranged as quickly as possible based on the circumstances of the event. HHS/CDC further notes that the definition of “reasonably believed to be infected” already requires the existence of “specific articulable facts” articulated by a public health officer. Such specific, articulable facts would, for instance, include “contact with an infected person or an infected person’s bodily fluids, a contaminated environment, or through an intermediate host or vector.”

HHS/CDC received a comment from a partnership of public health legal scholars and organizations expressing concern that the regulations do not appear to limit the invasiveness of a medical examination, so long as the examination itself is needed to diagnose or determine the presence or extent of infection with a quarantinable communicable disease. HHS/CDC

welcomes this opportunity to provide further clarifications. HHS/CDC notes that because medical examinations will occur in a hospital setting and be performed by the hospital's clinical staff, it will be incumbent upon clinical staff to obtain the patient's informed consent consistent with established standards of medical practice prior to any examination occurring and that such examinations may not be forcibly conducted. HHS/CDC has also added a requirement that the Director, as part of the Federal order, the individual that the medical examination shall be conducted by an authorized and licensed health worker with prior informed consent. Furthermore, HHS/CDC will implement this provision consistent with U.S. constitutional requirements and Articles 23 and 31 of the International Health Regulations, which requires that parties apply "the least intrusive and invasive medical examination that would achieve the public health objective."

After consideration of these comments, HHS/CDC has finalized the provisions relating to *Medical Examination* (§§ 70.12 and 71.36) as proposed, with the exception that the Director as part of the Federal order must advise the individual that the medical examination will be conducted by an authorized and licensed health worker with prior informed consent.

g. Requirements Relating to Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received several comments relating to the issuance of Federal orders for isolation or quarantine. A flight attendant union commented that crew lists should not be published as part of a quarantine order posted in a conspicuous location. This group further stated that quarantine orders for flight attendants should be treated differently than those applicable to passengers or other airline personnel because flight attendants are health and safety personnel trained in how to perform CPR and operate defibrillators. In response, HHS/CDC notes that if a public health order is publicly posted, the order will be written to refer to a group of individuals, such as all individuals onboard a particular affected interstate or international flight. Under such circumstances, HHS/CDC expects that all members of the group will receive individual copies of the public health order. In some circumstances, CDC anticipates that issuance of a group federal order to an individual may not be feasible—such as when the location of the individual is unknown. Thus, HHS/CDC does not

expect to publish the names of individual passengers or crew as part of a publicly posted quarantine order. Furthermore, while HHS/CDC agrees that flight attendants provide an important public health and safety role, HHS/CDC disagrees that acknowledging this role requires the issuance of different public health orders than those issued to other affected persons.

HHS/CDC received several comments requesting the "least restrictive" means with respect to quarantine and isolation. HHS/CDC agrees and clarifies that in all situations involving quarantine, isolation, or other public health measures, it seeks to use the least restrictive means necessary to prevent spread of disease. Regarding quarantine, as an example, during the 2014–2016 Ebola epidemic, HHS/CDC recommended monitoring of potentially exposed individuals rather than quarantine. Most of these people were free to travel and move about the community, as long as they maintained daily contact with their health department. For some individuals with higher levels of exposure, HHS/CDC recommended enhanced monitoring (involving direct observation) and, in some cases restrictions on travel and being in crowded places, but did not recommend quarantine. HHS/CDC has the option of "conditional release" as a less restrictive alternative to issuance of an order of quarantine or isolation. Under a conditional release order, the person would not be confined as long as the terms of the order were followed. Should a quarantine or isolation order be deemed necessary, home quarantine or isolation would be considered as a less restrictive option to confinement in a guarded facility as long as this was determined to be safe for other household members, appropriate based on the individual's ability and willingness to follow all necessary precautions, and based on the individual's history of compliance with public health recommendations.

One public health organization requested that HHS/CDC specify the types of locations of Federal quarantine and asked clarification of whether this would occur on lands or property under Federal jurisdiction, and whether Federal or State standards would apply to an individual quarantined on lands or property not under Federal control. In response, HHS/CDC notes that operational issues such as the exact location of a quarantine and whether Federal, State, and local orders would be issued separately or concurrently would depend on individual facts and circumstances unique to each case. HHS/CDC notes, however, that it is not

unusual for the Federal government to exercise jurisdiction concurrently with State and local governments.

One public health organization noted the longstanding difficulties faced by Federal, State and local authorities in identifying suitable facilities for quarantining of large groups of people (approximately 350, representing the potential complement of travelers onboard an international flight), including the immediate availability of such facilities in the event of an emergency. HHS/CDC acknowledges these difficulties and affirms that it is actively working with Federal partners to identify suitable locations to accommodate large groups of people while under a Federal public health order.

One commenter stated, "If this is enacted . . . everyone who works with diseases . . . CDC, WHO, Labs, Drs., nurses etc. would have to be arrested as potential carriers." HHS/CDC disagrees with this assertion. HHS/CDC is not a law enforcement agency and does not have authority to arrest individuals. HHS/CDC's authority to issue Federal public health orders is limited to those diseases defined by Executive Order as quarantinable communicable diseases. Furthermore, HHS/CDC does not recommend restriction of movement for healthcare workers, laboratory workers, or others whose occupations involve working with infectious pathogens as long as the recommended infection control precautions are followed. Workers who do not take the necessary precautions or have unprotected exposures to a quarantinable communicable disease may be subject to restrictions if they meet the requirements for issuance of Federal public health orders.

Some commenters indicated that vaccination or treatment should not be "conditions" under "conditional release." HHS/CDC confirms that this final rule does not compel mandatory vaccination or medical treatment of individuals. HHS/CDC clarifies that when medically appropriate, vaccination or treatment, may be "conditions" of an individual's release from quarantine or isolation. Individuals consent to these conditions.

A public health agency commented that HHS/CDC should consider the conditions of confinement to ensure that certain minimum requirements, such as access to telephones, and reasonable accommodation of dietary restrictions, are observed. Specifically, such conditions should be considered at different stages including as part of the issuance of an order, during the mandatory reassessment, and as a part

of the medical review. In response, HHS/CDC notes that in addition to implementing these regulations consistent with U.S. constitutional requirements, CDC's implementation will also be consistent with Article 32 of the International Health Regulations which, among other things, requires that in implementing health measures under the IHR the gender, sociocultural, ethnic and religious concerns of the traveler be taken into consideration. Furthermore, Article 32 requires arranging for adequate food and water, protection for baggage and other possessions, appropriate accommodation, appropriate medical treatment, and means of necessary communication for those subject to public health orders. Furthermore, as stated in the regulations, as part of a mandatory reassessment and medical review, HHS/CDC will consider whether the least restrictive means are being used to protect the public health. HHS/CDC, however, does not believe that it is necessary for "conditions of confinement" to be formally considered as part of an administrative review because many conditions of confinement, such as availability of entertainment or other amenities, may be raised through informal means such as making one's concern known to the facility where the individual is being housed.

HHS/CDC received a comment from a public health agency noting that it should assume the responsibility of providing translation and interpretation services when issuing an order for quarantine, isolation, or conditional release, or when conducting a medical review. HHS/CDC agrees and has incorporated these changes into the regulatory text.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations requesting clarification as to whether personal service will occur when a quarantine order is issued on a group basis and posted in a conspicuous location. In response, HHS/CDC notes that if a public health order is publicly posted, the order will be written to refer to a group of individuals, such as all individuals onboard a particular affected interstate or international flight. Under such circumstances, HHS/CDC expects that all members of the group will receive individual copies of the public health order, thus addressing any concerns about adequacy of notice. Because HHS/CDC, however, cannot foresee all of the circumstances that may arise in an emergency situation, HHS/CDC believes that it is appropriate for these regulations to authorize service

through posting or publication, but only when individual service is "impracticable."

After consideration of these comments, HHS/CDC has modified the provisions regarding requirements relating to *issuance of a Federal order for quarantine, isolation, or conditional release* (§§ 70.14 and 71.37). Paragraphs (a)(5) and (4) of these provisions have been modified, respectively, to require that the federal order include an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense. Paragraph (b) of these provisions has been modified to require that a Federal public health order be served within 72 hours of an individual's apprehension. A new provision, paragraph (c), has been added requiring that the Director arrange for translation and interpretation services of the Federal order as needed.

h. Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional Release

A number of commenters were confused regarding the 72-hour period, believing this period referred to the period of apprehension pending the issuance of a Federal public health order and asked why 72 hours were needed. The 72-hour period proposed referred to the timeframe in which HHS/CDC must conduct a mandatory reassessment of the continued need for isolating or quarantining an individual following the service of a Federal public health order. However, in response to public comments HHS/CDC has also added in sections 70.14(b) and 71.37(b) a requirement that it serve the individual with a Federal public health order within 72 hours of that individual's apprehension.

Some commenters, including a public health association, supported the mandatory 72-hour reassessment provision guaranteed by these regulations. One of these commenters also suggested the time be re-evaluated periodically in the event that technology provides a way of speeding up the diagnosis process; another suggested the time frame be expanded to five days to account for weekends; one more commenter noted that circumstances may arise where an additional 72 hours may be needed; and another commenter stated that a second 72-hour reassessment should be required. HHS/

CDC is committed to performing a reassessment within 72 hours of the federal public health order being served on the individual. If, at that time, HHS/CDC determines that the order was properly issued and that a public health risk continues to exist, the order would either be continued or HHS/CDC would work with the State and local health department to transfer custody. In the event that HHS/CDC continues the order, the individual may request a medical review at that time.

A few commenters stated that the reassessment of HHS/CDC's orders should be conducted in a shorter time period than 72 hours such as within 12 hours, performed electronically and conducted by a 3rd party. While HHS/CDC appreciates the input provided by these commenters, HHS/CDC finds these suggestions impractical. Medical examination to confirm or rule out infection with a quarantinable communicable disease may require up to 72 hours to allow for laboratory testing. While some communicable diseases (typically viral infections) may be diagnosed using molecular tests such as polymerase chain reaction (PCR) that take several hours to perform, others require that the organism be cultured to make a confirmed diagnosis or to conduct antimicrobial sensitivity testing in order to provide appropriate treatment. This is typically needed for bacterial infections, such as diphtheria or plague, and may take 48–72 hours (or longer) to complete. For some infectious tuberculosis cases, laboratory confirmation may take several weeks although preliminary molecular testing may assist in conducting an assessment of risk sufficient to continue or rescind the order. Specimen transportation time may also need to be factored in as testing for certain diseases is only available at state public health laboratories or CDC.

While HHS/CDC is required by this provision to reassess the need for a Federal public health order within 72 hours, HHS/CDC will immediately release individuals from detention if at any time it receives information confirming the absence of infection with a quarantinable communicable disease. We note that while the medical assessment is intended primarily as a review of available medical records and other relevant information, these regulations do not prohibit HHS/CDC from conducting the review electronically, for instance by relying on electronic medical records. Furthermore, HHS/CDC disagrees that relying on internal decision-makers for the reassessment is inappropriate or undesirable and thus does not consider

it necessary to rely on a “3rd party.” However, the CDC official or employee conducts the reassessment will not be the same person who issued the quarantine, isolation, or conditional release order. Following the reassessment, the detained individual may also request a medical review as described in these regulations.

HHS/CDC received a comment from a public health agency requesting clarification as to whether all individuals within a group will receive individual due process when a group order is issued. This agency also questioned the feasibility of providing a mandatory reassessment and medical review for large groups. In response, HHS/CDC confirms that if a group order is issued, all individuals within that group will be accorded due process. Furthermore, HHS/CDC has provided flexibility in the regulations to allow for a mandatory reassessment of the group order and consolidation of medical reviews where appropriate.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that while the rule requires consideration of least restrictive means upon reassessment of an order and as part of the medical review, HHS/CDC must also consider least restrictive means prior to the issuance of a quarantine or isolation order. HHS/CDC agrees that all means short of assuming legal custody of the individual including attempting to obtain voluntary compliance with public health measures should be explored. HHS/CDC notes, however, that an isolation or quarantine order is typically issued in time-sensitive situations where because of the exigent circumstances surrounding the risk of communicable disease spread it is not immediately possible to explore all available less restrictive means, including the appropriateness of a home environment, instead of a hospital. For this reason, HHS/CDC has chosen the mandatory reassessment and medical review as the appropriate time to conduct a formal assessment of least restrictive means. To the extent that the commenters suggest that due process requires more, we disagree. *See Yin v. California*, 95 F.3d 864, 870 (9th Cir. 1996) (recognizing that in searches and seizures justified by special needs, the government does not have to use the least restrictive means to further its interests); *Stockton v. City of Freeport, Texas*, 147 F.Supp.2d 642, 647 (S.D. Tex. 2001) (recognizing that the Fourth Amendment does not require that a search or seizure be conducted through the least restrictive means, but rather that the alleged personal invasion be

reasonable under all of the circumstances).

After consideration of these comments, HHS/CDC has finalized the provisions relating to *mandatory reassessment of a Federal order for quarantine, isolation, or conditional release* (§§ 70.15 and 71.38) as proposed.

i. Medical Review of a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received several comments arguing that its proposed medical review procedures are deficient. Specifically, one commenter stated that assessment procedures should be clearly communicated to all affected persons; that HHS/CDC should more clearly delineate “less restrictive alternatives;” that affected individuals should have a right to legal representation; and that access to independent judicial review is essential.

HHS/CDC agrees that it should clearly communicate review procedures to individuals subject to Federal isolation, quarantine, or conditional release. We note that sections 70.14 and 71.37 have been modified to require that the federal order authorizing isolation, quarantine, or conditional release include an explanation that the federal order will be reassessed 72 hours after it is served on the individual and of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense. We further note that the provisions relating to medical reviews, sections 70.16 and 71.39 have been revised to include new paragraphs (q) which states that “The Director shall arrange for translation or interpretation services as needed for purposes of this section.”

Similarly, in regard to minor children or adults with a cognitive disability, HHS/CDC will work with a competent guardian to ensure that procedures are clearly communicated. In regard to less restrictive alternatives, HHS/CDC believes that it is not possible to delineate with specificity all of the less restrictive options that may be available because such determinations will inevitably be based on the individual circumstances of each case, including the severity of the particular disease-causing agent, availability of treatment options should the disease not be adequately contained, the patient’s particular level of infectivity or

communicability, appropriateness of the home environment, and the individual patient’s understanding, ability, and willingness to comply with less restrictive alternatives. For this reason, HHS/CDC has made consideration of less restrictive alternatives a part of the medical review proceeding where evidence may be submitted into the record, testimony obtained, and a recommendation provided by the medical reviewer. As a general matter, however, HHS/CDC clarifies that less restrictive alternatives would refer to reasonable and available alternatives that are adequate to protect the public’s health other than confinement in a guarded facility, such as home quarantine, directly observed therapy, or other forms of supervised release.

In response to concerns about legal representation, HHS/CDC has amended the definition of “Medical representative” to “Representatives” and will now appoint “an attorney knowledgeable of public health practices” in addition to a “physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases.” HHS/CDC hopes that by appointing both an attorney and a qualified medical professional for indigent individuals it will alleviate concerns expressed by the public regarding the medical review process. We note that an attorney may become “knowledgeable of public health practices” in a number of ways, for instance, through prior representation of a public health agency or advocacy organization, training provided by a public health or advocacy organization or other training that would ordinarily occur through a Continuing Legal Education (CLE) event, law school coursework, or through independent study. We further note that for individuals qualifying as indigent, HHS/CDC intends to provide independent legal counsel from outside of the agency. In doing so, HHS/CDC may employ a variety of mechanisms, such as through agreements or memorandums of understanding with law school legal clinics, State or local bar associations, or public interest groups representing indigent clients. Individuals who do not qualify as indigent may choose to be represented at the medical review by an advocate (e.g., an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense.

HHS/CDC also agrees that access to independent judicial review is essential and assures the public that this final rule does not affect the constitutional or statutory rights of individual to seek

judicial review through such traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. As a Federal agency, however, HHS/CDC would lack the legal authority through regulation to grant Federal courts with jurisdiction that they would not otherwise possess because only Congress may expand a Federal court's jurisdiction.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that the CDC Director should not have unfettered discretion to accept or reject the medical reviewer's decision, but rather should only be allowed to reject a decision based on lack of substantial evidence. HHS/CDC believes that it would be inappropriate to mandate through regulation that the decision of a medical reviewer (which may include an HHS or CDC employee) should displace the decision of the CDC Director, particularly where the statute and delegation of authority have provided otherwise.

HHS/CDC received several comments stating that a medical representative should be appointed to anyone regardless of their ability to pay. HHS/CDC disagrees and notes that appointment of a representative at the government's expense without regard to the patient's indigence is not required. The status of "indigent" is self-reported as HHS/CDC will not require access to an individual's financial records. Those who self-identify as indigent may be required to sign an affidavit or declaration under penalty of perjury stating they meet the threshold of at least 200% of the applicable poverty guidelines.

HHS/CDC received a comment from a non-profit organization contending that the medical review does not comport with due process because there is no limit on the number of reviews that may be consolidated into a single proceeding, no access to legal counsel, no independence of the reviewer from the initial decision-maker, no confrontation or cross-examination of witnesses, no compulsory process for obtaining evidence or testimony, and no judicial review. This group contends that any detention that is non-exigent should occur only based on the "informed explicit written consent" of the patient or "utilize the existing legal procedures for involuntary commitment of persons."

HHS/CDC disagrees that the medical review as described and set forth in the regulations does not comport with due process. While HHS/CDC acknowledges that there is no numerical limit to the number of medical reviews that may be

consolidated, HHS/CDC believes that the circumstances giving rise to the need for consolidation will be exceedingly rare and that medical reviews will generally be conducted on an individual basis.

HHS/CDC also disagrees that there is no access to legal counsel because HHS/CDC will, consistent with principles of preventing communicable disease spread, allow persons subject to public health orders to communicate with family and legal counsel whom they hire at their own expense. Furthermore, as described above, the regulations have been amended to require the appointment of *both* an attorney *and* a medical professional if the detained individual qualifies as an indigent and requests a medical review. Individuals who do not qualify as indigent may also choose to be represented at the medical review by an advocate (*e.g.*, an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense.

HHS/CDC further believes that reliance on internal reviewers does not violate due process and notes that it is not unusual, for instance, for hospitals to rely on internal decision-makers when determining whether to commit a mental health patient on an emergency basis. The regulations, moreover, explicitly state that the medical reviewer will not be the same individual who initially authorized the quarantine or isolation order. We note further that the definition of both "representatives" and "medical reviewer" would in fact allow for the appointment of non-HHS/CDC employees in these capacities because both terms are broadly defined in terms of the professional qualifications and not employment status of these individuals. Thus, these regulations do not prohibit the CDC Director from appointing personnel from outside of the agency to assist in conducting a medical review. For individuals qualifying as indigent, HHS/CDC intends, generally, to provide independent legal counsel from outside of the agency.

HHS/CDC also clarifies that during the course of a medical review, a detained individual will be permitted to present witnesses and question any witnesses offered by HHS/CDC. Any "confrontation" of witnesses, however, will be conducted in a manner consistent with principles of preventing communicable disease spread. HHS/CDC, as a Federal agency, however lacks the legal authority to allow a detained individual to use compulsory processes, such as a subpoena, to compel the presence of witnesses. HHS/CDC will

nevertheless make reasonable efforts to produce any HHS/CDC employees that would be critical to a detained individual's presentation of evidence during a medical review.

HHS/CDC also disagrees that there is no judicial review and notes that these regulations do not impact an individual's constitutional or statutory rights to contest their Federal detention through such traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. To the extent, however, that the commenter contends that HHS/CDC should follow legal procedures other than those set forth through the Federal quarantine statute at 42 U.S.C. 264, we disagree. HHS/CDC notes that as a Federal agency it lacks the ability to rewrite Federal statutes or grant Federal courts with legal jurisdiction that they do not already possess. HHS/CDC also rejects as impractical and as insufficient to protect public health, the notion that isolation or quarantine should only occur based upon the consent of the subject individual.

HHS/CDC received a comment from a flight attendant union that as an important "safety net" HHS/CDC should pay for "second medical opinions." HHS/CDC declines to extend payment to medical examinations beyond those required as part of a public health order, but notes that as part of a medical review individuals may submit additional evidence into the record concerning their health status and potential public health risk to others.

One commenter noted language in the NPRM stating that the "medical review is not intended to address the concerns of individuals who take issue with amenities of their confinement . . .," interpreting this to mean that "no provision is made for those who must use a CPAP (continuous positive airway pressure) at night or who need orthopedic appliances, or who have food allergies, to name a few." In response, HHS/CDC states that, when confinement of an individual under Federal public health authorities is needed, HHS/CDC will ensure that such confinement will occur in a location and with necessary amenities to ensure the health and safety of the individual, including provision for medical or dietary requirements. Issues related to health and safety will be addressed at the time of the issuance of the order, or as soon as HHS/CDC is made aware of them, but are beyond the scope of the medical review which is intended to re-evaluate the continued need for the Federal public health order based on a review of the medical and other evidence submitted into the record.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that it should provide for an oral hearing whenever practical. HHS/CDC agrees that an oral hearing is appropriate and has modified the language to state: “The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.”

HHS/CDC received a comment from a partnership of public health legal scholars and organizations that the CDC Director’s written order, which constitutes final agency action, must advise individuals of their rights to appeal to Federal court. We note that the commenters specifically cite the Administrative Procedures Act (APA, 5 U.S.C. 704), which provides that “final agency action for which there is no other adequate remedy in a court are subject to judicial review.” While HHS/CDC agrees that independent judicial review of agency decisions is available, it takes no position as to whether such reviews should occur under the APA (as suggested by the commenters) or through other traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. For this reason, HHS/CDC believes that due process is satisfied by designating the Director’s written order as “final agency action” without further speculation as to the exact form of further legal review. However, to clarify HHS/CDC’s intended we have added the following language to the regulatory text: “Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.”

Accordingly, after consideration of these comments, HHS/CDC has modified paragraph (f) of the provisions regarding *medical review of a Federal order for quarantine, isolation, or conditional release* (§§ 70.16 and 71.39) to include the revised definition of “Representatives,” which now requires HHS/CDC to appoint both a medical professional and an attorney “to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent and cannot afford a representative.”

j. Administrative Records Relating to a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received a comment from a flight attendant union concerning whether an overlap existed between CDC’s maintenance of administrative records relating to the issuance of Federal public health orders and an employee’s access to exposure and medical records under OSHA (29 CFR 1910.1020). We note that since HHS/CDC is not a flight attendant’s employer, HHS/CDC would not be covered by this particular OSHA standard under these circumstances. Furthermore, because these regulations do not alter, define, or mandate the employer-employee relationship between flight attendants and their employers, to the extent that this question seeks input regarding an employer’s obligations under OSHA, HHS/CDC views the question as outside the scope of the rulemaking.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that the regulations should require quarterly reporting to Congress to facilitate transparency and oversight. While CDC recognizes the additional transparency that direct reporting of details related to quarantine activities may provide to the public, CDC notes that historically, the issuance of Federal orders is rare (*i.e.*, one to two orders issued per year). Thus, publication of the specifics surrounding individual quarantine cases may raise significant privacy concerns related to the individuals placed under federal orders.

CDC does routinely describe its practices in published Morbidity and Mortality Weekly Reports (MMWR) when new methods, technologies, or other changes make it possible to revise and improve programs (*e.g.* DNB, M&M guidance, change in air contact investigation algorithms), which all serve to enhance transparency. Such information is also found on CDC’s Web site and publicly available standard operating procedures.

After consideration of comments received and as further explained below, HHS/CDC has modified the provisions regarding *Administrative Records* relating to a Federal order for quarantine, isolation, or conditional release (§§ 70.17 and 71.29) to remove paragraphs (5) regarding agreements entered into between HHS/CDC and the individual.

k. Other Due Process Concerns

HHS/CDC received many additional comments from the public concerned over whether this regulation violates

rights guaranteed by the U.S. Constitution, such as Due Process and specifically during the medical review process. HHS/CDC disagrees that the regulations are insufficient to protect the constitutional rights of individuals. In regard to medical reviews, HHS/CDC asserts that allowing individuals to choose at the government’s expense who will conduct the medical review is not required by due process and that there is no conflict of interest in allowing the CDC Director to appoint who will conduct the medical review on the agency’s behalf. HHS/CDC asserts, however, that individuals will be allowed to submit relevant information, including information provided by outside doctors or other medical specialists during the medical review. HHS/CDC will further preserve relevant agency documents for purposes of ensuring a competent legal review in the event that the individual seeks judicial redress of their quarantine or isolation. As explained elsewhere, law enforcement support for quarantine or isolation orders will generally be provided by U.S. Customs and Border Protection, U.S. Coast Guard, or other Federal law enforcement programs, but HHS/CDC may also accept voluntary state and local assistance in enforcing its Federal orders.

HHS/CDC received public comment expressing concern with regard to potential language barriers experienced by foreign nationals during travel. HHS/CDC responds that it has revised those sections of the regulations dealing with issuance of Federal orders to require that HHS/CDC arrange for translation or interpretation services of the Federal order as needed. In circumstances where it would be impractical to provide a line-by-line translation of the order, HHS/CDC may take other steps to reasonably apprise individuals of the contents of the order, for example, by arranging for oral translation services.

One public health organization questioned the feasibility of CDC’s conducting the mandatory reassessment or medical review of a group quarantine order within the specified time frame. In response, HHS/CDC states that a group quarantine order would be issued on the basis of a shared exposure for all individuals in the group; therefore, the mandatory reassessment or medical review could be conducted based on the shared exposure, unless certain individuals in the group were determined to be immune to the quarantinable communicable disease in question. Part of the reassessment would include a determination of whether the group order should be revised as individual orders.

HHS/CDC also received a comment that the duration of a quarantine, isolation, or conditional release period is not adequately defined. HHS/CDC disagrees because the regulations limit these actions to only those who would pose a public health threat, for instance, by being in the “qualifying stage” or a quarantinable communicable disease. The “qualifying stage” of the disease is defined as a communicable stage of the disease or a precommunicable stage, but only if the disease would be likely to cause a public health emergency if transmitted to other individuals. We note that HHS/CDC’s “Health Information for International Travel” (also known as the Yellow Book) provides the public with general guidance regarding the expected length of communicability for many quarantinable communicable diseases. For more information, please see <http://wwwnc.cdc.gov/travel/yellowbook/2016/table-of-contents>.

HHS/CDC received a comment that the qualifications of who may issue a quarantine or isolation order are not defined leading to concerns that such orders will be issued by non-medically trained personnel. In regard to the qualifications of who may issue a Federal public health order, HHS/CDC notes that all orders are issued under the authority of the CDC Director, but that in practice such determinations are made only by personnel trained in public health and licensed to practice medicine in the United States.

One organization requested that HHS/CDC provide notification to the appropriate embassy if a foreign national is placed under a Federal order. In regard to non-resident foreign nationals, HHS/CDC clarifies that it will coordinate closely with the U.S. Department of State to ensure that all rights and obligations under the Vienna Convention on Consular Relations and bilateral agreements will be observed. Because of the complexity of this issue, including reliance on the interpretation of treaties and bilateral agreements, HHS/CDC believes that it is best to ensure compliance through operational procedures, rather than to formalize such obligations through regulatory text.

One commenter requested that HHS/CDC clarify its handling of issues relating to diplomatic immunity. HHS/CDC recognizes that under the Vienna Convention on Diplomatic Relations, diplomats are not liable to any form of “detention.” It is HHS/CDC’s policy to coordinate closely with the U.S. Department of State regarding any public health issues arising in regards to diplomats and HHS/CDC will continue to do so under these regulations.

One public health organization recommended that HHS/CDC include written notification to individuals under public health orders of the duration that the order will be in effect. HHS/CDC responds that it will provide information on the incubation and communicability period of the quarantinable communicable disease, if known, but that the duration of the public health order may depend on a variety of factors, such as demonstration of non-infectiousness through repeated laboratory testing. Thus, HHS/CDC is unable to provide an exact numerical limit (in terms of days or hours) that a public health order will remain in effect.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that in exigent circumstances HHS/CDC may isolate or quarantine an individual, but should then be required to hold a mandatory due process hearing within 48 hours before a neutral decision-maker. At the outset, HHS/CDC agrees with the commenters that the appropriate framework for determining the adequacy of due process procedures are the factors articulated by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976). These factors include: (1) The private interest affected by the government’s actions; (2) the risk of erroneous deprivation of such private interest through the procedures used and the probable value, if any, of additional or substitute procedures; and (3) the government’s interest, including the function involved and the fiscal and administrative burden of proposed additional or substitute procedures. Concerning the private interest at stake, HHS/CDC disagrees that this interest should be measured solely in terms of the physical liberty of the individual, but notes that the private interest also includes an interest in receiving medical treatment and in not harming others, as would occur if the individual was communicable. The Federal government’s interest, moreover, is particularly strong because it is not simply guarding the welfare of a single individual or even a small group of individuals, but rather protecting the public at large against the spread of a quarantinable communicable disease. Most importantly, HHS/CDC believes that mandatory administrative hearings are unlikely to significantly guard against erroneous deprivations. Unlike subjective determinations of behavior which typically form the basis of a mental health “civil commitment,” isolation and quarantine decisions are based on objective criteria such as

manifestations of physical illness or laboratory test results. Thus, weighing these factors, HHS/CDC disagrees that due process requires it to adopt a system of mandatory administrative hearings in the absence of the individual requesting a medical review.

Regarding the use of a “neutral” decision maker, HHS/CDC restates that the definition of both “representatives” and “medical reviewer” would in fact allow for the appointment of non-HHS/CDC employees in these capacities. The regulations, moreover, explicitly state that the medical reviewer will not be the same individual who initially authorized the quarantine or isolation order. Accordingly, HHS/CDC has determined that the procedures it has adopted for medical reviews comport with due process.

1. Privacy

Several people commented on the private nature of the doctor-patient relationship. HHS/CDC appreciates the opportunity to respond to this concern. HHS/CDC is charged with protecting the health of the public. At times, this requires obtaining private information about people’s health or exposure history and taking certain actions to protect others from becoming sick with a communicable disease. HHS/CDC works closely with State and local health departments to ensure that ill people detained or isolated under Federal orders receive appropriate care and treatment. HHS/CDC is also bound by the Privacy Act to protect personally identifiable information collected and maintained under that Act. For a more detailed explanation of how such information is protected, please see <http://www.cdc.gov/sornnotice/09-20-0171.htm>. For information on the retention and maintenance of such records, please see <https://www.archives.gov/records-mgmt/rcs>.

HHS/CDC received a comment from a professor of public health law and ethics stating that HHS/CDC should address how the HIPAA Privacy Rule, Americans with Disabilities Act (ADA), and Administrative Procedure Act (APA) counterbalance the powers set forth in the proposal and reflect “appropriate social distancing practices.” The commenter did not highlight which specific provisions of these laws HHS/CDC should address or the relationship that these laws have to social distancing. Notwithstanding, HHS/CDC may generally state that these regulations will be carried out consistent with Federal law.

We note that HHS is a hybrid entity under HIPAA, but only those parts of the Department that have been

determined to be health care components are subject to the HIPAA Privacy Rule. CDC is generally not a health care component treated as a “covered entity” under the HIPAA Privacy Rule. However, certain specific offices of HHS, CDC, and the National Institute for Occupational Safety and Health (NIOSH) performing activities related to the World Trade Center Health Program are considered health care components of HHS and must comply with HIPAA and the Privacy Rule.

CDC most often acts as a public health authority under the HIPAA Privacy Rule. During the course of a public health investigation it may seek the support of a covered entity, such as a hospital or private physician. The HIPAA Privacy Rule permits the disclosure of public health information to public health authorities, such as the CDC, and their authorized agents for public health purposes including but not limited to public health surveillance, investigations, and interventions. More information concerning the HIPAA Privacy Rule may be found here: <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.

Similarly, we note that this final rule while formalizing administrative policies and practices, does not affect the rights of individuals under the ADA or APA, which are statutes enacted by Congress. One commenter opined that collection of contact information as part of public health prevention measures and maintenance of administrative records raise privacy concerns and that HHS/CDC should consider “super-enhanced privacy protections” consistent with the Model State Public Health Privacy Act of 1999. HHS/CDC disagrees. As a Federal agency, HHS/CDC must abide by the laws established by Congress for the protection of records, specifically the Privacy Act of 1974, 5 U.S.C. 552. On December 13, 2007, HHS/CDC published a system of records notice (72 FR 70867) under the Privacy Act describing, among other things, safeguards for preventing the unauthorized use of information collected from travelers. HHS/CDC will make disclosures from this system only with the consent of the subject individual, in accordance with routine uses published in its system notice, or in accordance with an applicable exception under the Privacy Act.

m. Payment for Care and Treatment

HHS/CDC received several comments relating to payment for medical expenses. One commenter stated that HHS/CDC should assume payment for

all related medical expenses, housing costs, and other necessities for individuals or groups subject to deprivations of liberty and that it is “ethically unfair” for HHS/CDC to be the “payer of last resort.” Another commenter stated that “CDC must guarantee financial help after third party payments are exhausted.” While HHS/CDC acknowledges that it has an ethical, moral, and legal obligation to provide care and treatment for individuals under a Federal quarantine or isolation order, HHS/CDC disagrees that it is “ethically unfair” to excuse a medical insurer or other entity with a contractual obligation from paying for medical expenses. Accordingly, HHS/CDC has determined that it is appropriate for it to maintain and affirm its status as a “payer of last resort.”

Two public health organizations asked whether nonmedical costs such as training of staff, replenishing of personal protective equipment, managing and disposing of biological waste and contaminated supplies, etc., are also subject to HHS/CDC payment authorization. While the costs of care and treatment of individual patients under Federal public health orders are authorized by this rule, these additional costs to the extent that they are unrelated to the individual patient’s treatment and care would not be covered by this rule.

HHS/CDC received a comment suggesting that the regulations allow for charging detainees the medical and hospital costs of nonconsensual treatment. HHS/CDC disagrees and first, clarifies that these regulations do not authorize compulsory medical treatment. HHS/CDC further acknowledges that constitutional principles and medical ethics require that those detained under isolation or quarantine have access to adequate nourishment, appropriate accommodation, and medical treatment. However, HHS/CDC has determined that its obligation to pay for medical care and treatment should be secondary to the obligation of any third party, such as a medical insurer that may have a pre-existing contractual obligation with the patient to pay for hospital expenses. Accordingly, HHS/CDC declines to make any changes to the provisions authorizing payment for medical care and treatment.

A flight attendant union commented that HHS/CDC should pay for any outside costs that the flight attendant would normally incur relating to medical treatment, e.g., copayments, deductibles. HHS/CDC declines this suggestion and notes that while it is not HHS/CDC’s intent to unduly burden

individuals with the costs of their own isolation or quarantine, payment for expenses will be made consistent with constitutional and ethical obligations to provide for the basic necessities, e.g., food, medical treatment, for those subject to such public health orders. Furthermore, these regulations do not alter, define, or modify the contractual relationship between insurance companies and the insured.

After consideration of these comments, HHS/CDC has finalized the provisions relating to payment for care and treatment (§§ 70.13 and 71.30) as proposed.

n. Agreements

HHS/CDC received comments relating to the intention and use of agreements. Commenters worried that such “agreements” may be coerced, and individuals would be compelled to submit to involuntary testing or “research projects.” One commenter stated that the definition of agreement is circular and confusing because the word “agreement” appears in the definition. This commenter also suggested that what HHS/CDC proposes should more aptly be labeled as an “Affidavit” or “Affirmation” because the definition as proposed by HHS/CDC lacks bilateral obligations on both parties.

Due to the number of public comments received expressing confusion over this public health measure, HHS/CDC has removed the provisions on *Agreements* (70.18 and 71.40), and modified other provisions of the final rule (70.1, 71.1(b), and 70.5) to remove references to “agreements.”

o. Penalties

Many commenters expressed concern over the penalties provisions contained within the proposed regulation. Specifically, one association objected to “CDC’s proposed increase in penalties.” Another stated that “CDC is not qualified to decide upon the punishment.” HHS/CDC takes this time to better explain that the penalties listed in today’s final rule, which have been codified as proposed, are set forth by Congress via statutory language and codified into regulation to reflect current practice. This regulation serves to notify the public of the existing statutory penalties for violation of quarantine regulations, which HHS/CDC has no authority to change.

One organization requested that language be added to rules regarding the issuance of penalties if an employer provides an “unsafe work or unhealthful working condition.” HHS/CDC responds that such penalties are beyond the scope of this rule and refers

the commenter to regulations of the Occupational Safety and Health Administration.

HHS/CDC received a comment from a flight attendant union regarding criminal penalties stating that HHS/CDC should provide further clarification as to what constitutes a violation and clarify that flight attendants who act in accordance with their company's practices, policies, or procedures should not be held criminally liable. In response, HHS/CDC notes that while the text of the regulation is being updated, these regulations do not increase the criminal penalties that may be imposed for violations of quarantine regulations or alter the manner in which liability may be assessed. Rather, these regulations serve to inform the public of the criminal penalties that currently exist in statute (42 U.S.C. 271 and 18 U.S.C. 3571). Furthermore, HHS/CDC clarifies that criminal penalties, if any, would be assessed by a court of law based on an indictment or information filed by an Assistant U.S. Attorney based on individualized facts and circumstances, and would not be determined administratively by the CDC.

HHS/CDC offers the following explanation to inform the public regarding this section. As prescribed in section 368 (42 U.S.C. 271) and under 18 U.S.C. 3559 and 3571(c), criminal sanctions exist for violating regulations enacted under sections 361 and 362 (42 U.S.C. 264 and 265). 18 U.S.C. 3559 defines an offense (not otherwise classified by letter grade) as a "Class A misdemeanor" if the maximum term of imprisonment is "one year or less but more than six months." 18 U.S.C. 3571 provides that individuals found guilty of an offense may be sentenced to a fine. Specifically, an individual may be fined "not more than the greatest of"—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in death, not more than \$250,000; or (3) for a Class A misdemeanor that does not result in death, not more than \$100,000. Similarly, an organization, found guilty of an offense may be fined "not more than the greatest of"—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in a death, not more than \$500,000; or (3) for a Class A misdemeanor that does not result in death, not more than \$200,000. 42 U.S.C. 271 sets forth statutory penalties of up to 1 year in jail and a fine of \$1,000. Therefore, it is classified as a Class A misdemeanor under 18 U.S.C. 3559. Because the alternate fines set forth under 18 U.S.C. 3571 are greater

than the \$1,000 set forth under 42 U.S.C. 271 (which sets a maximum penalty of not more than \$1,000 or one year of jail, or both for violation of quarantine laws), and because 42 U.S.C. 271 does not exempt its lower penalties from 18 U.S.C. 3571(e), HHS/CDC has chosen to codify the greater penalties of 18 U.S.C. 3571(b)(5) and (c)(5) and to remove the lower penalties as stated in 42 CFR 71.2 from the regulation.

After consideration of these comments, HHS/CDC has finalized the provisions relating to *Penalties* (70.18 and 71.2) as proposed. *Penalties* has been moved to section 70.18, since proposed 70.18 *Agreements* has been removed from this final rule.

p. Economic Impact

Within the analysis published with the NPRM, HHS/CDC solicited public comment regarding the cost and benefit estimates for airlines and vessel operators associated with improved provision of traveler contact data. While HHS/CDC received support for the data collection from two public health associations, HHS/CDC received a comment from industry who misread the proposals to mean that aircraft operators would be required to develop new capacity and processes to capture and store a comprehensive set of sensitive data, archive this data, and then provide it to CDC.

HHS/CDC restates and clarifies that today's final rule does not impose any new burdens upon the airline industry but rather, codifies the current practice of receiving a passenger manifest order (if needed, as CDC currently collects passenger information from CBP via APIS and PNR) and providing HHS/CDC with any data in an airline's possession. This regulatory impact analysis has been revised to clarify that the rule does not require an airline to solicit or store additional data. Therefore, HHS/CDC does not expect that formalizing its current data collection practices will increase costs. Neither airlines nor U.S. Customs and Border Protection (CBP) will need to develop new data systems nor will travelers need to provide data as part of the "check in process."

The same industry organization also commented that they have been complying effectively with the existing requirements, but have, on occasion found it difficult to locate, extract, compile, format and transmit available information within the timeframe specified in orders from HHS/CDC. They note that delays sometimes arise because the manifest order may contain incorrect flight or passenger information. The discussion in the regulatory impact analysis section has

been revised to note that delays in compliance with manifest order requirements may result from HHS/CDC having incorrect traveler information in the manifest order.

The same industry organization also reports that all of the data available to them related to passengers are currently transmitted as Advance Passenger Information System (APIS), and potentially under Passenger Name Record (PNR), data to the Department of Homeland Security (DHS) and that there is no reason to burden airlines with an order for passenger data. HHS/CDC recognizes that industry does submit certain passenger data to DHS and it is not our intent to burden industry with duplicative requirements, but rather to effectively and efficiently protect public health. In the experience of the HHS/CDC, queries from APIS/PNR rarely result in full sets of contact information (*i.e.* the record includes all five additional data fields as outlined in the final rule). The data fields that are most commonly missing from the records are email addresses (missing 90 percent of the time), secondary phone number (missing 90 percent of the time), and street addresses (missing or insufficient for public health contact tracing up to 50 percent of the time). These data elements are vital to a contact tracing investigation. In looking at a random sample of 20% of the compiled international air travel manifests for 2015, those including a compiled data set from NTC and the airlines, 100% were missing at least one of the 5 data fields. Email address and secondary phone number were among those most frequently missing. For context, there were approximately 760,000 scheduled flights that arrived into the United States in 2015. In 2015, CDC issued passenger manifest requests for 64 international flights arriving into the United States. As noted in the RIA of the final rule, from 2010 to 2015, CDC conducted an average of 77 contact investigations per year involving arriving international flights.

Airlines are contacted for the majority of contact investigations using a manifest order document. At a minimum, CDC needs to confirm the ill traveler was on the flight and where the individual sat in relation to other travelers to determine risk of exposure.

In CDC's experience the following has been true:

- Only airlines can quickly and efficiently produce a partial manifest targeting affected rows;
- only airlines can confirm identity of "babes in arms" and their co-travelers (Parent); this is important for measles cases;

- only airlines can quickly confirm whether an individual actually flew (in instances where individuals deplane and do not re-board during a layover); and

- only airlines can confirm a plane's configuration if there is a question with the provided row numbers. Different aircraft have different seating arrangements depending on carrier and layout. It is important to know if a certain seat is separated by a bulkhead or is a window seat.

In addition, HHS/CDC only requires a partial manifest, e.g. 5 rows for travelers with infectious tuberculosis, so that NTC and HHS/CDC staff can limit the investigation to only those passengers at risk and supplement/cross reference with APIS and PNR data. If a partial manifest is not available from the airlines, then each passenger record must be researched individually to find a seat number, and then the configuration of an entire plane must be populated to determine where the index case sat in relation to other at-risk passengers. For large flights from Asia, this can pose a tremendous burden to NTC and CDC staff while slowing the ability of CDC to provide important contact information to state and local health departments. Manually populating multiple 300+ person flights is not feasible in a timely manner.

As part of its plan for retrospective analysis under E.O. 13563, HHS/CDC intends to synthesize, analyze, and report within the next two years on strategies to reduce duplication of the collection of passenger/crew manifest information in coordination with DHS/CBP. The report will include any recommendations (e.g., IT systems improvements to facilitate enhanced search capabilities of passenger data, increased efficiency to relay passenger data, improvements to the existing CDC-CBP MOU) to ensure that the collection of passenger or crew manifest information do not unduly burden airlines, vessels, and other affected entities. HHS/CDC intends to seek public comment on the report and any recommendations regarding the costs and benefits of activities implemented in 42 CFR parts 71.4 and 71.5. Estimates of both costs and benefits in the NPRM regulatory impact analysis were not very large because HHS/CDC is not implementing a new data collection requirement. The regulatory impact analysis for the final rule has been revised to reflect that HHS/CDC will work with CBP to search for responsive data to avoid duplicative data requirements. Estimates of costs in the revised regulatory impact analysis have not been revised because the airline

industry did not provide any new information regarding costs to search for responsive data when receiving manifest orders. The benefit estimate has been revised and is lower than the estimate for the NPRM to indicate that the airlines may not have any more contact data than is already provided in APIS or PNR data submitted to DHS.

HHS/CDC received a number of comments from the general public that compared the relatively small number of measles cases in any given year to the total numbers of vaccine-associated adverse events and health department spending to contain measles outbreaks. Based on this comparison, commenters believed that HHS/CDC and health departments spend too much money on communicable disease control and that resources would be better allocated to other activities. Some commenters suggested that the costs of these adverse events should be included in a Small Business Regulatory Enforcement Fairness Act analysis. In general, this type of analysis is outside the scope of this regulatory impact analysis because this final rule does not require measles vaccination. HHS/CDC's recommended vaccine schedule will not be affected by this final rule. Although HHS/CDC recommends that health departments offer measles vaccine to non-immune individuals exposed during travel, measles is not a quarantinable communicable disease and this final rule does not require any individual to receive a measles vaccine. Because health departments offer measles vaccines to exposed, non-immune travelers, HHS/CDC estimates that the final rule will only result in a small number (6) of additional measles vaccines. The costs of procuring and administering these vaccines is included in the analysis.

As noted in the regulatory impact analysis, there are only 564 travelers exposed to measles during international travel in a given year. Most of these travelers will already have immunity to measles and the final rule is only expected to have a small impact on the ability of health departments to contact travelers. The total costs of all measles vaccine-associated adverse events is outside the scope of the analysis for this final rule as mentioned above.

One commenter suggested that the cost estimates for the NPRM were too low because the analysis did not account for reduced willingness to travel if vaccines against measles and other communicable diseases are required to travel. HHS/CDC disagrees with this suggestion because vaccination is not a requirement in this final rule. HHS/CDC has on occasion

requested that DHS/TSA restrict interstate or international air travel for people known to be infectious with measles who were noncompliant with public health recommendations not to travel. However, HHS/CDC does not recommend restricting the air travel of persons who have not received the measles vaccine.

One commenter questioned whether the estimated value of statistical life (\$9.4 million) should be multiplied by the total number of measles vaccine-associated adverse events in the United States. HHS/CDC appreciates this thoughtful comment. This would result in a larger estimate in the cost of measles vaccine-associated adverse events. However, this is not a correct usage of the value of statistical life, which should only be multiplied by an estimated number of deaths. The regulatory impact analysis has been revised to better explain this distinction.

Another commenter suggested that public health department measles response costs were overestimated by using a model-based approach rather than estimating the cost of hiring of additional staff to deal with measles outbreaks. HHS/CDC addressed the comment in the regulatory impact analysis by clarifying that the analysis is a published model-based analysis and that the cost estimate is based on the opportunity cost of public health personnel and is not based on the cost of hiring additional staff.

HHS/CDC received comments from the airline industry indicating that the definition of ill person under 71.1 does align with Note 1 to Standard 8.15 of ICAO's Annex 9 to the Convention on International Civil Aviation. HHS/CDC also received comments from the airline industry regarding the change to the definition of ill person under 70.1 for interstate flights contending that these changes would increase costs. Specifically, the airline industry reported that not only does the expansion of the definition of *ill person* place a greater burden on airline staff, the ambiguity of that definition amplifies the burden or at least raises questions as to the particular obligations of the flight crew to determine if someone is an "ill person." Moreover, the airline industry wanted to know whether flight crews have an obligation to conduct a physical examination of the passenger to determine fever. The airline industry also noted that under the OSHA blood borne pathogens standard, employers are prohibited from exposing crewmembers to blood or other potentially infectious materials. The airline industry also questioned whether the fever-related illness

reporting in the proposal would require that all carriers have the equipment (thermometers) onboard to determine fever. The proposal, as noted, has two other ways to identify fever (warm to touch or history of fever) which the airline industry wanted to ensure would remain viable options within the final rule.

HHS/CDC notes that there is no expectation that flight crews should perform physical examinations as part of illness reporting. HHS/CDC also notes that the non-thermometer (warm to touch or history of fever) remain in the final rule. Regarding the potential for increased costs associated with the change in illness reporting for interstate flights, HHS/CDC notes that the current illness reporting requirements for interstate travel appear in 42 CFR 70.4 and state that “The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.” Communicable disease is defined in current 42 CFR 70.1 as “illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.”

The changes in this final rule will not result in substantially increased costs because airlines would either: (1) Be complying with the current regulatory requirement and report all cases or suspected cases of communicable disease to local health departments; or (2) report illnesses according to HHS/CDC guidance available at <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>, which is codified in this final rule. HHS/CDC notes that changes in this final rule align the symptoms requested for international and interstate illness reporting. In addition, according to guidance, reports received by HHS/CDC would be considered sufficient to satisfy the requirement to report to local health departments because HHS/CDC will coordinate response activities with the local health department after receiving an illness report. In response to these comments, HHS/CDC increased the expected number of illness reports in the upper bound analysis regulatory impact analysis for the final rule. This

upper bound analysis finds that a 100% increase in info-only reports and 50% increase in reports requiring response would result in a marginal cost of \$20,573 for airlines and vessel operators. This cost is negligible compared to the annual revenue of the international air and maritime travel markets. HHS/CDC also received a comment to include the cost of training for illness reporting in the regulatory impact analysis. HHS/CDC notes that illness reporting is already required under existing regulations and the changes in this final rule more closely align with ICAO guidance for illness reporting for international flights and represent a reduction in burden for interstate flights, where reporting of all cases or suspected cases of communicable diseases is required. HHS/CDC added an estimate of training costs to the upper bound cost analysis for airlines (an annualized \$356,000 per year).

HHS/CDC received a comment from a local health department concerning the rationale for reporting all illnesses and deaths that occur on interstate flights. This health department asked whether evaluating illnesses and deaths that occur on interstate flights may lead to an increase in costs for State and local health departments. HHS/CDC does not anticipate an increase in costs for State and local health departments because evaluating illnesses and deaths occurring on interstate flights is consistent with existing HHS/CDC guidance and represents a less restrictive alternative compared to the existing reporting requirement in 42 CFR 70.4. Furthermore, the costs to State and local health departments may decrease if HHS/CDC is able to filter out reports that do not require a public health response, which airlines would have previously reported directly to the health departments under 42 CFR 70.4. If there is an increase in the number of illness reports requiring a public health response, HHS/CDC believes the costs to health departments may decrease if the health department is notified earlier.

A public health research center questioned the value of nonmedical personnel being able to differentiate Ebola, Middle East respiratory syndrome (MERS) or measles from other medical issues. HHS/CDC appreciates the concern and notes that the final rule aligns the illness reporting requirement with international guidelines and represents a reduced burden for illness reporting on interstate flights compared to current regulatory language as mentioned above. The intent of illness reporting is not to diagnose disease during flight, but rather to identify a

limited number of instances in which it would be advantageous to follow up with ill travelers for an assessment upon disembarkation. The current numbers of illness reports received are summarized in the regulatory impact analysis and the number of reports is not expected to increase significantly because the regulatory text will better align with publically available HHS/CDC guidance.

A number of comments from the public questioned whether there would be a huge cost resulting from the broad definition of *ill person*. These commenters expressed concern that misdiagnosis by non-medically trained personnel would lead to reduced travel based on the public's fear of being wrongly detained by public health officials. HHS/CDC notes that illness reporting is already required for both interstate and international travel. We note that travelers are not placed under public health orders simply as a result of an illness report. Rather, orders are issued only if a licensed medical officer based on a public health risk assessment has sufficient reason to believe that the individual is infected with a quarantinable communicable disease. In addition, the new definition is consistent with existing international guidelines and HHS/CDC guidance. Thus, HHS/CDC does not believe the changes to illness reporting will result in a large burden to the general public. The cost analysis in the regulatory impact analysis has been updated to include the cost to travelers involved in public health follow-up after an illness report.

One commenter opposed the rule because of a perceived negative economic and/or social impact upon individuals placed under a public health order. Regarding the social impact of the individual who may be ostracized, HHS/CDC notes that public health measures such as quarantine and isolation are not new concepts or practices, HHS/CDC has been implementing these measures to protect public health for many years. We reemphasize that one compelling reason for the publication of this final rule is to make “quarantine” and “isolation” better understood by the public so that these terms, its purposes, and meanings become more familiar and thereby decrease public anxiety over these important protections. For the same reason, HHS/CDC does not believe the provisions in the final rule will increase or decrease the cost of isolation or quarantine. HHS/CDC does provide an estimate of traveler cost in the sections describing Ebola entry enhanced risk assessment and management and illness

reports in the regulatory impact analysis.

One commenter suggested that the costs incurred by airlines would be passed along to the general U.S. population purchasing tickets for air travel. HHS/CDC concurs and mentions this possibility in the regulatory impact analysis. However, changes included in this final rule are a codification of a current practice and estimated total costs are only \$11,000 to \$431,000 per year. Thus, significant changes in ticket prices are not expected.

One commenter suggested that changes in infectious disease caseloads would not result in cost savings to public health agencies or individuals because there is already a public health workforce in place. HHS/CDC calculates such costs based on the opportunity cost of public health staff under the presumption that such staff would be involved in other productive activities if not spending time addressing outbreaks.

HHS/CDC solicited comment from the public regarding potential public willingness to pay to be contacted in the event of an exposure to a communicable disease during travel. This was done to help estimate the potential benefit to the public of HHS/CDC's efforts to work with health departments to contact travelers exposed to meningococcal disease, viral hemorrhagic fevers, MERS or other severe acute respiratory syndromes, measles, and tuberculosis, among other diseases. HHS/CDC received a number of comments from several individuals that they believe public health measures to mitigate measles transmission are unnecessary. Some individuals also noted that Ebola and MERS cases in the United States have not led to widespread transmission. These commenters either indicated or inferred that they would be unwilling to pay to be informed of potential communicable disease exposures during travel. The discussion in the regulatory impact analysis has been updated to incorporate this feedback.

HHS/CDC solicited public comment on willingness to pay to reduce Ebola risk in the United States to near zero if another international outbreak of Ebola with widespread transmission occurs in the future. HHS/CDC received comments from an organization representing flight attendants indicating that they believe it is in the public interest to reduce Ebola risk in the United States to near zero in the event of a future outbreak. They indicated that there is no reason to believe that achieving this objective would require unsustainable levels of funding. HHS/CDC incorporated this comment

regarding public willingness to pay in the regulatory impact analysis.

HHS/CDC also received comments from several individuals regarding the high cost of the measures taken to reduce the risk of Ebola transmission in the United States during the 2014–2016 Ebola epidemic in West Africa. Several of these commenters indicated they had zero willingness to pay for future public health measures in the event of a large Ebola outbreak.

Many commenters stressed the need to reassess whether to implement such activities in the event of a future Ebola outbreak. An example of such comments is provided by a research center studying international response efforts to emerging infectious disease threats, who noted that despite 99% complete active monitoring by health departments, there was no evidence of incident Ebola cases among individuals traveling from Ebola-affected countries. This does not include the two incident cases that preceded active monitoring. The commenters state that given this evidence it is not advisable for HHS/CDC to recommend active monitoring in the event of future Ebola outbreaks.

In addition, a public health research center cautioned against extrapolating costs and benefits calculation methods for measles and tuberculosis to Ebola, MERS, and other rare diseases. The research center further noted that countermeasures for Ebola and MERS do not exist (other than isolation and quarantine). They suggest that this would limit the effectiveness of point of entry measures. These researchers also point to the fact that transmission of Ebola and MERS has not occurred during air travel. They noted that point of entry risk assessment programs may increase anxiety (and costs) if cases are detected in the community after the implementation of point of entry measures. Finally, the research center noted that the costs for State and local health departments to actively monitor all arriving travelers for 21 days were not included in the analysis.

In response to these comments, HHS/CDC concurs that it would not be wise to directly extrapolate approaches for measles and tuberculosis to rare diseases and has tried to provide as much information as possible around the decision to implement the Ebola risk assessment program and recommendations for active monitoring. HHS/CDC did not simply extrapolate the analysis for measles and tuberculosis to Ebola.

HHS/CDC does not have data on State and local spending to achieve the objective of the 21-day active monitoring program and concedes that

the cost of active monitoring would likely exceed the costs incurred at the airports. However, HHS/CDC did provide an estimate of total Federal spending for both domestic and international efforts to attempt to quantify the cost of these efforts. Federal money was used to support State/local surveillance efforts. Federal money was also used to support improvements in laboratory capacity by States and hospital infection control efforts, which should have benefits beyond the 2014–2016 Ebola epidemic. In addition, Federal funding supported research into potential Ebola vaccines and medicines. The cost for the Ebola enhanced entry risk assessment program was just a portion of these costs and HHS/CDC acknowledges that risk assessment program at airports by itself would have limited potential to reduce risk. However, HHS/CDC also notes that the costs of Ebola entry risk assessment at points of entry included efforts to (1) stratify travelers by risk level so that health departments could focus more intense monitoring efforts on travelers at higher risk and (2) educate travelers on Ebola risk factors and symptoms and provide informational materials, a thermometer, and a telephone to all travelers to improve compliance with active monitoring efforts. This led to a higher cost, but more effective program relative to an alternative in which travelers would only be screened once at the airport, such as occurred in other countries implementing screening programs during the 2003 Severe Acute Respiratory Syndrome (SARS) epidemic.

HHS/CDC believes that the risk of Ebola infection in the U.S. population was potentially reduced because of the combination of measures to protect against Ebola transmission in the United States, including risk assessment at ports of entry. HHS/CDC acknowledges the risk was probably very low in the absence of domestic activities.

HHS/CDC further notes that it recommended active monitoring of travelers as a less restrictive alternative to more stringent measures such as quarantines that were being demanded by some members of the public. Widespread implementation of quarantine, particularly for healthcare workers crucial to the response efforts in West Africa and the United States, would have greatly hampered outbreak control measures by providing a strong disincentive to healthcare workers participating in the response.

To estimate the potential benefits of the Ebola risk assessment program at ports of entry, HHS/CDC provided a cost comparison of the incident Ebola cases

that occurred in Texas compared to New York to estimate the difference in costs between an Ebola case that was detected quickly and treated in a pre-selected hospital identified to be capable of Ebola treatment in comparison to an Ebola infection that was not initially suspected to be Ebola leading to community exposures and hospital exposures in a hospital that was not a pre-selected hospital capable of Ebola treatment.

HHS/CDC also examined the recent MERS outbreak in South Korea to demonstrate that even relatively small outbreaks of rare diseases such as MERS and Ebola can have large economic costs despite a relatively small number of cases and deaths. HHS/CDC found that the number of international travelers (non-Korean citizens traveling to South Korea) decreased by 40–50% during the peak months of the 2015 MERS outbreak. HHS/CDC further notes that these declines in travel occurred in the absence of widespread travel restrictions. The costs incurred by South Korea during the outbreak were used to demonstrate the potential costs of a larger Ebola outbreak in the United States.

Given the evidence from the programs implemented to mitigate risk during the 2014–16 Ebola epidemic, *i.e.*, the small number of international air travelers from countries with widespread Ebola transmission that later developed Ebola and the very limited risk of transmission by asymptomatic individuals with Ebola infection, HHS/CDC may not elect to implement an Ebola entry risk assessment program in the event of a future outbreak or to recommend 21-day active monitoring of travelers from countries with widespread transmission.

HHS/CDC emphasizes that it will continue to consider cost and work with multiple U.S. government agencies, as well as with airport authorities and health departments in U.S. States and territories, to apply the latest evidence to future decision-making. In addition, HHS/CDC will try to employ the least restrictive measures to achieve public health objectives. HHS/CDC notes that, during the period that the Ebola entry risk assessment and monitoring program was in effect, only 0.08% (29/38,344) of travelers assessed at U.S. airports were recommended for medical evaluation at hospitals and that no Federal quarantine or isolation orders were issued during the epidemic, although some States did issue such orders under their own authorities. These considerations have been added to the regulatory impact analysis in the final rule. Since this analysis concerns a codification of

existing authorities, this analysis has been moved to a separate appendix after incorporating public feedback.

A number of commenters suggested that HHS/CDC did not include the cost for people participating in the Ebola enhanced risk assessment program. However, HHS/CDC did provide such an analysis of these costs. One public commenter suggested that the psychological cost of quarantine should be considered in the economic impact analysis. Although HHS/CDC generally concurs with the idea of accounting for all of the costs associated with time spent in quarantine, HHS/CDC's authority to issue quarantine orders will not change with the publication of this final rule. Thus, this final rule does not incur new psychological costs for persons under quarantine orders.

HHS/CDC notes the opportunity costs for persons undergoing risk assessment at airports and/or evaluation at hospitals during the 2014–16 Ebola entry risk assessment and management program. HHS/CDC estimates their opportunity costs based on average wage rates, but did not have additional data to estimate a marginal psychological cost. Opportunity costs were also estimated for a more restrictive option compared to the Ebola entry risk assessment and management program, *i.e.* a suspension of entry for 21 days after having been in an Ebola-affected country.

One commenter suggested that this rulemaking does not represent the “least burden on society” because HHS/CDC has failed to clearly identify a “compelling public need” for the rule. HHS/CDC appreciates the comment and responds that the regulatory impact analysis cites a specific market failure addressed by this final rule. The market failure is that the costs associated with the spread of communicable diseases impacts the entire U.S. population, not just the group of persons currently infected with communicable diseases. Since this final rule is primarily implementing current practice, HHS/CDC does not anticipate major new benefits or costs.

One commenter stated that the cost/benefit analyses was very vague, meaning that there is no accountability or way to measure whether or not the final rule will achieve its intended result of preventing the spread of quarantinable communicable diseases via travel, which the commenter stated was already an extremely low risk. HHS/CDC concurs that there is uncertainty in the regulatory impact analysis. However, HHS/CDC has tried to indicate that one of the reasons for this uncertainty is that this final rule is primarily implementing current

practice. Thus, where possible, HHS/CDC tried to provide data on the current burden of the provisions that are being updated in this final rule. HHS/CDC does not expect any major changes in practice as a result of this final rule.

One commenter suggests that the cost/benefit analyses was confusing because quarantinable and non-quarantinable diseases were not clearly identified. HHS/CDC appreciates this feedback and has updated the analyses to more clearly differentiate quarantinable and non-quarantinable diseases.

One commenter suggested that HHS/CDC took an unnecessarily extreme position in analyzing an alternative of removing all enforcement of current regulations. HHS/CDC used this as an alternative because this final rule is a codification of current practice and does not impose new regulatory burdens.

q. Paperwork Reduction Act

HHS/CDC published notices related to modifications and a new information collection in the Notice of Proposed Rulemaking. Those information collections are as follows:

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(2) Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(3) Airline and Vessel and Traveler Information Collection (42 CFR part 71)—New Information Collection Request—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

One commenter stated that there are no estimates of additional information collection requirements resulting in a clear violation of the Paperwork Reduction Act. The commenter further stated that requesting information when HHS/CDC has no idea of the impact is not a well thought out or planned rulemaking. This commenter further questioned the value of providing comment when the agency purportedly has no idea what additional burden it is imposing on the public. HHS/CDC disagrees with these assessments.

The focus of the final rule is to codify current practices and to update currently approved information collections to better align with operational procedures and other

industry guidance related to illness reporting on aircraft and vessels. Those information collections are currently approved under OMB control numbers 0920–0134 (Foreign Quarantine Regulations), 0920–0488 (Restrictions on Interstate Travel of Persons), and the new information collection request Airline and Vessel and Traveler Information Collection (42 CFR part 71), which is currently pending OMB approval. The estimates of the burden provided in the Paperwork Reduction Act section of the NPRM were based on previous experience with particular information collections solicited or required from the public or industry in the past. In some cases, larger estimates of the burden to account for an increased number of reports to HHS/CDC during disease outbreaks or public health emergencies were included. There are no information collections requirements that are wholly new, unreasonably burdensome, or outside the scope of historical HHS/CDC practices implemented to prevent the introduction or spread of communicable disease into or within the United States.

Another commenter suggested that training in recognizing ill travelers is a burden that was not adequately considered. HHS/CDC disagrees because it does not mandate specific training for recognition of ill travelers. HHS/CDC is seeking to better align the ill person definition with the ICAO standard and thus is not the only organization that has this requirement. HHS/CDC provides specific guidance for how to recognize ill travelers and report to HHS/CDC on its Web site. HHS/CDC also believes this training is most likely already part of the training process for flight crews. An analysis of potential training costs has been added to the upper bound cost analysis in the Regulatory Impact Analysis. The upper bound annualized costs for additional training are estimated at \$356,000.

Finally, HHS/CDC is re-inserting “Has a fever that has persisted for more than 48 hours” as a component in the definition of *Ill person* in § 70.1 General definitions and “Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater)” in § 71.1 General definitions. This language was quoted verbatim in the preamble of the NPRM at 81 FR

54305 but was inadvertently omitted from the proposed regulatory text.

B. Provisions Applicable Only to Part 70 Only (Domestic)

a. General

HHS/CDC received comments from the public asserting that State and local public health regulations already in place are sufficient to protect individuals without the need for Federal involvement. HHS/CDC agrees that State and local authorities play an integral role in protecting public health, but disagrees that there is no Federal role. HHS/CDC’s DGMQ maintains quarantine stations at major U.S. ports of entry that fulfill a primary purpose in preventing the introduction of communicable diseases into the United States, but also play an important role in containing the interstate spread of communicable disease. There are several broad areas of cooperation between quarantine field staff and State and local health agencies, such as contact tracing, which provide a framework for responding to communicable disease threats arising from interstate travel and at the local level. It is through these networks and established partnerships, in keeping with current practice, that the provisions of the final rule will be successfully implemented.

HHS/CDC received a comment to the effect that quarantine specifically should be left to the States. HHS/CDC received another comment stating that Federal authority should not take precedence over State authority. In contrast, a public health association suggested that these regulations should indicate that Federal public health measures “supersede activities taken by States.” We respond that while HHS/CDC works closely with State and local public health authorities, the Federal government has a traditional role in preventing introductions and spread of communicable diseases at ports of entry and interstate. HHS/CDC also disagrees with the suggestion that it should not intervene in the event of inadequate local control or lacks authority to protect the public’s health within the authority granted to it by Congress. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. Under, 42 CFR 70.2, HHS/CDC

make take action to prevent the interstate spread of communicable diseases in the event that the CDC Director determines that inadequate local control exists. This longstanding provision on preemption in the event of a conflict with Federal authority is left unchanged by this rulemaking.

One public health organization requested clarification of the process to transfer an individual from Federal to State custody and further stipulated that the State authority should require an independent State assessment of risk under State law. In response, HHS/CDC notes that the issuance of Federal public health orders is coordinated with State and, when appropriate, local public health authorities. Transfer of an individual from Federal to State custody would be similarly coordinated such that the State would need to agree to assume custody and the State’s order would need to be in place prior to HHS/CDC’s rescinding the Federal order. When custody of an individual is transferred to a State authority, the State may choose, but would not be under a Federal mandate, to conduct an independent assessment of risk pursuant to its own policies and procedures. Furthermore, once the transfer of custody has occurred, the State’s laws and standards for due process would apply.

Another public health authority asked for clarification of how jurisdictional issues regarding transfers of authority affecting more than one State would be handled for individuals under Federal quarantine. HHS/CDC responds that if more than one State is affected by the transfer of authority, HHS/CDC will work with all relevant States to determine the most appropriate State or local jurisdiction to accept custody of the individual. If it is necessary to transport the individual to another State, for example to the individual’s State of residence, HHS/CDC will work with the affected States to facilitate such a transfer under Federal orders.

One public health organization requested clarification of the procedures HHS/CDC would use to rescind a public health order. HHS/CDC responds that it would issue the detained individual a written order rescinding the isolation, quarantine, or conditional release. This would be based on either one of two criteria: The individual is determined to no longer pose a public health threat or custody of the individual has been transferred to a State or local public health authority.

HHS/CDC received a comment from a public health department stating that the regulations should include language that HHS/CDC will coordinate with

State and local public health authorities and law enforcement regarding any intended surveillance and enforcement activities. HHS/CDC strongly believes that coordination with State and local public health authorities, as well as relevant law enforcement entities, is essential to the public health response to individual cases as well as outbreaks of communicable disease. On the few occasions that HHS/CDC has issued Federal isolation orders for travelers with infectious tuberculosis, HHS/CDC has worked closely with State and local health departments to coordinate transportation, medical evaluation, and treatment of the ill traveler, including law enforcement when needed. During the 2014–2016 Ebola epidemic, HHS/CDC issued guidance and alerted health care and EMS workers to consider a diagnosis of Ebola if patients had compatible symptoms and had visited an affected country within the previous three weeks. HHS/CDC and State and local health departments worked closely to assess any potentially exposed individuals with symptoms compatible with Ebola to determine whether medical evaluation was needed and, if so, to ensure safe transportation to a medical facility designated by the health department. In light of HHS/CDC's history of close coordination with State and local public health authorities, including cooperating law enforcement entities when needed, HHS/CDC has determined that specific regulatory language is unnecessary.

b. Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release

Some commenters questioned HHS/CDC's authority, as well as the need, to restrict the movement of individuals who are not ill but have been exposed. HHS/CDC thanks these commenters for their review and input. Some quarantinable communicable diseases, such as novel pandemic influenza strains, may be contagious before the infected person becomes symptomatic. Therefore, in these situations, it may be necessary to restrict the movement of asymptomatic exposed people to make sure they do not expose others inadvertently while they are not aware that they are contagious. It may also be necessary to restrict movement of an exposed person if public health authorities are unable to ensure appropriate monitoring of the person, for example, if an individual is known to have a history of noncompliance with public health recommendations. Exposed people whose movement is restricted through quarantine or other means may be offered vaccination, if a

vaccine is available, but only with informed consent.

One commenter noted that the regulation allows HHS/CDC to issue interstate travel permits to an infected individual conditioned upon the individual taking “precautionary measures” as prescribed by HHS/CDC. This commenter requested that HHS/CDC clarify what precautionary measures may be prescribed and stated that such conditions should not be based on factors unrelated to the individual's health condition, *e.g.*, socio-economic, ethnic status. While HHS/CDC agrees that the issuance of a travel permit should not be based on such factors as race, gender, ethnicity, or socio-economic status, we note that the issuance of a travel permit may be conditioned on such factors as the individual's ability and willingness to comply with the terms of the permit. Furthermore, while the exact precautionary measures prescribed may vary based on the infectious agent, such measures, for instance, may include: Agreeing to minimize time in congregate settings while traveling; avoiding eating in restaurants or other enclosed public places; traveling with no other people in the vehicle or, if other people are needed to safely operate the vehicle, agreeing to wear a mask and ensure good ventilation; and reporting to the local health department upon arrival or on route as needed.

This commenter also requested clarification of the legal impact of a person who is denied a permit or has had a permit revoked. We note that per the terms of the regulation persons denied a travel permit or who have had a travel permit revoked may submit a written appeal. The right to a written appeal, as well as the means by which an appeal may be requested, will be addressed in the written order denying the request for a travel permit or revoking an existing permit. The appeal will be decided by an HHS/CDC official who is senior to the employee who denied or revoked the permit. HHS/CDC declines to speculate as to what else this commenter may be referring to by the term “legal impact,” but notes that the regulation does not impair the ability of persons to seek judicial review of final agency actions through the Administrative Procedure Act.

This commenter also requested clarification of how long an individual may be restricted in his or her travel under a Federal travel permit. We note first that the restriction only applies to those under a Federal public health order or under a State or local order if the State or local health department of jurisdiction requests Federal assistance

or there is inadequate local control. In further response, HHS/CDC notes that the restriction would remain in place so long as the individual is infected or capable of infecting others. This commenter further requested clarification of the impact of a disagreement between HHS/CDC and State or local public health authorities. We note that by the terms of 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations except in the event of a conflict with the exercise of Federal authority. Moreover, per the terms of 42 CFR 70.2, HHS/CDC may take action to prevent the interstate spread of communicable diseases in the event that the CDC Director determines that inadequate local control exists.

HHS/CDC received a comment from a flight attendant union requesting clarification as to whether an employee could be held criminally liable for knowingly transporting someone in violation of the terms of a travel permit as specified under section 70.5. In response, HHS/CDC clarifies that the term “operator” is defined under 70.1 consistent with 14 CFR 1.1 and with respect to an aircraft means, “any person who uses, causes to use or authorizes to use an aircraft, with or without the right of legal control (as owner, lessee, or otherwise).” We further note that criminal liability, if any, will be determined by a court of law and not administratively by HHS/CDC. Accordingly, we decline to speculate as to whether employees who knowingly violate the terms of a travel permit may be held criminally liable.

One public health organization asked for clarification of how local health departments would be engaged in conducting communicable disease screening activities or enforcing Federal public health travel restrictions for individuals traveling interstate, given that HHS/CDC staff are not present at many points of interstate travel. HHS/CDC acknowledges this limitation in their presence at some ports of entry and in regard to interstate travel and intends to address this through future guidance and discussion with stakeholders.

In regard to interstate air travel, HHS/CDC clarifies that the Federal public health Do Not Board tool will deny boarding of persons known to pose a public health risk to other air travelers. This tool is applicable to persons boarding a commercial aircraft with an origin or destination in the United States, including interstate travel. *See* 80 FR 16400 (Mar. 27, 2015).

For other modes of travel, HHS/CDC does not have a systematic mechanism

of denying boarding and these situations may need to be addressed on a case-by-case basis, either through direct communication with a conveyance operator or through application of other movement restrictions such as the issuance of State or Federal public health orders. Such situations will likely require the participation of State or local public health authorities; however, as noted by the commenting organization, the Federal and State/local costs and resources required during such operations are not known. The specific roles of State or local health departments will be addressed through future guidance or stakeholder discussion.

HHS/CDC received a comment contending that the extension of travel permits to intrastate travel is in violation of the Commerce Clause. HHS/CDC disagrees. We note that HHS/CDC will only require intrastate travel permits when a State or local health authority of jurisdiction requests federal assistance or in the event that State and local actions are inadequate to prevent interstate communicable disease spread. Under 42 U.S.C. 264, Congress acting pursuant to its Commerce Clause jurisdiction, has authorized HHS/CDC to take measures to prevent the foreign introduction and interstate spread of communicable diseases. It is well established that the Federal government may act to protect interstate commerce, even though the threat may come entirely from intrastate activities. *See United States v. Lopez*, 514 U.S. 549, 558–559 (1995).

One commenter requested that HHS/CDC replace the word “traveler” with “passenger” with respect to mandatory public health assessments, as a traveler could be taken to mean “anybody in a private vehicle lined up at a toll booth.” In response, HHS/CDC states that the use of the word “traveler” with respect to conveyances is intended to include both passengers and crew. Furthermore, HHS/CDC states that its authority extends to all individuals engaging in interstate travel including those traveling by private vehicle, particularly if they are in the “qualifying stage” of a quarantinable communicable disease.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations expressing concern that requiring application for a travel permit may be unduly burdensome because individuals who are served with a conditional release order at an airport would then need to apply for a separate travel permit to travel to their home State of residence. HHS/CDC disagrees because under such circumstances the conditional release

order itself would include authorization for these individuals to continue travel to their home State of residence provided that they subsequently report to public health authorities as needed. For example, during the response to Ebola, CDC worked with state public health authorities to allow certain individuals who met certain risk thresholds to travel in private vehicles to their place of residence while maintaining a focus on protecting public health. This was done on a case by case basis, depending on distance of travel and risk of exposure, and distance from a health care facility with adequate capacity to treat and contain Ebola. CDC would make similar assessments in the event that conditional release orders are needed for other quarantinable communicable diseases. We note that the conditional release order itself would provide permission to travel and have added clarifying language to the text.

HHS/CDC clarifies, however, that after arriving in their home State, should the individuals wish to engage in further travel, a travel permit may be needed at that time. In response to comments from this partnership organization, HHS/CDC also clarifies that the travel permit, as provided for in the regulations, will only be required under circumstances where the individual is already under a Federal, State or local order of quarantine, isolation, or conditional release. Because the travel permit requirement is only applicable to individuals who are already under a Federal, State, or local public health order, HHS/CDC believes that this provision does not impermissibly restrict an individual’s right to travel.

In response to comments regarding the time with which CDC may consider a travel permit request, the CDC Director shall respond to a request for a travel permit within 5 business days. Likewise, one public health association suggested that, in the event a travel permit is denied, these regulations should state the timeframe that HHS/CDC will issue a response to the appeal; another proposed the time period for CDC’s response to be 72 hours. In response to these comments, HHS/CDC has added a requirement in the regulation that in the event that a request for a travel permit is denied, it must decide an appeal from that denial within three (3) business days. HHS/CDC believes that this timeframe is appropriate because this provision only applies to individuals who already have had their travel restricted through the issuance of a public health order and deciding an

appeal may involve coordination with affected state or local jurisdictions.

After consideration of comments received, HHS/CDC has modified paragraphs (a), (b)(1), (b)(2), and (c) of the provision concerning *Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release* (§ 70.5) to remove “agreements,” referring to agreements entered into by the CDC. We have also modified paragraph (a)(5) to require that HHS/CDC must issue a written response to an appeal within three (3) business days. Other provisions of this section are finalized as proposed.

c. Report of Death or Illness Onboard Aircraft Operated by an Airline

Several commenters expressed concern that the new regulations remove the requirement for a local health authority to be notified when a passenger falls ill or dies on board a flight. The commenters insisted that this could interfere with effective local response to important communicable disease threats. They propose that local authorities should be notified in a timely manner, such as within one hour of initial reporting, and that HHS/CDC should consult with local health authorities on the necessary steps to contain the spread of communicable diseases. In contrast, one airline supported the direct reporting to HHS/CDC.

HHS/CDC carefully considered these comments and responds that it will continue its long standing partnership with local authorities. The rationale behind asking airlines to submit reports of deaths or reportable illnesses directly to HHS/CDC as opposed to local authorities is to simplify and streamline the reporting process for these airlines. Under the final rule, airlines will not be required to know the current points of contact for multiple local jurisdictions, but rather may report to HHS/CDC as a single point of contact. HHS/CDC will continue to share public health information with State and local health departments through approved electronic disease reporting networks such as the Epidemic Information Exchange (Epi-X), HHS/CDC’s secure, Web-based system. HHS/CDC may also notify State or local authorities via phone calls.

Some commenters questioned whether HHS/CDC has adequate resources to be the first responder at the local level. HHS/CDC responds that it regularly coordinates with Federal, State and local agencies and other partners in the airport environment. HHS/CDC intends to continue working closely with Federal, State, and local partners,

including first responders such as EMS and State and local health agencies, when assistance is needed.

One commenter suggested that the reporting of ill travelers “would be an invasion of our liberty and privacy.” HHS/CDC disagrees. The report of illness or death on board a carrier is a longstanding regulatory provision and practice. This final rule only changes to whom the report is made (directly to HHS/CDC), rather than to the local health department of destination. We further note that personally identifiable information collected and maintained under the Privacy Act will be handled in accordance with that Act and CDC’s system of records notice published at 72 FR 70867.

Another commenter worried that “having flight reservations require health reports will significantly impede air travel.” It is not HHS/CDC practice, nor a requirement under this regulation, for individuals to submit health reports prior to or after making a flight or vessel reservation. The only instance when health documents may be required prior to travel, is if a person is known to be infectious with a communicable disease that could spread during travel and has been placed on the Federal Public Health Do Not Board described in 80 FR 16400 (Mar. 27, 2015). Because this practice is not new, HHS/CDC believes it will not impede air travel.

A flight attendant association suggested that HHS/CDC should adopt training and awareness requirements for airline employers to provide to flight attendants concerning “what entails a qualifying stage.” Industry also expressed concern that flight crews may be held responsible and penalized for missed illness identification. HHS/CDC understands that the statutory definition of “qualifying stage” may be confusing to lay persons and does not expect air or vessel crewmembers to be trained in the nuances of such language. Instead, we have crafted a definition of *ill person* to focus, in plain language, on the signs and symptoms of communicable diseases of public health concern and quarantinable communicable diseases, while taking into account the medical resources available to aircrew. HHS/CDC intends to enforce this provision consistent with how reports of deaths and illnesses are currently handled in regard to foreign arrivals. We note that flight crews have not been penalized in the past for missed reports of illness.

HHS/CDC received comments from industry that the report of death or illness should not be limited only to the pilot in command, given the many duties already under his/her responsibility. HHS/CDC disagrees. We

clarify first that this domestic provision was proposed to mirror the current foreign provision under 42 CFR 71.21(b)—which HHS/CDC did not propose to change—and which states “the commander of an aircraft destined for a U.S. airport shall report immediately . . . any death or ill person among passengers or crew.” While we acknowledge the many duties of the pilot in command, because this individual is directly responsible and has final authority over the operation of the aircraft, in keeping with the practice already established through regulation under 42 CFR 71.21(b), we believe that the responsibility for reporting ill persons onboard should ultimately rest with the pilot in command as stated in the regulation. Thus, the text of the regulation has not changed from the proposal.

One industry group commented that the role of flight attendants in identifying sick travelers on board should be addressed through guidance developed in conjunction with HHS/CDC and industry. HHS/CDC responds that it routinely issues guidance for flight crews, including standard guidance for the recognition and reporting of ill travelers and disease- or situation-specific guidance during outbreaks. Such guidance is published on HHS/CDC’s Web site and disseminated through established list serves, industry associations, and any other available means. HHS/CDC will coordinate with industry partners to determine whether additional guidance may be needed and, if necessary, work with these partners to develop such guidance.

One industry organization commented that the proposed rule failed to recognize that airlines employ intermediary professional medical personnel. HHS/CDC responds that it recognizes the role of intermediary professional medical personnel in assisting flight crews in managing an ill traveler onboard and references such personnel in industry guidance issued at <http://www.cdc.gov/quarantine/air/index.html>.

It is not HHS/CDC’s intent for the public health assessment conducted by HHS/CDC public health officers to replace this role in medical management. However, HHS/CDC restates that the reporting of ill travelers to HHS/CDC is the ultimate responsibility of the pilot in command as noted above.

One association requested that the report of deaths on board a carrier be modified and limited to those deaths which resulted from a possible communicable disease. HHS/CDC

disagrees. In keeping with current practice, HHS/CDC will continue to require and receive the reports of *all* deaths that occur on board a carrier, regardless of the suspected cause, to allow a public health official to conduct an assessment.

One public health organization raised concerns about replacing reporting to local health authorities with reporting to HHS/CDC. In response, HHS/CDC notes that extensive input was sought in 2012 from the Association of State and Territorial Health officers (ASTHO) and National Association of County and City Health Officials (NACCHO). Representatives from those organizations recommended that requirements and protocols should be the same for international and interstate flights and procedures should be outlined describing how this would occur. These representatives recommended that airlines should report ill persons on domestic flights to HHS/CDC and that HHS/CDC should subsequently notify State or local health departments. Subsequently, HHS/CDC posted guidance to this effect on its Web site and has continued response planning and development of standard operating procedures to implement these recommendations. Thus, this rulemaking codifies the current practice and is consistent with recommendations provided by ASTHO and NACCHO.

One commenter stated that it appears HHS/CDC is “attempting to move towards mandatory reporting by carriers and border personnel, requiring reporting of persons with signs of illness as they cross borders, as opposed to having to do large-scale individual contact interviews and investigations after an outbreak occurs.” In response, HHS/CDC states that reporting by carriers is already required under the existing regulations and that this regulation only codifies current practice and guidance. In addition, DHS notifies HHS/CDC of ill travelers detected by border personnel. HHS/CDC and DHS agreed to this notification process in a memorandum of understanding and therefore changes to this regulation are unnecessary. HHS/CDC additionally coordinates notification and investigation of contacts during exposure or outbreak situations when necessary based on a public health risk assessment. Such investigations are standard public health practice and not mutually exclusive of reporting by carriers or notifications by border personnel.

After consideration of these comments, the title of the *Radio Report of Death or Illness* (71.21) in the provision has been finalized as

proposed to remove the word “Radio,” and now reads *Report of Death or Illness*.

C. Provisions Applicable to Part 71 Only (Foreign)

One commenter questioned the seriousness of communicable disease spread on aircraft and vessels. Another commenter noted an “extreme unlikelihood of contracting any communicable disease while traveling” and that, therefore, HHS/CDC failed to prove a “compelling need” for the proposed regulations. HHS/CDC appreciates the opportunity to respond to these comments. The spread of communicable diseases on aircraft and vessels is well documented. There are numerous reports in the medical and public health literature of spread of measles, tuberculosis, SARS-coronavirus, and influenza virus on aircraft. Outbreaks of varicella (chickenpox), influenza, and gastrointestinal viruses such as norovirus are common on cruise ships, and spread of other diseases such as measles, rubella (German measles), tuberculosis, and other gastrointestinal diseases has also been reported. Aircraft and vessels have people together in confined spaces for prolonged periods of time. Therefore, conducting contact investigations for certain communicable diseases identified on aircraft or vessels is standard public health practice, both in the United States and internationally, similar to public health practice in community settings.

HHS/CDC received comments from industry regarding ongoing efforts with DHS/CBP to improve passenger data collection, as announced in the NPRM. Several commenters stated that HHS/CDC should delay this final rule until DHS/CBP has published a regulation to ensure that a coordinated system is put in place. HHS/CDC thanks these commenters for their input but disagrees that this final rule should be delayed. This comprehensive regulation seeks to protect public health, by implementing, among other things, current passenger and crew data collection practices.

One commenter objected to the collection of health information prior to using public transportation. Another commenter opposed the idea of carriers being “forced to collect and report 17 data elements on American travelers.” A public health association also insisted that data elements should only be collected from people if there is a reasonable belief that the person is infected. This final rule does not require carriers to collect or transmit any data elements that are not currently collected and transmitted to CBP via APIS and

PNR as a result of normal operating procedures. We also take this time to emphasize two important points. First, passengers are not required by HHS/CDC to submit specific data elements provided by passengers. Second, HHS/CDC will only seek this information from CBP or the airline in the event of a confirmed or suspected communicable disease on board a carrier which requires contacting fellow passengers to inform them of possible exposure.

While HHS/CDC received support for the data collection from two public health associations, a commenter misread the proposals to mean that aircraft operators would be required to develop new capacity and processes to capture and store a comprehensive set of sensitive data, archive this data, and then provide it to HHS/CDC. HHS/CDC takes this opportunity to restate and clarify that these final regulations do not impose any new burdens upon the airline industry but rather, codify the current practice of receiving a passenger manifest order (as needed) and providing HHS/CDC with any data in an airline’s possession. This rule places no requirement on the airline to solicit or store additional data than current practices allow. Therefore, HHS/CDC does not expect this formalization of current practice to have an impact on operations, including “check-in process.” If an airline does not have in its possession the five additional data elements, it is not required to collect or submit them to CDC.

One airline industry group commented that the collection of information from screened individuals for the purpose of contact tracing should apply only to passengers because crewmember information would be provided by the employer. HHS/CDC responds that this may be the case operationally; however, HHS/CDC reserves the right to collect information directly from crew members if necessary.

HHS/CDC received a comment expressing concern that individuals may provide false contact information, e.g. emails and telephone numbers, to airlines, and thus that HHS/CDC would lack the means of contacting individuals. In response, HHS/CDC notes that airlines are not required to verify the accuracy of information collected and HHS/CDC takes no position on what consequences the airline may impose if a traveler refuses to provide information or provides inaccurate information.

One public health organization commented on the scope of HHS/CDC’s protocols for when contact investigations are conducted and how

exposed contacts are defined following exposures to measles or varicella on aircraft or vessels. HHS/CDC appreciates the comment but seeks to clarify that these protocols were mentioned in the NPRM solely for the purposes of providing context for the economic analysis and that the content of the protocols themselves is beyond the scope of this rulemaking.

One public health organization commented on the fact that buses and trains typically do not maintain or have access to passenger manifests that would allow for the collection of information by HHS/CDC for the purpose of contact tracing. HHS/CDC agrees with this comment and notes that these regulations do not require operators of buses or trains to maintain passenger manifests for purposes of contact tracing. The organization also commented on the utility of the requirement that operators of buses or trains not knowingly transport individuals subject to a Federal public health order. In response, HHS/CDC notes that it is useful to prohibit conveyance operators from knowingly transporting someone under a Federal public health order without a travel permit or in violation of the terms of a permit because this may limit communicable disease spread. This prohibition, however, would only apply in circumstances where the operator would know or have reason to know that a travel permit is required, for instance, if the conveyance operator has been directly informed by the HHS/CDC or another cooperating Federal, State, or local agency.

A non-profit organization also commented that requiring airlines to disclose passenger information, upon request, but without a warrant, for purposes of notifying passengers of their potential exposure to a communicable disease violates the Fourth Amendment to the U.S. Constitution. This organization also contends that HHS/CDC lacks the legal authority to require that travelers provide certain contact information, such as information concerning their intended destination, health status, and travel history as part of a public health investigation. Specifically, this group contends that “examination” as used in 42 U.S.C. 264(d)(1) should be understood as referring only to an “inspection” not an “interrogation.” This group further contends that because HHS/CDC lacks the legal authority to collect information under 42 U.S.C. 264 it also lacks the authority to collect information under the Privacy Act of 1974. Lastly, this group contends that any compulsory questioning of travelers about “acts of

assembly or association” violates the First Amendment to the U.S. Constitution.

HHS/CDC disagrees with these comments. HHS/CDC notes that the requirement of a judicial warrant is not applicable to requiring passenger and crew information from air carriers. Rather, this activity is permitted without a warrant under the special-needs doctrine articulated by the Supreme Court in *Skinner v. Railway Labor Executives’ Ass’n*, 489 U.S. 602 (1989) because of the “special need” in preventing communicable disease spread. Furthermore, requiring passenger information from airlines and questioning travelers is authorized under 42 U.S.C. 264(a), which allows for the promulgation of regulations necessary for preventing the spread of communicable diseases from foreign countries into the United States and interstate. In carrying out and enforcing these regulations, 42 U.S.C. 264(a), authorizes “inspection” and “other measures” as may be necessary which allows for inspection of airline records and questioning of travelers regarding their health status and travel history. While 42 U.S.C. 264(d)(1) is not directly implicated in questioning of travelers because such questioning may occur without a specific reason to believe that the individual traveler may be infected with a quarantinable communicable disease, we note that the commenter’s suggestion that an “examination” excludes “interrogation” is not supported by common understanding or language usage. We note that Merriam Webster defines “examination” among other things as “a formal interrogation.” Thus, this commenter’s suggestion that because HHS/CDC purportedly lacks the legal authority to collect traveler information under 42 U.S.C. 264 it also lacks authority to collect information under the Privacy Act is without merit.

HHS/CDC also rejects the suggestion that questioning of travelers violates their rights to free association under the First Amendment. The U.S. Supreme Court has recognized a “freedom of association” in only two distinct areas: (1) Choices to enter into and maintain certain personal human relationships (as an element of personal liberty); and (2) a right to associate for the purpose of engaging in other activities protected by the First Amendment, *i.e.*, speech, assembly, petition for redress of grievances, exercise of religious freedom. *City of Dallas v. Stanglin*, 490 U.S. 19, 23–24 (1989). The purpose of this proposed requirement is to protect the vital health interests of passengers and crew so that individuals who have been exposed to a communicable

disease during travel may be contacted, informed, and provided with appropriate public health follow-up. HHS/CDC measures to prevent the introduction, transmission, or spread of communicable diseases do not implicate any of these constitutionally-protected areas.

HHS/CDC further notes that its purpose in collecting passenger information is to notify passengers who have been potentially exposed to communicable diseases of public health concern. For some of these diseases, there are preventive medications or vaccines that the individual may be made aware of and wish to obtain to keep from becoming sick. Therefore, HHS/CDC considers the collection of passenger locating information to be of benefit to these passengers and in keeping with standard public health practice to prevent further communicable disease transmission.

After considering these comments, HHS/CDC has finalized these provisions (71.4 and 71.5) as proposed, with the exception that the title has been modified to remove references to “collection” and “storage” of information to more accurately reflect the requirements under this section. References to the CDC have also been replaced with Director throughout these sections.

a. Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States

Regarding provision 71.63 *Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States*, one public health association proposed that the restriction of animals should include an exception for ports of entry that could provide for physical inspection. In response, HHS/CDC clarifies that if the CDC Director determines an imported animal (or product) poses a significant public health threat, this provision requires the Director to designate the period of time and conditions under which entry into the United States shall be suspended, which may include limiting entries to certain ports where physical inspections are available. In keeping with current practice, HHS/CDC will implement public health protection measures that strike the appropriate balance between protecting the public’s health and continued importation and trade.

HHS/CDC received a comment that the term “thing” as used in 71.63 authorizing the suspension of “animals, articles, or things,” based on the existence of communicable disease in a

foreign country is unduly vague. In response, we explain that HHS/CDC may take public health measures in regard to animals, articles, or things, to prevent the introduction, transmission, and spread of communicable diseases into the United States and interstate. “Article” generally refers to an article of commerce, such as a specific product that someone wishes to import into the United States or move between States that poses a public health risk. In contrast, a “thing” simply refers to a material object that poses a public health risk regardless of whether there is a specific intent to import or move between States. For instance, on July 10, 2001, CDC issued an order under the authority of section 71.32(b) requiring that imports of “lucky bamboo” (a decorative plant) shipped in standing water be prohibited from entering the United States because the water (*i.e.*, the method of packing the lucky bamboo) constituted a potential vector for mosquito-borne illnesses. *See* 66 FR 35984 (July 10, 2001). In contrast, shipments of “lucky bamboo” that were packed dry (not in standing water) were permitted entry into the United States. In this case, “lucky bamboo” (the decorative plant) would constitute the “article” and the standing water would constitute the “thing.”

HHS/CDC received a question regarding the fate of animals or articles denied entry under this regulation, stating that “articles might presumably be forfeited and pets will be executed,” and questioning whether this provision aligns with due process, particularly with respect to the right to appeal. In response, HHS/CDC states that the provision authorizing temporary suspension of entry of certain animals, articles and things based on the existence of a communicable disease in a foreign country and to protect the public’s health is intended to prevent the arrival of these items at a U.S. port of entry. Therefore, HHS/CDC will seek to ensure travelers are informed of the restriction and will also work with carriers to prevent these animals or items from being loaded onto aircraft or vessels traveling to the United States. If such animals or items do arrive at a U.S. port of entry, HHS/CDC will take measures as needed to protect the public’s health. Such measures will be determined on a case-by-case basis and may include, at the owner’s expense, confinement, re-exportation, or destruction. Re-exportation may be considered if there is no public health risk during travel. HHS/CDC would also consider euthanasia of animals if there

are no other reasonable alternatives to protect the public's health.

In response to the concern expressed about an "appeal," HHS/CDC notes that the Director's suspension order would ordinarily constitute "final agency action" under the Administrative Procedure Act, 5 U.S.C. 704. However, HHS/CDC will consider the appropriateness of offering an administrative appeal as it develops the relevant suspension order.

After considering these comments, HHS/CDC has finalized the *Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States* (71.63) provision as proposed.

VI. Alternatives Considered

Under Executive Order 13563 agencies are asked to consider all feasible alternatives to current practice and the rulemaking as drafted. One less restrictive alternative would be for HHS/CDC to stop enforcing its regulations and make compliance with current regulations voluntary. Under this scenario, HHS/CDC would not obtain contact data from airlines or provide such data to health departments in order to conduct contact investigations. HHS/CDC would not require illness and death reports on aircraft or vessels, but would still follow-up with airlines and vessel operators upon request. This alternative would put travelers at greater risk of becoming infected with communicable diseases, reduce the ability of public health departments to offer post-exposure prophylaxis or other measures to prevent communicable disease spread from travelers known to have been exposed, and generally increase the risk of communicable disease transmission in the United States.

Another alternative, is to extend the scope of the regulations by closing U.S. borders and ports of entry to incoming traffic from countries experiencing widespread transmission of quarantinable communicable diseases to protect public health is also analyzed based on the 2014–16 Ebola outbreak in West Africa as well as recent importations of Middle East respiratory syndrome. HHS/CDC believes this approach is neither practicable nor is it desirable.

In a separate appendix, alternatives are considered to increase or decrease HHS/CDC's required payments for care and treatment for individuals under Federal orders as specified in 42 CFR 70.13 and 42 CFR 71.30. Also in a separate appendix, alternatives are also considered in which HHS/CDC does not implement temporary animal import

embargos (less restrictive) or does not allow importation of animals under temporary embargos for science, education, and exhibition when accompanied by a special permit.

We believe the regulations described above and set forth below in text offer the best solutions for protecting U.S. public health while allowing for continued travel. HHS/CDC believes that this rulemaking complies with Executive Order 13563; all of these changes provide good alternatives to the current baseline.

VII. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

HHS/CDC has examined the impacts of the final rule under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993)² and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011).³ Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: Quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose approaches that maximize net benefits including potential economic, environmental, public health and safety, and other advantages; support regulations that protect public health and safety; and minimize the adverse impact of regulation. HHS/CDC has analyzed the final rule as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act,⁴ as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA)⁵ and that, relative to the status quo, the final rule will not be economically significant because the sum of

annualized costs and benefits are estimated to be much less than \$100 million in any given year.

However, there is uncertainty about the appropriate analytic baseline, and relative to some possible baselines, the effects of the rule are non-negligible. For example, if in the absence this rule, some aspects of future HHS/CDC screening or risk assessment activities are found to be legally impermissible, then the status quo baseline would not represent a reasonable approximation of the state of the world without the rule. Relative to a non-status quo baseline, the rule would lead to activities (e.g., the 2014–16 Ebola risk assessment and management program) that have both substantial costs and substantial benefits. Analyses relative to this non-status quo baseline are presented in a separate appendix.

This Regulatory Impact Analysis (RIA) section presents the anticipated costs and benefits that are quantified where possible are relative to the status quo baseline. Where quantification is not possible, a qualitative discussion is provided of the costs and/or benefits that HHS/CDC anticipates from issuing these regulations.

Need for Rule

The 2014–2016 Ebola response highlights the inadequacies and limitations of the current regulatory provisions on the traveler data collection process in which CDC must request traveler manifests from airlines and manually search for contact data in order to know *who* enters the United States, *where* they go, and *how* to contact them.

Airlines have been slow to respond to HHS/CDC requests for traveler manifests:

- 30% arrive more than three days after a request,
- 15% arrive more than six days late.

In addition, available locating information is usually incomplete: HHS/CDC receives only the name and seat number for 61% of travelers, and one or more additional pieces of information for 39% of travelers. This final rule clarifies HHS/CDC's existing authority to request any available contact data from airlines and vessel operators, which may improve the timeliness and completeness of future requests from airlines or vessel operators for data not already submitted to the Department of Homeland Security.

Some traveler contact data is available in the APIS/PNR dataset already submitted by airlines to CBP. In the experience of the HHS/CDC, queries from APIS/PNR rarely result in full sets

² Executive Order 12866 of September 30, 1993: Regulatory Planning and Review. **Federal Register**. Monday, October 4, 1993; 58(190). <http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>. Accessed January 2016.

³ Executive Order 13563 of January 18, 2011: Improving Regulation and Regulatory Review. **Federal Register**. Friday, January 21, 2011; 76(14). <http://www.gpo.gov/jdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>. Accessed January 2016.

⁴ U.S. Small Business Administration. Regulatory Flexibility Act. <http://www.sba.gov/advocacy/823>. Accessed January 2016.

⁵ Summary of the Unfunded Mandates Reform Act. 2 U.S.C. 1501 *et seq.* (1995). <http://www2.epa.gov/laws-regulations/summary-unfunded-mandates-reform-act>. Accessed January 2016.

of contact information (*i.e.* the record includes all five additional data fields as outlined in the final rule). The data fields that are most commonly missing from the records are email addresses (missing 90 percent of the time), secondary phone number (missing 90 percent of the time), and street addresses (missing or insufficient for public health contact tracing up to 50 percent of the time). These data elements are vital to a contact tracing investigation. In looking at a random sample of 20% of the compiled international air travel manifests for 2015, those including a compiled data set from NTC and the airlines, 100% were missing at least one of the 5 data fields. Email address and secondary phone number were among those most frequently missing. For context, there were approximately 760,000 scheduled flights that arrived into the United States in 2015. In 2015, HHS/CDC issued passenger manifest requests for 64 international flights arriving into the United States. As noted in the RIA of the final rule, from 2010 to 2015, HHS/CDC conducted an average of 77 contact investigations per year involving arriving international flights.

Airlines are contacted for the majority of contact investigations using a manifest order document. At a minimum, HHS/CDC needs to confirm the ill traveler was on the flight and where the individual sat in relation to other travelers to determine risk of exposure. Further, in HHS/CDC's experience, only airlines can:

- Quickly and efficiently produce a partial manifest targeting affected rows
- confirm identity of "babes in arms" and their co-travelers (Parent); this is important for measles cases;
- quickly confirm whether an individual actually flew (in instances where individuals deplane and do not re-board during a layover); and
- confirm a plane's configuration if there is a question with the provided row numbers. Different aircraft have different seating arrangements depending on carrier and layout. It is important to know if a certain seat is separated by a bulkhead or is a window seat.

In addition, HHS/CDC only requires a partial manifest, *e.g.* 5 rows for travelers with infectious tuberculosis, so that NTC and HHS/CDC staff can limit the investigation to only those passengers at risk and supplement/cross reference with APIS and PNR data. If a partial manifest is not available from the airlines, then each passenger record must be researched individually to find a seat number, and then the configuration of an entire plane must be

populated to determine where the index case sat in relation to other at-risk passengers. For large flights from Asia, this can pose a tremendous burden to NTC and CDC staff while slowing the ability of CDC to provide important contact information to state and local health departments. Manually populating multiple 300+ person flights is not feasible in a timely manner.

Finally, CDC wishes to reiterate its desire for the above-described operations to be published in regulation to provide the public, as well as industry, with understanding of the efforts made by CDC to protect public health.

The other change to the economic baseline that may result from this final rule was the need to change the definition of an "ill person" to better match HHS/CDC guidance and the guidelines contained in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. Where possible, the marginal costs and benefits of these changes relative to the status quo baseline are monetized.

In addition, HHS/CDC believes that there is a need to better communicate to the public the actions that it has taken in accordance with its regulatory authority under *42 CFR 70.6 Apprehension and detention of persons with specific diseases, 42 CFR 71.32 Persons, carriers, and things, and § 71.33—Persons: Isolation and surveillance*. HHS/CDC believes it is necessary for the public to better understand actions that may be taken to prevent the importation of communicable diseases and to explain the due process available to individuals under Federal orders for isolation, quarantine, or conditional release. HHS/CDC also believes it is important to explain when HHS/CDC may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation and conditional release.

Finally, HHS/CDC believes it is important to explain its regulatory authority to suspend entry of animals, articles or things from designated foreign countries and places into the United States when importation increases the risk of the introduction and/or transmission of a communicable disease within the United States.

The specific market failure addressed by these regulations is that the costs associated with the spread of communicable diseases impacts the entire U.S. population, not just the group of persons currently infected with communicable diseases or with business interests in providing interstate or

international travel to persons or animals infected with communicable diseases.

The economic impact analysis of this final rule is subdivided into four sections:

1. An analysis of *42 CFR 70.1, 42 CFR 71.1/71.4/71.5*, for which the primary costs may be incurred by aircraft and vessel operators and the primary benefit is improved public health responsiveness to assess and provide post-exposure prophylaxis to travelers exposed to communicable diseases of public health concern.

2. An analysis of a number of provisions that aim to improve transparency of how HHS/CDC uses regulatory authorities to protect public health. These changes are not intended to provide HHS/CDC with new regulatory authorities, but rather to clarify the agency's standard operating procedures and policies, and due process rights for individuals. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way. In a separate appendix, HHS/CDC analyzes the costs and benefits associated with the 2014–2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits of implementation of some of these authorities, and are especially relevant when analyzing the effects of the rule relative to a non-status quo baseline.

3. In a separate appendix, HHS/CDC provides an analysis of the revisions to *42 CFR 70.13/71.30: Payment for care and treatment*, which are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The primary benefit of codification is increased transparency around HHS/CDC policies to assist in paying for treatment or transportation for individuals under Federal orders. The analysis for these provisions is an examination in potential transfer payments between HHS/CDC and healthcare facilities that provide treatment to individuals under Federal orders or to other payers.

4. In a separate appendix, HHS/CDC provides an analysis of *42 CFR 71.63: Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States*. In this final rule, HHS/CDC is

explaining its existing regulatory authority. HHS/CDC cannot predict how often such authority may be used in the future or for what purpose. HHS/CDC previously exercised this authority on June 11, 2003, when under 42 CFR 71.32(b), HHS/CDC implemented an immediate embargo on the importation

of all rodents from Africa (order Rodentia).⁶ A simple economic impact analysis of this embargo is performed to demonstrate the costs and benefits of one example, but HHS/CDC does not anticipate an increase in frequency of such actions based on the provisions included in this final rule. The primary

purpose of the analysis is to demonstrate potential costs and benefits using a realistic example.

Table 1 provides a summary of whether quantitative or qualitative analyses were performed for each of the provisions in the final rule.

TABLE 1—SUMMARY OF PROVISIONS INCLUDED IN THIS FINAL RULE

Provision	Qualitative impacts only	Codification of existing authority
§ 70.1/§ 71.1 General Definitions	No ^a	Yes (except definition of “ill person”).
§ 70.5 Requirements relating to travelers under a federal order of isolation, quarantine, or conditional release	Yes	Yes.
§ 70.6 Apprehension and detention of persons with specific diseases; § 71.32 Persons, carriers, and things (no change to title).	Yes	Yes.
§ 70.10/§ 71.20 Public health prevention measures to detect communicable disease	Yes ^b	Yes.
§ 70.11 Report of death or illness onboard aircraft operated by an airline	Yes	Yes.
§ 70.12/§ 71.36 Medical examinations	Yes	Yes.
§ 70.13/§ 71.30 Payment for Care and Treatment	Yes ^c	Yes.
§ 70.14/§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.	Yes	Yes.
§ 70.15/§ 71.38 Mandatory reassessment of a federal order for quarantine, isolation, or conditional release ...	Yes	Yes.
§ 70.16/§ 71.39 Medical review of a federal order for quarantine, isolation, or conditional release	Yes	Yes.
§ 70.17/§ 71.29 Administrative records relating to federal quarantine, isolation, or conditional release	Yes	Yes.
§ 70.18/§ 71.2 Penalties	Yes	Yes.
§ 71.4 Requirements relating to collection, storage and transmission of airline passenger, crew and flight information for public health purposes.	No ^a	Yes.
§ 71.5 Requirements relating to collection, storage and transmission of vessel passenger, crew, and voyage information for public health purposes.	No ^a	Yes.
§ 71.33 Persons: Isolation and surveillance	Yes	Yes.
§ 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.	Yes ^d	Yes.

^a Analyzed in RIA.

^b The costs and benefits associated with the 2014–2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits in a separate appendix.

^c In a separate appendix, an analysis of previous HHS/CDC payments for care and treatment is provided. However, the provisions in the Final Rule are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders.

^d In a separate appendix, HHS/CDC provides an analysis of this provision based on past experience when HHS/CDC implemented an immediate embargo on the importation of all rodents from Africa.

Executive Summary of the Costs and Benefits of 42 CFR 70.1, 42 CFR 71.1/ 71.4/71.5

Estimated Costs

The quantified costs and benefits of the final rule are estimated for the following stakeholders: Air and maritime conveyance operators, State and local public health departments (PHDs), individuals exposed to communicable diseases during travel and United States Government (USG). The most likely estimates of primary costs are low (\$32,622, range \$10,959 to \$430,839) because the final rule primarily codifies existing practice or improves alignment between regulatory text and the symptoms reporting guidelines provided by the International Civil Aviation Organization (ICAO). The

cost estimates are based on an increase in:

- The number of illness reports delivered by airlines and vessel operators to CDC, relay of air illness reports to CDC by the Federal Aviation Administration (FAA) when such reports are received by FAA air traffic service units, illness reports processed by HHS/CDC and time for travelers;
- increased costs for airlines and vessel operators to comply with HHS/CDC requests for traveler contact data;
- increased costs for State and local public health departments to follow up with a larger number of travelers exposed to communicable diseases during travel;
- The upper bound cost estimate also includes a substantial increase in training costs for the changes to illness reporting.

Estimated Benefits

The best estimate of quantified benefits of the final rule is also relatively small \$110,045 (range \$26,337 to \$297,393). This estimate is based on expected improvements in illness reporting and in the timeliness, completeness, and accuracy of contact data. These improvements should result in increased efficiencies for HHS/CDC and State and local public health departments in conducting contact investigations among travelers exposed to communicable diseases on aircraft and vessels and reduced illness costs associated with the reduced risk of measles and tuberculosis morbidity and mortality in exposed travelers.

Other potential but non-quantified benefits of the final rule would be associated with future outbreaks of

infectious disease cases for which improved compliance by airlines and vessel operators to provide available traveler contact data would reduce onward spread of disease in the destination communities of exposed travelers. In addition, the change to the definition of “ill person” may also increase reporting of communicable diseases of public health concern onboard conveyances. Reduction in onward spread would also lead to the ability of the public health establishment to reduce effects of disease outbreaks, *e.g.*, delay the spread of disease until a vaccine is available or limit the numbers of outbreaks and cases or reduce public anxiety associated with the risk of transmission. There may also be a reduction in the economic costs of many business sectors such as avoidance of costs to the travel and tourism industry^{7 8} when a disease is contained in its early stages.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of [\$146,000,000 in 2015 USD] or more.” Not only will this final rule not cost State, local and tribal governments any expenditure, it is possible that these stakeholders who might be engaged in contact tracing may see a reduction in costs if the final rule is implemented and there is an improvement in airline compliance with HHS/CDC requests to provide traveler data.

The Final Rule

Traveler contact information will only be requested by HHS/CDC after a case of serious communicable disease (index case) is reported in a person who traveled on a commercial airline or vessel while contagious. Examples of serious communicable diseases include measles, novel influenzas, and viral hemorrhagic fevers such as Ebola among others. This type of situation necessitates identifying and locating passengers seated near the index case in order to conduct a contact investigation (CI). This final rule would lead to better health outcomes if public health departments are more quickly and

effectively able to contact persons potentially exposed to the index case on an aircraft or vessel. These increased efficiencies should lead to smaller infectious disease outbreaks and fewer public health resources needed to control an outbreak.

There are multiple communicable diseases including quarantinable (*e.g.*, tuberculosis, MERS, and Ebola) and non-quarantinable (*e.g.*, measles, varicella, pertussis, rabies, meningococcal, and rubella) diseases that may necessitate a contact investigation to prevent spread of disease in the community. HHS/CDC notes that for non-quarantinable diseases, HHS/CDC efforts would primarily be limited to assisting health departments to notify individuals of their potential exposures. HHS/CDC was unable to quantify the benefits of preventing the spread of all diseases as a group because of differences in the characteristics of each disease. The differences with respect to potential spread and impact make it difficult to assess the benefits that may accrue from reduced spread of all diseases. The quantified analysis focuses on the two diseases that generate the greatest number of contacts to follow up: Measles and tuberculosis.

The ongoing persistence of measles in the United States provides a good example of the need for this final rule. In 2000, measles was declared no longer endemic in the United States due to high vaccination rates. Cases and outbreaks of measles continue to occur, however, as a result of importation from other countries and lack of adherence to the recommendation for measles vaccination (<http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html>). The United States is currently discovering the greatest number of measles cases that have been identified since the declaration of measles elimination; 97% of recent cases were associated with importations from other countries. Of 45 direct importations, 40 occurred in U.S. citizens after traveling abroad.⁹

Among air travelers exposed to measles during flights, post-exposure prophylaxis (PEP) with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days) can prevent onset of disease,¹⁰ halting outbreaks before they begin. However,

without accurate and timely contact data, it is frequently difficult to intervene within these timelines. A recent analysis showed that 9 cases likely occurred as a result of exposure during 108 flights with 74 case-travelers over 3 years. Although there was no onward transmission from these 9 cases,¹¹ future cases may lead to larger outbreaks.

Measles outbreaks can have substantial associated costs. One model-based analysis showed that 16 outbreaks with 107 confirmed measles cases cost an estimated \$2.7 million to \$5.3 million U.S. dollars for public health departments to contain.¹² The estimate is based on outbreak-specific travel expenses and the opportunity cost of diverting public health staff to outbreak response activities and is not based on the cost of hiring additional staff. This corresponds to an average cost per outbreak of about \$250,000 in 2015 USD. In comparison, a total of 125 cases occurring in 8 States and three countries were associated with a single measles outbreak that originated in late December 2014 in amusement theme parks in Orange County, California.¹³ Thus, the number of cases in this one outbreak exceeded the total number of outbreak-associated cases identified in 16 outbreaks during 2011. The source of the initial exposure has not been identified so it is not possible to determine where this index case was exposed. However, this example demonstrates the speed with which communicable diseases can be transmitted and the importance of quickly identifying persons that may have been exposed during air or maritime travel. It is possible that the costs of this one outbreak, which spread across 8 States, exceeded the total costs of all 16 outbreaks that occurred in 2011 and were estimated to cost public health departments a total of \$2.7 million to \$5.4 million dollars.¹⁴

In the absence of interventions by public health departments, travelers

¹¹ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

¹² Ortega-Sanchez, I.R., M. Vijayaraghavan, A.E. Barskey and G.S. Wallace (2012). “The economic burden of sixteen measles outbreaks on United States public health departments in 2011.” *Vaccine* 32(11).

¹³ Jennifer Zipprich, Kathleen Winter, Jill Hacker, Dongxiang Xia, James Watt, Kathleen Harriman. (2015) Measles Outbreak—California, December 2014–February 2015. *MMWR/February 20, 2015/Vol. 64/No. 6*: 153–154.

¹⁴ Ortega-Sanchez, I.R., M. Vijayaraghavan, A.E. Barskey and G.S. Wallace (2012). “The economic burden of sixteen measles outbreaks on United States public health departments in 2011.” *Vaccine* 32(11).

⁷ Rassy D, Smith RD. The economic impact of H1N1 on Mexico's tourist and pork sectors. *Health Econ.* 2013;22(7):824–34. doi: 10.1002/hec.2862. PubMed PMID: 23744805.

⁸ Keogh-Brown MR, Smith RD. The economic impact of SARS: How does the reality match the predictions? *Health Policy.* 2008;88(1):110–20.

⁹ Gastañaduy, P.A., S.B. Redd, A.P. Fiebelkorn, J.S. Rota, P.A. Rota, W.J. Bellini, J.F. Seward and G.S. Wallace (2014). “Measles—United States, January 1–May 23, 2014.” *MMWR* 63(22): 496–499.

¹⁰ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

infected with measles during international travel would be as likely as any other individuals to initiate a measles outbreak. In the absence of HHS/CDC efforts to retrieve and transmit contact data, public health departments would not be able to contact travelers to offer post-exposure prophylaxis and to recommend self-monitoring for potential measles symptoms.

Summary of Quantifiable and Qualitative Results of the Regulatory Impact Analysis

The Summary Table provides estimated total monetary results for stakeholders' costs and benefits of implementing the final rule. The Summary Table (Table 2) includes estimates associated with changes to the definition of 'ill person' in 42 CFR 70.1/71.1 and the codification of international traveler data collection processes of aircraft and vessel contact investigations under 42 CFR 71.4/71.5. The best estimates of annual costs are \$32,622 compared to the best estimate of annual benefits at \$110,045. The upper bound annual quantified costs are

\$430,839 and the upper bound quantified benefits are \$297,393. Lower bound quantified costs are \$10,959 and benefits are \$26,337.

The measles and tuberculosis examples should not be considered a complete estimate of non-quantified benefits associated with this final rule, because the impact of this final rule to mitigate many different types of infectious disease outbreaks cannot be quantified. It just provides examples based on the two diseases for which contact investigations are most frequently undertaken. Besides communicable diseases commonly reported in the United States (e.g., measles, tuberculosis), this final rule may also improve HHS/CDC's ability to respond to diseases that are infrequently diagnosed in the United States (e.g., Ebola, novel influenza, Middle East Respiratory Syndrome). For example, it is possible that HHS/CDC may need to prepare to address both Ebola and another disease such as novel influenza or Middle East Respiratory Syndrome (MERS) occurring in two separate countries or regions during a given year.

For example, in 2014, two international travelers on commercial flights from the Middle East arrived in the United States while infected with MERS and two international travelers on commercial flights from West Africa arrived while infected with Ebola. Regardless of the infectious disease scenarios faced by HHS/CDC in a given year, this final rule should improve HHS/CDC's ability to mitigate infectious diseases in the future. To the extent that the final rule would lead to improved responsiveness of airlines and vessel operators to HHS/CDC traveler data requests via manifest orders, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale contact investigations in response to a new infectious disease or one with serious public health and medical consequences like Ebola.

TABLE 2—SUMMARY OF MONETIZED AND QUALITATIVE BENEFITS AND COSTS OF THE FINAL RULE
[2015 USD]

Category	Most likely estimate	Lower bound estimate	Upper bound estimate	Source citation (RIA, preamble, etc.)
BENEFITS				
Annual monetized routine benefits from reduced effort by CDC and health department to search for exposed contacts (0% discount rate).	\$12,218	\$0	\$12,218	RIA.
Annual monetized routine benefits from reduced illness (0% discount rate)	\$97,828	\$26,337	\$272,958	RIA.
Total annual monetized routine benefits (0% discount rate)	\$110,045	\$26,337	\$285,175	RIA.
Qualitative (unquantified benefits)	To the extent that airlines or vessel operators have data available and improve responsiveness of airlines and vessel operators to HHS/CDC traveler data requests results from the implementation of the provisions in this final rule, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale CIs in response to a new infectious disease or one with serious public health and medical consequences like Ebola.			RIA.
COSTS				
Annual monetized costs for changes to illness reporting (airlines and vessel operators, 0% discount rate) *.	\$0	\$0	\$376,554	RIA.
Annual monetized costs for changes to codification of manifest order process (airlines and vessel operators), 0% discount rate) *.	\$12,654	\$0	\$25,308	RIA.
Annual monetized costs for additional activities by health department contacting individuals exposed to communicable diseases during international travel (0% discount rate).	\$19,968	\$10,959	\$28,977	RIA.
Total annual monetized routine costs (0% discount rate)	\$32,622	\$10,959	\$430,839	RIA.

TABLE 2—SUMMARY OF MONETIZED AND QUALITATIVE BENEFITS AND COSTS OF THE FINAL RULE—Continued
[2015 USD]

Category	Most likely estimate	Lower bound estimate	Upper bound estimate	Source citation (RIA, preamble, etc.)
Annual quantified, but unmonetized, costs		None		RIA.
Qualitative (unquantified) costs		None		RIA.

The second analysis in this final rule is of a number of provisions that aim to improve transparency of how HHS/CDC uses its regulatory authorities to protect public health. These changes are not intended to provide HHS/CDC with new regulatory authorities, but rather to clarify the agency's standard operating procedures and policies with regard to pre-existing regulations in 42 CFR parts 70 and 71 including due process rights for individuals under Federal orders. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and

procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way.

Economic Baseline

Regulated Entities: Airlines and Vessel Operators

The group of entities that may be affected by this final rule would include international and interstate aircraft operators, vessel operators, travelers, State or local health departments and the Federal government agencies that interact with these groups. Since this

final rule primarily updates regulatory requirements to better match current practice, the economic impacts are marginal changes to current practice that result from codification of current practices.

The North American Industry Classification System (NAICS) is used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. A summary of the total numbers of each entity is summarized in Table 3.

TABLE 3—SUMMARY OF THE NUMBER OF FIRMS ENGAGED IN INTERSTATE AND INTERNATIONAL AIR AND MARITIME TRAVEL

NAICS codes	NAICS description	Number of firms in industry
481111	Scheduled Passenger Air Transportation	264
481112	Scheduled Freight Air Transportation	212
481219	Other Nonscheduled Air Transportation	516
483111	Deep Sea Freight Transportation	191
483112	Deep Sea Passenger Transportation	54
483113	Coastal and Great Lakes Freight Transportation	337
483114	Coastal and Great Lakes Passenger Transportation	110
483211	Inland Water Freight Transportation	318
483212	Inland Water Passenger Transportation	193

Statistics of U.S. Businesses, 2013 U.S. all industries.¹⁵
2012 North American Industry Classification System (NAICS).¹⁶

According to a report by the Federal Aviation Administration, in 2012, U.S. civil aviation-related economic activity generated \$1.5 trillion and supported 11.8 million jobs with \$459.4 billion in earnings.¹⁷ In 2015, the domestic U.S. market for air travel included 696 million passengers and the international market included another 198 million travelers.¹⁸

In 2011, there were approximately 11 million North American cruise ship passengers spending 71.8 million passenger nights on board vessels. The cruise ship market was highly concentrated with four firms accounting for 98% of the total market.¹⁹ In total, approximately 18 million travelers enter the United States each year via cruise or cargo ships.²⁰

The domestic/international air carrier market is an ever-shifting corporate

landscape. Both U.S. and foreign airlines engage in “code-sharing” arrangements, whereby the marketing carrier places its call sign (or code) on the operating carrier's flight. For purposes of this rule, reporting duty would require the operating carrier to report on *all* passengers and crewmembers, whether traveling on the operator's code or another carrier's.

The complexity of the domestic/foreign airline-corporations' legal and financial arrangements makes it very difficult to ascertain exactly how each and every domestic and foreign airline would be affected by the implementation costs associated with this final rule; presumably, some of the costs might be passed along to the carrier putting its code on the operating carrier, pursuant to the particular terms of each applicable contract.

¹⁵ <http://www.census.gov/econ/susb/>.

¹⁶ <https://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

¹⁷ U.S. Department of Transportation, Federal Aviation Administration (January 2015) The Economic Impact of Civil Aviation on the U.S. Economy: Economic Impact of Civil Aviation by State. http://www.faa.gov/air_traffic/publications/media/2015-economic-impact-report.pdf (Accessed 5/2/2016).

¹⁸ Bureau of Transportation Statistics T-100 Market data. <http://www.transtats.bts.gov/DataElements.aspx?Data=1> (Accessed 5/2/2016).

¹⁹ U.S. Department of Transportation Maritime Administration (March 2012) North American Cruise Statistical Snapshot, 2011 http://www.marad.dot.gov/wp-content/uploads/pdf/North_American_Cruise_Statistics_Quarterly_Snapshot.pdf (Accessed 5/2/2016).

²⁰ According to the U.S. Department of Homeland Security, 54,236 passengers and crew arrive via vessel each day, which correspond to approximately 18 million per year. <https://www.transportation.gov/policy/aviation-policy/us-international-air-passenger-and-freight-statistics-report> Accessed on 5/2/2106.

Under this final rule, the operator of any airline operating a flight arriving into the United States must make certain contact information described below available within 24 hours of a request by HHS/CDC, to the extent that such data are available to the operator. This requirement also applies to the operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined in under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10–25). This requirement is a codification of current practice, and applies to any of the data elements that the airline or vessel operator may have available and authorizes the airline or vessel operator to transmit the contact information in any format and through any system available and acceptable to both the airline and HHS/CDC. Again, because this is a codification of current practices, HHS/CDC assumes airlines and vessel operators will continue to submit data through current mechanisms, although HHS/CDC will accept others that are mutually acceptable.

To simplify the analysis and to develop conservative cost estimates, HHS/CDC assumed that all costs to airlines and vessel operators would be passed along to U.S.-based airlines, vessel operators, or U.S. consumers.

Diseases Affected by the Rule

HHS/CDC has gathered statistics, or reported information on, a number of notifiable and quarantinable diseases (Table 4) that form the basis for estimates of quantitative and qualitative benefits. The final rule provides CDC with the authority to take certain actions with regard to both quarantinable and non-quarantinable diseases. For non-quarantinable diseases, efforts would be primarily limited to early identification and notification of exposed individuals and transmission of contact data to local and State health departments. For

quarantinable diseases, efforts could include issuance of Federal orders for quarantine, isolation, or conditional release of exposed/infected individuals.

TABLE 4—DISEASES ANALYZED

Non-quarantinable	Quarantinable
Measles Pertussis Rabies Meningococcal disease Varicella Rubella	Tuberculosis. Viral Hemorrhagic Fevers. Middle East Respiratory Syndrome Coronavirus (MERS).

In addition, these diseases for which HHS/CDC currently issues manifest orders and conducts contact investigations can also be subdivided to identify those encountered with some frequency (routine diseases): Tuberculosis, measles, meningococcal disease, pertussis and rubella. Among these diseases, only tuberculosis is a quarantinable disease. The second class is a group of new or emerging diseases, or diseases with serious public health and medical consequences, that are not currently prevalent, but are foreseeable as a future threat, *e.g.*, severe acute respiratory syndromes (including SARS and MERS), Ebola. This second group only includes quarantinable diseases, which may be updated in the future by Executive Order, but which are not being updated as a part of the final rule. Although HHS/CDC may help identify travelers ill with or exposed to measles, meningococcal disease, pertussis, rubella, rabies, and varicella, HHS/CDC does not have the authority to place any travelers with such illnesses or exposures under Federal orders. For quarantinable diseases, illness reporting could lead to issuance of Federal orders if travelers are reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage. Such restrictions would not occur based simply on an illness report by

airline or vessel operator staff and would require a medical assessment by a public health professional.

Contact Investigations and Diseases—Interstate and International

The number of travelers exposed to an index case that are subject to a contact investigation (CI) varies by disease and may include only the two passengers sitting adjacent to the index case (meningococcal disease or pertussis) or as much as the entire aircraft (*e.g.*, initial investigations of cases of MERS or Ebola) (Table 5). The entire aircraft or vessel may be subject to CI if the disease is new and transmission patterns are not well understood (*e.g.*, MERS) or if the disease is felt to have serious medical or public health consequences (*e.g.*, Ebola). Some CIs are only initiated for long-duration travel (*e.g.*, tuberculosis for flights of 8 hours or longer). For other diseases (*e.g.*, measles, MERS), CIs are undertaken regardless of duration.

The table also includes criteria to be considered a contact for persons exposed on vessels. In contrast to air contact investigations, most maritime contact investigations are undertaken before travelers disembark from vessels. Another difference between air and maritime contact investigations is that varicella contact investigations are frequently undertaken among maritime travelers on vessels, but are not pursued for air travelers. In addition, HHS/CDC has not yet had to conduct a contact investigation for Middle East Respiratory Syndrome or viral hemorrhagic fever for travelers exposed on vessels. The criteria listed in Table 5 are current as of October 2016, but may be updated in the future based on reviews of the effectiveness of contact investigations. For example, HHS/CDC stopped providing contact data to health departments for mumps investigations after reviewing evidence of the effectiveness of mumps contact investigations.

TABLE 5—CONTACT INVESTIGATION CRITERIA BY DISEASE, PHD FOLLOW UP

Disease	CI initiated if	Persons contacted, aircraft	Persons contacted, vessels	Recommended activities
Ebola (Quarantinable).	All cases	All passengers and crew as of April 2016. In the future, the recommendation may change to include fewer passengers and crew.	Cruise vessel—any passenger or crew who made have come into contact with the index case's body fluids while the index case was symptomatic. Cargo vessel—all on board the vessel while the index case was symptomatic.	Monitoring for 21 days after last potential exposure.

TABLE 5—CONTACT INVESTIGATION CRITERIA BY DISEASE, PHD FOLLOW UP—Continued

Disease	CI initiated if	Persons contacted, aircraft	Persons contacted, vessels	Recommended activities
Measles (Non-quarantinable).	All cases if notification received within 21 days of flight.	Passengers seated within 2 rows either direction of the index case, all babies-in-arms, crew in same cabin. All passengers and crew on flights with <50 seats.	Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient.	Offer MMR vaccination if non-immune and <72 hrs. since exposure; immune globulin if indicated and within 6 days of exposure.
Meningo-coccal disease (Non-quarantinable).	Case meets the definition of meningococcal disease within 14 days of travel. For air travel: Flight >8 hrs. (or shorter flights if direct exposure reported).	Passengers or crew sitting directly to the left and right of the index case or with potential for direct contact with oral or respiratory secretions.	Cruise vessels—Cabin mates of or potential for direct contact with oral or respiratory secretions of case-patient during the 7 days prior to symptom onset until 24 hours after implementation of effective antimicrobial therapy. Cargo vessels—All on board the vessel during the 7 days prior to symptom onset of case-patient until 24 hours after implementation of effective antimicrobial therapy.	Post-exposure chemoprophylaxis.
New or re-emerging influenza viruses (Quarantinable).	All cases during early stages of international spread.	All passengers and crew	All crew and passengers	Monitoring for 10 days after last potential exposure; possible serologic testing.
Pertussis (Non-quarantinable).	All cases if notification is received within 21 days of travel.	Passengers sitting next to index case.	Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient.	Post-exposure chemoprophylaxis.
Rubella (Non-quarantinable).	All cases if notification is received within 60 days of travel.	Passengers seated within 2 rows + crew in same cabin. All passengers and crew on flights with <50 seats.	Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient.	Serologic testing and guidance for pregnant women.
Severe Acute Respiratory Syndromes (Quarantinable).	All cases	SARS-Coronavirus: All passengers and crew. MERS: All passengers and crew contacted during 2014 CIs. Future CIs will include passengers seated within 2 rows of index case.	Cruise vessel—any passenger or crew who had direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient. Cargo vessel—all on board the vessel while the index case was symptomatic.	Monitoring for 10–14 days after last potential exposure; potential serologic testing.
TB (Quarantinable).	Notification received within 3 months of travel, clinical criteria met For air travel: Flight >8 hrs.	Passengers seated within 2 rows.	Cargo vessel: All crew members within 3 months of diagnosis who worked with case-patient. Cruise vessel: Passenger travel companions or crew working in close proximity/ sharing living quarters.	Aircraft: Testing for latent TB infection; chest radiograph if the LTBI test is positive. Vessels: Clinical assessment for symptoms and chest radiograph.
Varicella (Non-quarantinable).	All cases on vessels	NA	Any person who has had ≥5 minutes of direct face-to-face contact with a varicella case during the infectious period.	Varicella vaccination if unvaccinated/non-immune and <3 days since exposure (possibly up to 5 days). High-risk contacts evaluated Varicella Zoster immune globulin if <10 days after exposure.

The Quarantine Activity Reporting System (QARS), which contains, among other data, information collected under OMB Control Numbers 0920–0134, 0920–0488, 0920–0821, and 0920–0900, is a web-based and secure electronic system that supports collection of data for ill persons on inbound or interstate

flights and vessels and at land border crossings; infectious disease threats, and follow-up actions. Currently, HHS/CDC Quarantine Stations at U.S. ports of entry are using the system to record their daily activities. All CIs undertaken by HHS/CDC are documented in QARS.

CIs for international flights from January 2010 through December 2015 are summarized in Table 6. More than half (73.2%) were initiated as a result of tuberculosis cases. Measles is the next most common disease (20.8%). The remaining 6% are subdivided across rubella, pertussis, meningococcal

disease and other diseases. This table also includes CIs undertaken for MERS.

TABLE 6—INTERNATIONAL AIR CONTACT INVESTIGATIONS, AVERAGE NUMBER OF ANNUAL INVESTIGATIONS AND CONTACTS BY DISEASE, JAN 2010 THROUGH DEC 2015
[QARS data]^a

Disease	Total investigations	Total contacts	Average investigations per year	Average contacts per year	Percent of total contacts
Influenza, avian	0	0	0.0	0.0	0.0
MERS Coronavirus ^b	2	270	0.3	45.0	1.7
Measles	94	3,381	15.7	563.5	20.8
Meningococcal disease	8	9	1.3	1.5	0.1
Other	3	97	0.5	16.2	0.6
Pertussis	11	18	1.8	3.0	0.1
Rabies	3	4	0.5	0.7	0.0
Rubella	17	532	2.8	88.7	3.3
TB (clinically active)	318	11,928	53.0	1,988.0	73.2
Viral hemorrhagic fever	7	53	1.2	8.8	0.3
Total	463	16,292	77.2	2,715	

^aIn May 2011, CIs were discontinued for international outbound flights. To give a better picture of what CIs will look like under this new protocol, flights from January 2010 to May 2011 have been excluded from the above-reported counts. In addition, CIs for mumps have been discontinued. Prior to discontinuation, there were approximately 25 contacts per year investigated for mumps.

^bFor these CIs, contact information for the entire flight was required.

In rare instances, a disease is ruled out after a CI has happened.

HHS/CDC also requests traveler contact data to support contact investigations for travelers exposed to infectious diseases on interstate flights. The numbers of investigations and contacts during 2010–15 are

summarized in Table 7. In contrast to international flights, very few contact investigations for tuberculosis were undertaken on interstate flights, because most interstate flights do not meet the 8-hour time requirement for

tuberculosis contact investigations (Table 5). The majority of contacts were investigated after exposure to measles cases (76%) followed by MERS (8.4%) and viral hemorrhagic fevers including Ebola (8.0%).

TABLE 7—INTERSTATE AIR CONTACT INVESTIGATIONS, AVERAGE NUMBER OF ANNUAL INVESTIGATIONS AND CONTACTS BY DISEASE, JANUARY 2010 THROUGH DECEMBER 2015
[QARS data]

Disease	Total investigations	Total contacts	Average number of investigations per year	Average number of contacts per year	Percent of total contacts
Measles	72	3033	12.0	505.5	76.1
Meningococcal disease	1	1	0.2	0.2	0.0
MERS Coronavirus ^a	2	334	0.3	55.7	8.4
Other	0	0	0.0	0.0	0.0
Pertussis	43	83	7.2	13.8	2.1
Rabies	3	3	0.5	0.5	0.1
Rubella	8	172	1.3	28.7	4.3
TB (clinically active)	2	40	0.3	6.7	1.0
Viral hemorrhagic fever	4	319	0.7	53.2	8.0
Total	135	3,985	22.5	664.2	

Notes:

^aFor these CIs, contact information for the entire flight was required.

In rare instances, a disease is ruled out after a CI has happened.

The numbers of contacts for maritime contact investigations are summarized in Table 8. For maritime investigations, the majority of contacts were investigated for varicella (~79%) followed by tuberculosis (~13%) and

measles (~6%). Most of the varicella and measles contact investigations were initiated while travelers were still on vessels. Besides the investigations listed in Table 8, gastrointestinal illness cases on cruise vessels carrying 13 or more

passengers are reported to HHS/CDC's Vessel Sanitation Program and cases of Legionnaires' disease are reported directly to HHS/CDC's Respiratory Diseases Branch.

TABLE 8—MARITIME PASSENGER DATA COLLECTION, AVERAGE NUMBER OF ANNUAL CONTACTS BY DISEASE
[January 2010–December 2015]

Passengers per voyage	Total investigations	Total contacts	Average number of investigations per year	Average number of contacts per year	Percent of total contacts
Measles	5	288	0.83	48	6.3
Meningococcal disease	3	22	0.5	3.67	0.5
MERS Coronavirus **	0	0	0	0	0.0
Other	1	9	0.17	1.5	0.2
Pertussis	3	14	0.5	2.33	0.3
Rabies	0	0	0	0	0.0
Rubella	2	26	0.33	4.33	0.6
TB (clinically active)	50	585	8.3	97.5	12.8
Viral hemorrhagic fever	0	0	0	0	0.0
Varicella (chickenpox) ^a	206	3,627	34.3	604.5	79.3
Total	270	4,571	45	761.8	100.0

^aOne CI for varicella involved entire crew of the vessel (1224).

Traveler Manifest Orders for Airlines

Contact tracing is most effective at reducing cases of communicable disease at the early stages of a potential outbreak as soon after initial exposure as possible. Therefore, if an efficient contact system is not in place when the first ill travelers arrive, the benefits of contact tracing are greatly diminished.

Contact data requests only occur after a case of serious communicable disease (index case) is reported in a person who traveled on a commercial airline or vessel while contagious. This type of situation necessitates identifying and locating travelers seated near the index case in order to conduct a CI.

At present, HHS/CDC uses a multi-step process to obtain traveler contact information from airlines. HHS/CDC issues a written order to the airline that requires the airline to provide HHS/CDC with contact information about the index case and traveler contacts. The order cites current regulatory language in 42 CFR 71.32(b), as authorized by 42 U.S.C. 264. HHS/CDC requires that the airline provide it with the traveler's first and last name, seat number, two phone numbers and email address. HHS/CDC instructs airlines and vessel operators to provide data when available or to report when data are unavailable. The time it takes for HHS/CDC to obtain the available traveler contact data can range from a few hours to a few days. From 2010 through May 2015, about 70% of manifests from airlines arrived within 3 days of the request, 15% arrived between 3 and 6 days after a request, 15% arrived after more than six days, and nine requests took more than a month or were never received by HHS/CDC.

At present, HHS/CDC requests that airlines and vessels provide available traveler contact data within 24 hours for

“urgent” manifest requests. In current practice, requests for contact data are only considered “non-urgent” for contact investigations in which travelers had rubella (for which there is no available prophylaxis) or tuberculosis or for situations in which HHS/CDC is not notified of travelers diagnosed with some communicable diseases until after a certain amount of time during which prophylaxis would be effective (*e.g.*, for measles: 6 days). If the analysis is limited to diseases where requests for traveler contact data are marked “urgent” by HHS/CDC (measles, meningococcal disease, MERS, viral hemorrhagic fevers, and rabies), performance improved such that 51% arrived within 24 hours of a request, 33% arrived between 1–3 days after a request, 13% between 3–6 days and only 3% arrived after 6 days. HHS/CDC notes that there may be instances where CDC may not have included the correct information in a manifest order (*e.g.*, flight number or port of entry). The provision of incorrect flight information may have caused delay submission in some of the instances cited above.

While HHS/CDC requires that all information be provided upon first order for information, HHS/CDC has consistently seen that the information provided by a majority of airlines appears limited to frequent flyer information, or other limited contact information. Overall, the completeness of data provided by airlines varied such that airlines generally fell into two categories. Some airlines always provided only the passenger name and seat number. Other airlines would provide some additional contact information for passengers. However, even among these airlines, contact data for some of the passengers only included names and seat numbers.

Considering all requests from 2014, at least one additional piece of contact information was provided for only about 39% of passengers. If the sample were restricted to only flights for which any contact information was provided (1,270 out of 2,411 total passengers), the fraction of passengers with at least one piece of contact information beyond name and seat number increased from 39% to 73.9%. This contact information would include U.S. address for 41.7% of passengers and one phone number for 45% of passengers. As a result of HHS/CDC's use of available information and technology and its partnerships with other Federal agencies, contact tracing of exposed travelers can now be accomplished more rapidly than would be possible if only the contact data provided by airlines were used. However, if airlines or vessel operators have additional data relative to what is currently provided to DHS, the efficiency of contact investigations could improve.

Change to Definition of an “Ill Person”

HHS/CDC is updating the definition of “ill person” in 42 CFR 70.1 and 71.1 to better facilitate identification of communicable diseases of public health concern aboard flights and voyages. However, HHS/CDC currently requests that aircraft and vessels report several of the symptoms included in the revised definition of ill person. Besides aircraft and vessel operators, quarantine stations also receive illness reports from U.S. Customs and Border Protection, U.S. Coast Guard, State and local health departments, and health facilities. These reports are not included in this analysis, which focuses on reporting during travel.

HHS/CDC has crafted the definition of “ill person” in such a way that it should

be understood by non-medically trained crewmembers and used to discern illnesses of public health interest that HHS/CDC would like to be made aware of according to 42 CFR 70.4 from those that it does not (e.g., common cold), while more closely aligning the definition with the symptoms reporting guidelines published by ICAO in *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. To further assist flight crewmembers (and vessel crewmembers under part 71) in identifying individuals with a reportable illness, HHS/CDC provides the following in-depth explanations and examples of the communicable diseases that such signs and symptoms might indicate. Note that these explanations also apply to the definition of “ill person” under part 71 and are discussed in the preamble of this final rule.

The current illness reporting requirements for interstate travel are summarized in 42 CFR 70.4 and state that “The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.” Communicable disease is defined in 42 CFR 70.1 as “illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or

indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.”

Thus, the changes in this final rule would amount to fewer illness reports than may be anticipated under the current regulation. However, in practice, according to CDC guidance available at <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>, the symptoms requested for international and interstate illness reporting are the same subset. In addition, according to guidance, reports received by HHS/CDC would be considered sufficient to satisfy the requirement to report to local health departments since HHS/CDC would coordinate any response activities with the local health department after receipt of the illness report.

This final rule would align the definition from CDC guidance with regulatory text by requiring reports of ill travelers with fever and persistent cough, persistent vomiting, difficulty breathing, headache with stiff neck, decreased consciousness, travelers appearing obviously unwell, or unexplained bleeding. In practice, the codification of such guidance may increase costs to some or all airlines and vessel operators who submit illness reports based only upon symptoms currently identified in 42 CFR 71.1 and not based on HHS/CDC guidance. For illness reports from aircraft, DOT/FAA may also incur additional costs if the number of illness reports made by aircraft pilots in command to air traffic control and reported to HHS/CDC via the Domestic Events Network increases.

For aircraft, the updated definition better aligns with symptoms reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. Therefore, HHS/CDC does not anticipate much additional burden on airlines and vessel operators to report ill travelers during travel.

Although HHS/CDC estimates the net change will be no cost to airline or vessel operators, it may be possible to examine the potential increase using simple assumptions. Table 9 shows the number of reports by pilots in command during flights and recorded in HHS/CDC's Quarantine Activity Reporting System (QARS). These include reports of illness that fit the illness definition specified in current 42 CFR 71.1, reports based on HHS/CDC's guidance for airlines and vessel operators, reports made based on the guidelines in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation, or illness reports unrelated to current regulation or guidance. Such reports can also be subdivided into reports requiring HHS/CDC response (“response reports”) and reports that HHS/CDC receives, but which do not require an HHS/CDC response (“info-only reports”). Info-only reports may include symptoms included in HHS/CDC guidance, but for which the underlying condition can easily be diagnosed not to be a communicable disease of public health concern (e.g., influenza-like illness on an aircraft). Info-only reports can also be based on illnesses not requested by HHS/CDC guidance (e.g., motion sickness).

TABLE 9—TOTAL NUMBERS OF REPORTS MADE DURING FLIGHT BY AIRCRAFT OPERATORS, 2011 TO 2015
[HHS/CDC QARS data]

Year	Category	Based on symptoms included in current regulation	Based on symptoms included in final rule	Reports not based on symptoms included in either current regulation or final rule	Total
2015	Info-only	30	55	43	128
	Response	33	22	15	70
2014	Info-only	33	61	42	136
	Response	19	36	12	67
2013	Info-only	31	46	29	106
	Response	21	25	4	50
2012	Info-only	34	58	38	130
	Response	12	18	2	32
2011	Info-only	27	39	25	91
	Response	25	29	13	67
Average, Info-only		31	51.8	35.4	118.2
Average Response		22	26	9.2	57.2
Average, total		53	77.8	44.6	175.4

In addition to illness reports, HHS/CDC receives an average of 10 death reports during air travel each year. Since death reporting requirements are not changing, these are not analyzed.

Table 9 shows that HHS/CDC already receives a number of reports based on symptoms included in HHS/CDC guidance that will be codified with this final rule. On average, among the total 175 illness reports per year, about 78 annual reports are based on symptoms included in the final rule, but not in current regulations compared to 53 reports based on symptoms already listed in current regulations. The remaining 45 reports would include those based on fever alone or based on

symptoms not included either in current regulatory text or in this final rule.

The number of illness reports from master of vessels during voyages is summarized in Table 10. Compared to the breakdown in reports for aircraft, the vast majority of illness reports during voyages are for response as opposed to info-only. There may be greater specificity in reports from cruise vessels because of the presence of medical officers onboard vessels. On average, there were about 208 reports requiring

follow-up and 10.6 info-only reports each year. In contrast to reports from aircraft, most of the reporting for vessels pertains to symptoms included in the current regulation (175 per year) as opposed to those specified in this final rule (32 per year). Very few reports from vessels (3.4 per year) were based on fever only or based on symptoms not included in either current regulation or specified in this final rule.

TABLE 10—TOTAL NUMBERS OF ILLNESS REPORTS (EXCLUDING INFLUENZA-LIKE ILLNESS) MADE DURING VOYAGE BY MASTERS OF VESSELS, 2011 TO 2015
[HHS/CDC QARS data]

Year	Type of report	Based on symptoms included in current regulation	Based on symptoms included in final rule	Reports not based on symptoms included in either current regulation or final rule	Total
2015	Info-only	5	4	4	13
	Response	179	21	1	201
2014	Info-only	6	3	3	12
	Response	168	21	12	201
2013	Info-only	1	1	3	5
	Response	145	48	11	204
2012	Info-only	5	7	3	15
	Response	167	19	1	187
2011	Info-only	1	3	4	8
	Response	196	32	19	247
Average, Info-only		3.6	3.6	3.4	10.6
Average Response		171	28.2	8.8	208
Average, total		174.6	31.8	12.2	218.6

In addition to the illness reports reported in the table, HHS/CDC receives about 115 reports of death during maritime travel each year. In addition, HHS/CDC requests, but not require reporting of influenza-like-illness from cruise vessels (also not included in above table).

Baseline Contact Investigation Process for Routinely Imported Diseases

This section reports the primary steps of CIs for routine diseases:

- A traveler (the index case) is identified as ill either during the flight or voyage with a reportable illness or after with a notifiable disease. The aircraft pilot in command or master of vessel may report the illness directly to HHS/CDC. Illnesses on aircraft may also be reported indirectly to HHS/CDC via air traffic control. The FAA then passes the report to CDC through the Domestic Event Network. If the report occurs after travel, a healthcare facility would then report the illness either to HHS/CDC or public health departments (PHDs).

- If CI criteria are met, HHS/CDC contacts the airlines for

- a manifest to determine where the index case was seated in relation to other passengers or crew members,

- HHS/CDC then requests information available from DHS' databases to verify or obtain passenger contact information not included in the manifest.

- If data are not available in DHS databases, HHS/CDC will require (as part of the manifest order) for the airlines to provide any available traveler contact information. The number of travelers for which contact data will be requested is based on the disease-specific criteria listed in Table 5.

Once HHS/CDC has the traveler contact information and flight-seating chart, the CI begins. Current CI procedures are cumbersome, in part because of the difficulties associated with obtaining traveler contact information. HHS/CDC staff may contact airlines more than once to obtain traveler contact data including email address, one or two phone numbers, and address in the United States for U.S. citizens and permanent residents.

When passenger contact information is delayed or partial, State/local public health departments are delayed in starting CIs and, depending on the disease, this delay could make it impossible to prevent illness and/or the transmission of disease. Further, PHDs

could have improved success contacting passengers with more accurate or timelier data.

The model for estimating the benefits of CIs is: Current number of CIs × (reduction in HHS/CDC and health department staff time/resources per contact) × value of staff time.

The rest of this section reports both the quantifiable benefits arising from streamlining the CI process and a discussion of health benefits. The differential impacts of the various diseases make it hard to summarize the final rule's effects given uncertainty around future probabilities of case(s) of multiple such notifiable disease(s). The timeliness of contact investigations could also be improved if improvements in illness reporting led to earlier diagnoses of communicable diseases.

Estimating the Number of Infected Travelers

Most air travelers with illness are not identified in flight, but rather seek medical care and are identified as an

index case after their travel is completed. Compared to air travelers, maritime travelers spend more time on vessels during voyages and medical officers may be employed on cruise vessels.

When communicable diseases are diagnosed after travel, the medical practitioner should notify HHS/CDC or a PHD if the diagnosed disease is on either the list of quarantinable communicable diseases or the list of notifiable diseases. If HHS/CDC can draw upon improved contact information based on the codification of requests for traveler contact data to aircraft and vessel operators as set forth in this final rule, the risk of onward disease transmission can be reduced. By contacting ill travelers more quickly, HHS/CDC may slow the spread and the severity of the outbreak. The benefits therefore depend on:

- How many infected travelers are expected to enter the United States;
- How many quarantinable or notifiable diseases are detected either on-board the aircraft/vessel or reported to HHS/CDC by PHDs;
- How many exposed travelers will become ill as a result of exposure during travel;
- How the infection will be transmitted within the U.S. population;
- How effective public health agency contact tracing will be with and without the final rule.

In addition to improved efficiencies associated with more timely or more complete provision of traveler contact data by airlines and vessel operators, there may also be an increase in the number of reports of ill travelers during travel that require HHS/CDC follow-up. Under the most likely scenario, there will not be a change in these reports, since the new definition better corresponds to reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation and current HHS/CDC guidance. However, there may be an increase in illness reports depending on whether airlines and vessel operators increase reporting for required rather than recommended symptoms.

Contact Investigations Supported by CDC and Undertaken by Partners at State and Local Health Departments

The change to the definition of an “ill person” for the purposes of illness reporting and the codification of HHS/CDC requests from airlines and vessel operators for traveler contact data may improve HHS/CDC’s ability to respond effectively and mitigate infectious disease outbreaks. There are a number

of intermediate steps between either an illness report or receiving more complete or timelier traveler data and stopping an infectious disease outbreak. For example, the travelers exposed to the infectious disease would have to be contacted by health departments and comply with recommended public health measures, which could include some form of public health or medical follow up to mitigate their risk of becoming ill, or self-monitoring/quarantine to mitigate the risk of transmitting that disease to other individuals.

The amount of time HHS/CDC staff spend per air or maritime contact varies with the size of the CI because some tasks are CI-specific, such as filling out reports or obtaining manifests, and some are contact-specific such as determining a specific traveler’s contact information. The CI-specific labor time costs less per contact when an investigation includes more contacts, *e.g.*, a manifest that takes 60 minutes of HHS/CDC staff time to obtain for 2 contacts is the equivalent of 30 minutes-staff-time-per-contact while the same manifest listing 30 contacts is the equivalent of 2 minutes-staff-time-per-contact. On the other hand, the traveler-specific time tends to increase-per-contact with less information and decrease-per-contact with more information.²¹ Further, the QARS system used to document and follow up on CIs requires full-time personnel to maintain the system, pull regular reports, and monitor follow-up of travelers contacted during CIs. Finally, HHS/CDC has two full-time persons regularly assigned as liaisons to DHS whose duties include gathering contact information from DHS systems. Therefore, for HHS/CDC staff time to initiate and follow up on different sized CIs, to track down traveler contact information from multiple sources, to work with PHDs, document and report on CIs, update and train in systems, and manage the staff involved in CIs, a cost of \$180 per contact is estimated. This is the equivalent of 2 hours of a HHS/CDC staff person’s being paid the salary of a GS–13, step 4 plus 100% for benefits and employee overhead costs (Table 11).

For PHD resources, HHS/CDC also estimated a cost-per-contact of \$180, which is consistent with HHS/CDC costs and a recent publication adjusted to 2015 dollars.²² PHD processes vary greatly from State to State and at the

local level within a State. A couple of examples:

- One State assigns 2 registered nurses (RNs) who perform 5 CIs or fewer per year for the entire State another State assigns 3 RNs, a Public Health Service Medical Officer, a physician, and a data analyst and conducts about 25 CIs a year.²³

- When one State receives information about passenger contacts from HHS/CDC, the State epidemiologist creates several documents to fax to the relevant county health departments, a team of an epidemiologist and RNs at the county then either call or visit the contacts if there is an address. But the State epidemiologist will make every effort to locate travelers even if their final destination is unclear.²⁴

Finally, different diseases may elicit different levels of response at the PHD level, with a more rapid response for highly infectious diseases like measles that can be prevented with timely post-exposure prophylaxis and a more measured response for less infectious diseases like TB. By using the same cost for HHS/CDC and for PHDs, HHS/CDC believes the potential reductions in cost from reduced effort for PHDs to locate infectious disease contacts are conservatively estimated.

TABLE 11—COST-PER-CONTACT

CDC	PHD
\$180	\$180

Infectious Disease Transmission During International Travel

For some diseases, there is empirical data from which onboard transmission can be estimated. According to a published analysis of the outcomes of measles contact investigations (74 case-travelers on 108 flights resulting in 3,399 contacts) in the United States between December 2008 and December 2011, HHS/CDC could not assign 9% of measles contacts (322) to a health department due to insufficient contact data. Another 12% of these contacts (397) were believed to be outside the United States.²⁵ After HHS/CDC provides contact data to State health departments, HHS/CDC requests, but does not require health departments to

²³ Personal communication from states to Dr. Margaret S. Coleman 2010.

²⁴ Discussion between Dr. Brian Maskery, Dr. Margaret S. Coleman and State and County Health Department contacts 11/21/2014.

²⁵ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

²¹ Margaret S. Coleman, unpublished data.

²² Coleman, M.S., Marienau, K.J., Marano, N., Marks, S.M., Cetron, M.S. (2014). “Economics of United States tuberculosis airline contact investigation policies: a return on investment analysis.” *TMAID* 12(1):63–71.

provide data on the outcomes of their attempts to follow-up with travelers. Among the 2,673 contacts assigned to U.S. public health departments in 2008–11, HHS/CDC only received outcome data for 1,177 out of the 2,673 assigned contacts. This outcome data included reports from State health departments that 225 out of the 1,177 assigned contacts could not be located (19%). Among the 952 contacts for which HHS/CDC received measles outcome data from health departments, there were 9 lab-confirmed measles cases (1%). Since there may be reporting bias from health departments (*i.e.* health departments would be more likely to report outcome data for contacts that developed measles than for other exposed travelers that did not develop measles, HHS/CDC considers a range of measles incidence rates among exposed travelers from 9 cases/2,673 contacts assigned to health departments (0.34%) to 9 cases/952 exposed contacts with outcome data reported to HHS/CDC (0.95%). This probability could overstate or understate the true transmission rate depending on the length of the flight and seating configuration. On the other hand, it may understate the probability if cases were not reported or occurred overseas.

The majority of travelers exposed to measles on aircraft (~74%) had pre-existing immunity based on past measles immunization, past measles illness, or being born prior to 1957 and thus likely to have measles immunity even if they do not recall experiencing the disease.²⁶ Among the 952 exposed travelers, 8 cases occurred in the 247 contacts (3.2%) without known pre-existing immunity compared to 1 case in the 705 contacts with past history of vaccination or measles illness (0.1%). The median age of measles cases in exposed air traveler contacts was 1.6 years.

Intervention by public health departments mitigates the risk of measles transmission in two ways. First, exposed travelers without measles immunity may be offered voluntary post-exposure prophylaxis with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days),²⁷ which can prevent onset of disease, halting outbreaks before they begin. Under the status quo, relatively few exposed travelers receive post-exposure prophylaxis (just 11 out of 248

travelers with no history of measles immunization or infection). Second, exposed travelers would be counseled by health departments to self-isolate and seek treatment if they started to experience symptoms consistent with measles onset. For example infants exposed during travel and too young to be vaccinated could arrange for special precautions if they visit a pediatrician after becoming ill with measles-like symptoms to minimize the transmission to other unvaccinated infants. Both activities will limit the possibility of measles transmission to family members or others in the community. The attack rate for measles is estimated to be 90%, but the high background immunization rate and high efficacy of measles vaccine attenuates the burden of measles outbreaks in the United States.

In summary, the potential size of a measles outbreak occurring depends on:

- The number of persons contacted by the infectious measles patient
- Background immunity among persons contacted
- Survey estimates have shown considerable heterogeneity in background vaccination rates such that 80% of unvaccinated children live in counties comprising 40% of the total population.²⁸

For tuberculosis, it is difficult to estimate the transmission rate on an aircraft or vessel. A modeling study suggests that the risk of infection is about 1/1000 on an 8.7 hour flight and that persons seated closer to the index case are at greater risk of infection.²⁹ Only 5–10% of persons infected with the bacteria *Mycobacterium tuberculosis* will go on to develop active, infectious disease and the risk of progression is greatest within the first two years after infection.³⁰

An analysis of the epidemiology and outcomes of HHS/CDC-led flight-related tuberculosis contact investigations conducted in the United States from January 2007 to June 2008 examined 131 case-travelers and 4,550 passenger-contacts.³¹ Among 3,375 (74%)

passenger-contacts whose information was provided to health departments, HHS/CDC received results for 861 (26%). HHS/CDC found that 103/861 (12%) had a previous history of a positive TB screening test result or treatment for latent tuberculosis or active disease and were not re-tested. Of the remaining 758 passenger contacts, 182 (24%) tested positive. The majority of travelers with data about TB risk factors (other than exposure to cases during air travel) had at least one risk factor (130/142 or 92%). Risk factors included having been born or lived in a country with high TB prevalence (prevalence >100 per 100,000 population). Although passenger-contacts with risk factors were more likely to have pre-existing latent tuberculosis infection, the authors could not exclude the possibility that infection was acquired during the flights when the travelers were exposed.

Furthermore, because outcomes data were reported for only 26% of passenger contacts forwarded to U.S. health departments (19% of all passenger contacts) the precise determination of in-flight transmission risk of *M. tuberculosis* was not feasible.³²

The results from this investigation were used in a cost-effectiveness study to estimate the return on investment for tuberculosis CIs. The authors examined a range of latent tuberculosis prevalence rates among exposed travelers that varied between 19% and 24% for two different HHS/CDC CI protocols for flight-related TB investigations. The return on investment was calculated based on the likelihood that travelers with latent tuberculosis infection would initiate and complete a treatment regimen to clear the infection, the average cost of tuberculosis treatment, a tuberculosis case fatality rate of 5% and a conservative value of statistical life estimate of \$4.2 million (in 2009 USD) to account for the value of mortality risk reduction from avoided tuberculosis disease. The return on investment depended on the probability assumed for persons with latent TB infection to develop active disease (5–10%) and variation in the costs to health departments to locate exposed travelers (\$28 to \$164). Using the expected latent tuberculosis prevalence rate of 19% in travelers identified for contact investigations on flights and a health department cost per contact of \$164, the return on investment was estimated to

²⁶ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

²⁷ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

²⁸ Smith P, Marcuse E, Seward J, Zhao Z, WA O. Children and Adolescents Unvaccinated Against Measles: Geographic Clustering, Parents' Beliefs, and Missed Opportunities. *Public Health Rep.* 2015;5:485–504.

²⁹ Ko G, Thompson KM, Nardell EA. Estimation of tuberculosis risk on a commercial airliner. *Risk Anal* 2004;24:379e88.

³⁰ Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. *Travel Med Infect Dis.* 2014;12(1):54–62.

³¹ Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. *Travel Med Infect Dis* 2010;8:104e12.

³² Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. *Travel Med Infect Dis* 2010;8:104e12.

vary between \$1.01 and \$3.20. The return on investment formula was calculated based on (Expected benefits – Expected costs)/Expected costs. Thus, for each \$1 in Federal and State resources spent on contact investigations and offering treatment to persons infected with latent tuberculosis infections would result in benefits in excess of costs equal to \$1.01 to \$3.20^{33,34} on average. At the upper bound latent tuberculosis prevalence estimate (24%), the return on investment was estimated to vary between \$1.35 and \$3.92.

There is also empirical data for SARS infections occurring on an aircraft. A study reported that 37 infections resulted from 40 flights with infectious passengers on board. Of the 40 flights, four have documented aircraft sizes. They average 127 passengers per plane.³⁵ Therefore the on board transmission rate could be estimated to be 0.73% among all travelers. In comparison, there is no evidence of transmission of MERS Coronavirus or

viral hemorrhagic fevers during travel on aircraft or vessels. However, there have not been enough observations to determine that there is no risk.

For the remainder of the diseases, empirical data does not exist. Like measles, immunizations are recommended to prevent pertussis, rubella, and meningococcal disease. Since meningococcal conjugate vaccine was more recently added to the United States vaccination schedule, it is likely that background immunity is much lower relative to measles, rubella or pertussis.

In the absence of data for some diseases, the infection rate of measles is used to estimate the infection rates by using the ratio of basic reproduction numbers (R_0). The basic reproduction number is a measure of disease infectiousness. Specifically, it is an estimate of new infections in a completely susceptible population. For example, rubella has an R_0 of 9 to 10 while measles has an R_0 of 15 to 17.³⁶ The infection rate of measles is

multiplied (0.0034 to 0.0095) by the ratio of the average basic reproductive numbers (9.5/16) to arrive at a transmission rate (0.002 to 0.006) for rubella on airplanes. This rate is approximately 60% of the rate for measles. The estimated transmission rates for some diseases are reported in Table 12. The exceptions are for meningococcal disease and tuberculosis. For meningococcal disease, the risk of transmission in household contacts 0.002 to 0.004³⁷ is used in the absence of other data and taking account that CIs are only performed for travelers sitting adjacent to the index case or in the event of other known exposures. For tuberculosis, the probability that exposed travelers have latent tuberculosis³⁸ (19%–24%) is used, although infection may have occurred prior to air travel. For the purposes of evaluating the economic impact of tuberculosis investigations, it does not matter if travelers were infected during travel or before.

TABLE 12—ESTIMATED TRANSMISSION RATE ON PLANE FOR EXPOSED TRAVELERS

Disease	R_0	Estimated transmission rate on aircraft to exposed passengers	
		Lower bound	Upper bound
Diphtheria (quarantinable)	11 to 14	0.0026	0.0074
Measles (non-quarantinable)	15 to 17	0.0034	0.0095
Meningococcal Disease (non-quarantinable)	NA	<2/1000	<4/1000
Pertussis (non-quarantinable)	4 to 5	0.001	0.003
Rubella (non-quarantinable)	9 to 10	0.002	0.006
TB (quarantinable)	NA	0.19	0.24

Estimated Number of Cases in Traveler Contacts

The number of potential contacts for each disease can be multiplied by the estimated transmission rate by disease in Table 12 to generate a rough estimate of the annual number of cases among traveler contacts. These numbers of contacts for each disease are summarized in Tables 6 and 7 for interstate and international CIs

respectively. Contact investigations on vessels are excluded for this analysis. Based on this analysis, tuberculosis (19 to 48) and measles cases (3.6 to 10.1) are the most likely diseases that will be diagnosed among contacts exposed during travel (Table 13). Tuberculosis contact investigations only occur for international flights with the very rare exception of a domestic flight with a duration greater than 8 hours. The numbers of contacts and outcomes are

much more uncertain for other diseases. The number of tuberculosis cases are adjusted from the number of contacts with tuberculosis by assuming that only 5% (lower bound) to 10% (upper bound) of infected contacts will go on to develop clinical disease.³⁹

For viral hemorrhagic fevers and MERS, there is no evidence of transmission, but there have not been very many observations.

³³ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

³⁴ Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. Travel Med Infect Dis 2010;8:104e12.

³⁵ Mangili A, Gendreau MA. Transmission of infectious diseases during commercial air travel. Lancet. 2005;365:989–96.

³⁶ Anderson RM. The concept of herd immunity and the design of community-based immunization programmes. Vaccine. 1992;10(13):928–35.

³⁷ Chapter 14. Meningococcal Disease, The Pink Book, CDC <http://www.cdc.gov/vaccines/pubs/pinkbook/mening.html> Accessed 5/2/2016.

³⁸ Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. Travel Med Infect Dis 2010;8:104e12.

³⁹ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

TABLE 13—ANNUAL ESTIMATED NUMBER OF CASES AMONG INTERNATIONAL PASSENGER CONTACTS BY DISEASE

Passengers per flight	Number of contacts	Expected incidence among contacts (lower bound)	Expected incidence among contacts (upper bound)	Expected number of new cases (lower bound)	Expected number of new cases (upper bound)
MERS Coronavirus (quarantinable)	101	Insufficient data			
Measles (non-quarantinable)	1,069	0.0034	0.0095	3.6	10.1
Meningococcal Disease (non-quarantinable)	1.7	0.00200	0.00400	0.0033	0.0067
Pertussis (non-quarantinable)	16.8	0.001	0.003	0.02	0.04
Rubella (non-quarantinable)	117	0.002	0.006	0.2	0.7
TB ^a (quarantinable)	1,995	^b 0.19	^b 0.24	^c 18.9	^c 47.90
Viral Hemorrhagic Fever (quarantinable)	62.0	Insufficient data			
Total	3,362			22.8	58.7

^a For tuberculosis, travelers contacts are typically found to test positive for infection, but do not have active disease.

^b These probabilities indicate the likelihood that a contact will test positive for infection.

^c The expected numbers of cases adjust for the finding that only 5–10% of individuals that test positive for infection will go on to develop clinical disease.

These estimates of cases may be a lower bound, because potential cases resulting from flights in which contact investigations were not performed are not included. Especially for tuberculosis cases, many international travelers may return to their home countries before seeking treatment and such cases may not lead to contact investigations if HHS/CDC is not informed.

Marginal Costs of Final Rule

Data Collection

Since the final rule does not change the timeframe or amount of data requested from airlines or vessel operators, the most likely economic impact is a small change in the amount of effort for airlines to provide more complete and timely information. To the extent that airlines would respond more quickly or with additional data, it would require some airline information technology staff to expedite requests or to search in more depth for available data. HHS/CDC estimates this may require one hour of staff time per request. HHS/CDC has no way to predict how much more complete, timely, or accurate contact from airlines would become as a result of this final rule. On

average, HHS/CDC acted upon 77 requests per year to airlines for international traveler contact data between 2010 and 2015 (Table 6). In addition, HHS/CDC made 22.5 requests per year for interstate traveler data (Table 7) over the same period. There were 45 contact investigations per year among travelers on vessels (Table 8); however, most of these were undertaken before travelers disembarked vessels in which case contact data could be collected directly from exposed travelers as part of the investigation. The number of maritime contact investigations requiring manifest requests after disembarkation is estimated to be less than 10 per year.

Overall, including international air and maritime activities, the estimated number of contact data requests after disembarkation was estimated at 100 to account for the fact that HHS/CDC sometimes requests traveler contact data for infectious disease events prior to confirmed diagnoses. On occasion, it turns out that travelers are not infected with diseases that require a public health response. This rounding up should also account for a year in which there is a significant increase in the

number of contact investigations among exposed air or maritime travelers. HHS/CDC notes the manifest order process for interstate flights is not codified in the final rule. The data is provided here for completeness.

The average wages for computer and information systems managers (occupation code 11–3021) reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics⁴⁰ were \$63.27 per hour. On average, under the baseline, HHS/CDC assumes that it would require 6 hours of work by airlines to search databases and provide data. For the final rule, HHS/CDC assumes that a management-level computer specialist will spend additional time to provide the best possible contact data for potentially exposed travelers. The base salary is multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee (Table 14). The lower bound estimate (\$0) is no change from current practice, while the upper bound estimate assumes 2 hours of time instead of one (\$25,308). These costs are applied to an estimated 100 manifest requests per year.

TABLE 14—ESTIMATE OF COSTS FOR AIRLINES AND VESSEL OPERATORS TO IMPROVE COMPLIANCE WITH HHS/CDC REQUESTS FOR TRAVELER CONTACT DATA, 2015 USD

	Average number of manifest requests per year	Increased effort to provide more complete or timelier passenger contact data (hrs.)	Average hourly wage rate of IT staff (2015 USD)	Overhead multiplier (%)	Total cost
Baseline	100	6	\$63.27	100	\$75,924
Best estimate	100	1	63.27	100	12,654

⁴⁰ http://www.bls.gov/oes/current/oes_nat.htm.

TABLE 14—ESTIMATE OF COSTS FOR AIRLINES AND VESSEL OPERATORS TO IMPROVE COMPLIANCE WITH HHS/CDC REQUESTS FOR TRAVELER CONTACT DATA, 2015 USD—Continued

	Average number of manifest requests per year	Increased effort to provide more complete or timelier passenger contact data (hrs.)	Average hourly wage rate of IT staff (2015 USD)	Overhead multiplier (%)	Total cost
Lower bound	100	0	63.27	100	0
Upper bound	100	2	63.27	100	25,308

Illness Reporting Costs

When reports are received, public health officers at Quarantine Stations perform case assessments, may request follow-up information, and may consult with HHS/CDC medical officers to determine if additional action such as a contact investigation, onboard response, or notification to State and local health departments is warranted. Under one assumed upper bound scenario, the change in the definition of “ill person” included in the final rule could result in a 100% increase in the number of info-only reports from airlines and a 25% increase from vessels. On average, there are 129 info-only reports for aircraft and vessels each year and these increases would correspond to an annual increase of 119 info-only reports on aircraft and 3 info-only reports on vessels (Table 15). If the average time for each report is estimated to be 2 minutes for aircraft pilots in command or masters of vessels to make the report, 10 minutes for a traveler to discuss the illness with

public health officer, and 60 minutes for HHS/CDC to document the info-only report, the estimated cost of the additional reports can be estimated based on the opportunity cost of time for each type of personnel. In addition to the time required for aircraft pilots in command and masters of vessels to make reports, the personnel in the Department of Transportation’s Federal Aviation Administration (DOT/FAA) may incur additional costs to relay reports of suspected cases of communicable disease received by air traffic control to CDC through the Domestic Events Network. The amount of DOT/FAA staff time is estimated at 26 minutes for a government employee at GS-level 15, step 6 based in Washington, DC. In reality, there would be three DOT/FAA employees involved including 1 GS–15/16 level employee at air traffic control (10 minutes), 1 GS–15 level employee at the Domestic Events Network (10 minutes), and 1 GS–14 level employee at DOT/FAA’s

Washington Operations Center Complex (6 minutes).⁴¹

For aircraft pilots in command or masters of vessels (occupation codes 53–2011 and 53–5021) and travelers (average across all occupations code 00–0000), their opportunity cost is estimated from Bureau of Labor Statistics, May 2015 Occupational Employment Statistics⁴² based on the average salary of aircraft pilots or copilots (\$57.35 per hour), traveler (\$23.23 per hour) or vessel captain, mate, or pilot (\$39.95 per hour). For HHS/CDC employees, the average wage rate is based on the Federal government’s general salary scale for a GS–12, step 5 employee based in Atlanta, GA). Base salaries are multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee. Travelers do not have overhead costs. The annual quantified costs of 122 additional info-only reports would be \$17,471.

TABLE 15—CHANGES IN NUMBERS OF INFO-ONLY REPORTS AND ASSOCIATED COSTS FOR THE FINAL RULE UPPER BOUND, 2015 USD

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost
Aircraft:					
Aircraft Pilots or Copilots	119	2	\$57.35	100	\$455
CDC employee	119	60	39.83	100	9,480
DOT/FAA employees	119	26	70.57	100	7,278
Traveler	119	10	23.23	0	461
Air total					17,213
Vessels:					
Air or maritime conveyance officer					
Captains, Mates, and Pilots of Water Vessels	3	2	39.95	100	8
CDC employee	3	60	439.83	100	239
Traveler	3	10	23.23	0	12
Maritime total					259
Total costs, aircraft and vessels					17,471

Notes: Assumes 100% increase in info-only reports from airlines and 25% from vessel operators.

⁴¹ Personal communication between Dr. Brian Maskery and DOT/FAA.

⁴² http://www.bls.gov/oes/current/oes_nat.htm.

Besides the possible change in costs of info-only reports, the other potential change would be an increase in the number of reports that require HHS/CDC follow-up. Under the most likely scenario, there will not be a change in these reports since the new definition better corresponds to HHS/CDC guidance and to reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. However, there may be an increase in the number of reports requiring a response. Under this scenario, there may be an increase in costs for air or masters of vessels to report illnesses. The upper bound increase in reports requiring response is assumed to be 50% of the average annual illness reports from airlines and a 10% increase from vessels (refer to Tables 10 and 11 for baseline number of

reports): 29 reports per year on aircraft and 21 reports per year on vessels. HHS/CDC assumes that the time required to submit illness reports and for DOT/FAA staff to relay reports requiring responses is the same as for info-only reports (2 minutes for pilots in command and masters of vessels and 26 minutes for DOT/FAA to relay reports, Table 16). Further, HHS/CDC assumes that travelers could spend up to 60 minutes talking to HHS/CDC and/or State and local public health officers for reports requiring response. The upper bound estimate of total costs associated with the increase in the number of illness reports requiring response is estimated to be \$3,102.

There would likely be no change or a decrease in HHS/CDC costs because earlier reporting would lead to a more efficient HHS/CDC response relative to an alternative in which the illness was

not reported during travel, but instead was later reported by a public health department to HHS/CDC. In addition, the public health response to the illness would likely be more efficient because exposed travelers could be contacted earlier. In rare situations, such travelers may potentially be informed of their potential exposure at the gate after disembarking the aircraft or vessel. Such actions should not result in significant delays by holding travelers on board.

HHS/CDC did not include any training costs because the change in the “ill person” definition in this final rule is consistent with the internationally recognized and accepted illness reporting guidelines published by ICAO for international travelers and represents a reduced burden compared to the previous illness reporting regulations for interstate travelers.

TABLE 16—CHANGES IN ANNUAL NUMBERS OF REPORTS REQUIRING RESPONSE AND ASSOCIATED COSTS FOR THE FINAL RULE UPPER BOUND, 2015 USD

Employee type	Change in number of reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost (2015 USD)
Aircraft:					
Aircraft Pilots or Copilots	29	2	\$57.35	100	\$111
CDC employee	29	0	39.83	100	0
DOT/FAA employee	29	26	70.57	100	1,774
Traveler	29	60	23.23	0	674
Total					2,558
Vessels:					
Captains, Mates, and Pilots of Water Vessels	21	2	39.95	100	56
CDC employee	21	0	39.83	100	0
Traveler	21	60	23.23	0	488
Total					544
Total					3,102

Notes: Assume 50% increase in air illness and a 10% increase in maritime illness reports requiring response (international and interstate).

There may also be a one-time cost associated with updating training to reflect the new regulatory text. As noted above, HHS/CDC reiterates that the change to regulatory text is a codification of HHS/CDC guidance and better aligns with international guidance (Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation). Further for interstate travel, these changes result in relaxed illness reporting compared to status quo regulatory text. Thus any airlines using either ICAO or HHS/CDC guidance to support training efforts for illness reporting should not need to change training materials. At most, it may be necessary to clarify that some symptoms that were previously requested are now required. However, for some airlines or

vessel operators, it may be necessary to revise training materials.

The cost of training was estimated based on the number of pilots and flight attendants and their average wage rates as reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics.⁴³ HHS/CDC assumes that the opportunity cost of employee time spent in training would be the primary cost as opposed to the cost of developing training materials. As an upper bound, HHS/CDC assumed the cost of training could be estimated based on assuming that all employees would require 10 minutes of training to summarize the changes. As noted above, since this change aligns regulatory text

with existing HHS/CDC and ICAO guidance documents, this change may not result in a new training requirement for all airlines since some presumably already use HHS/CDC guidance in training. This 10 minute estimate does not necessarily mean all 230,000 pilots and flight attendants each require 10 minutes of training. For example, 50% of each could require 20 minutes of training, while the other 50% may already conduct training in accordance with either CDC or ICAO guidance. The total cost of the one-time change in training is about \$3.1 million. If this cost is annualized over 10 years, the average annual cost depends on the discount rate assumed and varies from \$313,000 per year (7% discount rate) to \$416,000 (0% discount rate). These

⁴³ http://www.bls.gov/oes/current/oes_nat.htm.

results are summarized in Table 17. These costs (3% discount rate) are added to the upper bound cost estimate

for illness reporting. The lower bound and best estimates are \$0 since the

changes to the definition better align with existing CDC and ICAO guidance.

TABLE 17—ESTIMATED COSTS FOR ONE-TIME TRAINING ABOUT CHANGES IN ILLNESS REPORTING FOR AIRLINES, 2015 USD

Employee type		Number of employees	Amount of time required for training per employee (minutes)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost or benefit (2015 USD)
Aircraft Pilots or Copilots		121,110	10	57.35	100	2,315,220
Flight attendants		108,510	10	22.46	100	812,465
Total						3,127,685
Annualized cost over 10-year time horizon	3% discount rate ...	\$355,981	0% discount rate ...	\$416,179	7% discount rate ...	\$312,768

The monetized annual costs resulting from the change in the definition of “ill

person” are summarized in Table 18. The benefits in regard to reductions in

communicable disease transmission are summarized in a subsequent section.

TABLE 18—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF THE CHANGES IN ANNUAL MONETIZED BENEFITS AND COSTS AS A RESULT OF THE CHANGE TO THE REPORTABLE ILLNESS DEFINITION, 2015 USD

	Best estimate	Lower bound	Upper bound
Costs			
Final Rule:			
Aircraft	\$0	\$0	\$375,751
Vessels	0	0	802
Total	0	0	376,554

The total costs of the final rule are summarized in Table 19 and include the

costs of the change to the definition of an “ill person” and the codification of

the requirement for airlines to provide passenger contact data for the final rule.

TABLE 19—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)

	Best estimate	Lower bound	Upper bound
Costs			
Final Rule:			
71.4 and 71.5 Passenger data collection	\$12,654	\$0	\$25,308
70.1 and 71.1 Change in definition of an “ill person”	0	0	376,554
Total costs	12,654	0	401,862

Benefits From Streamlining the CI Process for Routinely Imported Diseases

This section reports the benefits that HHS/CDC anticipates from implementation of the final rule in avoiding the costs incurred annually for CIs of infectious diseases. The model for estimating the benefits of CIs is: Current number of CIs × (reduction in HHS/CDC and health department staff time/resources per contact) × value of staff time.

HHS/CDC obtained the total number of contacts traced (2,715 per year, Table

6) for all diseases reported on international flights. International flight data were extracted for this analysis because the codification of the requirements to provide timelier and more complete contact data is limited to international arrivals. In comparison, HHS/CDC requests contact information for approximately 664 contacts per year on interstate flights (Table 7). HHS/CDC also supports contact investigations affecting an average of 762 contacts per year for illnesses on board vessels (Table 8); however, many of these investigations occur before travelers

disembark vessels. By limiting the analysis to contacts on international flights, HHS/CDC conservatively estimates the potential benefits associated with this final rule. HHS/CDC multiplied the average annual number of contacts on international flights by the cost-per-contact for HHS/CDC and PHDs (Table 11) to estimate the costs of CIs under the current baseline.

To estimate the benefits (Tables 20 and 21), HHS/CDC assumed a percent reduction in staff time for CIs at HHS/CDC (0–3%) and PHD levels (0–2%)

based on internal conversations with personnel directly involved in the CI process. The reduction in staff time that would result from implementation of this final rule would arise from the ability of HHS/CDC to have a better starting point with which to provide traveler contact data to State and local health departments as a result of the receipt of more complete and timely traveler contact data from airlines. The impact of codification is expected to be limited and would depend on instances in which airlines have more data than what is currently provided to DHS. Better data would improve HHS/CDC's ability to transmit information to destination States more quickly and for States to contact exposed travelers earlier. This would allow States to start their investigations more quickly, contact more travelers faster to conduct public health assessments and potentially offer preventive medications

or vaccines in a more timely fashion or to recommend self-monitoring to mitigate onward transmission. In addition, it would be less likely that HHS/CDC would send incorrect contact data to States. With all of the preceding factors in mind, HHS/CDC estimated that the final rule would reduce labor time by between 0% to 3% at HHS/CDC, and 0% to 2% at PHDs. The higher percentage of avoided costs at HHS/CDC reflect reduced efforts by HHS/CDC to search for accurate contact data for travelers due to untimely or inaccurate data. The lower percentage of avoided costs at PHDs reflects a more diffuse (e.g., multiple local PHDs in a State) infrastructure and the more labor-intensive tasks of following up on individuals. These estimates are small because the change is a clarification and codification of a current practice authorized under broad statutory and regulatory authority rather than a new

regulatory requirement. In addition, the change to the definition of "ill person" may lead to the earlier diagnoses of some travelers with communicable disease, which may lead to earlier and more efficient public health responses.

HHS/CDC annual costs to engage in international air, interstate air, and maritime CIs are about \$745,000 or roughly the equivalent of 3.8 HHS/CDC full-time employees (FTEs) at the wage level of GS-13, step 4 plus benefits and overhead (Table 21). The final rule should have the greatest effect on the international air CIs. The annual reduction in contact tracing costs from implementing the final rule (Table 22) for HHS/CDC ranged from \$0 to \$14,661 based on a 0–3% reduction in effort on international CIs. For PHDs, the reduction in costs ranged from \$0 at the lower bound to \$9,774 at the upper bound (Table 22).

TABLE 20—ANNUALLY FOR HHS/CDC AND PHD: BASELINE COSTS

	Annual number contacts	HHS/CDC	PHD costs	Total costs
HHS/CDC and PHD Baseline Costs (Current Practice)				
International air contacts	2,715	\$488,700	\$488,700	\$977,400
Interstate air contacts	664	119,520	119,520	239,040
Maritime contacts	762	137,160	137,160	274,320
Total baseline costs	4,141	745,380	745,380	1,490,760
Viral hemorrhagic fever, MERS, and SARS contacts	163	29,340	29,340	58,680

TABLE 21—ANNUAL FOR HHS/CDC AND PHDs: BASELINE COSTS, FINAL RULE COSTS, BENEFITS WITH THE FINAL RULE (NUMBER CONTACTS ANNUALIZED FROM JANUARY 2010 TO DECEMBER 2015), 2015 USD

HHS/CDC and PHD Baseline Costs (Current Practice)				
	Annual number contacts	HHS/CDC	PHD	
International contacts	2,715	\$488,700	\$488,700	
HHS/CDC and PHD Costs With the Final Rule				
	Estimated Costs for HHS/CDC After Efficiency Improvement with Final Rule		Estimated Costs for PHDs After Efficiency Improvement with Final Rule	
	0%, Lower bound	3%, Upper bound	0%, Lower bound	2%, Upper bound
International contacts costs assuming reduction in time (2,715)	\$488,700	\$474,039	\$488,700	\$478,926
Benefits From Implementing the Final Rule				
	HHS/CDC 0% and 3% Reduction in effort		PHD (0% and 2% Reduction in effort)	
Benefits (Reduced costs)	\$0	\$14,661	\$0	\$9,774

The best estimate of benefits are the midpoint of the lower bound and upper bound estimates for both HHS/CDC and

PHDs (\$12,218). The lower bound (\$0) and upper bound estimates (\$24,435) for

both entities are also reported in Table 22.

TABLE 22—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES (FINAL RULE), 2015 USD

	HHS/CDC benefits	PHD benefits	Total
Best estimate	\$7,331	\$4,887	\$12,218
Lower bound	0	0	0
Upper bound	14,661	9,774	24,435

The total annual monetized benefits by stakeholder from the potential reduced effort for contact investigations are summarized in Table 23.

TABLE 23—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES, 2015 USD

	HHS/CDC benefits, USD	PHD benefits, USD	Airlines, USD	Total
Best estimate	\$7,331	\$4,887	\$0	\$12,218
Lower bound	0	0	0	0
Upper bound	14,661	9,774	0	24,435

Marginal Impact of Final Rule—Measles Health Outcome Benefits

On average, HHS/CDC identified 564 travelers exposed to measles cases on international flights during 2010–2015 (Table 6). The final rule may affect the cost for health departments to implement public health measures in two ways: (1) Health departments may contact exposed travelers more quickly and (2) health departments may be able to contact a higher percentage of exposed travelers. For the first set of travelers that are contacted earlier with the final rule than under the status quo, the cost to both the contacted travelers and to health departments should be less than under the status quo. For measles contacts, earlier follow-up with public health departments should lead to more travelers being offered voluntary measles vaccines within 72 hours. This would potentially reduce the cost of following up with exposed travelers at which time health departments could offer to administer immune globulin or health departments may monitor travelers that have been located after the 72-hour window in

which measles vaccination would reduce their risk of developing symptomatic measles. At present, very few travelers receive post-exposure prophylaxis, 11/248 or 4.4%.⁴⁴ In addition, health departments have implemented quarantine (usually voluntary) for unvaccinated, high risk measles exposures.⁴⁵ HHS/CDC notes that measles is not a quarantinable communicable disease under Federal regulations, but may be quarantinable under a State's authorities. HHS/CDC also notes that measles vaccine is recommended for all persons lacking immunity. Thus, the costs of vaccination for exposed travelers as part of the contact investigation may have been incurred at a later date if travelers' health care providers recommended measles vaccination at a more routine health care visit in the future.⁴⁶ However, to be conservative, HHS/CDC includes the full additional cost to administer such vaccines to persons contacted.

Among the contacts, HHS/CDC estimates that approximately 25% (141 contacts per year) cannot be located by

public health departments (Table 24), either because HHS/CDC cannot assign the contacts to health departments or because the information provided by HHS/CDC is not sufficient to enable health departments to locate contacts after assignment from HHS/CDC. Among these contacts, HHS/CDC assumes that 10% of all contacts (56) are not located because HHS/CDC cannot assign contacts to State health departments due to insufficient data. For these contacts, health departments would not incur any contact tracing costs because such contacts would not be assigned. HHS/CDC assumes a 15% improvement from baseline as a result of this final rule (Table 24). This would result in 8.5 additional contacts per year assigned to health departments for contact tracing. As shown in Table 11, HHS/CDC estimates that health departments incur an estimated cost of \$180 per contact. The marginal cost incurred from this final rule for additional measles contacts assigned to health departments would be $180 \times 8.5 = \$1,530$ per year (Table 25).

TABLE 24—ESTIMATED MARGINAL IMPROVEMENT IN THE NUMBERS OF MEASLES CONTACTS WHO COULD BE TREATED WITH FINAL RULE

Description	n	Reference
Average contacts per year for measles, (a)	564	Table 6.
Estimated number of contacts for which HHS/CDC cannot assign to a health department, (b) = 10% × (a).	56	Nelson et al. 2013. ⁴⁷

⁴⁴ Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States. *Travel Medicine and Infectious Disease* (2013) 11, 81e89. 2013;11:81–9.

⁴⁵ P Kutty, J Rota, W Bellini, SB Redd, A Barskey, G Wallace. (2014) Manual for the Surveillance of Vaccine-Preventable Diseases: Chapter 7 Measles. <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html> Accessed 5/8/2016.

⁴⁶ CDC (2015) Epidemiology and Prevention of Vaccine-Preventable Diseases: Measles. <http://www.cdc.gov/vaccines/pubs/pinkbook/meas.html> Accessed 5/8/2016.

TABLE 24—ESTIMATED MARGINAL IMPROVEMENT IN THE NUMBERS OF MEASLES CONTACTS WHO COULD BE TREATED WITH FINAL RULE—Continued

Description	n	Reference
Estimated improvement in HHS/CDC's ability to assign contacts to health department (c) = 15% × (b).	8.5	Assumption.
Numbers of people who are not currently contacted due to lack of contact information, (d) = (a) × 25%.	141	Nelson et al. 2013.
Expected numbers of people who could be contacted with final rule, (e) = (d) × 15%	21	Assumption.
Among those contacted, 70% would have evidence of measles immunity (f) = (e) × 70%	15	Nelson et al. 2013 (Table 2).
Among those contacted, 30% may be susceptible to measles (g) = (e) × 30%	6	Nelson et al. 2013 (Table 2).

⁴⁷ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

TABLE 25—ESTIMATED MARGINAL COSTS FOR HEALTH DEPARTMENTS TO CONTACT EXPOSED TRAVELERS AND OFFER MEASLES POST-EXPOSURE PROPHYLAXIS (VACCINATION), 2015 USD

Number of additional names sent to health department, (c)	8.5
Additional cost per contact to health department to search for and examine contacts (USD per contact) (h)	\$180
Additional cost to health department to search for contacts, total (USD), (i) = (c) × (h)	\$1,530
MMR vaccine price per dose (USD) (j)	\$39
Vaccine administration (k)	\$31
Estimated cost prophylactic measles vaccine per person (USD), (l) = (j) + (k)	\$70
Number of individuals who may receive measles vaccine, (g)	6
Cost of measles vaccination, total (USD) (m) = (g) × (l)	\$420
Total additional annual cost to follow up with more contacts (USD), (i) + (m)	\$1,950

In addition, HHS/CDC assumes that the final rule could improve health departments' abilities to contact 15% of those who could not be currently contacted because of insufficient contact information (21 contacts per year). HHS/CDC does not have any data to measure the magnitude of improvement and applies a range of 10% to 20% to calculate lower and upper bounds. If airlines and vessel operators do not have any additional data besides what is already transmitted to DHS, there will

be very little improvement. Among the 21 additional exposed travelers that would be contacted, 70% of them (15 per year) are expected to have measles immunity because they were born before 1957, had history of measles, or received one or more doses of measles vaccine. The remaining 6 travelers per year without proven measles immunity would incur additional costs if they are vaccinated (vaccine costs + vaccine administration, Table 25).

To be conservative, HHS/CDC assumes that all 6 exposed travelers

would be adults and would be vaccinated with the measles-mumps-rubella (MMR) vaccine. The vaccine price for adults is estimated from the Vaccines for Children vaccine price archives (July 2014 and July 2015)⁴⁸ based on the public sector price for the vaccine. Vaccine administration costs are estimated from Healthcare Solutions' 2015 Physicians' Fee & Coding Guide (CPT 90471).⁴⁹ Total costs resulting from the final rule are summarized in Table 26.

TABLE 26—MARGINAL IMPACT OF FINAL RULE TO IMPROVE CONTACT INVESTIGATIONS

Marginal cost for measles investigations	Additional names provided to health departments	Addition contacts reached by health departments	Number of travelers provided post-exposure prophylaxis	Number of travelers identified earlier	Average probability that contact is infected
\$1,950	8.5	21	6	Unknown	0.0035–0.0095

In the absence of interventions by public health departments, travelers infected with measles during international travel would be as likely as any other individuals to spark a measles outbreak. In the absence of HHS/CDC efforts to retrieve and transmit contact data, public health departments would not be able contact travelers to offer post-exposure prophylaxis and/or to recommend self-

monitoring for potential measles symptoms.

For measles in 2011, 16 outbreaks occurred leading to 107 cases. An outbreak was defined based on 3 or more cases in a cluster.⁵⁰ The remaining 113 cases reported in 2011 resulted in one or two cases per cluster. Thus, the probability that any individual measles index case leads to an outbreak was between $16/(16+113) = 12.4\%$ and $16/$

$(16+57) = 20.1\%$. The lower bound represents an assumption that all of the 113 cases unassociated with outbreaks of 3 or more cases occurred in clusters with just one case each. The upper bound represents a scenario with 56 clusters of two cases each with one cluster with one case. Thus, the probability that any individual measles case could spark an outbreak of 3 or more cases is 12.4% to 20.1%. The

⁴⁸ <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/archive.html> Accessed 5/2/2016.

⁴⁹ InGauge Healthcare Solutions. 2015 Physicians' Fee & Coding Guide. Atlanta GA2013.

⁵⁰ Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen

measles outbreaks on United States public health departments in 2011. *Vaccine*. 2012;32(11).

average cost to public health departments per measles outbreak is \$250,000 and the upper bound cost is \$1 million.⁵¹

HHS/CDC assumes that the probability that a measles case resulting from exposure during travel and that is not contacted by a public health department is as likely as any other measles case to initiate a measles outbreak of 3 or more cases, which occurs at an approximate probability of 12.4% to 21.9%. The average cost to health departments is \$250,000 for each of these outbreaks and the average outbreak size is about 7 cases (107 cases/16 outbreaks).

The estimated illness costs for measles are \$300 (\$86–\$515) for outpatient cases and \$24,500 (\$3,900–\$45,052) for inpatient cases.⁵² The probability of hospitalization is estimated to be 44.3%.⁵³ A range of hospitalization rates is estimated based on 50% to 150% of this base case estimate (22%–66%). The measles case fatality rate has been estimated to be 0.2%.⁵⁴ HHS/CDC assumes that the value of statistical life is \$9.4 million (range \$4.3 million to \$14.2 million). This value is an estimate of the average willingness to pay to reduce one's mortality risk by a small increment not an estimate of the value of any specific

person's life. For example if 1,000 people were willing to pay \$1,000 each to reduce their risk of death by 1/1,000, the value of statistical life would be equal to \$1,000/0.001 change in risk of death = \$1 million. Alternatively 1,000 people each experiencing a mortality risk reduction of 0.001 would correspond to 1,000 people $\times$ 0.001 mortality risk reduction = 1 statistical life; 1,000 people each willing to pay \$1,000 = 1,000 $\times$ \$1,000 = \$1 million to avert that one statistical death. Using these estimates, the average illness costs associated with a measles case (Table 27) is about \$30,000 (\$9,500 to \$58,000).

TABLE 27—ESTIMATED ILLNESS AND MORTALITY COSTS PER MEASLES CASE

	Best estimate	Lower bound	Upper bound
Outpatient cost, a	\$300	\$86	\$515
Inpatient cost, b	\$24,500	\$3,943	\$45,052
Hospitalization rate, c	44.30%	22.0%	66.0%
Case fatality rate, d	0.2%	0.2%	0.2%
VSL, e	\$9,400,000	\$4,300,000	\$14,200,000
Total cost per case ($b \times c + a \times (1 - c) + d \times e$)	\$29,821	\$9,535	\$58,309

The estimated number of measles cases that will occur in contacts exposed during travel (3.6 to 10.1) can be multiplied by the probability of an outbreak with 3 or more cases (12.4% to 21.7%) to estimate the expected number

of outbreaks in the absence of public health intervention to conduct contact investigations in exposed travelers. For each outbreak, HHS/CDC assumes that an average of 6 additional cases occur with associated morbidity and mortality

costs. The estimated costs of measles outbreaks in the absence of contact investigations for exposed travelers is presented in Table 28.

TABLE 28—ESTIMATED ILLNESS, MORTALITY, PUBLIC HEALTH RESPONSE COSTS ASSOCIATED WITH MEASLES OUTBREAKS

	Best estimate	Lower bound	Upper bound
Estimated number of measles cases among contacts, a	6.85	3.6	10.1
Probability of measles outbreak, b	17	12.4	21.9
Number of additional cases per outbreak, c	6	6	6
Estimated number of outbreaks, $d = a \times b$	1.18	0.45	2.22
Estimated number of outbreak cases, $e = a \times b \times c$	7.06	2.68	13.29
Estimated health department costs per outbreak, f	250,000	250,000	250,000
Estimated health department costs, $g = f \times d$	293,989	111,607	553,758
Average cost per case, h	29,821	9,535	58,309
Estimated illness costs, $i = h \times e$	210,406	25,539	774,944
Estimated total costs, $g + i$	504,395	137,146	1,328,703

HHS/CDC has not received any reports of large measles outbreaks associated with measles cases in patients exposed during travel and contacted by State or local public health departments. As a result, HHS/CDC believes that when measles cases occur in contacts reached by health departments, the probability of an

outbreak is significantly mitigated by pre-warning of exposure before disease onset. Given that HHS/CDC estimates that health departments are able to reach approximately 75% of contacts under the status quo, HHS/CDC assumes that the risk of an outbreak has been reduced by at least 60% under the status quo. Further, HHS/CDC assumes that

the provisions in the final rule further improve health departments' ability to prevent measles outbreaks in cases that occur among travelers exposed during flights. A modest improvement of 15% is assumed (range 10%–20%) resulting in estimated benefits of about \$45,000 (\$8,000 to \$159,000) in Table 29.

⁵¹ Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. *Vaccine*. 2012;32(11).

⁵² Zhou F, Shefer A, Wenger J, Messonnier M, Wang LY, Lopez A, et al. Economic Evaluation of the Routine Childhood Immunization Program in

the United States, 2009. *Pediatrics*. 2014;133:577–85.

⁵³ Mason WH, Ross LA, Lanson J, Wright HT. Epidemic measles in the postvaccine era: evaluation of epidemiology, clinical presentation, and complications during an urban outbreak. *Pediatr Infect Dis J*. 1993;12:42–8.

⁵⁴ Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th Edition—Measles April 2015 <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf>. Accessed 6/13/2016.

TABLE 29—ESTIMATED BENEFITS ASSOCIATED WITH IMPROVEMENT OF MEASLES CONTACT INVESTIGATIONS AS A RESULT OF THIS FINAL RULE

	Best estimate	Lower bound	Upper bound
Estimated total costs without intervention, $j = g + i$	\$504,395	\$137,146	\$1,328,703
Estimated effectiveness of outbreak prevention baseline, k	60%	60%	60%
Estimated cost of measles outbreaks under baseline, $j \times (1 - k)$	\$201,758	\$54,858	\$531,481
Estimated effectiveness of outbreak prevention with final rule, l	69%	66%	72%
Estimated cost of measles outbreaks with final rule, $m = j \times (1 - l)$	\$156,363	\$46,630	\$372,037
Estimated benefit associated with final rule, $n = j - m$	\$45,396	\$8,229	\$159,444

Marginal Impact on Tuberculosis Investigations

Although measles is not a quarantinable disease and tuberculosis is a quarantinable disease, HHS/CDC's and health departments' approaches to contact investigations are relatively similar. However, HHS/CDC may issue isolation orders for individuals with active tuberculosis in some situations, but would not have authority to issue isolation (or quarantine orders) for individuals with measles. The expected benefits associated with reduced tuberculosis morbidity and mortality of contact investigations for exposed travelers are based on a previous analysis, which estimated a return on investment of \$1.01 to \$3.20 for the baseline situation in which an estimated 19% of exposed contacts are found to

have latent tuberculosis infection.⁵⁵ The contact rate for exposed tuberculosis contacts is probably higher than for measles because the vast majority of tuberculosis contacts are exposed during international travel as exposed to measles contacts, which are approximately evenly divided between interstate and international travel.

The estimated costs to provide testing and treatment to contacts that test positive for latent tuberculosis infection are estimated to be \$1,044 for infected contacts that complete a full course of treatment and \$591 for infected contacts that discontinue treatment after 30 days.⁵⁶ Following the assumptions in the article, an estimated 28% of persons who test positive for latent tuberculosis infection do not start treatment. An estimated 46% start and complete

treatment and the remaining 26% start, but do not complete treatment. The authors estimated that the risk of progression to active tuberculosis is reduced by 80% for those that complete treatment. The authors assumed that there is no effect for individuals that start, but do not complete treatment. HHS/CDC assumes that under the status quo that health departments are able to contact 75% of exposed travelers (based on the reported outcomes from measles contact investigations).⁵⁷

The costs to provide treatment for latent tuberculosis infections under the status quo are summarized in Table 30. In total, the costs are almost \$900,000 including about \$720,000 to locate contacts and about \$180,000 to provide treatment to individuals with latent tuberculosis infection.

TABLE 30—BASELINE ESTIMATED COSTS TO CONDUCT TUBERCULOSIS CONTACT INVESTIGATIONS AND TO PROVIDE TREATMENT

	Number of contacts	Estimated cost per contact	Estimated cost	Notes
Estimated cost of contact investigations	1,995	\$360	\$718,092	Number of contacts from Table 13 and cost per contact from Table 11.
Estimated number of contacts reached by health departments (75%).	1,496	NA		Estimated at 75% similar to measles from Table 24.
Estimated number of contacts reached by health departments and have latent TB infection (19% of 75%).	284	NA		Estimated 19% of contacts have LTBI (Table 13).
Number of contacts that never start treatment (28%).	79.6	0	0	28% of 284 contacts with LTBI.
Number of contacts that complete treatment (46%).	130.8	1,044	136,506	46% of 284 contacts with LTBI.
Number of contacts that start, but not complete treatment, (26%).	73.9	591	43,677	26% of 284 contacts with LTBI.
Total cost			898,275	

The benefits associated with tuberculosis contact investigations are estimated from a published article, which reported a range of \$1.01 to \$3.20. This analysis did not include the potential benefits from reduced onward

transmission of tuberculosis among averted cases, potentially resulting in a conservative estimate of the return on investment. The formula used to derive estimated benefits from the return on investment (ROI) is Estimated Benefits =

Estimated Costs $\times$ ROI + Estimated Costs. The estimated benefits are \$2.6 million and are shown in Table 31 (range: \$1.8 million to \$3.8 million).

⁵⁵ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

⁵⁶ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

⁵⁷ Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States, December 1, 2008–December 31, 2011. Travel Med Infect Dis. 2013;11(2):81–9.

TABLE 31—BASELINE ESTIMATED COSTS AND BENEFITS FOR TUBERCULOSIS CONTACT INVESTIGATIONS, 2015 USD

	Best estimate	Lower bound	Upper bound	Notes
Estimate costs for contact investigations and treatment.	\$898,260	\$898,260	\$898,260	Table 30.
Return on investment from tuberculosis contact investigations.	1.91	1.01	3.20	Coleman et al.
Estimated benefits	2,613,936	1,805,502	3,772,691	= Cost × ROI + Costs.

The provisions in the final rule should result in a small increase (assumed baseline of 10%, range: 5–15%) in the number of contacts reached by health departments and offered treatment for latent tuberculosis infection. This estimated improvement is less than that assumed for measles because tuberculosis usually involves a

much longer period of latent infection prior to active disease; thus, tuberculosis contact investigations are less time sensitive relative to measles contact investigations. The estimated costs associated with this marginal improvement to reach more contacts can be estimated by multiplying the costs of providing latent tuberculosis (\$180,000)

by this range of improvement (5%–15%) as shown in Table 32. This results in marginal increased costs associated with the final rule of \$18,000 (range: \$9,000 to \$27,000). The estimated benefits (Table 32) associated with the final rule are \$52,000 (range: \$18,000 to \$114,000).

TABLE 32—ESTIMATED COSTS AND BENEFITS FOR TUBERCULOSIS CONTACT INVESTIGATIONS ASSOCIATED WITH THIS FINAL RULE, 2015 USD

	Best estimate	Lower bound	Upper bound	Notes
Baseline contact investigation costs	\$718,080	\$718,080	\$718,080	Table 30 costs for latent tuberculosis treatment and testing.
Baseline latent tuberculosis treatment costs ..	\$180,180	\$180,180	\$180,180	
Estimated improvement in health departments' abilities to contact exposed travelers.	10%	5%	15%	Assumed.
Estimated increased cost for latent tuberculosis treatment under final rule.	\$18,018	\$9,009	\$27,027	Estimated cost for improvement in contact rate as result of final rule.
Estimated costs under final rule	\$916,278	\$907,269	\$925,287	Estimated baseline cost + increased cost as result of final rule.
Estimated ROI	\$1.91	\$1.01	\$3.20	Table 30.
Estimated benefits for final rule	\$2,666,368	\$1,823,610	\$3,886,204	= Cost × ROI + Costs.
Estimated costs associated with final rule	\$18,018	\$9,009	\$27,027	Calculated from the difference in costs for the final rule—Baseline costs.
Estimated benefits associated with final rule	\$52,432	\$18,108	\$113,513	Calculated from the difference in benefits for the final rule—Baseline benefits.

Total Costs and Benefits for Measles and Tuberculosis Contact Investigations

The total costs for measles and tuberculosis contact investigation

activities are estimated by summing the costs and benefits of measles contact investigations (Table 29) and tuberculosis contact investigations

(Table 32). The results are summarized in Table 33.

TABLE 33—CHANGES IN MEASLES AND TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound
Final rule benefits	\$97,828	\$26,337	\$272,958
Final rule costs	19,968	10,959	28,977

Note: This table includes the sum of results in Tables 29 and 32.

Total Annual Benefits Resulting From Codification of Traveler Data Collection (71.4 and 71.5) and Change to Definition of “Ill Person” (70.1 and 71.1) Leading to Improved Contact Investigations and Health Outcomes for Measles and Tuberculosis

The total quantified benefits (Table 34) resulting from the improvement of

the quality and timeliness of traveler contact data or the improvement of illness reporting is summarized by summing the improved efficiency for HHS/CDC to provide contact data to health departments and improved efficiency for health departments to contact exposed travelers (Table 23) and the reductions associated with measles

and tuberculosis morbidity and mortality (Table 33).

TABLE 34—TOTAL ANNUAL COSTS AND BENEFITS ASSOCIATED WITH IMPROVED EFFICIENCY PUBLIC HEALTH RESPONSE ACTIVITIES, 2015 USD

	Best estimate	Lower bound	Upper bound
Final rule benefits	\$110,045	\$26,337	\$297,393
Final rule costs	19,968	10,959	28,977

The benefits and costs associated with improved effectiveness of contact investigations (Table 34) can be combined with the increased costs to

airlines, vessel operators, DOT/FAA, and HHS/CDC to submit and respond to illness reports or to provide more timely and complete traveler contact data for

manifest requests (Table 19) to estimate the total annual costs and benefits of the final rule (Table 35).

TABLE 35—TOTAL ANNUAL COSTS AND BENEFITS OF THE FINAL RULE, 2015 USD

	Best estimate	Lower bound	Upper bound
Final rule benefits	\$110,045	\$26,337	\$297,393
Final rule costs	32,622	10,959	430,839

Other Diseases (Besides Measles and Tuberculosis)

HHS/CDC does not have sufficient data to quantify the health impact of contact investigations for pertussis, rubella, varicella (vessels only), viral hemorrhagic fevers (including Ebola), MERS, or SARS. HHS/CDC attempts to continuously update its contact investigation protocols based on available evidence. In the past few years, HHS/CDC has stopped requesting data to conduct mumps contact investigations⁵⁸ and has modified its protocol to reduce the number of tuberculosis contacts investigated.⁵⁹

Experience from interstate flight contact investigations suggest that travelers may want to know when they have been exposed to communicable diseases during flights. The first Ebola contact investigation conducted in the United States occurred in October, 2014, and found that 60 travelers out of 164 had no contact information on the manifest that was provided by the airline. A second request was made to the airline after it was announced to the media that the airline had contacted over 800 travelers, including travelers who had flown on the same plane subsequent to the flight with the Ebola. At that time the airline was able to provide HHS/CDC more complete information for all travelers.

It is likely that the need for CDC to put out media requests for travelers to

contact the Agency created a level of fear in the general population that may not have been necessary if better contact data were available. In addition, this fear may have led to non-health costs (such as fear of airplane travel) that would have been mitigated if the Agency were able to contact all passengers without the media request. However, when HHS/CDC solicited public comment about perceived willingness to pay to be contacted in the event of an exposure to a communicable disease during, HHS/CDC only received a few public comments, all of which indicated that they had zero willingness to pay in the event of an exposure to a communicable disease.

In summary, improved alignment between regulatory text and HHS/CDC's publicly available guidance should reduce compliance costs for airlines and vessel operators while improving HHS/CDC's ability to respond to public health threats associated with international and interstate travel. To the extent that airlines and vessel operators improve responsiveness to HHS/CDC traveler data requests, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale CIs in response to a new infectious disease or one with serious public health and medical consequences like Ebola. HHS/CDC will make all reasonable efforts to work with DHS/CBP via CDC's liaison located at the National Targeting Center, as provided through internal Memorandum of Understanding, to

search and obtain data collected from their APIS and PNR data sets prior to contacting airlines or vessel operators with duplicate data requests.

Analysis of Alternatives

Traveler Contact Data Alternatives

For the less restrictive alternative, HHS/CDC assumes that the process of requesting contact data from airlines and vessel operators would be discontinued. Thus, the cost to provide such data can be modeled as a benefit to airlines and vessel operators equal to their costs under the baseline. For the more restrictive alternative, HHS/CDC assumes that suspension of entry may be implemented for travelers from countries experiencing widespread transmission of quarantinable communicable diseases. HHS/CDC notes that suspension of entry would not be considered for non-quarantinable diseases (refer to Table 4). Specifically, HHS/CDC assumes that persons traveling from affected countries are not permitted entry to the United States unless such persons spend an amount of time equivalent to the incubation period for the target disease at a location where they are not at risk of exposure and are also screened for symptoms of the disease prior to travel to the United States. During the 2014–2016 Ebola epidemic, travelers from Liberia, Sierra Leone or Guinea would not be able to enter until 21 days in another country or within the affected country but separated from others in a manner that excludes the possibility of interaction with potentially infected individuals.

On average, HHS/CDC has conducted about 2.5 contact investigations for viral hemorrhagic fevers and MERS coronavirus over the past six years. HHS/CDC assumes that if suspensions

⁵⁸ Nelson KR, Marienau KJ, Barskey AE, Schembri C. No evidence of mumps transmission during air travel, United States, November 1, 2006–October 31, 2010. *Travel Medicine and Infectious Disease*. 2012;10:165–71.

⁵⁹ Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. *Travel Med Infect Dis*. 2014;12(1):54–62.

of entry may be in place, some fraction of these contact investigations may not be conducted.

Thus, the cost to airlines and vessel operators to provide traveler contact data would decrease for the less

restrictive alternative resulting in estimated benefits of \$75,924. For the more restrictive scenario, the costs are relatively similar as for the final rule except for the reduction in cost associated with providing contact data

for 2.5 investigations (\$12,338 vs. \$12,654) and calculating the cost reduction of doing 2.5 fewer contact investigations each year (\$1,898) (Table 36).

TABLE 36—ESTIMATE OF THE COSTS AND BENEFITS TO AIRLINES AND VESSEL OPERATORS TO PROVIDE TRAVELER CONTACT DATA, 2015 USD

	Baseline	Final rule	Less restrictive alternative ^a	More restrictive alternative ^b
Baseline number of contact investigations	100	100	0	97.5
Costs				
Best estimate	NA	\$12,654	\$0	\$12,338
Lower bound	NA	0	0	0
Upper bound	NA	25,308	0	24,802
Benefits				
Best estimate	NA	\$0	\$75,924	\$1,898
Lower bound	NA	0	75,924	1,898
Upper bound	NA	0	75,924	1,898

^a The less restrictive alternative is less expensive than the status quo, because HHS/CDC does not request data from airlines and attempt to provide data to health departments to follow up with exposed travelers.

^b The more restrictive alternative also could potentially reduce costs to airlines and vessel operators because HHS/CDC would restrict travel to countries undergoing widespread transmission of quarantinable communicable diseases such as viral hemorrhagic fevers, MERS or SARS.

Illness Reporting Alternatives

HHS/CDC examines two alternatives: A less restrictive alternative in which HHS/CDC relaxes its regulatory authorities to make illness reporting compliance voluntary rather than compulsory. Under the more restrictive alternative HHS/CDC may enforce the current requirement that airlines report all persons with communicable diseases to local health departments in addition to reporting to HHS/CDC.

The current status quo for illness reporting is summarized in Tables 9 and 10. Reports can be subdivided by illnesses that fit (1) the ill person definition specified in current 42 CFR 71.1, (2) reports based on HHS/CDC's guidance for airlines and vessel operators, or (3) illness reports unrelated to current regulation or guidance. As shown in Table 9, only about 53 out of 175.4 (30%) illness reports during air travel appear to be based on symptoms included in the current definition of an ill person in existing 71.1. The remaining 70% of

reports are based on symptoms currently requested by HHS/CDC, but not required. In addition, only 67% of illness reports during air travel require HHS/CDC response and follow-up. In comparison, illness reports from vessels are much more likely to be based on the definition of ill person as defined in current 71.1 (174.6/218.6 or 80%). In addition, a much greater proportion of reports require an HHS/CDC follow-up (>95%). This may result from differences in the types of illnesses observed on vessels relative to aircraft or because of the presence of medical officers on cruise vessels, who may be better able to identify communicable diseases of public health concern during travel relative to aircraft personnel.

If illness reporting were entirely voluntary, HHS/CDC assumes the number of reports (both info-only and reports requiring response) would decrease by 50% from both airlines and vessel operators (refer to Tables 9 and 10) from the current status quo. HHS/CDC does not have any data to estimate

the magnitude of decrease in reporting. HHS/CDC believes that both HHS/CDC and DOT/FAA would continue to maintain their current infrastructure to effectively respond to public health emergencies either on aircraft or vessels. Thus, relative to the status quo, the primary impact of voluntary reporting would be reduced incremental time costs for pilots in command and masters of vessels, travelers, DOT/FAA, and HHS/CDC, especially for info-only illness reports. This 50% reduction in illness reporting would generate benefits from cost reductions for airlines and vessel operators, HHS/CDC, travelers, and DOT/FAA of approximately \$14,700 (Tables 37 and 38).

The adverse impact for the less restrictive alternative relative to the baseline would be reduced capacity for HHS/CDC to respond quickly to communicable disease threats occurring during travel. This is analyzed in a subsequent section on the health impact of regulated activities.

TABLE 37—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING

[Effect on info-only reports, 2015 USD]

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (per hr.)	Overhead multiplier (%)	Estimated benefit (cost reduction)
Aircraft:					
Aircraft Pilots or Copilots	60	2	\$57.35	100	\$229

TABLE 37—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING—Continued

[Effect on info-only reports, 2015 USD]

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (per hr.)	Overhead multiplier (%)	Estimated benefit (cost reduction)
CDC employee	60	60	39.83	100	4,780
DOT/FAA employees	60	26	70.57	100	3,670
Traveler	60	10	23.23	0	232
Air total					8,911
Vessels:					
Captains, Mates, and Pilots of Water Vessels	6	2	39.95	100	16
CDC employee	6	60	39.83	100	478
Traveler	6	10	23.23	0	23
Maritime total					517
Total (Air + Maritime)					9,428

Assume 50% reduction in reports.

TABLE 38—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING

[Effect on reports requiring response, 2015 USD]

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (per hr.)	Overhead multiplier (%)	Estimated benefit (cost reduction)
Aircraft:					
Aircraft pilots or copilots	29	2	\$57.35	100	\$111
CDC employee	29	0	39.83	100	
DOT/FAA employee	29	26	70.57	100	1,774
Traveler	29	60	23.23	0	674
Total					2,558
Vessels:					
Captains, mates, and pilots (masters) of vessels	104	2	39.95	100	277
CDC employee	104	0	39.83	100	
Traveler	104	60	23.23	0	2,416
Total					2,693
Total (Air + Maritime)					5,251

Notes: Assume 50% reduction in air illness reports and 15% of maritime illness reports (response, international and interstate).

Under the more restrictive alternative, HHS/CDC would require duplicate illness reporting both to HHS/CDC and to local health departments with jurisdiction upon arrival for interstate flights and voyages. This alternative is based upon the existing regulatory text under 42 CFR 70.4. HHS/CDC assumes that 50% of illness reports occur during interstate (relative to international) air travel and that 15% of maritime illness

reports occur during interstate travel. The time required for pilots in command and masters of vessels is assumed to be about 4 minutes. This duration is greater than the amount of time estimate for reporting to HHS/CDC because pilots in command and masters of vessels may have to search for contact information for local health departments and because local health departments may have less experience dealing with

illness reports than HHS/CDC. The costs to airlines and vessel operators is estimated to be \$848 per year (Table 39). Since HHS/CDC would coordinate responses to illness reports with local health departments under the status quo, there are no additional costs or benefits to requiring duplicative reports to local health departments. These costs would be added to the costs of the changes resulting from the final rule.

TABLE 39—MORE RESTRICTIVE ALTERNATIVE (ILLNESS REPORTING IN DUPLICATE TO HHS/CDC AND TO LOCAL HEALTH DEPARTMENTS), 2015 USD

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost (\$2015 USD)
Aircraft pilots or copilots	88	4	\$57.35	100	\$673

TABLE 39—MORE RESTRICTIVE ALTERNATIVE (ILLNESS REPORTING IN DUPLICATE TO HHS/CDC AND TO LOCAL HEALTH DEPARTMENTS), 2015 USD—Continued

Employee type	Change in number of info-only reports	Amount of time required per report (min)	Estimated wage rate (2015 USD per hr.)	Overhead multiplier (%)	Estimated cost (\$2015 USD)
Captains, mates, and pilots (masters) of vessels	33	4	39.83	100	175
Total					848

The total costs and benefits associated with the more and less restrictive illness reporting scenarios as compared to the final rule are summarized in Table 40.

TABLE 40—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF THE CHANGES IN ANNUAL MONETIZED BENEFITS AND COSTS AS A RESULT OF THE CHANGE TO THE REPORTABLE ILLNESS DEFINITION, 2015 USD

	Best estimate	Lower bound	Upper bound
Costs			
Final Rule:			
Aircraft	\$0	\$0	\$375,751
Vessels	0	0	802
Total	0	0	376,554
Less Restrictive Alternative: ^a			
Aircraft	0	0	0
Vessels	0	0	0
Total	0	0	0
More Restrictive Alternative:			
Aircraft	673	673	376,424
Vessels	175	175	978
Total	848	848	377,402
Benefits			
Final Rule:			
Aircraft	0	0	0
Vessels	0	0	0
Total	0	0	0
Less Restrictive Alternative: ^a			
Aircraft	11,469	11,469	11,469
Vessels	3,210	3,210	3,210
Total	14,679	14,679	14,679
More Restrictive Alternative:			
Aircraft	0	0	0
Vessels	0	0	0
Total	0	0	0

^a For the less restrictive scenario, the current reporting requirement is relaxed leading to a reduction in costs.

The total costs of the alternatives compared to the final rule are summarized in Table 41 and include the costs of the change to the definition of an “ill person” and the codification of the requirement for airlines to provide passenger contact data for the final rule, the less restrictive alternative, and the more restrictive alternative.

TABLE 41—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)

	Best estimate	Lower bound	Upper bound
Costs			
Final Rule:			
71.4 and 71.5 Passenger data collection	\$12,654	\$0	\$25,308

TABLE 41—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)—Continued

	Best estimate	Lower bound	Upper bound
70.1 and 71.1 Change in definition of an “ill person”	0	0	376,554
Total costs	12,654	0	401,862
Less Restrictive Alternative:			
71.4 and 71.5 Passenger data collection	0	0	0
70.1 and 71.1 Change in definition of an “ill person”	0	0	0
Total costs	0	0	0
More Restrictive Alternative:			
71.4 and 71.5 Passenger data collection	12,338	0	24,802
70.1 and 71.1 Change in definition of an “ill person”	848	848	377,402
Total costs	13,186	848	402,204
Benefits			
Final Rule:			
71.4 and 71.5 Passenger data collection	0	0	0
70.1 and 71.1 Change in definition of an “ill person”	0	0	0
Total benefits	0	0	0
Less Restrictive Alternative:			
71.4 and 71.5 Passenger data collection	75,924	75,924	75,924
70.1 and 71.1 Change in definition of an “ill person”	14,679	14,679	14,679
Total benefits	90,603	90,603	90,603
More Restrictive Alternative:			
71.4 and 71.5 Passenger data collection	1,898	1,898	1,898
70.1 and 71.1 Change in definition of an “ill person”	0	0	0
Total benefits	1,898	1,898	1,898

Staff Time for Contact Investigations

For the less restrictive alternative, the change relative to baseline is equal to the current cost of performing CIs for travelers exposed on international flights (\$745,000 each for HHS/CDC and local health departments or a total of about \$1.5 million, Table 20). Under the

more restrictive alternative (*i.e.* implementing travel restrictions immediately upon evidence of widespread transmission of viral hemorrhagic fevers, SARS or MERS, the costs of these contact investigations are assumed to be avoided (potential cost reductions of about \$29,000 each to

HHS/CDC and health departments or \$58,000 in total). The benefits of the avoided contacted investigations are then added to the cost savings for the remaining contacts assuming a 0–3% improvement in HHS/CDC efficiency and a 0–2% improvement in PHD efficiency as for the final rule (Table 42).

TABLE 42—ESTIMATED BENEFITS ASSOCIATED WITH REDUCED COSTS TO CONDUCT CONTACT INVESTIGATIONS

	HHS/CDC benefits	PHD benefits	Total
Final Rule:			
Best estimate	\$7,331	\$4,887	\$12,218
Lower bound	0	0	0
Upper bound	14,661	9,774	24,435
Less Restrictive Alternative:			
Best estimate	745,380	745,380	1,490,760
Lower bound	745,380	745,380	1,490,760
Upper bound	745,380	745,380	1,490,760
More Restrictive Alternative:			
Best estimate	36,671	34,227	70,898
Lower bound	29,340	29,340	58,680
Upper bound	44,001	39,114	83,115

Measles Contact Investigation Health Outcomes—Alternatives

For this analysis, under the less restrictive alternative, HHS/CDC assumes that no contact investigations are performed for measles. As a result,

the probability of onward transmission from 3.6 to 10.1 measles patients exposed each year during travel greatly increases and is modeled based on the estimated costs of measles in the absence of intervention \$504,000 (range:

\$137,000 to \$1.3 million) (Table 28). Measles outcomes for the more restrictive alternative are the same as estimated for the final rule since there is no difference in measles efforts between the final rule and the more

restrictive alternative because measles is not a quarantinable disease. The comparative benefits relative to the

status quo baseline are shown in Table 43. For the less restrictive alternative, costs are estimated based on an increase

in measles outbreak costs relative to the baseline.

TABLE 43—ESTIMATED BENEFITS ASSOCIATED WITH AVERTED COSTS FROM MEASLES OUTBREAKS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound
Benefits			
Final Rule	\$45,396	\$8,229	\$159,444
Less Restrictive Alternative	0	0	0
More Restrictive Alternative	45,396	8,229	159,444
Costs			
Final Rule	1,950	1,950	1,950
Less Restrictive Alternative ^a	201,758	54,858	531,481
More Restrictive Alternative	1,950	1,950	1,950

^aFor the less restrictive alternative, contact investigations are not performed so the cost can be estimated based on the estimated public health benefit of contact investigations performed under the baseline (Table 29).

Tuberculosis Contact Investigations Health Outcomes—Alternatives

Under the less restrictive alternative, tuberculosis contact investigation are no longer conducted for persons exposed during travel. Relative to the baseline, there are neither costs to conduct such investigations (resulting in benefits of

about \$180,000 to forego providing treatment for latent tuberculosis treatment) or benefits associated with reduced tuberculosis morbidity and mortality. Relative to the baseline, the estimated cost of increased tuberculosis morbidity and mortality is estimated to be \$2.6 million (range: \$1.8 million to \$3.8 million). Under the more restrictive

alternative in which suspension of entry is enforced in response to quarantinable communicable disease outbreaks, there is no change relative to the final rule results because it is unlikely that a tuberculosis outbreak would cause suspension of entry. Results are summarized in Table 44.

TABLE 44—CHANGES IN TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound	Notes
Benefits				
Final Rule	\$52,432	18,108	113,513	Table 32. Assumed to be the cost to provide LTBI treatment under the baseline (Table 32). The more restrictive alternative has the same effect on TB contact investigations as the final rule.
Less Restrictive Alternative	180,180	180,180	180,180	
More Restrictive Alternative	52,432	18,108	113,513	
Costs				
Final Rule	18,018	9,009	27,027	Table 32. Estimated based on the benefits of avoided TB morbidity and mortality resulting from contact investigations under the baseline. The more restrictive alternative has the same effect on TB contact investigations as final rule.
Less Restrictive Alternative	\$2,613,936	\$1,805,502	\$3,772,691	
More Restrictive Alternative	18,018	9,009	27,027	

The total costs and benefits of changes in health outcomes associated with the more and less restrictive alternatives compared to the provisions included in the Final Rule are summarized in Table 45. The less restrictive alternative in

which contact investigations are no longer pursued shows a large increase in costs relative to the baseline and in comparison to the provisions in the final rule. In addition, there are some benefits, but not enough to offset the

costs. The more restrictive alternative does not change health outcomes for tuberculosis and measles in comparison to the final rule.

TABLE 45—CHANGES IN MEASLES AND TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

	Best estimate	Lower bound	Upper bound
Benefits			
Final Rule	\$97,828	\$26,337	\$272,958
Less Restrictive Alternative	180,180	180,180	180,180.
More Restrictive Alternative	97,828	26,337	272,958
Costs			
Final Rule	19,968	10,959	28,977
Less Restrictive Alternative	2,815,694	1,860,360	4,304,172
More Restrictive Alternative	19,968	10,959	28,977

Note: This table includes the sum of results in Tables 43 and 44.

The total quantified costs and benefits (Table 46) resulting from the additional data provision and timeliness of traveler contact data or the improvement of illness reporting for alternatives to the provisions included in the final rule is summarized by summing the improved efficiency for HHS/CDC to provide contact data to health departments and improved efficiency for health departments to contact exposed travelers (Table 42) and the reductions associated with measles and tuberculosis morbidity and mortality (Table 45).

TABLE 46—TOTAL ANNUAL COSTS AND BENEFITS ASSOCIATED WITH IMPROVED EFFICIENCY PUBLIC HEALTH RESPONSE ACTIVITIES, 2015 USD

	Best estimate	Lower bound	Upper bound
Benefits			
FR	\$110,045	\$26,337	\$297,393
Less Restrictive Alternative	1,670,940	1,670,940	1,670,940
More Restrictive Alternative	168,725	85,017	356,073
Costs			
FR	19,968	10,959	28,977
Less Restrictive Alternative	2,815,694	1,860,360	4,304,172
More Restrictive Alternative	19,968	10,959	28,977

The total annual costs and benefits for the alternatives compared to the final rule are summarized in Table 47. Although the benefits for the more restrictive alternative in which suspensions of entry would be implemented for countries experiencing outbreaks of quarantinable communicable diseases are greater than the quantified annual benefits of the final rule, the costs are underestimated. HHS/CDC does not have sufficient data to quantify the long term costs of implementing suspensions of entry for countries experiencing outbreaks of quarantinable diseases; however, such costs would probably exceed the \$100,000 in estimated benefits associated with suspensions of entry that may result in fewer contact investigations for quarantinable diseases such as Ebola and MERS. Refer to the appendix for some details of potential costs associated with hypothetical suspensions of entry for the countries with widespread Ebola transmission during the 2014–2016 global Ebola epidemic.

TABLE 47—TOTAL ANNUAL COSTS AND BENEFITS OF THE FINAL RULE, LESS RESTRICTIVE AND MORE RESTRICTIVE ALTERNATIVES, 2015 USD

	Best estimate	Lower bound	Upper bound
Benefits			
Final Rule	\$110,045	\$26,337	\$297,393
Less Restrictive Alternative	1,780,524	1,780,524	1,780,524
More Restrictive Alternative	170,623	86,915	357,971
Costs			
Final Rule	32,622	10,959	430,839
Less Restrictive Alternative	2,815,694	1,860,360	4,304,172
More Restrictive Alternative	33,154	11,807	431,181

Codification of Current Practice (Multiple Provisions in Final Rule)

HHS/CDC does not expect that most of the provisions included in the final rule will result in measurable changes relative to the economic baseline. The primary purpose of the provisions summarized in list below is to explain how HHS/CDC interprets its current statutory and regulatory authority under the Public Health Service Act (42 U.S.C. 264, 265) and regulations at 42 CFR parts 70 and 71. HHS/CDC is grouping the complementary provisions in part 70 and part 71 in the list below, when they align, to facilitate public review of the current provisions as well as those included in the final rule. These changes are intended to clarify the agency's standard operating procedures and policies, and due process rights for individuals. HHS/CDC believes that such clarity is an important qualitative benefit of the provisions in this final rule, but is not able to monetize this impact in a significant way.

• New Provisions: § 70.5

Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

○ Baseline and Current Regulatory Provision: § 70.5 Certain communicable disease; special requirements.

■ Without the final rule, HHS/CDC may issue Federal orders to restrict travel for persons infected or exposed to quarantinable communicable diseases. However, this process is less transparent and efficient than allowing travel (*i.e.* issue travel permits to allow interstate travel to persons under Federal orders for diseases not currently identified under existing 42 CFR 70.5.) Under current practice, HHS/CDC issues approximately one Federal order per year, most frequently for tuberculosis, which is a disease not included in the current 70.5.

○ Change relative to baseline as result of final rule

■ With the final rule, HHS/CDC is aligning the list of diseases for which individuals under Federal orders may be allowed to travel with the quarantinable communicable diseases specified in Executive Order. A potential future qualitative benefit would be to reduce uncertainty by the individual subject to the order, carrier operators, and cooperating health and law enforcement entities about whether HHS/CDC could issue a travel permit to an individual under a Federal order and quantifiable benefit would be the avoided cost of potential legal challenge.

○ Qualitative benefit/cost of final rule

■ Improved transparency for HHS/CDC's ability to allow individuals under

Federal orders to issue travel permits to allow individuals to travel (interstate). HHS/CDC may allow persons under Federal orders to travel interstate for whom there is greater uncertainty regarding HHS/CDC restricting their travel.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

• New provisions: § 70.6

Apprehension and detention of persons with specific diseases; § 71.32 Persons, carriers, and things (no change to title)

○ Baseline and Current Regulatory Provision:

■ Under current 42 CFR 70.6 and § 71.32, HHS/CDC has regulatory authority to apprehend and detain individuals with quarantinable communicable diseases.

○ Change relative to baseline as result of final rule

■ As a result of these new provisions, the major change would be improved transparency of HHS/CDC's regulatory authority with regard to the issuance of Federal quarantine, isolation, or conditional release orders of individuals traveling interstate.

○ Qualitative benefit/cost of final rule

■ Improved transparency and compliance with Federal orders.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process may result in fewer resources and time expended by individuals under orders, cooperating entities, and CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

• New Provisions: § 70.10 Public health prevention measures to detect communicable disease; § 71.20 Public health prevention measures to detect communicable disease.

○ Baseline and Current Regulatory Provisions: No explicit regulatory provision.

■ In the absence of the final rule and under existing statutory authority provided in the Public Health Service Act and regulatory authority provided by 42 CFR 70.2 and 71.32(b), HHS/CDC could still implement public health measures at locations where individuals may gather for interstate travel or at U.S. ports of entry. However, without more

transparent regulatory authority to require such measures, travelers may be less likely to comply, either by refusing to answer risk assessment questions or providing false information. This lack of compliance may require that HHS/CDC, if it reasonably believes that the individual is infected with or has been exposed to a quarantinable communicable disease, to quarantine, isolate, or place the individual under surveillance under 42 CFR 70.6 or 71.32 and 71.33. HHS/CDC has not implemented public health measures at locations where individuals may congregate for the purposes of interstate travel in at least 50 years and cannot predict if or how often it may implement measures in the future.

○ Change relative to baseline as result of final rule

■ Improved transparency and potentially improved compliance in the event that HHS/CDC implements such measures in the future.

○ Qualitative benefit/cost of final rule

■ Improved transparency and public understanding of HHS/CDC's rationale and authority to conduct such measures and require individuals to comply.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process procedures may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

• New Provisions: § 70.12 Medical examinations; § 71.36 Medical Examinations

○ Baseline and Current Regulatory Provisions: 71.33 Persons: Isolation and Surveillance.

■ This is carried out under statutory authority and under the regulatory authorities in 42 CFR 70.6 and 71.32(a), 71.33, which would allow for medical examinations of individuals under Federal orders.

○ Change to baseline as result of final rule

■ With the final rule, the major change would be an alignment between the statutory language in the Public Health Service Act and improved transparency of HHS/CDC's regulatory authority.

○ Qualitative benefit/cost of final rule

■ Improved transparency and public understanding of HHS/CDC's rationale and authority to conduct such measures and require individuals to comply.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process procedures may result in fewer

resources and time expended by individuals under orders, cooperating entities, and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.13 Payment for Care and Treatment; § 71.30 Payment for Care and Treatment

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- This addition is not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The provisions included in the final rule are similar to a Memorandum of Agreement between a number of hospitals and HHS/CDC. Under the terms of the Memorandum of Agreement, the hospital can be reimbursed for incurred medical expenses subject to HHS/CDC's discretion, availability of appropriations, and limited to what a hospital would bill Medicare. The Memorandum of Agreement also indicates that HHS/CDC should be the payer of last resort.

- HHS/CDC issued 12 isolation orders between Jan 1, 2005 and May 10, 2016, which would correspond to an average of about 1 order per year over the past 11.3 years. HHS/CDC has information on payments made for 3 of the 12 cases. In most cases, HHS/CDC makes payment directly to healthcare facilities, sometimes in lieu of payments that would be made by State or local health departments. Among the three instances for which HHS/CDC has some data on payments for treatment, care, and transportation of individuals under Federal orders:

- HHS/CDC's expected annual payments for care and treatment are estimated to be between \$0 and \$1,000,000 in any given year under the current baseline. This upper bound cost would correspond to a year in which HHS/CDC would have to incur the costs of two patients at \$500,000 per patient. This roughly corresponds to the average cost to treat an extremely drug-resistant tuberculosis case (XDR-TB). Alternatively, this could represent a situation in which HHS/CDC may have to pay a significant fraction of the total costs for one very complicated illness associated with a quarantinable communicable disease not endemic to the United States (e.g., Ebola).

- HHS/CDC has not incurred any costs for the care and treatment of any

individuals besides for those under Federal isolation orders.

- Change to baseline as result of final rule

- Improved transparency around HHS/CDC's authority for, and requirements and processes related to payment for care and treatment.

- Qualitative benefit/cost of final rule
 - Improved transparency and public knowledge of HHS/CDC's procedures and regulatory requirements.

- Monetized benefit/cost of final rule
 - None. This is a clarification of HHS/CDC's current practice. (For more details, please refer to separate RIA Appendix)

- New Provisions: § 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release; § 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision

- Without the final rule, HHS/CDC can under current statutory provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to issue Federal quarantine, isolation, or condition release orders. However, the issuance of federal orders is implemented through internal policies and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule

- Improved transparency around HHS/CDC's authority for, and requirements and processes related to, the issuance of Federal quarantine, isolation, and conditional release orders.

- Qualitative benefit/cost of final rule
 - Improved transparency and public knowledge of HHS/CDC's procedures and regulatory requirements.

- Monetized benefit/cost of final rule
 - None. This is a clarification of HHS/CDC's current practice.

- New Provisions: § 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release; § 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can under current statutory authority provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to

issue Federal quarantine, isolation, or conditional release orders. However, the process for reassessing a Federal order is implemented through internal policy and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule:

- With the final rule, individuals under Federal order may be more aware of the mandatory reassessment of a Federal quarantine, isolation, or conditional release order.

- Qualitative benefit/cost of final rule
 - Improved transparency and understanding of due process protections under a Federal public health order.

- Monetized benefit/cost of final rule
 - Increased clarity around due process protections may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release; § 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can under current statutory authority provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32, 71.33 continue to issue Federal quarantine, isolation, or conditional release orders. However, the process for a medical review of a Federal order is outlined in internal policy and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule:

- With the final rule, individuals under Federal order may become aware of their right to a medical review, and exercise that right, under this due process provision.

- Qualitative benefit/cost of final rule
 - Improved transparency and understanding of due process afforded to individuals under a Federal order

- Monetized benefit/cost of final rule
 - Increased clarity around due process protections may result in fewer resources and time expended by individuals under orders and HHS/CDC

in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- One potential change that could have an economic effect is the requirements to appoint medical and legal representatives for individuals that qualify as "indigent". The status of "indigent" is self-reported as HHS/CDC will not require access to an individual's financial records. Those who self-identify as indigent may be required to sign an affidavit or declaration under penalty of perjury stating they meet the threshold of at least 200% of the applicable poverty guidelines. HHS/CDC notes that in practice it has never denied a request for a representative. HHS/CDC estimates the cost of providing one medical representative and one legal representative based on the average hourly wage for physicians and surgeons (\$97.33, occupation code 29–1060) and lawyers (\$65.51, occupation code 23–1011) as reported from the Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates. Assuming that it takes about 40 hours of physician time and 40 hours of lawyer time per review and an overhead cost multiplier of 100%, the expected cost is about \$13,000 per review. HHS/CDC notes that public health orders are issued on average once per year. The need for HHS/CDC to pay for medical and legal representatives will depend on the income level for persons placed under federal orders, but should not exceed this \$13,000 estimate in most years and will be \$0 in many years. Without the new regulatory provision, as part of current practice, HHS/CDC would still attempt to appoint legal and medical representatives if requested for the medical review by individuals unable to afford the cost of such representation. Thus, relative to current practice, there should be minimal costs associated with this provision.

- New Provisions: § 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release; § 71.29 Administrative records relating to Federal quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can issue under current statutory provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to

issue Federal quarantine, isolation, or conditional release orders. However, the process for documenting the administrative record is implemented internal policy and standard operating procedures that are not as transparent to the public as a detailed regulation outlining this requirement.

- Change to baseline as result of final rule

- The requirement, with which HHS/CDC is already complying, will clarify for the public that certain documents must be retained for the administrative record.

- Qualitative benefit/cost of final rule

- Improved transparency

- Monetized benefit/cost of final rule

- Not applicable. This is a codification of an administrative activity within HHS/CDC.

- New Provisions: § 70.18 Penalties/ § 71.2 Penalties

- Baseline and Current Regulatory Provision: § 71.2 Penalties. Part 70 currently has no penalties provision.

- Without the final rule, individuals may not be aware that 18 U.S.C. 3559 and 3571 increased the maximum penalties for violations of regulations under 42 CFR part 70 and part 71. And it may not be clear to individuals that violating quarantine regulation under 42 CFR part 70 may result in criminal penalties.

- Change to baseline as result of final rule

- With the NRPM, there will be less confusion about the maximum criminal penalties for a violation of regulations under 42 CFR 70 and 71.

- Qualitative benefit/cost of final rule

- Improved transparency and alignment with current law under 18 U.S.C. 3559 and 3571.

- Monetized benefit/cost of final rule
- No individual or organization has been assessed criminal penalties for violating these regulations, so monetizing this benefit or cost is not feasible. This is simply an effort to align the domestic and foreign quarantine penalties provisions, and updates outdated regulatory language so that it reflects current statutory language concerning criminal penalties.

- New Provisions: § 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States

- Baseline and Current Regulatory Provision: § 71.32(b) has previously been used to justify the temporary embargo of imported African rodents prior to the codification of this as a requirement in existing 42 CFR 71.56.

- Without the final rule, individuals may not be aware that HHS/CDC's authority to temporarily suspend entry

of animals, articles or things from designated foreign countries and places into the United States based on existing 42 CFR 71.32(b).

- Change to baseline as result of final rule

- With the NRPM, there will be less confusion about HHS/CDC's ability to temporarily restrict importations associated with communicable disease risks.

- Qualitative benefit/cost of final rule

- Improved transparency.

- Monetized benefit/cost of final rule

- Refer to the appendix for an analysis of the temporary embargo of African rodents implemented in 2003.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), agencies are required to analyze regulatory options to minimize significant economic impact of a rule on small businesses, small governmental units, and small not-for-profit organizations. We have analyzed the costs and benefits of the final rule, as required by Executive Order 12866, and a preliminary regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. Based on the cost benefit analysis, we expect the rule to have little or no economic impact on small entities.

C. The Paperwork Reduction Act

HHS/CDC has determined that this final rule contains proposed information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). A description of these proposed provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. Comments are invited on the following subjects.

- Whether the proposed collection of information is necessary for the proper performance of the functions of HHS/CDC, including whether the information will have practical utility.

- The accuracy of HHS/CDC's estimate of the burden of the collection of information.

- Ways to enhance the quality, utility, and clarity of the information to be collected.

• Ways to minimize the burden of the collection of information on respondents, including by using information technology.

While HHS/CDC currently has approval to collect certain information concerning illnesses and travelers under OMB Control Numbers 0920–0134 (*Foreign Quarantine Regulations*, expiration date 05/31/2019) and 0920–0488 (*Restrictions on Interstate Travel of Persons*, expiration date 05/31/2019), CDC is requesting updates to certain information collections within these control numbers.

In another information collection request associated with this final rule, CDC is also requesting approval to require that airlines and vessels provide certain data elements to CDC, as described in proposed 71.4 and 71.5, for the purposes of contact tracing. This information is used to locate individuals, both passengers and crewmembers, who may have been exposed to a communicable disease during travel and to provide them with appropriate public health follow-up.

Written comments should be received within 30 days of the publication of this final rule. Please send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806.

Proposed Projects

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(2) Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(3) Airline and Vessel and Traveler Information Collection (42 CFR and 71)—New Information Collection Request—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Description

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and interstate. Legislation and existing regulations governing foreign and

interstate quarantine activities (42 CFR parts 70 and 71) authorize quarantine officers and other personnel to inspect and undertake necessary control measures in order to protect the public health. Currently, with the exception of the CDC's Vessel Sanitation Program, inspections are performed only on those vessels and aircraft that report illness before arriving or when illness is discovered upon arrival. Other inspection agencies assist quarantine officers in public health risk assessment and management of persons, pets, and other importations of public health importance. These practices and procedures ensure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting as well as a minimum of interference with trade and travel. The information collection burden is associated with these recordkeeping and reporting requirements.

At present, HHS/CDC has approval from OMB to collect certain information and impose recordkeeping requirements related to foreign quarantine responsibilities under OMB Control Number 0920–0134 (expiration 05/31/2019). The specific provisions within 42 CFR part 71 that include information collection under are as follows:

42 CFR 71.21(a), (b), and (c) Report of death and illness.

42 CFR 71.33(c) Report of persons held in isolation or surveillance.

42 CFR 71.35 Report of death or illness on carrier during stay in port.

42 CFR 71.51 Dogs and cats.

42 CFR 71.52 Turtles, terrapins, tortoises.

42. CFR 71.56 African Rodents

HHS/CDC has also used its authority under 42 CFR 71.32 to require importers to submit statements or documentation of non-infectiousness for those items that may constitute a public health risk if not rendered non-infectious.

Finally, HHS/CDC has approval from OMB to collect from importers/filers certain documents and data elements to identify and clear HHS/CDC regulated imports via the Automated Commercial Environment and the International Trade Data System using the Document Imaging System and Partner Government Agency Message Sets. These CDC Partner Government Agency Message Sets are currently limited to: CDC PGA Message Set for Importing Cats and Dogs, CDC PGA Message Set for Importing African Rodents, CDC PGA Message Set for Importing African Rodent and All Family *Viverridae* Products.

In this final rule, CDC is requesting approval from OMB for 4 non-substantive changes to OMB Control Number 0920–0134 Foreign Quarantine Regulations (42 CFR part 71):

(1) Updating the definition of “ill person,” which relates to the illness reporting requirements under 42 CFR 71.21(a), (b), and (c) for airlines and vessels arriving into the United States. CDC is updating the definition of “ill person” by implementing current practice with the anticipated effect of better facilitating identification of communicable diseases of concern and quarantinable communicable diseases aboard flights and maritime voyages to the United States, diseases such as measles, viral hemorrhagic fevers, active tuberculosis, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. CDC is also including a provision to allow the Director to add new symptoms to the definition of ill person to respond to unknown communicable diseases that may emerge as future concerns.

The final rule updates the current definition of ill person to better focus on the signs and symptoms of communicable diseases of public health concern and quarantinable communicable diseases. The changes define an ill person in the context of the medical resources available to the operator of an airline or vessel.

CDC already requests from pilots in command of aircraft and commanders of vessels several of the symptoms included in the revised definition of ill person through publicly available guidance to airlines and vessels. Moreover, for airlines, the updated definition also better aligns with symptoms reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation, and the definition of “acute gastroenteritis” is used by the WHO and is currently included in reporting guidance from CDC's Vessel Sanitation Program. Therefore, CDC does not anticipate additional burden on airlines or vessel operators to respond to these information collections.

(2) CDC is requesting a change in the title of the information collection pertaining to reports of death and illness from vessels to CDC. The former title is *Radio Report of death or illness*—illness reports from ships. CDC sought a change to remove “Radio” from the title. This change reflects the fact that reports to CDC primarily via means other than radio, such as the Maritime Illness and Death Reporting System, managed by CDC's Vessel Sanitation Program. CDC

did not receive any public comments to this change, and it is therefore finalized as proposed.

(3) CDC is seeking a change in the title of a specific information collection pertaining to reports of gastro-intestinal illness to CDC. CDC is updating the definition of ill person and is replacing the term “gastro-intestinal” with “acute gastroenteritis”; therefore, the title change is requested to align with the definition.

(4) CDC is seeking a change in title of respondents from “Maritime Conveyance Operator” to “Maritime Vessel Operator” and from “Airline

Commander or Operator” to “Pilot in Command.”

Table 1 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the rule changes.

Description of Respondents.

Respondents to this data collection include pilots in command of aircraft, maritime vessel operators, importers/filers, and travelers/general public. The nature of the response to HHS/CDC dictates which forms are completed and by whom. The total requested burden hours are 82,779.

There is no burden to respondents other than the time taken to complete the reports to CDC, maintain recordkeeping of illness aboard vessels and records of sickness or death in imported cats and dogs, as outlined in the table below. If a cat or dog is ill upon arrival, or dies prior to arrival, an exam is required, the initial exam fee may be between \$100 and \$200. Rabies testing on a dog that dies may be between \$50 and \$100. The expected number of ill or dead dogs arriving into the United States for which CDC may require an examination is estimated at less than 30 per year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 0920–0134

Type of respondent	Regulatory provision or form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Maritime Vessel Operators	42 CFR 71.21(a) Report of illness or death from ships—Maritime Vessel Illness or Death Investigation Form/Cumulative Influenza/Influenza-Like Illness (ILI) Form/Radio report or transcribed email.	2,000	1	2/60	67
Pilot in Command	42 CFR 71.21 (b) Death/Illness reports from aircraft	1,700	1	2/60	57
Maritime Vessel Operators	42 CFR 71.21(c) (MIDRS) Acute Gastro-Enteritis reports (24 and 4 hours before arrival).	17,000	1	3/60	850
Maritime Vessel Operators	42 CFR 71.21 (c) Recordkeeping-Medical logs	17,000	1	3/60	850
Isolated or Quarantined individuals.	42 CFR 71.33 Report by persons in isolation or surveillance.	11	1	3/60	1
Maritime Vessel Operators	42 CFR 71.35 Report of death/illness during stay in port.	5	1	30/60	3
Importer	42 CFR 71.51(c)(1), (d)—Valid Rabies Vaccination Certificates.	245,310	1	15/60	61,328
Importer	CDC Form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement.	1,400	1	10/60	233
Importer	42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate.	43,290	1	15/60	10,823
Importer	42 CFR 71.51(c)(2), (d) Application for a Permit to Import A Dog Inadequately Immunized Against Rabies.	1,400	1	15/60	350
Importer	42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths.	20	1	15/60	5
Importer/Filer	42 CFR 71.51_CDC Requested Data on Regulated Imports: Domestic Dogs and Cats (PGA Message Set).	30,000	1	15/60	7,500
Importer	42 CFR 71.52(d) Turtle Importation Permits	5	1	30/60	3
Importers	42 CFR 71.55, 42 CFR 71.32 Dead Bodies—Death certificates.	5	1	1	5
Importer	42 CFR 71.56 (a)(2) African Rodents—Request for exemption.	20	1	1	20
Importer	42 CFR 71.56(a)(iii) Appeal	2	1	1	2
Importer/Filer	42 CFR 71.56 CDC Requested Data on Regulation Imports: Live African Rodents (PGA Message Set).	60	1	15/60	15
Importer/Filer	42 CFR 71.32 Statements or documentation of non-infectiousness.	2,000	1	5/60	167
Importer/Filer	42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents; Products of all Family Viverridae (PGA Message Set).	2,000	1	15/60	500
Total					82,779

The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR part 71, with additional burden included to

account for the potential for increased reports of illness during an outbreak and for reports of disease that may have

been missed by airlines or vessels and are reported to CDC after travel.

Under this final rule, CDC is also requesting a nonmaterial/non-

substantive change to Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488). The regulations at 42 CFR part 70 are intended to prevent the interstate spread of disease, and include a requirement that the master of vessel or person in charge of conveyance to report the occurrence on board of communicable disease. Under this regulation and control number, CDC has approval to collect the following information:

- 42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel.

Through this final rule, CDC is adding the provision 70.11 *Report of death or illness onboard aircraft operated by airline*, which specifies that the pilot in command of an aircraft operating on behalf of an airline who conducts a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to HHS/CDC the occurrence onboard of any deaths or ill persons among passengers or crew and take such measures as HHS/CDC may direct to prevent the potential spread of the communicable disease. HHS/CDC notes that it is changing the existing regulatory requirement at 42 CFR 70.4, which states that the master of a vessel or person in charge of any conveyance engaged in interstate traffic

on which a case or suspected case of communicable disease develops shall, as soon as practicable, notify the local health authority.

Under the final rule, pilots in command of an aircraft, operating on behalf of an airline, that submit the ill person or death report to HHS/CDC under new 70.11 will not be required to also submit a report to the local health authority under current 70.4. HHS/CDC will continue to share public health information with State and local health departments through electronic disease reporting networks. It is unlikely that HHS/CDC would request follow-up reports of illnesses that are reported to the local health authorities, unless there was an urgent public health need. Therefore, CDC does not anticipate any additional burden to the respondents; however, the accounting for burden in Table 2 will add 70.11 *Report of death or illness onboard aircraft operated by airline*.

As a result of this final rule, CDC does not anticipate a change in total burden. CDC is instead allocating 95% of the reports of illness or death within the proposed 70.11 *Report of death or illness onboard aircraft operated by airline*. The remains 5% will remain within 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while

in interstate travel, in the event that some reports are still made to State health authorities.

In addition to the requirement to report directly to HHS/CDC, HHS/CDC is updating the definition of “ill person” for the purposes of illness reports to HHS/CDC in 42 CFR part 70. HHS/CDC has, as a matter of agency guidance, communicated with airlines that the same current set of required and requested signs and symptoms of disease, as well as any death, apply to domestic as well as international flights. This guidance is similar to that of the guidelines issued by ICAO under *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. Therefore, the new proposed definition of ill person should not affect standard practice, and no change in burden is anticipated.

Table 2 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the rule changes.

Description of Respondents

Respondents to this data collection include masters of vessels or persons in charge of conveyance and pilots in command of aircraft.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN 0920–0488

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pilot in command	42 CFR 70.11 Report of death or illness onboard aircraft operated by airline.	190	1	7/60	22
Master of vessel or person in charge of conveyance.	42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel.	10	1	7/60	1
Total		200			23

The total requested burden hours are 23. There is no burden to respondents other than the time taken to complete the reports. The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR part 70, and take into account the potential for additional burden from increased reports of illness during an outbreak and for reports of disease that may have been missed by respondents during travel and are reported to CDC by other means.

Finally, under this final rule HHS/CDC is requesting approval for a new information collection, Airline and Vessel and Traveler Information Collection (42 CFR part 71). This information collection request accompanies the codification of issuing orders to airlines and vessel operators for the provision to CDC of airline and vessel and traveler information (aka manifests) in the event that a quarantinable communicable disease or a communicable disease of public health concern, or a death caused by a quarantinable communicable disease or

communicable disease of public health concern, occurs during travel to the United States and public health follow-up is warranted. These proposed provisions are found in 42 CFR 71.4 for airlines and 71.5 for vessels.

The ordering of manifests from airlines and vessel operators arriving into the United States is an ongoing activity executed under CDC’s broad regulatory authority found at 42 CFR 71.32 *Persons, carriers, and things*. To increase transparency with regard to CDC’s authorities and manifest order process, CDC is proposing specific

regulatory provisions that outline the particular data elements CDC requires to perform contact tracing investigations. As stated in the final rule, CDC is not mandating the collection of additional data. Only that if the airlines or maritime operators have the data elements listed in 71.4 and 71.5 in their

possession, they must be provided to CDC within 24 hours.

Table 3 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the final rule changes.

Description of Respondents

Respondents to this data collection include the Airline Medical Officer or Equivalent and a Computer and Information Systems Manager.

TABLE 3—ESTIMATE OF ANNUAL BURDEN AIRLINE AND VESSEL MANIFEST ORDERS

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International TB Manifest Template	67	1	360/60	402
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International Non-TB Manifest Template.	29	1	360/60	174
Total		96			576

The total requested burden hours included in this final rule is 576. There is no burden to respondents other than the time taken to complete the manifest information and send to CDC. The estimates are based on experience to date with current manifest order process.

D. National Environmental Policy Act (NEPA)

HHS/CDC has determined that the amendments to 42 CFR parts 70 and 71 will not have a significant impact on the human environment.

E. Executive Order 12988: Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this final rule meets the standard in the Executive Order.

F. Executive Order 13132: Federalism

Under Executive Order 13132, a Federalism analysis is required if a rulemaking has Federalism implications, would limit or preempt State or local law, or impose substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public

health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Additionally, there are no provisions in these regulations that impose direct compliance costs on State and local governments. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

G. The Plain Language Act of 2010

Under 63 FR 31883 (June 10, 1998), Executive Departments and Agencies are required to use plain language in all proposed and final rules. HHS/CDC received several comments suggesting that the proposed regulation was not written in plain language and was therefore difficult to understand. Prior to publication, this final rule was reviewed by specialists in health communication and education to ensure the content and intention, as well as substance, were clear and accurate.

List of Subjects in 70.1, 70.5, 70.6, 70.10–70.18, 71.1, 71.2, 71.4, 71.5, 71.12, 71.20, 71.29, 71.30, 71.36–71.39, 71.63

Apprehension, Communicable diseases, Conditional release, CDC, Ill person, Isolation, Non-invasive, Public health emergency, Public health prevention measures, Qualifying stage,

Quarantine, Quarantinable Communicable Disease.

For the reasons discussed in the preamble, we amend 42 CFR parts 70 and 71 as follows:

PART 70—INTERSTATE QUARANTINE

■ 1. The authority citation for part 70 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243) section 361–369, PHS Act, as amended (42 U.S.C. 264–272); 31 U.S.C. 9701.

■ 2. Amend § 70.1 by—

■ a. Adding in alphabetical order definitions for “Airline”, “Apprehension”, and “Communicable stage”;

■ b. Revising the definition of “Conditional release”;

■ c. Adding in alphabetical order a definitions for “Contaminated environment”;

■ d. Revising the definition of “Conveyance”;

■ e. Adding in alphabetical order definitions for “Electronic or Internet-based monitoring” and “Ill person”;

■ f. Revising the definition of “Incubation period”;

■ g. Adding in alphabetical order a definition for “Indigent”;

■ h. Revising the definition of “Interstate traffic”;

■ i. Revising the definition of “Master or operator”;

■ j. Adding in alphabetical order definitions for “Medical examination”, “Medical reviewer”, “Non-invasive”, “Precommunicable stage”, “Public health emergency”, “Public health

prevention measures”, “Qualifying stage”, “Reasonably believed to be infected, as applied to an individual”, and “Representatives”.

The additions and revisions read as follows:

§ 70.1 General definitions.

Airline means any air carrier or foreign air carrier providing air transportation as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether Federal quarantine, isolation, or conditional release is warranted.

* * * * *

Communicable stage means the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual.

Conditional release means the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or Internet-based monitoring.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

Conveyance means an aircraft, train, road vehicle, vessel (as defined in this section) or other means of transport, including military.

* * * * *

Electronic or Internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a Web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director or supervising health authority.

Ill person means an individual who:

(1) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury),

persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(2) Has a fever that has persisted for more than 48 hours; or

(3) Has symptoms or other indications of communicable disease, as the CDC may announce through posting of a notice in the **Federal Register**.

Incubation period means the time from the moment of exposure to an infectious agent that causes a communicable disease until signs and symptoms of the communicable disease appear in the individual or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear. For a quarantinable communicable disease, incubation period means the precommunicable stage.

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

Interstate traffic (1) Means:

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(ii) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(iii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

* * * * *

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a conveyance. Consistent with the definition of “operate” in 14 CFR 1.1, “operator” means, with respect to aircraft, any person who uses, causes to use, or authorizes to use an aircraft, for the

purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of an aircraft, with or without the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual’s health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

Non-invasive means procedures conducted by an authorized public health worker (*i.e.*, an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

* * * * *

Precommunicable stage means the stage beginning upon an individual’s earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage.

Public health emergency as used in this part means:

(1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or

(2) Any communicable disease event described in a declaration by the

Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or

(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or

(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or

(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual's health status and potential public health risk to others.

Qualifying stage is statutorily defined (42 U.S.C. 264(d)(2)) to mean:

(1) The communicable stage of a quarantinable communicable disease; or

(2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

* * * * *

Reasonably believed to be infected, as applied to an individual, means specific articulable facts upon which a public health officer could reasonably draw the inference that an individual has been exposed, either directly or indirectly, to the infectious agent that causes a quarantinable communicable disease, as through contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector, and that as a consequence of the exposure, the individual is or may be harboring in the body the infectious agent of that quarantinable communicable disease.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases,

and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

* * * * *

Secretary means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.

* * * * *

■ 3. Revise § 70.5 to read as follows:

§ 70.5 Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

(a) The following provisions are applicable to any individual under a Federal order of isolation, quarantine, or conditional release with regard to a quarantinable communicable disease or to any individual meeting the requirements of paragraph (d), (e), or (f) of this section:

(1) Except as specified under the terms of a Federal conditional release order, no such individual shall travel in interstate traffic or from one State or U.S. territory to another without a written travel permit issued by the Director.

(2) Requests for a travel permit must state the reasons why the travel is being requested, mode of transportation, the places or individuals to be visited, the precautions, if any, to be taken to prevent the potential transmission or spread of the communicable disease, and other information as determined necessary by the Director to assess the individual's health condition and potential for communicable disease spread to others.

(3) The Director will consider all requests for a permit and, taking into consideration the risk of introduction, transmission, or spread of the communicable disease, may condition the permit upon compliance with such precautionary measures as the Director shall prescribe. The Director shall respond to a request for a permit within 5 business days.

(4) An individual to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances, as required by its terms.

(5) An individual who has had his/her request for a permit denied, or who has had a travel permit suspended or

revoked, may submit a written appeal to the Director (excluding the CDC official who denied, suspended, or revoked the permit). The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Director (excluding the CDC official who denied, suspended, or revoked the permit) within 10 calendar days of the denial, suspension, or revocation of the permit. The Director (excluding the CDC official who denied, suspended, or revoked the permit) will issue a written response to the appeal within 3 business days, which shall constitute final agency action.

(b) The operator of any conveyance operating in interstate traffic shall not:

(1) Accept for transportation any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release, unless such an individual presents a permit issued by the Director or a copy of the Federal conditional release order authorizing such travel;

(2) Transport any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release in violation of any of the terms or conditions prescribed in the travel permit or conditional release order issued by the Director.

(c) Whenever a conveyance operating in interstate traffic transports an individual under a Federal order or travel permit, the Director may require that the operator of the conveyance submit the conveyance to inspection, sanitary measures, and other measures, as the Director deems necessary to prevent the possible spread of communicable disease.

(d) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals traveling entirely intrastate and to conveyances that transport such individuals upon the request of a State or local health authority of jurisdiction. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(e) The Director may additionally apply the provisions in paragraphs (a) through of this section (c) to individuals traveling interstate or entirely intrastate and to conveyances that transport such individuals whenever the Director makes a determination under 42 CFR 70.2 that based on the existence of inadequate local control such measures are needed to prevent the spread of any

of the communicable diseases from such State or U.S. territory to any other State or U.S. territory.

(f) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals under a State or local order, or written agreement, for quarantine, isolation, or conditional release and to conveyances that may transport such individuals, upon the request of a State or local health authority of jurisdiction or whenever the Director makes a determination of inadequate local control under 42 CFR 70.2. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(g) The Director may exempt individuals and non-public conveyances, such as ambulances, air ambulance flights, or private vehicles, from the requirements of this section.

■ 4. Revise § 70.6 to read as follows:

§ 70.6 Apprehension and detention of persons with quarantinable communicable diseases.

(a) The Director may authorize the apprehension, medical examination, quarantine, isolation, or conditional release of any individual for the purpose of preventing the introduction, transmission, and spread of quarantinable communicable diseases, as specified by Executive Order, based upon a finding that:

(1) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and is moving or about to move from a State into another State; or

(2) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and constitutes a probable source of infection to other individuals who may be moving from a State into another State.

(b) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for individuals who are apprehended or held in quarantine or isolation under this part.

■ 5. Add §§ 70.10 through 70.18 to read as follows:

Sec.
* * * * *

70.10 Public health prevention measures to detect communicable disease.

70.11 Report of death or illness onboard aircraft operated by an airline.

70.12 Medical examinations.

70.13 Payment for care and treatment.

70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.

70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.

70.18 Penalties.

§ 70.10 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures at U.S. airports, seaports, railway stations, bus terminals, and other locations where individuals may gather to engage in interstate travel, through non-invasive procedures determined appropriate by the Director to detect the presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

§ 70.11 Report of death or illness onboard aircraft operated by an airline.

(a) The pilot in command of an aircraft operated by an airline who is conducting a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to the Director the occurrence onboard of any deaths or the presence of ill persons among passengers or crew and take such measures as the Director may direct to prevent the potential spread of the communicable disease, provided that such measures do not affect the airworthiness of the aircraft or the safety of flight operations.

(b) The pilot in command of an aircraft operated by an airline who reports in accordance with paragraph (a) of this section shall be deemed to satisfy the reporting obligation under 42 CFR 70.4.

§ 70.12 Medical examinations.

(a) The Director may require an individual to undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release for a quarantinable communicable disease.

(b) The Director shall promptly arrange for the medical examination to

be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require an individual to provide information and undergo such testing as may be reasonably necessary to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected based on the results of a medical examination may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

§ 70.13 Payment for care and treatment.

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the CDC's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (*i.e.*, any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual or group for the time period beginning when the Director refers the individual or group to the hospital or medical facility and ends when, as determined by the Director,

the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the individual's safe medical transport.

§ 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is in the qualifying stage of a quarantinable communicable disease;

(4) An explanation of the factual basis underlying the Director's reasonable belief that the individual is moving or about to move from one State into another or constitutes a probable source of infection to others who may be moving from one State into another;

(5) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(6) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(7) An explanation that if a medical examination is required as part of the Federal order that the examination will

be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in this section shall affect the constitutional or statutory rights of individuals to obtain judicial review of their Federal detention.

§ 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue and serve a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the

individual, except that the Federal order may be served by publication or by posting in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

§ 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.

(a) The Director shall, as soon as practicable, arrange for a medical review upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under section 70.15 and following the service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease in a qualifying stage.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual under Federal quarantine, isolation, or conditional release may authorize an advocate (*e.g.*, an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in

the medical review that pertain to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should be rescinded, continued, or modified. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's authorized advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional

release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual and the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

§ 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.

(a) The administrative record of an individual under Federal quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order,

or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the Federal quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the individual under Federal quarantine, isolation, or conditional release, or by any authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall upon request be served with a copy of his or her own administrative record in its entirety.

§ 70.18 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law.

(b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

PART 71—FOREIGN QUARANTINE

■ 6. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243) section 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 7. Amend § 71.1, paragraph (b), by—

■ a. Adding in alphabetical order definitions for “Airline” and “Apprehension”;

■ b. Revising the definition of “Commander”;

■ c. Adding in alphabetical order definitions for “Conditional release”, “Contaminated environment”, and “Electronic or Internet-based monitoring”;

■ d. Revising the definition of “Ill person”;

■ e. Adding in alphabetical order a definition for “Indigent”;

■ f. Revising the definition of “International voyage”;

■ g. Adding in alphabetical order definitions for “Master or operator”, “Medical examination”, “Medical reviewer”, “Non-invasive”, “Public health prevention measures”, “Representatives”, and “Secretary”.

The additions and revisions read as follows:

§ 71.1 General definitions.

* * * *

(b) * * *

Airline means any air carrier or foreign air carrier providing air transportation, as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether quarantine, isolation, or conditional release is warranted.

* * * *

Commander means the pilot in command of an aircraft as defined in 14 CFR 1.1.

* * * *

Conditional release means surveillance as defined under this part and includes public health supervision through in-person visits by a health official or designee, telephone, or through any electronic or internet-based means as determined by the Director.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

* * * *

Electronic or internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director.

Ill person means an individual:

(i) Who if onboard an aircraft:

(A) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(B) Has a fever that has persisted for more than 48 hours; or

(C) Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the **Federal Register**.

(ii) Who if onboard a vessel:

(A) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater; or feels warm to the touch; or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing or suspected or confirmed pneumonia, persistent cough or cough with bloody sputum, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent vomiting (other than sea sickness), headache with stiff neck; or

(B) Has a fever that has persisted for more than 48 hours; or

(C) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater); or

(D) Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the **Federal Register**.

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

* * * *

International voyage means:

(i) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or

(ii) In the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

* * * *

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a carrier. Consistent with the definition of “operate” in 14 CFR 1.1, “operator” means, with respect to aircraft, any person who uses, causes to use or authorizes to use aircraft, for the purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of aircraft, with or without

the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual’s health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

* * * *

Non-invasive means procedures conducted by an authorized public health worker (*i.e.*, an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

* * * *

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual’s health status and potential public health risk to others.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases, and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

* * * *

Secretary means the Secretary of Health and Human Services (HHS) or

any other officer or employee of that Department to whom the authority involved has been delegated.

* * * * *

■ 8. Revise § 71.2 to read as follows:

§ 71.2 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law. (b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

■ 9. Add 71.4 to subpart A to read as follows:

§ 71.4 Requirements relating transmission of airline passenger, crew and flight information for public health purposes.

(a) Any airline with a flight arriving into the United States, including any intermediate stops between the flight's origin and final destination, shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already available and maintained by the airline, within 24 hours of an order by the Director and in a format available and acceptable to both the airline and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available, middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Airline name;

- (12) Flight number;
- (13) City of departure;
- (14) Departure date and time;
- (15) City of arrival;
- (16) Arrival date and time; and
- (17) Seat number.

(c) No later than February 18, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 10. Add § 71.5 to subpart A to read as follows:

§ 71.5 Requirements relating transmission of vessel passenger, crew, and voyage information for public health purposes.

(a) The operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10–25), shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already in the operator's possession, within 24 hours of an order by the Director and in a format available and acceptable to both the operator and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the United States (number and street, city, State, and zip code; as applicable);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Vessel operator;
- (12) Vessel name;
- (13) Voyage number;

- (14) Embarkation port and date;
- (15) Disembarkation port and date;
- (16) All port stops; and
- (17) Cabin number.

(c) No later than February 21, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 11. Add § 71.20 to subpart C to read as follows:

§ 71.20 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures, at U.S. ports of entry or other locations, through non-invasive procedures as defined in section 71.1 to detect the potential presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

■ 12. Add §§ 71.29 and 71.30 to subpart D to read as follows:

§ 71.29 Administrative records relating to quarantine, isolation, or conditional release.

(a) The administrative record of an individual under quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order, or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the

individual under Federal quarantine, isolation, or conditional release, or by an authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall, upon request, be served with a copy of his or her own administrative record in its entirety.

§ 71.30 Payment for care and treatment.

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the Director's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual for the time period beginning when the Director refers the individual to the hospital or medical facility and ends when, as determined by the Director, the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness

other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the safe medical transport of the individual.

■ 13. Amend § 71.33 by revising paragraphs (a) and (c) to read as follows:

§ 71.33 Persons: Isolation and surveillance.

(a) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for persons who are apprehended or held in isolation or quarantine under this subpart.

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and submit to surveillance, including electronic and internet-based monitoring as required by the Director or by the State or local health department having jurisdiction over the areas to be visited, and report for such medical examinations as may be required.

(2) Inform the Director prior to departing the United States or prior to traveling to any address other than that stated as the intended destination.

■ 14. Add §§ 71.36 through 71.39 to subpart D to read as follows:

- Sec.
- * * * * *
- 71.36 Medical examinations.
- 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.
- 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).
- 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.

§ 71.36 Medical examinations.

(a) The Director may require that an individual arriving into the United States undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release.

(b) The Director shall promptly arrange for the medical examination to be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require

that an individual provide information and undergo such testing, as may be reasonably necessary, to diagnose or confirm the presence, absence, or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected, based on the results of a medical examination, may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is exposed to or infected with a quarantinable communicable disease;

(4) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(5) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(6) An explanation that if a medical examination is required as part of the Federal order that the examination will be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.

§ 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the individual, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

§ 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.

(a) The Director shall, as soon as practicable, arrange for a medical review

upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under 71.38 and following the issuance and service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual subject to Federal quarantine, isolation, or conditional release may authorize an advocate (e.g., an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he/she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in the medical review pertaining to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall

consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should continue. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or

representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individual's and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual or the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or

desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

■ 15. Add § 71.63 to subpart F to read as follows:

§ 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.

(a) The Director may suspend the entry into the United States of animals, articles, or things from designated foreign countries (including political subdivisions and regions thereof) or places whenever the Director determines that such an action is necessary to protect the public health and upon a finding that:

(1) There exists in a foreign country (including one or more political subdivisions and regions thereof) or place a communicable disease the introduction, transmission, or spread of

which would threaten the public health of the United States; and

(2) The entry of imports from that country or place increases the risk that the communicable disease may be introduced, transmitted, or spread into the United States.

(b) The Director shall designate the foreign countries or places and the period of time or conditions under which the introduction of imports into the United States shall be suspended. The Secretary or Director will coordinate in advance with other Federal agencies that have overlapping authority in the regulation of entry of animals, articles, or other things, as may be necessary to implement and enforce this provision.

Dated: January 9, 2017.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2017-00615 Filed 1-12-17; 4:15 pm]

BILLING CODE 4163-18-P