

public procedure as unnecessary. For this same reason, pursuant to 5 U.S.C. 553(d)(3), CBP finds that good cause exists for dispensing with the requirement for a delayed effective date.

The Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12866

As these amendments are technical corrections to the regulations to reflect statutory changes, these amendments do not meet the criteria for a “significant regulatory action” as specified in Executive Order 12866.

Signing Authority

This document is limited to technical corrections of the CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b)(1).

List of Subjects

19 CFR Part 171

Administrative practice and procedure, Customs duties and inspection, Law enforcement, Penalties, Seizures and forfeitures.

19 CFR Part 172

Administrative practice and procedure, Customs duties and inspection, Penalties.

Amendments to the CBP Regulations

For the reasons stated in the preamble, parts 171 and 172 of title 19 of the Code of Federal Regulations (19 CFR parts 171 and 172) are amended as set forth below.

PART 171—FINES, PENALTIES, AND FORFEITURES

■ 1. The authority citation for part 171 is revised to read as follows:

Authority: 18 U.S.C. 983; 19 U.S.C. 66, 1592, 1593a, 1618, 1624; 22 U.S.C. 401; 31 U.S.C. 5321.

§ 171.11 [Amended]

■ 2. Section 171.11(a) is amended by removing the phrase “, or section 320 of title 46, United States Code App. (46 U.S.C. App. 320),”.

§ 171.12 [Amended]

■ 3. Section 171.12 is amended by:
 ■ a. Adding the word, “or”, before the phrase “section 5321(c) of title 31, United States Code (31 U.S.C. 5321(c))”;
 ■ b. Removing the phrase “, or section 320 of title 46, United States Code App. (46 U.S.C. App. 320),”;

■ c. Removing the words “, unless there has been no delegation to act by the Secretary of the Treasury or his designee”;

■ d. Removing the last sentence of the paragraph; and

■ e. Adding the punctuation “.” after the word “appropriate”.

PART 172—CLAIMS FOR LIQUIDATED DAMAGES; PENALTIES SECURED BY BONDS

■ 4. The authority citation for part 172 is revised to read as follows:

Authority: 19 U.S.C. 66, 1618, 1623, 1624.

§ 172.11 [Amended]

■ 5. Section 172.11(a) is amended by removing the phrase “, or section 320 of title 46, United States Code App. (46 U.S.C. App. 320),” and by removing the word “shall” and adding in its place the word “will”.

§ 172.12 [Amended]

■ 6. Section 172.12 is amended by:

■ a. Removing the phrase “, or section 320 of title 46, United States Code App. (46 U.S.C. App. 320),”;

■ b. Adding the words “International Trade,” after the words, “Office of”; and

■ c. Removing the word “Customs” and adding in its place the term “CBP”.

Dated: March 28, 2012.

David V. Aguilar,

Acting Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2012-7814 Filed 3-30-12; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2012-N-0165]

Medical Devices; Immunology and Microbiology Devices; Classification of Norovirus Serological Reagents; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: In the *Federal Register* of March 9, 2012 (76 FR 14272), the Food and Drug Administration (FDA) classified norovirus serological reagents into class II (special controls) because special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness of

these devices. The document published with inadvertent errors in the Analysis of Impacts section. This document corrects those errors.

DATES: Effective April 9, 2012.

FOR FURTHER INFORMATION CONTACT:

Steven Gitterman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5518, Silver Spring, MD 20993-0002, 301-796-6694.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012-5675 appearing on page 14272 in the *Federal Register* of Friday, March 9, 2012, the following corrections are made:

1. On page 14274, in the first column, in section VI. Analysis of Impacts, in the first paragraph, in the last sentence, correct the phrase “proposed rule” to read “final rule”, and in the second paragraph, in the last sentence, correct the phrase “proposes to certify” to read “certifies”.

2. On page 14274, in the second column, in the first full sentence, correct the phrase “proposed rule” to read “final rule”.

Dated: March 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-7757 Filed 3-30-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2012-0039]

RIN 1625-AA08

Special Local Regulations; Savannah Tall Ships Challenge, Savannah River, Savannah, GA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations on the Savannah River in Savannah, Georgia during the Savannah Tall Ships Challenge. The Savannah Tall Ships Challenge will take place from Thursday, May 3, 2012 through Monday, May 7, 2012. Approximately 15 vessels are anticipated to participate in the event. These special local regulations are necessary to provide for the safety of life and property on navigable waters of the United States during the event. The special local regulations establish the following three areas: Mooring zones; buffer zones; and

a staging area. First, mooring zones will be established around vessels participating in the Savannah Tall Ships Challenge while the vessels are moored at their mooring locations along the right and left descending banks of the Savannah River in Savannah, Georgia. Second, buffer zones will be established around vessels participating in the Savannah Tall Ships Challenge as they transit from their mooring locations on the Savannah River to the staging area. Third, a staging area will be established, where vessels participating in the Savannah Tall Ships Challenge will congregate before commencing their voyage to the next port as part of the 2012 Tall Ships Challenge. Persons and vessels that are not participating in the Savannah Tall Ships Challenge are prohibited from entering, transiting through, anchoring in, or remaining within the mooring zones, buffer zones, or staging area unless authorized by the Captain of the Port Savannah or a designated representative.

DATES: This rule is effective from 10:30 a.m. on May 3, 2012 through 4:30 p.m. on May 7, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0039 and are available online by going to <http://www.regulations.gov>, inserting USCG–2012–0039 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call or email Chief Petty Officer Benjamin Mercado, Marine Safety Unit Savannah Office of Waterways Management, Coast Guard; telephone (912) 652–4353, email Benjamin.Mercado@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 7, 2012, we published a notice of proposed rulemaking (NPRM) entitled Special Local Regulations; Savannah Tall Ships Challenge, Savannah River, Savannah, GA in the **Federal Register** (77 FR 6039). We received two comments on the proposed

rule. No public meeting was requested, and none was held.

Basis and Purpose

The legal basis for the temporary final rule is the Coast Guard’s authority to establish special local regulations: 33 U.S.C. 1233. The purpose of the rule is to insure safety of life and property on navigable waters of the United States during the Savannah Tall Ships Challenge.

Discussion of Comments and Changes

The Coast Guard received two comments regarding the NPRM. One comment stated that the proposed rule provided the Captain of the Port of Savannah with almost unlimited discretion as to navigation of regions of the Savannah River for the time period in question. As a result, the comment recommended that the proposed rule be rewritten to limit the discretion of the Captain of the Port of Savannah to ensure large shipping vessels are not disrupted from their activities at the Port of Savannah. There was also concern that many such ships are traveling from a great distance and would not receive notice of any disruption in the Port, and the ramifications of such ships being unable to make a delivery could be significant.

The Coast Guard understands these concerns. However, the Captain of the Port has the authority under 33 U.S.C. 1233 and 33 CFR 100.35 to promulgate special local regulations to promote the safety of life on navigable waters of the United States during regattas or marine parades. These regulations may include restrictions and controls over vessel movement immediately before, during, and after the event. The Coast Guard issued a marine event permit for the Savannah Tall Ships Challenge under 33 CFR part 100 because the event (due to its nature, circumstances, or location) will introduce extra or unusual hazards to the safety of life on the navigable waters of the United States. Specifically, the Coast Guard believes the Savannah Tall Ships Challenge will attract a significant amount of recreational boating traffic not normally present on the Savannah River. Additionally, due to the narrow width of the Savannah River, the Coast Guard finds it necessary to establish the mooring and buffer zones to protect the vessels participating in the Savannah Tall Ships Challenge, as well as the commercial and recreational vessels that will be present on the Savannah River during the event. Before publishing the NPRM, the Coast Guard limited the scope of the special local regulations to the extent necessary to provide for the safety of life and

property on navigable waters of the United States during the event. The Coast Guard also understands the concerns about large shipping vessels not having notice or being able to make a delivery. As such, the NPRM was published in the **Federal Register** 85 days prior to the enforcement date of this temporary final rule, this rule will be published in the **Federal Register** at least 30 days before it is enforced, and the Coast Guard will provide notice of the Savannah Tall Ships Challenge via Local Notice to Mariners, Broadcast Notice to Mariners, and a Maritime Safety and Security Bulletin. Finally, persons and vessels may request authorization from the Captain of the Port Savannah to enter, transit through, anchor in, or remain within the regulated areas by contacting the Captain of the Port Savannah by telephone at (912) 652–4353, or a designated representative via VHF radio on channel 16.

The second comment requested a change to the location of the Tall Ships Challenge race start. The comment stated that the race start in the NPRM is in the middle of a pilot boarding area, and because these tall ships are under sail power they require space away from commercial vessel traffic to maneuver safely. Therefore, it was recommended that the race start be moved. The Coast Guard understands this comment about the starting area to be referring to the staging area that is set forth in the NPRM. The Coast Guard concurs with the recommendation to move the staging area. As a result, the Coast Guard has moved the staging area to encompass all waters within one nautical mile radius of position 31°59’30” N 80°42’55” W. This new area is approximately two miles north of the original area. If you are aware of problems caused by this new area, please contact the person indicated in the **FOR FURTHER INFORMATION CONTACT** section, above.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

Regulatory Planning and Review

Executive Orders 13563, Improving Regulation and Regulatory Review, and 12866, Regulatory Planning and Review, direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this rule under Executive Order 12866.

The economic impact of this rule is not significant for the following reasons: (1) The special local regulations will be enforced for a total of 102 hours; (2) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the regulated areas without authorization from the Captain of the Port Savannah or a designated representative, they may operate in the surrounding area during the enforcement periods; (3) persons and vessels will still be able to enter, transit through, anchor in, or remain within the regulated areas if authorized by the Captain of the Port Savannah or a designated representative; and (4) the Coast Guard will provide advance notification of the special local regulations to the local maritime community by Local Notice to Mariners, Broadcast Notice to Mariners, and a Maritime Safety and Security Bulletin.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of the Savannah River encompassed within the special local regulations from 10:30 a.m. on May 3, 2012 through 4:30 p.m. on May 7, 2012. For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In the NPRM, and in accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce or determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(h), of the Instruction. This rule involves establishing special local regulations issued in conjunction with a regatta or marine parade. Under figure 2-1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a temporary § 100.35T07-0039 to read as follows:

§ 100.35T07-0039 Special Local Regulations; Savannah Tall Ships Challenge, Savannah River, Savannah, GA.

(a) *Regulated Areas.* The following regulated areas are established as special local regulations during the Savannah Tall Ships Challenge, with the specific enforcement period for each of the regulated areas. All coordinates are North American Datum 1983.

(1) *Mooring Zones.* All waters of the Savannah River within 25 yards of vessels participating in the Savannah Tall Ships Challenge while such vessels are moored. These regulated areas will be enforced from 10:30 a.m. on May 3, 2012 until 3 p.m. on May 7, 2012.

(2) *Buffer Zones.* All waters of the Savannah River within 200 yards of vessels participating in the Savannah Tall Ships Challenge as they transit from their mooring locations to the

staging area. These regulated areas will be enforced from 11:30 a.m. until 3 p.m. on May 7, 2012.

(3) *Staging Area.* All waters within a one nautical mile radius of position 31°59'30" N 80°42'55" W. This regulated area will be enforced from 11:30 a.m. until 4:30 p.m. on May 7, 2012.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Savannah in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated areas unless authorized by the Captain of the Port Savannah or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated areas may contact the Captain of the Port Savannah by telephone at (912) 652-4353, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated areas is granted by the Captain of the Port Savannah or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Savannah or a designated representative.

(3) The Coast Guard will provide notice of the regulated areas, including the names and mooring locations of the vessels participating in the Savannah Tall Ships Challenge and the identities of the lead safety vessel and the last safety vessel as the vessels transit to the staging area, prior to the event by Local Notice to Mariners, Broadcast notice to Mariners, and a Maritime Safety and Security Bulletin. Notice will also be provided by on-scene designated representatives.

(d) *Enforcement Date.* This rule will be enforced from 10:30 a.m. on May 3, 2012 through 4:30 p.m. on May 7, 2012.

Dated: March 21, 2012.

J.B. Loring,

Commander, U.S. Coast Guard, Captain of the Port Savannah.

[FR Doc. 2012-7793 Filed 3-30-12; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[Docket No. USCG-2011-0187]

RIN 1625-AB76

MARPOL Annex V Special Areas: Wider Caribbean Region

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: By this final rule, the Coast Guard amends the list of special areas in effect under Annex V of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978, as amended, to include the Wider Caribbean Region special area. The current list of special areas in effect is outdated because it does not include this special area, which went into effect May 1, 2011. This rule will correct the list of special areas in effect to provide accurate information to the public.

DATES: This final rule is effective April 2, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2011-0187 and are available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2011-0187 in the “Keyword” box, and then clicking “Search.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email David Condino, U.S. Coast Guard Office of Port and Facility Activities; telephone 202-372-1145, email David.A.Condino@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

- I. Abbreviations
- II. Regulatory History
- III. Basis and Purpose
- IV. Background
- V. Discussion of Comments and Changes
- VI. Regulatory Analyses
 - A. Regulatory Planning and Review