

Administration, Piccard Dr., Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-5302, appearing on page 11310 in the **Federal Register** of Wednesday, March 10, 2004, the following correction is made:

§ 807.22 [Corrected]

On page 11311, in the third column, in part 807, amendatory instruction no. 6 is corrected to read as follows:

■ “6. Section 807.22 is amended by revising paragraphs (a) and (b) to read as follows:

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on Form FDA-2801 (Initial Registration of Device Establishment). Forms are available upon request from the Office of Compliance, Center for Devices and Radiological Health (HFZ-308), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-4015, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDA-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FDA-2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FDA-2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FDA-2892, tapes for computer input or hard copy computer output may be submitted if equivalent in all elements of information as specified in form FDA-2892. All formats proposed for use in lieu of form FDA-2892 require initial review and approval by the Food and Drug Administration.”

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-8022 Filed 4-7-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07-04-035]

Drawbridge Operation Regulations; Jensen Beach (SR 707) Bridge, Atlantic Intracoastal Waterway Mile 981.4, Stuart, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Jensen Beach (SR 707a) (Frank A. Wacha) Bridge across the Atlantic Intracoastal Waterway, mile 981.4, Stuart, Florida. This deviation allows the bridge to operate only a single-leaf opening with a double-leaf opening available with a three-hour notice to the bridge tender during certain times of the day.

DATES: This deviation is effective from 8 a.m. on March 31 until 5 p.m. on April 30, 2004.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket [CGD07-04-035] will become part of this docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, Florida 33131-3050 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch at (305) 415-6744.

SUPPLEMENTARY INFORMATION: The Jensen Beach (SR 707a) (Frank A. Wacha) Bridge across the Atlantic Intracoastal Waterway, mile 981.4, Stuart, Florida, is a double-leaf bascule bridge with a vertical clearance of 24 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 90 feet. The current operating regulation in 33 CFR 117.261(o) requires that the draw shall open on signal; except that from December 1 through May 1, from

7 a.m. to 6 p.m., Monday through Friday, except Federal holidays, the draw need open only on the hour and half-hour.

On February 4, 2004, the bridge owner, Florida Department of Transportation, requested a deviation from the current operating regulations to allow the owner and operator to only open a single-leaf of this bridge from 7 a.m. to 6 p.m. daily, Monday through Friday, March 23 through April 30, 2004, with a double-leaf opening available with a three hour notice to the bridge tender. This deviation is necessary to protect workers' safety during the construction of the new fender system. The Commander, Seventh Coast Guard District, has granted a temporary deviation from the operating requirements listed in 33 CFR 117.261(o) to complete repairs to the bridge fender system. Under this deviation, the Jensen Beach (SR 707) Bridge, Atlantic Intracoastal Waterway mile 981.4, Stuart, Florida, shall only open a single-leaf of this bridge from 7 a.m. to 6 p.m. daily, Monday through Friday, March 31 through April 30, 2004, with a double-leaf opening available with a three hour notice to the bridge tender.

Dated: March 29, 2004.

Greg Shapley,

Chief, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 04-7957 Filed 4-7-04; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 04-006]

RIN 1625-AA00

Security Zone; Suisun Bay, Concord, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary security zones in the navigable waters of the United States adjacent to two piers at the Military Ocean Terminal Concord (MOTCO), California (formerly United States Naval Weapons Center Concord, California). In light of recent terrorist actions against the United States, these security zones are necessary to ensure the safe onloading and offloading of military equipment and to ensure the safety of the public from potential

subversive acts. The security zones will prohibit all persons and vessels from entering, transiting through or anchoring within portions of the Suisun Bay within 600 yards of Pier Two or Pier Three at the MOTCO facility unless authorized by the Captain of the Port (COTP) or his designated representative.

DATES: This rule is effective from 7 a.m. PDT on April 8, 2004, to 11:59 p.m. PDT on May 6, 2004. If the need for these security zones ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zones and will announce that fact via Broadcast Notice to Mariners.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket [COTP San Francisco Bay 04-006] and are available for inspection or copying at Coast Guard Marine Safety Office San Francisco Bay, Coast Guard Island, Alameda, California 94501, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Doug Ebbers, U.S. Coast Guard Marine Safety Office San Francisco Bay, at (510) 437-3073.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM because the duration of the NPRM rulemaking process would extend beyond the actual period of the scheduled operations and defeat the protections afforded by the temporary rule to the cargo vessels, their crews, the public and national security.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** as the schedule and other logistical details were not known until a date fewer than 30 days prior to the start date of the military operation. Delaying this rule's effective date would be contrary to the public interest since the safety and security of the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas would be jeopardized without the protection afforded by this security zone.

Background and Purpose

Since the September 11, 2001 terrorist attacks on the World Trade Center in New York, the Pentagon in Arlington, Virginia and Flight 93, the Federal Bureau of Investigation (FBI) has issued several warnings concerning the

potential for additional terrorist attacks within the United States. In addition, the ongoing hostilities in Afghanistan and the conflict in Iraq have made it prudent for U.S. ports to be on a higher state of alert because Al-Qaeda and other organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

The threat of maritime attacks is real as evidenced by the attack on the USS Cole and the subsequent attack in October 2002 against a tank vessel off the coast of Yemen. These threats manifest a continuing threat to U.S. assets as described in the President's finding in Executive Order 13273 of August 21, 2002 (67 FR 56215, September 3, 2002) that the security of the U.S. is endangered by the September 11, 2001 attacks and that such aggression continues to endanger the international relations of the United States. See also Continuation of the National Emergency with Respect to Certain Terrorist Attacks (67 FR 58317, September 13, 2002), and Continuation of the National Emergency with Respect to Persons Who Commit, Threaten To Commit, Or Support Terrorism (67 FR 59447, September 20, 2002). The U.S. Maritime Administration (MARAD) in Advisory 02-07 advised U.S. shipping interests to maintain a heightened status of alert against possible terrorist attacks. MARAD more recently issued Advisory 03-05 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States. The ongoing foreign hostilities have made it prudent for U.S. ports and waterways to be on a higher state of alert because the Al-Qaeda organization and other similar organizations have declared and ongoing intention to conduct armed attacks on U.S. interests worldwide.

In its effort to thwart terrorist activity, the Coast Guard has increased safety and security measures on U.S. ports and waterways. As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99-399), Congress amended section 7 of the Ports and Waterways Safety Act (PWSA), 33 U.S.C. 1226, to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. The Coast Guard also has authority to establish security zones pursuant to the Act of June 15, 1917, as amended by the Magnuson Act of August 9, 1950 (50 U.S.C. 191 *et seq.*) and implementing regulations promulgated by the President in

subparts 6.01 and 6.04 of part 6 of title 33 of the Code of Federal Regulations.

In this particular rulemaking, to address the aforementioned security concerns, United States Army officials have requested that the Captain of the Port, San Francisco Bay, California, establish temporary security zones in the navigable waters of the United States within 600 yards of Pier Two and Pier Three at the Military Ocean Terminal Concord (MOTCO), California, to safeguard vessels, cargo and crew engaged in military operations. These temporary security zones are necessary to safeguard the MOTCO terminal and the surrounding property from sabotage or other subversive acts, accidents or criminal acts. These zones are also necessary to protect military operations from compromise and interference and to specifically protect the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas.

Discussion of Rule

In this temporary rule, the Coast Guard is establishing fixed security zones encompassing the navigable waters, extending from the surface to the sea floor, within 600 yards of any portion of both Pier Two and Pier Three at Military Ocean Terminal Concord (MOTCO), California. There are 3 existing piers at the MOTCO facility. Originally there were 4 piers, numbered One through Four from west to east, but Pier One was destroyed in an explosion in 1944. Therefore, Pier Two and Pier Three are now the 2 easternmost piers. Because of the close proximity of these 2 piers, there is a portion of these two security zones that overlap. The area encompassed by these two security zones includes portions of the Port Chicago Reach and the Roe Island Channel sections of the deepwater channel. Persons and vessels are prohibited from entering, transiting through or anchoring within these security zones unless authorized by the Captain of the Port (COTP) or his designated representative.

Vessels or persons violating this section will be subject to the penalties set forth in 33 U.S.C. 1232 and 50 U.S.C. 192. Pursuant to 33 U.S.C. 1232, any violation of the security zones described herein, is punishable by civil penalties (not to exceed \$32,500 per violation, where each day of a continuing violation is a separate violation), criminal penalties (imprisonment up to 6 years and a maximum fine of \$250,000), and in rem liability against the offending vessel. Any person who violates this section using a dangerous weapon, or who engages in conduct that causes bodily injury or fear of imminent

bodily injury to any officer authorized to enforce this regulation, will also face imprisonment up to 12 years. Vessels or persons violating this section are also subject to the penalties set forth in 50 U.S.C. 192: Seizure and forfeiture of the vessel to the United States, a maximum criminal fine of \$10,000, and imprisonment up to 10 years, and a civil penalty of not more than \$25,000 for each day of a continuing violation. The Captain of the Port will enforce these zones and may enlist the aid and cooperation of any Federal, State, county, municipal, and private agency to assist in the enforcement of the regulation. This regulation is proposed under the authority of 33 U.S.C. 1226 in addition to the authority contained in 50 U.S.C. 191 and 33 U.S.C. 1231.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

Although this regulation restricts access to portions of navigable waters, the effect of this regulation will not be significant because mariners will be advised about the zones via public notice to mariners, and the zones will encompass only a small portion of the waterway for a short duration. In addition, vessels and persons may be allowed to enter these zones on a case-by-case basis with permission of the Captain of the Port or his designated representative.

The size of the zones is the minimum necessary to provide adequate protection for MOTCO, vessels engaged in operations at MOTCO, their crews, other vessels operating in the vicinity, and the public. The entities most likely to be affected are commercial vessels transiting to or from Suisun Bay via the Port Chicago Reach section of the channel.

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 will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to anchor or transit to or from Suisun Bay via the Port Chicago Reach section of the channel. Although the security zones will occupy a section of the navigable channel (Port Chicago Reach) adjacent to the Marine Ocean Terminal Concord (MOTCO), vessels may receive authorization to transit through the zones by the Captain of the Port or his designated representative on a case-by-case basis. Additionally, vessels engaged in recreational activities, sightseeing and commercial fishing will have ample space outside of the security zones to engage in those activities. Small entities and the maritime public will be advised of these security zones via public notice to mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise 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).

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,

if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it 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.

Environment

We have analyzed this rule under Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because we are establishing a security zone.

A final “Environmental Analysis Check List” and a final “Categorical Exclusion Determination” are available in the docket where located under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–008 to read as follows:

§ 165.T11–008 Security Zones; Navigable Waters of the United States Surrounding Pier Two and Pier Three at Military Ocean Terminal Concord (MOTCO), Concord, California.

(a) *Location.* The security zones, which will be marked by lighted buoys, will encompass the navigable waters, extending from the surface to the sea floor, within 600 yards of any portion of both Pier Two and Pier Three at Military Ocean Terminal Concord (MOTCO), California.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entering, transiting through or anchoring in these zones is prohibited unless authorized by the Coast Guard Captain of the Port, San Francisco Bay, or his designated representative.

(2) Persons desiring to transit the area of these security zones may contact the Patrol Commander on scene on VHF-FM channel 13 or 16 or the Captain of the Port at telephone number 415–399–3547 to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his designated representative.

(c) *Effective period.* This section becomes effective at 7 a.m. PDT on April 8, 2004, and terminates at 11:59 p.m. PDT on May 6, 2004. If the need for these security zones ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zones and will announce that fact via Broadcast Notice to Mariners.

Dated: March 31, 2004.

Gerald M. Swanson,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco Bay, California.

[FR Doc. 04–7996 Filed 4–7–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 167

[USCG–2001–11201]

Port Access Routes Study; Along the Sea Coast and in the Approaches to the Cape Fear River and Beaufort Inlet, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of study results.

SUMMARY: The Coast Guard announces the completion of a Port Access Route Study that evaluated the need for modifications to current vessel routing and traffic management measures along the sea coast and in the approaches to the Cape Fear River and Beaufort Inlet, North Carolina. The study was completed in February 2004. This notice summarizes the study recommendations, which include the creation of a traffic separation scheme and an offshore anchorage area in the approach to the Cape Fear River and an offshore anchorage area in the vicinity of Beaufort Inlet, North Carolina.

ADDRESSES: Comments and material received from the public, as well as the

actual study and other documents mentioned in this notice, are part of docket USCG–2001–11201 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC, 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: For further information on this notice, contact John Walters, Aids to Navigation and Waterways Management Branch, Fifth Coast Guard District, telephone 757–398–6230, e-mail jwalters@lantd5.uscg.mil; or George Detweiler, Office of Vessel Traffic Management, Coast Guard, telephone 202–267–0416, e-mail Gdetweiler@comdt.uscg.mil. For questions on viewing the docket, contact Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202–366–0271.

SUPPLEMENTARY INFORMATION: You may obtain a copy of the Port Access Route Study by contacting either person listed under the **FOR FURTHER INFORMATION CONTACT** section. A copy is also available in the public docket at the address listed under the **ADDRESSES** section and electronically on the DMS Web Site at <http://dms.dot.gov>.

Definitions

The following definitions are from the International Maritime Organization’s (IMO’s) “Ships’ Routeing Guide” (except those marked by an asterisk) and should help you review this notice:

*Offshore anchorage area** means an anchorage area located in the 3-to-12-nautical-mile belt of the territorial sea in which vessels directed by the Captain of the Port (COTP) to await further orders before entering a U.S. port may stand-by or anchor.

Precautionary area means a routing measure comprising an area within defined limits where vessels must navigate with particular caution and within which the direction of traffic flow may be recommended.

Separation Zone or separation line means a zone or line separating the traffic lanes in which vessels are proceeding in opposite or nearly opposite directions; or from the adjacent sea area; or separating traffic lanes designated for particular classes of vessels proceeding in the same direction.

Traffic lane means an area within defined width in which one-way traffic is established. Natural obstacles,