

whether FDA planned to exempt the device from premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)).

Correction

In the **Federal Register** of July 28, 2017, in FR Doc. 2017-15901, the following correction is made:

On page 35066, at the bottom of the page below table 1, beginning in the first column, the third paragraph is corrected as follows:

“Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the adjunctive cardiovascular status indicator they intend to market.”

Dated: October 2, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-21659 Filed 10-6-17; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0792]

RIN 1625-AA00

Safety Zone; Atlantic Intracoastal Waterway, Camp Lejeune, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Atlantic Intracoastal Waterway in Camp Lejeune, North Carolina in support of military training exercises. This temporary safety zone is intended to restrict vessel traffic from a portion of the Atlantic Intracoastal Waterway between Mile Hammock Bay and Onslow Beach Swing Bridge during military training operations. This action

is intended to restrict vessel traffic on the Atlantic Intracoastal Waterway to protect mariners, vessels, and training exercise participants from the hazards associated with military training operations. Entry of vessels or persons into this safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) North Carolina or a designated representative.

DATES: This rule is effective from October 10, 2017 through October 30, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2017-0792 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Petty Officer Matthew Tyson, Waterways Management Division, U.S. Coast Guard Sector North Carolina, Wilmington, NC; telephone: 910-772-2221, email: Matthew.I.Tyson@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
ICW IntraCoastal Waterway

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. The Coast Guard was notified of the final dates needed for this rule on August 17, 2017. It is impracticable and contrary to the public interest to delay this action. Waiting for a comment period to run would inhibit the Coast Guards’ ability to protect the public and participants from the dangers associated with the military exercises scheduled from October 10 through October 30, 2017.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. Immediate implementation is required to protect the public and participants from the dangers associated with the military training exercises.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP North Carolina has determined that potential hazards associated with the military exercises scheduled from October 10 through October 30, 2017, is a safety concern for mariners and participants. The military training exercises involve building temporary bridges, crossing with amphibious vehicles, and other military operations on the ICW. These military training activities will block the waterway in a manner that restricts all vessel navigation and movement within this segment of the ICW. This rule is necessary to protect persons and vessels from the potential hazards associated with the military training exercises.

IV. Discussion of the Rule

The safety zone will be enforced on the following dates and times in October 2017:

Date	Time
10th–12th	8 a.m. through 11 a.m. and 1 p.m. through 4 p.m.
13th	9 a.m. through 12 p.m. and 1 p.m. through 4 p.m.
18th	8 a.m. through 12 p.m.
24th	8 a.m. through 12 p.m. and 1 p.m. through 4 p.m.
25th–26th	9 a.m. through 1 p.m. and 2 p.m. through 5 p.m.
27th–28th	7 a.m. through 5 p.m.
29th–30th	7 a.m. through 11 a.m.

The safety zone will include all navigable waters of the ICW from Mile Hammock Bay, approximate position 34°32'46" N., 77°19'17" W., to Onslow Beach Swing Bridge approximate position 34°34'25" N., 77°16'14" W. (NAD 1983), an approximately four mile portion of the ICW. The duration of this zone is intended to protect mariners from the hazards associated with military training operations. No vessel or person will be permitted to enter the safety zone unless specifically authorized by the Captain of the Port North Carolina or a designated representative. The regulatory text appears at the end of this document.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic will not be allowed to enter or transit a portion of the ICW for up to 10 hours on 12 separate days. The Coast Guard will issue a Local Notice to Mariners and transmit a Broadcast Notice to Mariners via VHF-FM marine channel 16 regarding the safety zone. This portion of the ICW has been determined to be a low traffic area. Vessels needing to transit the area during these times can safely transit offshore using New River Inlet to the south and Browns Inlet to the north. This rule does not allow vessels to request permission to enter the safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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.

While the precise number of small entities impacted is unknown, the ICW has a low number of vessels transiting the area planned for the safety zone during the enforcement period.

Although some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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). 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.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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 have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. 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 (adjusted for inflation) 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.

F. 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 (42 U.S.C. 4321–4370f), and have determined 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 involves a safety zone lasting for up to 10 hours on 12 separate days that would prohibit entry into an approximately four mile portion of the ICW for military training exercises. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

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. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0792 to read as follows:

§ 165.T05–0792 Safety Zone, Atlantic Intracoastal Waterway; Camp Lejeune, NC.

(a) *Location.* The following area is a safety zone: All waters on the Atlantic Intracoastal Waterway, from approximate position 34°32'46" N., 77°19'17" W. to 34°34'25" N., 77°16'14" W. (NAD 1983) at Camp Lejeune, NC.

(b) *Definitions.* As used in this section, “*designated representative*” means a Coast Guard Patrol Commander, including a Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port North Carolina (COTP) for the enforcement of the safety zone. “*Captain of the Port*” means the Commander, Sector North Carolina. “*Participants*” means persons and vessels involved in support of a military exercise.

(c) *Regulations.* (1) The general regulations governing safety zones in § 165.23 apply to the area described in paragraph (a) of this section.

(2) With the exception of participants, entry into or remaining in this safety zone is prohibited unless authorized by the Captain of the Port, North Carolina or designated representative(s).

(3) All vessels within this safety zone when this section becomes effective must depart the zone immediately.

(4) The Captain of the Port, North Carolina can be reached through the Coast Guard Sector North Carolina Command Duty Officer, Wilmington, North Carolina at telephone number 910–343–3882.

(5) The Coast Guard and designated security vessels enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65 MHz) and channel 16 (156.8 MHz).

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement periods.* This section will be enforced on the following dates and times in October 2017:

Date	Time
10th–12th	8 a.m. through 11 a.m. and 1 p.m. through 4 p.m.
13th	9 a.m. through 12 p.m. and 1 p.m. through 4 p.m.

Date	Time
18th	8 a.m. through 12 p.m.
24th	8 a.m. through 12 p.m. and 1 p.m. through 4 p.m.
25th–26th	9 a.m. through 1 p.m. and 2 p.m. through 5 p.m.
27th–28th	7 a.m. through 5 p.m.
29th–30th	7 a.m. through 11 a.m.

Dated: October 3, 2017.

Bion B. Stewart,

Captain, U.S. Coast Guard, Captain of the Port North Carolina.

[FR Doc. 2017–21709 Filed 10–6–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R09–OAR–2017–0092, FRL–9968–97–Region 9]

Approval and Promulgation of Air Quality Implementation Plans; Arizona; Regional Haze State and Federal Implementation Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a source-specific revision to the Arizona state implementation plan (SIP) that provides an alternative to Best Available Retrofit Technology (BART) for the Coronado Generating Station (“Coronado”), owned and operated by the Salt River Project Agricultural Improvement and Power District (SRP). The EPA has determined that the BART alternative for Coronado would provide greater reasonable progress toward natural visibility conditions than BART, based on the criteria established in the EPA’s Regional Haze Rule. In conjunction with this approval, we are withdrawing those portions of the federal implementation plan (FIP) that address BART for Coronado. We are also codifying the removal of those portions of the Arizona SIP that have either been superseded by this approval of the SIP revision for Coronado or by previously-approved revisions to the Arizona SIP.

DATES: This rule is effective November 9, 2017.

ADDRESSES: The EPA has established Docket ID No. EPA–R09–OAR–2017–0092 for this action. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential

Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Krishna Viswanathan, EPA, Region IX, Air Division, Air Planning Office, (520) 999–7880 or viswanathan.krishna@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us,” and “our” refer to the EPA.

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I. General Information*Definitions*

For the purpose of this document, we are giving meaning to certain words or initials as follows:

- The initials *ADEQ* mean or refer to the Arizona Department of Environmental Quality.
- The words *Arizona* and *State* mean the State of Arizona.
- The word *Coronado* refers to the Coronado Generating Station.
- The initials *BART* mean or refer to Best Available Retrofit Technology.
- The initials *BOD* mean or refer to boiler operating day.
- The term *Class I area* refers to a mandatory Class I Federal area.¹
- The initials *CAA* mean or refer to the Clean Air Act.
- The words *EPA*, *we*, *us*, or *our* mean or refer to the United States Environmental Protection Agency.
- The initials *FIP* mean or refer to federal implementation plan.
- The initials *lb/MMBtu* mean or refer to pounds per million British thermal units.
- The initials *NAAQS* mean or refer to National Ambient Air Quality Standards.

¹ Although states and tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to mandatory Class I Federal areas. When we use the term “Class I area” in this action, we mean a “mandatory Class I Federal area.”