

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, and thermal safety.

(2) Appropriate verification, validation, and hazard analysis must be performed on the device software and firmware.

(3) The elements of the device that contact the patient must be assessed to be biocompatible.

(4) Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. This includes full characterization of the magnetic pulse output and resulting magnetic field map. This also includes characterization of the sound level of the device during use.

(5) Clinical testing must demonstrate that the device is safe and effective for treating headache in the indicated patient population.

(6) The physician and patient labeling must include the following:

(i) A summary of the clinical performance testing, including any adverse events and complications.

(ii) The intended use population in terms of the types of headaches appropriate for use with the device.

(iii) Information on how to report adverse events and device malfunctions.

(iv) A diagram or picture depicting the proper placement of the device on the user.

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-15876 Filed 7-7-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG-2013-0904]

Special Local Regulations and Safety Zones; Recurring Events in Northern New England

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulations.

SUMMARY: The Coast Guard will enforce the events throughout the Sector Northern New England Captain of the Port (COTP) Zone. This action is necessary to protect marine traffic and spectators from the hazards associated with powerboat races, regattas, boat parades, rowing and paddling boat

races, swim events, and fireworks displays. During the enforcement period, no person or vessel may enter the Special Local Regulation area or Safety Zone without permission of the COTP.

DATES: The marine events listed in 33 CFR 100.120 and 33 CFR 165.171 will take place from July 30, 2014 through September 26, 2014, during the times and dates specified in Tables 1 and 2 below.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Elizabeth Gunn, U.S. Coast Guard, Sector Northern New England, Waterways Management Division, via telephone at 207-347-5014 or email at Elizabeth.V.Gunn@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Special Local Regulations and Safety Zones listed in 33 CFR 100.120 and 33 CFR 165.171. These regulations will be enforced for the duration of each event, on or about the dates indicated in Tables 1 and 2. This is the second Notice of Enforcement published for events occurring in 2014. For the enforcement details of events other than the events listed here, refer to the Notice of Enforcement published in the **Federal Register** on May 20, 2014 (79 FR 28834) under the same docket number.

TABLE 1
[33 CFR 100.120]

July	
Tall Ships Visiting Portsmouth	<ul style="list-style-type: none"> • Event Type: Regatta and Boat Parade. • Sponsor: Portsmouth Maritime Commission, Inc. • Date: July 30, 2014. • Time: 9:00 am to 8:00 pm. • Location: The regulated area includes all waters of Portsmouth Harbor, New Hampshire in the vicinity of Castle Island within the following points (NAD 83): <ul style="list-style-type: none"> 43°03'11" N, 070°42'26" W. 43°03'18" N, 070°41'51" W. 43°04'42" N, 070°42'11" W. 43°04'28" N, 070°44'12" W. 43°05'36" N, 070°45'56" W. 43°05'29" N, 070°46'09" W. 43°04'19" N, 070°44'16" W. 43°04'22" N, 070°42'33" W.
August	
Southport Rowgatta Rowing and Paddling Boat Race	<ul style="list-style-type: none"> • Event Type: Rowing and Paddling Boat Race. • Sponsor: Boothbay Region YMCA. • Date: August 9, 2014. • Time: 7:00 am to 4:00 pm. • Location: The regulated area includes all waters of Sheepscot Bay and Boothbay, on the shore side of Southport Island, Maine within the following points (NAD 83): <ul style="list-style-type: none"> 43°50'26" N, 069°39'10" W. 43°49'10" N, 069°38'35" W. 43°46'53" N, 069°39'06" W. 43°46'50" N, 069°39'32" W. 43°49'07" N, 069°41'43" W.

TABLE 1—Continued
[33 CFR 100.120]

	43°50'19" N, 069°41'14" W. 43°51'11" N, 069°40'06" W.
Winter Harbor Lobster Boat Races	<ul style="list-style-type: none"> • Event Type: Power Boat Race. • Sponsor: Winter Harbor Chamber of Commerce. • Date: August 9, 2014. • Time: 9:00 am to 3:00 pm. • Location: The regulated area includes all waters of Winter Harbor, Maine within the following points (NAD 83): 44°22'06" N, 068°05'13" W. 44°23'06" N, 068°05'08" W. 44°23'04" N, 068°04'37" W. 44°22'05" N, 068°04'44" W.
Lake Champlain Dragon Boat Festival	<ul style="list-style-type: none"> • Event Type: Rowing and Paddling Boat Race. • Sponsor: Dragonheart Vermont. • Date: August 3, 2014. • Time: 7:00 am to 5:00 pm. • Location: The regulated area includes all waters of Burlington Bay within the following points (NAD 83): 44°28'49" N, 073°13'22" W. 44°28'41" N, 073°13'36" W. 44°28'28" N, 073°13'31" W. 44°28'38" N, 073°13'18" W.
Merritt Brackett Lobster Boat Races	<ul style="list-style-type: none"> • Event Type: Power Boat Race. • Sponsor: Town of Bristol, Maine. • Date: August 10, 2014. • Time: 9:30 am to 3:00 pm. • Location: The regulated area includes all waters of Pemaquid Harbor, Maine within the following points (NAD 83): 43°52'16" N, 069°32'10" W. 43°52'41" N, 069°31'43" W. 43°52'35" N, 069°31'29" W. 43°52'09" N, 069°31'56" W.
Multiple Sclerosis Harbor Fest Regatta And Lobster Boat/Tugboat Races.	<ul style="list-style-type: none"> • Event Type: Regatta and Sailboat Race; Power Boat Race. • Sponsor: Maine Chapter, Multiple Sclerosis Society. • Date: August 16 & 17, 2014. • Time: 10:00 am to 4:00 pm. • Location: The regulated area for the start of the race includes all waters of Casco Bay, Maine in the vicinity of Peaks Island within the following points (NAD 83): 43°40'25" N, 070°14'21" W. 43°40'36" N, 070°13'56" W. 43°39'58" N, 070°13'21" W. 43°39'46" N, 070°13'51" W.

TABLE 2
[33 CFR 165.171]

August	
Westerlund's Landing Party Fireworks	<ul style="list-style-type: none"> • Event Type: Fireworks Display. • Sponsor: Portside Marina. • Date: August 2, 2014. • Time: 8:00 pm to 10:30 pm. • Location: In the vicinity of Westerlund's Landing in South Gardiner, Maine in approximate position: 44°10'19" N, 069°45'24" W. (NAD 83).
Y-Tri Triathlon	<ul style="list-style-type: none"> • Event Type: Swim Event. • Sponsor: Plattsburgh YMCA. • Date: August 2, 2014. • Time: 8:00 am to 10:00 am. • Location: The regulated area includes all waters of Treadwell Bay on Lake Champlain in the vicinity of Point Au Roche State Park, Plattsburgh, New York within the following points (NAD 83): 44°46'30" N, 073°23'26" W. 44°46'17" N, 073°23'26" W. 44°46'17" N, 073°23'46" W.

TABLE 2—Continued
[33 CFR 165.171]

	44°46'29" N, 073°23'46" W.
York Beach Fire Department Fireworks	<ul style="list-style-type: none"> • Event Type: Fireworks Display. • Sponsor: York Beach Fire Department. • Date: August 3, 2014. • Time: 8:30 pm to 11:30 pm. • Location: In the vicinity of Short Sand Cove in York, Maine in approximate position: 43°10'27" N, 070°36'25" W. (NAD 83).
Tri for Preservation	<ul style="list-style-type: none"> • Event Type: Swim Event. • Sponsor: Tri-Maine Productions. • Date: August 17, 2014. • Time: 7:30 am to 9:00 am. • Location: In the vicinity of Crescent Beach State Park in Cape Elizabeth, Maine in approximate position: 43°33'46" N, 070°13'48" W. 43°33'41" N, 070°13'46" W. 43°33'44" N, 070°13'40" W. 43°33'47" N, 070°13'46" W.
North Hero Air Show	<ul style="list-style-type: none"> • Event Type: Air Show. • Sponsor: North Hero Fire Department. • Date: August 10, 2014. • Time: 10:00 am to 5:00 pm. • Location: In the vicinity of Shore Acres Dock, North Hero, Vermont in approximate position: 44°48'24" N, 073°17'02" W. 44°48'22" N, 073°16'46" W. 44°47'53" N, 073°16'54" W. 44°47'54" N, 073°17'09" W.
September	
Eastport Pirate Festival Fireworks	<ul style="list-style-type: none"> • Event Type: Fireworks Display. • Sponsor: Eastport Pirate Festival. • Date: September 6, 2014. • Time: 7:00 pm to 10:00 pm. • Location: From the Waterfront Public Pier in Eastport, Maine in approximate position: 44°54'17" N, 066°58'58" W. (NAD 83).
The Lobsterman Triathlon	<ul style="list-style-type: none"> • Event Type: Swim Event. • Sponsor: Tri-Maine Productions. • Date: September 6, 2014. • Time: 8:00 am to 11:00 am. • Location: The regulated area includes all waters in the vicinity of Winslow Park in South Freeport, Maine within the following points (NAD 83): 43°47'59" N, 070°06'56" W. 43°47'44" N, 070°06'56" W. 43°47'44" N, 070°07'27" W. 43°47'57" N, 070°07'27" W.
Eliot Festival Day Fireworks	<ul style="list-style-type: none"> • Event Type: Fireworks Display. • Sponsor: Eliot Festival Day Committee. • Date: September 26, 2014. • Time: 8:00 pm to 10:30 pm. • Location: In the vicinity of Eliot Town Boat Launch, Eliot, Maine in approximate position: 43°08'56" N, 070°49'52" W. (NAD 83).

For events where the date is different from the dates previously published for that event, new Temporary Rules may be issued to enforce limited access areas for the marine event. The Coast Guard may patrol each event area under the direction of a designated Coast Guard Patrol Commander (PATCOM). The

PATCOM may be contacted on Channel 16 VHF-FM (156.8 MHz) by the call sign "PATCOM." Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP, Sector Northern New England. For information about

regulations and restrictions for waterway use during the effective periods of these events, please refer to 33 CFR 100.120 and 33 CFR 165.171.

This notice is issued under authority of 33 CFR 100.120, 33 CFR 165.171, and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast

Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: June 24, 2014.

B.S. Gilda,

Captain, U.S. Coast Guard, Captain of the Port Sector Northern New England.

[FR Doc. 2014-15932 Filed 7-7-14; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2014-0522]

RIN 1625-AA00

Safety Zone, Metedeconk River; Brick Township, NJ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the enforcement date of a safety zone for one recurring fireworks display in the Fifth Coast Guard District. This regulation applies to only one recurring fireworks event held in the waters of Metedeconk River in Brick Township, NJ. Instead of the usual enforcement periods—July 4, every Thursday in August, and the first Thursday in September—in 2014 enforcement will take place on July 3, July 17, and August 14. The safety zone is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of Metedeconk River near Brick Township, NJ, during the event.

DATES: This rule is effective from July 8, 2014 through August 14, 2014 and will be enforced from 8:30 p.m. to 10:00 p.m. on July 3, July 17, and August 14, 2014.

ADDRESSES: Submit comments using one of the listed methods, and see

SUPPLEMENTARY INFORMATION for more information on public comments.

- *Online*—<http://www.regulations.gov> following Web site instructions.

- *Fax*—202-493-2251.

- *Mail or hand deliver*—Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140,

1200 New Jersey Avenue SE., Washington, DC 20590-0001. Hours for hand delivery are 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays (telephone 202-366-9329).

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Brennan Dougherty, U.S. Coast Guard, Sector Delaware Bay, Chief Waterways Management Division, Coast Guard; telephone (215) 271-4851, email Brennan.P.Dougherty@uscg.mil. If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security

FR Federal Register

NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The governing regulation for this fireworks display event is 33 CFR 165.506. The specifics for this event are listed in the Table to § 165.506, section (a), item 9.

We are issuing this final rule without prior notice and opportunity to comment, and to take effect less than 30 days after publication in the **Federal Register**, pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b) and (d)(3), which authorize an agency to issue a rule without following usual APA procedures when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” We find that good cause exists for not following usual procedures because to do so would delay issuance of this rule beyond some of the dates for which it is intended, thereby exposing mariners and the public to dangers associated with fireworks displays, contrary to the public interest in safety.

B. Basis and Purpose

The legal basis of this rule is found in 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Public Law 107-295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1. The purpose of this rule is to promote public and maritime safety during a fireworks display.

C. Discussion of the Final Rule

We are temporarily changing the enforcement periods for Brick Township safety zone, to reflect that in 2014 fireworks will be held on July 3, July 17, and August 14. This change is needed

to accommodate the sponsor’s event plan. No other portion of the Table to § 165.506 or other provisions in § 165.506 is affected by this regulation.

The regulated area of this safety zone includes all the waters of the Metedeconk River within a 500 yard radius of the fireworks launch platform in approximate position latitude 40°03’24” N, longitude 074°06’42” W, near the shoreline at Brick Township, NJ.

During the period of the safety zone, all persons and vessels will be prohibited from entering, transiting, mooring, or remaining within the zone, unless specifically authorized by the Captain of the Port Delaware Bay, or her designated representative. Those persons authorized to transit through the safety zone shall abide by and follow all directions provided by the Captain of the Port Delaware Bay, or her designated representative, in order to ensure they are not disrupting the fireworks display. U.S. Coast Guard Sector Delaware Bay will notify the public by broadcast notice to mariners at least one hour prior to the times of enforcement.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. Although this regulation will restrict access to the regulated area, the effect of this rule will not be significant because: (i) The Coast Guard will make extensive notification of the Safety Zone to the maritime public via maritime advisories so mariners can alter their plans accordingly; (ii) vessels may still be permitted to transit through the safety zone with the permission of the Captain of the Port on a case-by-case basis; and (iii) this rule will be enforced for only the duration of the fireworks display.