

purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification*. Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

Dated: July 21, 1998.

Elizabeth D. Jacobson,

Deputy Director for Science, Center for Devices and Radiological Health.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-98-063]

RIN 2115-AE 46

Special Local Regulations for Marine Events; Prospect Bay, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the "Thunder on the Narrows" hydroplane races to be held on the waters of Prospect Bay near Kent Narrows, Maryland. These regulations are needed to protect boaters, spectators and participants from the dangers associated with the event. This action is intended to enhance the safety of life and property during the event.

DATES: This temporary final rule is effective from 12 p.m. EDT (Eastern Daylight Time) to 6 p.m. EDT on August 1 and August 2, 1998.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore Maryland, 21226-1791, telephone number (410) 576-2674.

SUPPLEMENTARY INFORMATION:

Regulatory History

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good

cause exists for making it effective less than 30 days after **Federal Register** publication. The application for this event was not received until June 24, 1998. Following normal rulemaking procedures would have been impractical since there is not sufficient time remaining to publish a proposed rule in advance of the event or to provide for a delayed effective date. Immediate action is needed to protect vessel traffic from the potential hazards associated with congested waterways.

Background and Purpose

The Kent Narrows Racing Association has submitted a marine event application to the U.S. Coast Guard for the "Thunder on the Narrows" hydroplane races, to be held on the waters of Prospect Bay on August 1 and 2, 1998. The event will consist of 75 hydroplanes racing in heats counter-clockwise around an oval race course. A large fleet of spectator vessels is anticipated. Due to the need for vessel control during the races, vessel traffic will be temporarily restricted to provide for the safety of spectators, participants and transiting vessels.

Discussion of Regulations

The Coast Guard will establish temporary special local regulations on specified waters of Prospect Bay. The temporary special local regulations will be in effect from 12 p.m. EDT (Eastern Daylight Time) to 6 p.m. EDT on August 1 and 2, 1998, and will restrict general navigation in the regulated area during the event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area. These regulations are needed to control vessel traffic during the marine event to enhance the safety of participants, spectators, and transiting vessels.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This conclusion is based on the fact that the regulated areas will only be in effect for a limited

amount of time, and extensive advisories have been and will be made to the affected Maritime Community so that they may adjust their schedules accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). Because it expects the impact of this rule to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this temporary final rule will not have a significant economic impact on a substantial number of small entities because of the event's short duration.

Collection of Information

These regulations contain no Collection of Information requirements under the Paperwork Reduction Act (44 U.S.C. 3501-3520).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under figure 2-1, paragraph (34)(h) of COMDTINST M16475.1C, this rule is categorically excluded from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine parade are excluded under that authority.

List of Subjects in 33 CFR Part 100

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

Temporary Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations is amended as follows:

PART 100—[AMENDED]

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

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary section, § 100.35–T05–063 is added to read as follows:

§ 100.35–T05–063 Prospect Bay, Maryland.

(a) *Definitions.*

(1) *Regulated area.* The waters of Prospect Bay, between Kent Island and Hog Island enclosed by:

Latitude	Longitude
38°57'52.0" North	76°14'48.0" West, to
38°58'02.0" North	76°15'05.0" West, to
38°57'38.0" North	76°15'29.0" West, to
38°57'28.0" North	76°15'23.0" West, to
38°57'52.0" North	76°14'48.0" West

[Datum: NAD 1983]

(2) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Activities Baltimore.

(b) *Special local regulations.* (1) All persons and/or vessels not authorized as participants or official patrol vessels are considered spectators. The "official patrol" consists of any Coast Guard, public, state, county or local law enforcement vessels assigned and/or approved by Commander, Coast Guard Activities Baltimore.

(2) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(3) The operator of any vessel in this area shall:

(i) Stop the vessel immediately when directed to do so by any official patrol, including any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign.

(ii) Proceed as directed by any official patrol, including any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign.

(c) *Effective dates.* This section is effective from 12 p.m. EDT (Eastern Daylight Time) to 6 p.m. EDT on August 1 and 2, 1998.

Dated: July 14, 1998.

Roger T. Rufe, Jr.,

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–94–028]

RIN 2115–AE47

Drawbridge Operating Regulation; Kelso Bayou, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulation governing the operation of the State Route 27 swing span drawbridge across Kelso Bayou, mile 0.7, at Hackberry, Cameron Parish, Louisiana. The change requires four hours advance notification at night from May 20 through December 22. The change will increase the advance notification from four hours to 24 hours from December 23 through May 19. This action provides relief to the bridge owner and still provides for the reasonable needs of navigation.

DATES: This rule is effective August 31, 1998.

ADDRESSES: Unless otherwise indicated, documents referred to in this notice are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 501 Magazine Street, New Orleans, Louisiana 70130–3396 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. Commander (ob) maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION:

Regulatory History

On October 4, 1994, the Coast Guard published a notice of proposed rulemaking (NPRM) in the **Federal Register** (59 FR 50528). The NPRM proposed a change to the advance notification required prior to opening the bridge.

The Coast Guard received four letters in response to the NPRM. One of the letters was from a business owner whose business was dependent upon access by waterway users to deliver their product to his facility. He stated that the change would force a closure of his business. The applicant and the bridge owner began discussions to attempt to resolve their differences, but were unable to reach any agreement.

Since that time, the business owner has sold his business. Subsequently, the business closed completely. The Louisiana Department of Transportation and Development (LDOTD) resubmitted a proposal requesting a new operating schedule.

On April 15, 1998, the Coast Guard published a Supplemental Notice of Proposed Rulemaking entitled Drawbridge Operation Regulation; Kelso Bayou, LA in the **Federal Register** (63 FR 18350). The Coast Guard received one letter commenting on the proposal. A public hearing was not requested and one was not held.

Background and Purpose

The Kelso Bayou bridge is a 406-foot long structure. Navigational clearances provided by the bridge are 9.1 feet vertical above mean high water in the closed position and unlimited in the open position. Horizontal clearance is 50 feet. Navigation on the waterway consists mainly of small and large fishing boats and occasional small oil field work boats.

LDOTD requested the new regulation because of a decline in vessel traffic that passes the Kelso Bayou bridge at Hackberry during certain times of the year. The rule allows the bridge owner relief from having a person available at the bridge site during the periods when vessel traffic is less frequent. This rule creates a saving to the taxpayer while still serving the reasonable needs of navigational interests.

The regulation requires that from May 20, through October 31, the draw opens on signal from 7 a.m. until 7 p.m. From 7 p.m. until 7 a.m., the draw opens on signal if at least four hours notice is given. From November 1, through December 22, the draw opens on signal from 7 a.m. to 3 p.m. From 3 p.m. to 7 a.m., the draw opens on signal if at least four hours notice is given. From December 23, through May 19, the draw opens on signal if at least 24 hours notice is given. Alternate routes are available.

Data provided by LDOTD show that from January 1, through December 31, 1997, the number of vessels that passed the bridge totaled 803. Between January 1, and May 20, the bridge opened a total of 13 times for the passage of vessels. Due to the limited number of openings, LDOTD requested an increase in notification from four hours to 24 hours between December 23, and May 19. Between May 20, and October 31, the bridge open 682 times for the passage of vessels. Between November 1, and December 31, the bridge opened 108 times for the passage of vessels. Of the 803 openings, 579 occurred between the