

**PART 864—HEMATOLOGY AND PATHOLOGY DEVICES**

■ 1. The authority citation for 21 CFR part 864 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. In subpart J, add § 864.9165 to read as follows:

**§ 864.9165 Blood establishment computer software and accessories.**

(a) *Identification.* Blood establishment computer software (BECS) and BECS accessories are devices used in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions. A BECS accessory is intended for use with BECS to augment its performance or to expand or modify its indications for use.

(b) *Classification*—Class II (special controls). The special controls for these devices are:

(1) Software performance and functional requirements including detailed design specifications (*e.g.*, algorithms or control characteristics, alarms, device limitations, and safety requirements).

(2) Verification and validation testing and hazard analysis must be performed.

(3) Labeling must include:

(i) Software limitations;

(ii) Unresolved anomalies, annotated with an explanation of the impact on safety or effectiveness;

(iii) Revision history; and

(iv) Hardware and peripheral specifications.

(4) Traceability matrix must be performed.

(5) Performance testing to ensure the safety and effectiveness of the system must be performed, including when adding new functional requirements (*e.g.*, electrical safety, electromagnetic compatibility, or wireless coexistence).

Dated: February 24, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 100**

[Docket Number USCG-2016-0134]

RIN 1625-AA08

**Special Local Regulations; Fajardo Offshore Challenge; Rada Fajardo; Fajardo, Puerto Rico**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a special local regulation on the waters of Rada Fajardo in Fajardo, Puerto Rico during the Fajardo Offshore Challenge, a high speed boat race. The event is scheduled to take place on Sunday, April 4, 2016. Approximately 30 high-speed power boats will be participating in the races. The special local regulation is necessary for the safety of the race participants, participant vessels, and the general public during the event. The special local regulation would establish the following two areas: one race area, where all persons and vessels, except those persons and vessels participating in the high-speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within; and a buffer zone around the race area, where all persons and vessels, except those persons and vessels enforcing the buffer zone, are prohibited from entering, transiting through, anchoring in, or remaining within unless authorized by the Captain of the Port San Juan or a designated representative. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before March 21, 2016.

**ADDRESSES:** You may submit comments identified by docket number USCG-2016-0134 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Mr. Efrain Lopez, Sector San Juan Prevention Department, Coast Guard; telephone (787) 289-2097, email [efrain.lopez1@uscg.mil](mailto:efrain.lopez1@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

CFR Code of Federal Regulations

DHS Department of Homeland Security

FR Federal Register

NPRM Notice of proposed rulemaking

U.S.C. United States Code

**II. Background, Purpose, and Legal Basis**

On April 4, 2016, Puerto Rico Offshore Series, Inc. is sponsoring the Fajardo Offshore Challenge, a series of high-speed boat races. The races will be held on the waters of Rada Fajardo in Fajardo, Puerto Rico. Approximately 30 high-speed power boats and PWCs will be participating in the races.

The purpose of this proposed rulemaking is to ensure the safety of vessels and the navigable waters within the regulated areas before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

**III. Discussion of Proposed Rule**

The special local regulation encompass certain waters of Rada Fajardo in Fajardo, Puerto Rico. The proposed special local regulation would be enforced from 10 a.m. until 4 p.m. on April 4, 2016. The special local regulation consist of the following two areas: (1) A race area, where all persons and vessels, except those persons and vessels participating in the high-speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within; and (2) a buffer zone around the race area, where all persons and vessels, except those persons and vessels enforcing the buffer zone, are prohibited from entering, transiting through, anchoring in, or remaining within unless authorized by the Captain of the Port San Juan or a designated representative. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the race area or buffer zone by contacting the Captain of the Port San Juan by telephone at (787) 289-2041, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the race area or buffer zone is granted by the Captain of the Port San Juan or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port San Juan or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

#### IV. Regulatory Analyses

We developed this proposed 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulation. The economic impact of this proposed rule is not significant for the following reasons: (1) The special local regulation will be enforced for only six hours; (2) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the race area and buffer zone without authorization from the Captain of the Port San Juan or a designated representative, they may operate in the surrounding area during the enforcement period; and (3) the Coast Guard will provide advance notification of the Special Local Regulation to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

##### 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 proposed rule would 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 Rada Fajardo in Fajardo encompassed within the special local regulations from 10 a.m. until 4 p.m. on April 4, 2016.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

##### C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

##### 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

##### F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination 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 proposed rule would implement a special local regulation lasting less than 6 hours that would prohibit entry from non-participants and persons or vessels not involved in the event from enter in, transiting through, anchoring in, or remaining within the race area or buffer zone. Normally such actions are categorically excluded from further review under paragraph 34(h) of Figure 2–1 of Commandant Instruction M16475.ID. A preliminary environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

##### 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.

##### V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you

submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

#### 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 proposes to amend 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 33 CFR 100.35T07–0134 to read as follows:

#### § 100.35T07–0134 Special Local Regulations; International Dinghy Regatta; San Juan Harbor, Puerto Rico.

(a) *Regulated Areas.* The following regulated areas are established as Special Local Regulations. All coordinates are North American Datum 1983.

(1) *Race Area.* All waters of Rada Fajardo, Fajardo, Puerto Rico encompassed within an imaginary line connecting the following points: starting at Point 1 in position 18°21.433' N, 65°37.242' W; thence southeast to Point 2 in position 18°21.402' N, 65°37.162'

W; thence northeast to Point 3 in position 18°22.937' N, 65°36.358' W; thence northwest to point 4 in position 18°22.980' N, 65°36.492' W; thence northwest back to origin. All persons and vessels, except those persons and vessels participating in the high-speed boat race, are prohibited from entering, transiting through, anchoring in, or remaining within the race area.

(2) *Buffer Zone.* All waters of Rada Fajardo, Fajardo, Puerto Rico encompassed within an imaginary line connecting the following points: starting at Point 1 in position 18°21.425' N, 65°37.277' W; thence southeast to Point 2 in position 18°21.366' N, 65°37.158' W; thence northeast to Point 3 in position 18°22.951' N, 65°36.314' W; thence northwest to point 4 in position 18°23.017' N, 65°36.507' W; thence southwest back to the origin. All persons and vessels except those persons and vessels enforcing the buffer zone are prohibited from entering, transiting through, anchoring in, or remaining within the buffer zone.

(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 San Juan in the enforcement of the regulated areas.

(c) *Regulations.* (1) Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated areas by contacting the Captain of the Port San Juan by telephone at (787) 289–2041, or a designated representative via VHF radio on channel 16. If authorization is granted by the Captain of the Port San Juan or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port San Juan or a designated representative.

(2) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement Date.* This rule is enforced from 10 a.m. until 4 p.m. on April 4, 2016.

Dated: February 24, 2016.

**R. W. Warren,**

*Captain, U.S. Coast Guard, Captain of the Port San Juan.*

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**BILLING CODE 9110–04–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA–R08–OAR–2016–0014; FRL–9943–01–Region 8]

#### Approval and Promulgation of Air Quality Implementation Plans; Wyoming; Revisions to Wyoming Air Quality Standards and Regulations; Chapter 6, Permitting Requirements, Section 13, Nonattainment New Source Review Permit Requirements, and Section 14, Incorporation by Reference

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Wyoming on November 6, 2015. This submittal revises the Wyoming Air Quality Standards and Regulations (WAQSR) that pertain to the issuance of Wyoming air quality permits for major sources in nonattainment areas. This action is being taken under section 110 of the Clean Air Act (CAA).

**DATES:** Written comments must be received on or before March 31, 2016.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2016–0014 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Kevin Leone, Air Program, U.S. Environmental Protection Agency