

A. Redesignating paragraphs (e)(26)(ii)(B)(2), (3) and (4) as paragraphs (e)(26)(ii)(B)(3), (4) and (5);

B. Adding a sentence to the end of the introductory text in paragraph (e)(26)(ii)(B);

C. Revising paragraph (e)(26)(ii)(B)(1)(ii);

D. Revising paragraph (e)(26)(ii)(B)(1)(iv);

E. Adding new paragraph (e)(26)(ii)(B)(1)(v); and

F. Adding a new paragraph (e)(26)(ii)(B)(2) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(26) * * *

(ii) * * *

(B) * * * Additionally, Phase I studies may be approved on a case by case basis when the requirements below are met.

(1) * * *

(i) Such treatments are NCI sponsored Phase I, Phase II or Phase III protocols; and

* * * * *

(iv) The institutional and individual providers are CHAMPUS authorized providers; and,

(v) The requirements for Phase I protocols in paragraph (e)(26)(ii)(B)(2) of this section are met:

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and,

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(ii)(B)(2)(i) through (e)(26)(ii)(B)(2)(iii) of this section.

* * * * *

Dated: May 15, 2009.

Patricia Toppings,

*OSD Federal Register Liaison Officer,
Department of Defense.*

[FR Doc. E9-14441 Filed 6-19-09; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[USCG-2009-0400]

RIN 1625-AA08

Regattas and Marine Parades; Great Lakes Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend special local regulations for annual regattas and marine parades in the Captain of the Port Sault Sainte Marie zone. This action is necessary to protect and separate the public from the hazards of these events. This proposed rule will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after regattas or marine parades.

DATES: Comments and related materials must reach the Coast Guard on or before July 22, 2009.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG-2009-0400 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* 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.

(3) *Hand delivery:* Room W12-140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* 202-493-2251.

FOR FURTHER INFORMATION CONTACT:

LCDR Christopher Friese, Prevention Dept. Chief, Sector Sault Sainte Marie, 337 Water St., Sault Sainte Marie, MI 49783; 906-635-3220.

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have

provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2009-0400), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name, mailing address, and an e-mail address or other contact information in the body of your document to ensure that you can be identified as the submitter. This also allows us to contact you in the event further information is needed or if there are questions. For example, if we cannot read your submission due to technical difficulties and you cannot be contacted; your submission may not be considered. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> at any time, click on "Search for Dockets," and enter the docket number for this rulemaking (USCG-2008-XXXX) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

C. Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the

Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://DocketsInfo.dot.gov>.

SUPPLEMENTARY INFORMATION:

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Commander, Coast Guard Sector Sault Sainte Marie at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

This proposed rule will add several regattas and marine parades not previously listed in 33 CFR Part 100. The specific events to be added are Copperhead Regatta, Houghton, MI, Spirit of the Lake Regatta, Superior, WI, Point to LaPoint Swim, LaPoint, WI, Duluth Rowing International Regatta, and Grand Marais Splash In, Grand Marais, MI.

Discussion of Proposed Rule

This proposed rule is intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after regattas or marine parades. This proposed rule will establish restrictions upon and control the movement of vessels through a specified area immediately prior to, during, and immediately after regattas or marine parades.

The Captain of the Port will cause notice of enforcement of the special local regulations established by this section to be made by all appropriate means to the affected segments of the public. Such means of notification will include, but is not limited to, Broadcast Notice to Mariners and Local Notice to Mariners. The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the special local regulations is terminated.

Regulatory Evaluation

This proposed 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.

We expect the economic impact of this proposed rule to be so minimal that

a full Regulatory Evaluation is unnecessary.

The Coast Guard's use of these special local regulations will be periodic in nature, of short duration, and designed to minimize the impact on navigable waters. These special local regulations will only be enforced immediately before and during the time the marine events are occurring. Furthermore, these special local regulations have been designed to allow vessels to transit unrestricted to portions of the waterways not affected by the special local regulations. The Coast Guard expects insignificant adverse impact to mariners from the activation of these special local regulations.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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 proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the areas designated as special local regulations in this rule during the dates and times the special local regulations are being enforced.

These special local regulations would not have a significant economic impact on a substantial number of small entities for the following reasons. The special local regulations in this proposed rule would be in effect for short periods of time, and only once per year. The special local regulations have been designed to allow traffic to pass safely around the zone whenever possible and vessels will be allowed to pass through the zones with the permission of the Captain of the Port.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed 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 proposed rule would economically affect it.

Assistance for Small Entities

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 so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact LCDR Christopher Friese, Prevention Dept. Chief, Sector Sault Sainte Marie, 337 Water St., Sault Sainte Marie, MI 49783; 906–635–3220. 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.

Collection of Information

This proposed 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, Federalism, 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 proposed 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 proposed rule will not result in such expenditure, we nevertheless discuss its effects elsewhere in this preamble.

Taking of Private Property

This proposed 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed 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

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these safety zones and fishing rights protection need not be incompatible. We have also determined that this proposed 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. Nevertheless, Indian Tribes that have questions concerning the provisions of this proposed rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

We have analyzed this proposed 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an

explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.ID and Department of Homeland Security Management Directive 023-01, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment. An environmental analysis checklist supporting this preliminary determination is 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.

List of Subjects in 33 CFR Part 100

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, 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 § 100.921 to read as follows:

§ 100.921 Copperhead Regatta, Houghton, MI.

(a) Regulated Area. A regulated area is established to encompass all waters west of the boundary line created by points 47°06'48" N, 088°30'04" W and 47°06'34" N, 088°30'48" W to the Houghton area lift Bridge (NAD 1983).

(b) Special Local Regulations. The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) Effective date: The last Saturday in September. The exact dates and times for this event will be determined annually, and published through Local Notice to Mariners and Broadcast Notice to Mariners.

3. Add § 100.922 to read as follows:

§ 100.922 Spirit of the Lake Regatta, Superior, WI.

(a) Regulated Area. A regulated area is established to encompass all waters within the Superior Front Channel bounded by a line starting at 46°42.47' N, 092°02.42' W then running northeast to position 46°42.52' N, 092°02.36' W then running northwest to position 46°44.30' N, 092°04.75' W then running southwest to position 46°44.26' N, 092°05.03' W then running southeast back to the starting point (NAD 1983).

(b) Special Local Regulations. The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) Effective Date. This event occurs the second weekend in September. The exact dates and times for this event will be determined annually, and published through Local Notice to Mariners and Broadcast Notice to Mariners.

4. Add § 100.923 to read as follows:

§ 100.923 Pointe to LaPointe Swim, LaPointe, WI.

(a) Regulated Area. A regulated area is established to include all waters of Lake Superior extending 50 yards on both sides of a line starting at position 46°48.50' N, 090°48.41' W then running southeast to position 46°47.12' N, 090°47.19' W (NAD 1983).

(b) Special Local Regulations. The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) Effective Date. This event occurs the second weekend in August. The exact dates and times for this event will be determined annually and published through Local Notice to Mariners and Broadcast Notice to Mariners.

5. Add § 100.924 to read as follows:

§ 100.924 Duluth Rowing International Regatta.

(a) Regulated Area. A regulated area is established to include all waters adjacent to Park Point in Duluth-Superior Harbor within the following boundaries beginning at latitude 46°45'19.3" N, longitude 92°04'43" W; thence to latitude 46°45'11.7" N, longitude 92°05'01" W; thence to latitude 46°44'21.2" N, longitude 92°04'15.7" W; thence to latitude

46°44'29.4" N, longitude 92°03'57.5" W; thence to the point of beginning (NAD 1983). This area is also the Special Anchorage Area for Duluth-Superior Harbor as designated in 33 CFR § 110.77a.

(b) Special Local Regulations. The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) Effective Date. This event occurs the second weekend in July. The exact dates and times for this event will be determined annually and published through Local Notice to Mariners and Broadcast Notice to Mariners.

6. Add § 100.925 to read as follows:

§ 100.925 Grand Marais Splash In, Grand Marais, MI.

(a) Regulated Area. A regulated area is established to include all waters of Lake Superior within a 1500-foot radius of position 46°40.37' N, 085°58.74' W (NAD 1983).

(b) Special Local Regulations. The regulations of § 100.901 apply. No vessel may enter, transit through, or anchor within the regulated area without the permission of the Coast Guard Patrol Commander.

(c) Effective Date. This event occurs the third week in June. The exact dates and times for this event will be determined annually and published through Local Notice to Mariners and Broadcast Notice to Mariners.

Dated: June 8, 2009.

M.J. Huebschman,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. E9-14552 Filed 6-19-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 146

[Docket Number USCG-2008-1088]

RIN 1625-AB28

Notice of Arrival on the Outer Continental Shelf

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to enhance maritime domain safety and security awareness on units and personnel engaging in activities on the Outer Continental Shelf by proposing regulations which will require notice of

arrival for units planning to engage in Outer Continental Shelf activities. The proposed rules would implement provisions of the Security and Accountability for Every Port Act of 2006 and increase overall maritime domain awareness by requiring owners or operators of United States and foreign flag floating facilities, mobile offshore drilling units, and vessels to submit notice of arrival information to the National Vessel Movement Center prior to engaging in Outer Continental Shelf activities.

DATES: Comments and related material must either be submitted to our online docket via <http://www.regulations.gov> on or before September 21, 2009 or reach the Docket Management Facility by that date.

Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before September 21, 2009.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG-2008-1088 using any one of the following methods:

(1) *Federal eRulemaking Portal*

<http://www.regulations.gov>;

(2) *Fax:* 202-493-2251.

(3) *Mail:* 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.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these methods. For instructions on submitting comments, see the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

Collection of Information Comments: If you have comments on the collection of information discussed in section V.D. of this notice of proposed rulemaking (NPRM), you must also send comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget. To ensure that your comments to OIRA are received on time, the preferred methods are by e-mail to oira_submission@omb.eop.gov (include the docket number and "Attention: Desk Officer for Coast Guard, DHS" in the subject line of the e-mail) or fax at 202-395-6566. An alternate, though slower, method is by U.S. mail to the Office of Information and Regulatory Affairs, Office of

Management and Budget, 725 17th Street, NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Mr. James M. Magill, Vessel and Facility Operating Standards Division (CG-5222), Coast Guard; telephone 202-372-1414, e-mail James.M.Magill@uscg.mil. If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2008-1088), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comments online, go to <http://www.regulations.gov>, select the