

**XIII. Proposed Effective Date**

FDA is proposing that any final rule based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final rule.

**List of Subjects in 21 CFR Part 870**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Part 870 be amended as follows:

**PART 870—CARDIOVASCULAR DEVICES**

1. The authority citation for 21 CFR Part 870 continues to read as follows:

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

2. Section 870.3610 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 870.3610 Implantable pacemaker pulse generator.**

(a) *Identification.* An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.

\* \* \* \* \*

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE **FEDERAL REGISTER**], for any implantable pacemaker pulse generator that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE **FEDERAL REGISTER**], been found to be substantially equivalent to any implantable pacemaker pulse generator that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 22, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-18957 Filed 7-26-11; 8:45 am]

**BILLING CODE 4160-01-P**

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

[Docket No. USCG-2011-0629]

RIN 1625-AA08

**Special Local Regulations for Marine Events; Temporary Change of Dates for Recurring Marine Events in the Fifth Coast Guard District, Wrightsville Channel; Wrightsville Beach, NC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to temporarily change the enforcement period of one special local regulation for a recurring marine event in the Fifth Coast Guard District. The "Wilmington YMCA Triathlon," conducted on the waters of Wrightsville Channel near Wrightsville Beach, North Carolina normally would take place on September 24, 2011; this year, the sponsor would like to have the event on September 17, 2011. This Special Local Regulation is necessary to provide for the safety of life on navigable waters during the event, which has been rescheduled from the last Saturday in September to the second-to-last Saturday in September. This action is intended to restrict vessel traffic on Wrightsville Channel during the swimming portion of this event.

**DATES:** Comments and related material must be received by the Coast Guard on or before August 26, 2011.

**ADDRESSES:** You may submit comments identified by docket number USCG-2011-0629 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 four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call or e-mail BOSN3 Joseph M. Edge, Coast Guard Sector North Carolina, Coast Guard; telephone 252-247-4525, e-mail [Joseph.M.Edge@uscg.mil](mailto:Joseph.M.Edge@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:****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.

**Submitting Comments**

If you submit a comment, please include the docket number for this rulemaking (USCG-2011-0629), 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 (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG-2011-0629" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments 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 and may change the rule based on your comments.

#### 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>, click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2011–0629” and click “Search.” Click the “Open Docket Folder” in the “Actions” column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

#### Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

#### Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting 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**.

#### Basis and Purpose

The YMCA sponsors an annual Triathlon, “Wilmington YMCA Triathlon”, in the Wrightsville Beach area of North Carolina. The Triathlon consists of three events: a running portion, a bike-riding portion, and a swimming portion. The swimming portion of the Triathlon takes place in the waters adjacent to Wrightsville

Beach. A special local regulation is effective annually to create a safety zone for the swimming portion of the Triathlon.

The regulation listing annual marine events within the Fifth Coast Guard District and their regulated dates is 33 CFR 100.501. A Table to § 100.501 identifies marine events by Captain of the Port zone. This particular marine event is listed at line No. 57.

While, according to the regulation at line No. 57, the Triathlon should take place this year on September 24, 2011, this year the event will take place instead on September 17, 2011.

The swim portion of the Triathlon, scheduled to take place on Saturday September 17, 2011, will consist of two groups of 750 swimmers entering Banks Channel at the Blockade Runner Hotel and swimming northwest along Motts Channel to Seapath Marine. A fleet of spectator vessels are expected to gather near the event site to view the competition.

To provide for the safety of the participants, spectators and other transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during this event. The regulation at 33 CFR 100.501 would be enforced from 7 a.m. to 9 a.m. on September 17, 2011; vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander.

#### Discussion of Proposed Rule

The Coast Guard is proposing to temporarily suspend the regulation listed at line No. 57 in Table to § 100.501 and will insert this new temporary regulation at Table to § 100.501 line No. 63, in order to reflect the change in the date for this event this year. This change is needed to accommodate the change in date of the annual Triathlon. No other portion of the Table to § 100.501 or other provisions in § 100.501 shall be affected by this regulation.

This safety zone will restrict vessel movement on the specified waters of Wrightsville Channel, Wrightsville Beach, NC. The regulated area will be established in the interest of participant safety during the swim portion of the “Wilmington YMCA Triathlon” and will be enforced from 7 a.m. to 9 a.m. on September 17, 2011. The Coast Guard, at its discretion, when practical will allow the passage of vessels. During the Marine Event no vessel will be allowed to transit the waterway unless the vessel is given permission from the Patrol Commander to transit.

Any vessel transiting the regulated area must do so at a no-wake speed

during the effective period. Nothing in this proposed rule negates the requirement to operate at a safe speed as provided in the Navigational Rules and Regulations.

#### Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

#### Regulatory Planning and Review

This proposed 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, 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. Although this regulation prevents traffic from transiting waters of Wrightsville Channel during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect. Extensive advance notification will be made to the maritime community via marine information broadcast and local area newspapers so mariners can adjust their plans accordingly. Additionally, this rulemaking does not change the permanent regulated areas that have been published in 33 CFR 100.501, Table to § 100.501. Vessel traffic will be able to transit the regulated area before and after the races, when the Coast Guard Patrol Commander deems it is safe to do so. Coast Guard vessels enforcing this regulated area can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz).

#### 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 rule will affect the following entities, some of which may be small entities: The owners of operators of vessels intending to transit Wrightsville Channel from 7 a.m. to 9 a.m. on September 17, 2011.

This rule will not have a significant economic impact on a substantial number of small entities for the following reasons. The regulation will be enforced for only two hours. Although the regulated area will apply to Motts, Banks and Wrightsville Channels, traffic may be allowed to pass through the regulated area with the permission of the Coast Guard Patrol Commander. In the case where the Patrol Commander authorizes passage through the regulated area, vessels shall proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the swim course. The Patrol Commander will allow non-participating vessels to transit the event area once all swimmers are safely clear of navigation channels and vessel traffic areas. Before the enforcement period, we will issue maritime advisories so mariners can adjust their plans accordingly.

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.

#### **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 rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact BOSN3 Joseph Edge, Prevention Department, Sector North Carolina, 252-247-4525. 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 would call 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 (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.

#### **Taking of Private Property**

This proposed rule would not cause 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 rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

#### **Indian Tribal Governments**

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.

#### **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 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 (NEPA) (42 U.S.C. 4321-4370f), and have made a preliminary determination, under figure 2-1, paragraph 34(h) of the Instruction, that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves implementation of regulations within 33 CFR Part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative impact on the safety or other interest of waterway users and shore side activities in the event area. This special local regulation is necessary to provide for the safety of the general public and

event participants from potential hazards associated with movement of vessels near the event area. 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

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. In § 100.501, suspend line No. 57 and add line No. 59 in the Table to read as follows:

#### § 100.501 Special Local Regulations; Recurring Marine Event in the Fifth Coast Guard District.

\* \* \* \* \*

#### COAST GUARD SECTOR NORTH CAROLINA—COTP ZONE

Number	Date	Event	Sponsor	Location
59. ....	September 17, 2011	Wilmington YMCA Triathlon	Wilmington YMCA	The waters of, and adjacent to, Wrightsville Channel from Wrightsville Channel Day beacon 14 (LLNR 28040), located at 34°12'18" N, longitude 077°48'10" W, to Wrightsville Channel Day beacon 25 (LLNR 28080), located at 34°12'51" N, longitude 77°48'53" W.

\* \* \* \* \*

Dated: July 18, 2011.

**A. Popiel,**

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

[FR Doc. 2011-19020 Filed 7-26-11; 8:45 am]

**BILLING CODE 9110-04-P**

#### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2011-0318]

**RIN 1625-AA87**

#### Security Zone; Escorted Vessels in Captain of the Port Ohio Valley Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to implement fixed and moving security zones around High Capacity Passenger Vessels (HCPVs) and vessels carrying Certain Dangerous Cargo (CDC) while they are being escorted in the navigable waters of the Captain of the Port (COTP), Sector Ohio Valley Zone. As used in this section, HCPVs are defined as any commercial vessel carrying 500 or more passengers and CDC is defined in 33 CFR 160.204. The proposed security zones would control the movement of vessels within 50 yards of a HCPV or vessel carrying a CDC. These security zones would mitigate potential terrorist acts and would enhance public and maritime safety and security.

**DATES:** Comments and related material must be received by the Coast Guard on or before August 26, 2011.

**ADDRESSES:** You may submit comments identified by docket number USCG-2011-0318 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 four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call or e-mail LCDR Derek Schade, Sector Ohio Valley Response Department, Coast Guard; telephone 502-779-5413, e-mail [derek.t.schade@uscg.mil](mailto:derek.t.schade@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

#### 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.

#### Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2011-0318), 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 (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will