PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 is revised to read as follows:

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

■ 2. Add § 890.3450 to subpart D to read as follows:

§ 890.3450 Upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components.

(a) *Identification.* A upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.

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

(1) Appropriate analysis/testing must validate electronic compatibility, electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

(2) Appropriate software verification, validation, and hazard analysis must be performed.

(3) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

(i) Mechanical bench data, including durability testing, to demonstrate that the device will withstand forces, conditions, and environments encountered during use.

(ii) Simulated use testing to demonstrate performance of arm commands and available safeguard(s) under worst case conditions and after durability testing.

(iii) Verification and validation of force sensors and hand release button, if applicable, are necessary.

(iv) Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor and brake performance.

(v) The accuracy of the device features and safeguards.

(4) Non-clinical and clinical performance testing must demonstrate the accuracy of device features and safeguards.

(5) Elements of the device that may contact the patient must be demonstrated to be biocompatible.

(6) Documented clinical experience and human factors testing must demonstrate safe and effective use, capture any adverse events observed during clinical use and demonstrate the accuracy of device features and safeguards.

(7) Labeling for the Prosthetist and User Guide must include:

(i) Appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities that may put the user at greater risk (*e.g.,* driving).

(ii) Specific instructions and the clinical training needed for the safe use of the device, which includes:

(A) Instructions on assembling the device in all available configurations,

(B) Instructions on fitting the patient,

(C) Instructions and explanations of all available programs and how to program the device,

(D) Instructions and explanation of all controls, input, and outputs,

(E) Instructions on all available modes or states of the device,

(F) Instructions on all safety features of the device, and

(G) Instructions for maintaining the device.

(iii) Information on the patient population for which the device has been demonstrated to be effective.

(iv) A detailed summary of the non-clinical and clinical testing pertinent to use of the device.

Dated: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25001 Filed 10–17–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0610]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway (AIWW), Wrightsville Beach, NC and Northeast Cape Fear River, Wilmington, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedules that govern the S.R. 74 (Wrightsville Beach) Bridge across the Atlantic Intracoastal Waterway (AIWW), mile 283.1, at Wrightsville Beach, NC and the Isabel S. Holmes Bridge across the Northeast Cape Fear River, mile 1.0, at Wilmington, NC. The deviation is necessary to facilitate the 2016 PPD IRONMAN North Carolina ''Beach2Battleship'' Triathlon. This deviation allows these bridges to remain in their closed-to-navigation position.

DATES: The deviation is effective from 6:30 a.m. to 6 p.m. on October 22, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0610] is available at *http://www.regulations.gov*. Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6557, email *Michael.R.Thorogood@uscg.mil*.

SUPPLEMENTARY INFORMATION: PPD Ironman North Carolina, on behalf of the North Carolina Department of Transportation, who owns the S.R. 74 (Wrightsville Beach) Bridge across the Atlantic Intracoastal Waterway (AIWW), mile 283.1, at Wrightsville Beach, NC and the Isabel S. Holmes Bridge across the Northeast Cape Fear River, mile 1.0, at Wilmington, NC, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.821(a)(4) and 33 CFR 117.829(a), respectively, to ensure the safety of the participants and spectators associated with the 2016 PPD IRONMAN North Carolina ''Beach2Battleship'' Triathlon.

Under this temporary deviation, the S.R. 74 (Wrightsville Beach) Bridge will be maintained in the closed-to-navigation position from 6:30 a.m. to 11

a.m. on October 22, 2016, and the Isabel S. Holmes Bridge will be maintained in the closed-to-navigation position from 9:30 a.m. to 6 p.m. on October 22, 2016. These bridges are both double bascule drawbridges and have vertical clearances in the closed-to-navigation position of 20 feet and 40 feet, respectively, above mean high water.

The Atlantic Intracoastal Waterway is used by a variety of vessels including, small commercial fishing vessels and recreational vessels. The Northeast Cape Fear River is used by a variety of vessels including, small commercial fishing vessels, recreational vessels, and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through these bridges in their closed positions may do so at any time. These bridges will be able to open for emergencies and there are no immediate alternative routes for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedules for these bridges so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), these drawbridges must return to their regular operating schedules immediately at the end of the effective periods of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 13, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–25183 Filed 10–17–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 33

[EPA–HQ–OA–2016–0457; FRL–9954–30–OA]

RIN 2090–AA40

Participation by Disadvantaged Business Enterprises in Procurements Under EPA Financial Assistance Agreements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Because EPA received comments which could be construed as adverse, we are withdrawing the direct final rule to amend Part 33—Participation by Disadvantaged Business Enterprises in Procurements under EPA Financial Assistance Agreements published on July 28, 2016.

DATES: Effective October 18, 2016 the rule published in the **Federal Register** of July 28, 2016 (81 FR 49539) (FRL–9946–27–OA) is withdrawn.

FOR FURTHER INFORMATION CONTACT: Teree Henderson, Office of the Administrator, Office of Small Business Programs (mail code: 1230A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–566–2222; fax number: 202–566–0548; email address: *henderson.teree@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 28, 2016, we published a direct final rule (81 FR 49539) and a parallel proposal (81 FR 49591) amending the provisions for Part 33—Participation by Disadvantaged Business Enterprises in Procurements under EPA Financial Assistance Agreements. These amendments were issued as a direct final rule, along with a parallel proposal to be used as the basis for final action in the event EPA received any adverse comments on the direct final amendments. Because EPA received comments which could be construed as adverse, we are withdrawing the direct final rule to amend the general provisions for part 33 published on July 28, 2016.

We stated in the direct final rule that if we received adverse comment by August 29, 2016, the direct final rule would not take effect and we would publish a timely withdrawal in the **Federal Register**. We subsequently received comments that could be construed as adverse on that direct final rule. We will address those comments in a subsequent final action based on the parallel proposal published on July 28, 2016 (81 FR 49591). As stated in the direct final rule and the parallel proposed rule, we will not institute a second comment period on this action.

List of Subjects in 40 CFR Part 33

Environmental protection, Grant programs.

Dated: October 12, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–25169 Filed 10–17–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 52, 55, 70, 71 and 124

[EPA–HQ–OAR–2015–0090; FRL–9954–10–OAR]

RIN 2060–AS59

Revisions to Public Notice Provisions in Clean Air Act Permitting Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is revising the public notice rule provisions for the New Source Review (NSR), title V and Outer Continental Shelf (OCS) permit programs of the Clean Air Act (CAA or Act) and corresponding onshore area (COA) determinations for implementation of the OCS air quality regulations. This final rule removes the mandatory requirement to provide public notice of a draft air permit (as well as certain other program actions) through publication in a newspaper. Instead, this final rule requires electronic notice (e-notice) for EPA actions (and actions by permitting authorities implementing the federal permitting rules) and allows for e-notice as an option for actions by permitting authorities implementing EPA-approved programs. When e-notice is provided, the final rule requires, at a minimum, electronic access (e-access) to the draft permit. However, this final rule does not preclude a permitting authority from supplementing e-notice with newspaper notice and/or additional means of notification to the public. The EPA anticipates that e-notice, which is already being practiced by many permitting authorities, will enable permitting authorities to communicate permitting and other affected actions to the public more quickly and efficiently and will provide cost savings over newspaper publication. The EPA further anticipates that e-access will expand access to permit-related documents.

DATES: The effective date of this final rule is November 17, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0090. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on