

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

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(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 [date 90 days after date of publication of the final rule in the **Federal Register**], for any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the **Federal Register**], been found to be substantially equivalent to any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976. Any other cardiopulmonary bypass pulsatile flow generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 882—NEUROLOGICAL DEVICES

5. The authority citation for 21 CFR part 882 continues to read as follows:

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

6. Section 882.1790 is amended by revising paragraph (c) to read as follows:

§ 882.1790 Ocular plethysmograph.

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(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 [date 90 days after date of publication of the final rule in the **Federal Register**], for any ocular plethysmograph that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the **Federal Register**], been found to be substantially equivalent to any ocular plethysmograph that was in commercial distribution before May 28, 1976. Any other ocular plethysmograph shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: November 6, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03-28741 Filed 11-17-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket No. S-030]

RIN No. 1218-AC01

Safety Standards for Cranes and Derricks

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Notice of Negotiated Rulemaking Committee meetings.

SUMMARY: The Occupational Safety and Health Administration (OSHA) announces the fifth and sixth meetings of the Crane and Derrick Negotiated Rulemaking Advisory Committee (C-DAC). The Committee will review summary notes of the prior meeting, review draft regulatory text and continue to address substantive issues. The meetings will be open to the public.

DATES: The meetings will be on December 3, 4, 5, 2003, and January 5, 6, 7, 2004. The December meeting will begin each day at 8:30 a.m. The January meeting will begin at 1 p.m. on January 5th and at 8:30 a.m. the last two meeting days. Individuals with disabilities wishing to attend should contact Luz Delacruz by telephone at 202-693-2020 or by fax at 202-693-1689 to obtain appropriate accommodations no later than Friday, November 21, 2003, for the December meeting and no later than Monday, December 22, 2003, for the January meeting. Each C-DAC meeting is expected to last two and a half days.

ADDRESSES: The December meeting will be held at the U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210 and will be in conference room N-4437 B, C, D. The January meeting will be held at the UBC International Training Center, 6801 Placid Street, Las Vegas, NV 89119.

Written comments to the Committee may be submitted in any of three ways: by mail, by fax, or by email. Please include "Docket No. S-030" on all submissions.

By mail, submit three (3) copies to: OSHA Docket Office, Docket No. S-030, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N-2625, Washington, DC 20210, telephone (202) 693-2350. Note that receipt of comments submitted by mail may be delayed by several weeks.

By fax, written comments that are 10 pages or fewer may be transmitted to the

OSHA Docket Office at fax number (202) 693-1648.

Electronically, comments may be submitted through OSHA's Web page at <http://ecomments.osha.gov>. Please note that you may not attach materials such as studies or journal articles to your electronic comments. If you wish to include such materials, you must submit three copies to the OSHA Docket Office at the address listed above. When submitting such materials to the OSHA Docket Office, clearly identify your electronic comments by name, date, subject, and Docket Number, so that we can attach the materials to your electronic comments.

FOR FURTHER INFORMATION CONTACT: Michael Buchet, Office of Construction Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3468, 200 Constitution Avenue, NW., Washington, DC 20210; Telephone: (202) 693-2345.

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2002, OSHA published a notice of intent to establish a negotiated rulemaking committee, requesting comments and nominations for membership (Volume 67 of the **Federal Register**, page 46612). In subsequent notices the Department of Labor announced the establishment of the Committee (Volume 68 of the **Federal Register**, page 35172, June 12, 2003), requested comments on a list of proposed members (68 FR 9036, February 27, 2003), published a final membership list (68 FR 39877, July 3, 2003), announced the first meeting, (68 FR 39880, July 3, 2003), which was held July 30–August 1, 2003. The Agency published notices announcing the subsequent meetings.

II. Agenda

The Committee will review draft materials prepared by the Agency on issues discussed at prior meetings and address additional issues. While the pace of the discussions at the C-DAC meetings varies, C-DAC anticipates discussing the following items at the December meeting: wire rope, hoisting personnel, access to work zones, overhead and gantry cranes, and responsibility for site and ground conditions. At the January meeting, C-DAC anticipates discussing crane operations near electric power lines.

III. Anticipated Key Issues for Negotiation

OSHA anticipates that key issues to be addressed at future C-DAC meetings will include:

Being Discussed

1. Scope.
2. Definitions.
3. Assembly & Disassembly (including reeving/rigging).
4. Operation Procedures.
5. Signals.
6. Operator Qualifications, Training & Testing.
7. Inspections.
8. Modifications.
9. Keeping Clear of the Load.
10. Fall Protection.
 - a. Ladder access and cat walks.
 - b. Fall arrest.
11. Hoisting Personnel.
12. Machine Guarding.
13. Qualifications of Maintenance & Repair Workers.
14. Work Zone Control.

Additional Subjects (anticipated order):

1. Wire Rope.
2. Responsibility for environmental considerations, site conditions and ground conditions.
3. Safety Devices: fail-safe, warning, secondary brake system, and other safety-related devices/technology.
4. Operating Near Power Lines.
5. Floating Cranes; Cranes on Barges.
6. Overhead & Gantry Cranes.
7. Derricks.
8. Verification criteria for the structural adequacy of crane components and stability testing requirements.
9. Free Fall/Power Down.
10. Critical Lifts and Engineered Lifts.
11. Tower Cranes.
12. Operator Cab Criteria (roll over, visibility, overhead protection).
13. Limited Requirements for cranes with a rated capacity of 2,000 pounds or less.

IV. Public Participation

All interested parties are invited to attend these public meetings at the times and places indicated above. Note, however, that a government issued photo ID card (State or Federal) is required for entry into the Department of Labor building. No advance registration is required. The public must enter the Department of Labor for the December meeting through the 3rd and C Street, NW., entrance. Seating will be available to the public on a first-come, first-served basis. Individuals with disabilities wishing to attend should contact Luz Delacruz by telephone at 202-693-2020 or by fax at 202-693-1689 to obtain appropriate accommodations no later than Friday, November 21, 2003, for the December meeting and no later than Monday, December 22, 2003, for the January

meeting. Each C-DAC meeting is expected to last two and a half days.

In addition, members of the general public may request an opportunity to make oral presentations to the Committee. The Facilitator has the authority to decide to what extent oral presentations by members of the public may be permitted at the meeting. Oral presentations will be limited to statements of fact and views, and shall not include any questioning of the committee members or other participants.

Minutes of the meetings and materials prepared for the Committee will be available for public inspection at the OSHA Docket Office, room N-2625, 200 Constitution Ave., NW., Washington, DC 20210; Telephone (202) 693-2350. Minutes will also be available on the OSHA Docket Web page: <http://dockets.osha.gov/>

The Facilitator, Susan Podziba, can be reached at Susan Podziba and Associates, 21 Orchard Road, Brookline, MA 02445; telephone (617) 738 5320, fax (617) 738-6911.

Signed at Washington, DC, this 12th day of November, 2003.

John L. Henshaw,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 03-28767 Filed 11-17-03; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF DEFENSE**Department of the Army, Corps of Engineers****33 CFR Part 334****United States Navy Restricted Area, Narragansett Bay, East Passage, Coasters Harbor Island, Naval Station Newport, Newport, RI**

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Corps of Engineers is proposing regulations to establish a restricted area on the east side of the East Passage of Narragansett Bay around Coasters Harbor Island in the vicinity of Naval Station Newport. These regulations will enable the Navy to enhance safety and security around Coasters Harbor Island. It will create an area of separation between general navigation on the East Passage of Narragansett Bay and Naval Station Newport. The regulations will safeguard government personnel and property plus United States government

contractor facilities located onboard Naval Station Newport from sabotage and other subversive acts, accidents, or incidents of similar nature. These regulations are also necessary to protect the public from potentially hazardous conditions that may exist as a result of Navy use and security of the area.

DATES: Written comments must be submitted on or before December 18, 2003.

ADDRESSES: U. S. Army Corps of Engineers, ATTN: CECW-OR, 441 G Street, NW., Washington, DC 20314-1000.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Torbett, Headquarters Regulatory Branch, Washington, DC at (202) 761-4618, or Mr. Michael Elliott, Corps of Engineers, New England District, at (978) 318-8131 or 1-800-343-4789.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX, of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps proposes to amend the restricted area regulations in 33 CFR Part 334 by adding Section 334.82 which establishes a restricted area in the navigable waters immediately adjacent to Coasters Harbor Island and enclosing the island and mainland shoreline of Naval Station Newport from Coddington Point south to the Naval Hospital on the eastern side of the East Passage of Narragansett Bay in Newport, Rhode Island. To better protect the Naval War College and vessels and personnel stationed at the facility and the general public, the Navy, has requested the Corps of Engineers establish a Restricted Area. This will enable the Navy to keep persons and vessels out of the area at all times, except with the permission of the Commanding Officer Naval Station Newport, USN Newport, Rhode Island or his/her authorized representative.

Procedural Requirements*a. Review Under Executive Order 12866*

This proposed rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

b. Review Under the Regulatory Flexibility Act

These proposed rules have been reviewed under the Regulatory Flexibility Act (Public Law 96-354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.*, small