

device to accord to the foreign purchaser's specifications, not be in conflict with the laws of the foreign country to which the device is being exported, be labeled on the outside of the shipping package that the device is intended for export, and not be sold or offered for sale in domestic commerce).

The only regulation pertaining to exports of unapproved devices for investigational use is at 21 CFR 812.18(b). The provision, which was originally written decades ago, simply stated that, "A person exporting an investigational device subject to this part shall obtain FDA's prior approval as required by section 801(d) of the act." However, since the provision was written, Congress has amended the act twice; under the Drug Export Amendments Act of 1986, section 801(d) of the act was renumbered to become section 801(e) of the act, and the Export Act of 1996 established section 802 of the act as an alternative export mechanism for unapproved devices for investigational use. Consequently, FDA is amending § 812.18(b) to state that, "A person exporting an investigational device subject to this part shall obtain FDA's prior approval as required by section 801(e) of the act or shall comply with the applicable export requirements in section 802 of the act." This amendment reflects the correct paragraph in section 801 of the act that applies to investigational device exports as well as the export mechanisms in section 802 of the act.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). Notice and public procedure are unnecessary because FDA is merely correcting a statutory reference.

List of Subjects in 21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 812 is amended as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

1. The authority citation for 21 CFR part 812 is revised to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801, 802, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383); secs. 215, 301, 351, 354–360F of the

Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

2. Section 812.18 is amended by revising paragraph (b) to read as follows:

§ 812.18 Import and export requirements.

* * * * *

(b) *Exports.* A person exporting an investigational device subject to this part shall obtain FDA's prior approval, as required by section 801(e) of the act or comply with section 802 of the act.

Dated: May 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12524 Filed 5–12–97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CCGD11–97–003]

RIN 2115–AE46

Special Local Regulations: California Cup

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements 33 CFR 100.1101, "Southern California Marine Events," for the 1997 California Cup Race. This event consists of a sailboat race with approximately 250 participants. These regulations will be effective in the portion of Santa Monica Bay off Santa Monica, California described in Table 1 to 33 CFR 100.1101. Implementation of section 33 CFR 11.1101 is necessary to control vessel traffic in the regulated area during the race to ensure the safety of participants and spectators.

DATES: The regulations in 33 CFR 100.1101 are effective from 2 p.m. until 5 p.m. on 23 May 1997, and from 11 a.m. until 5 p.m. on 24 and 25 May 1997, unless cancelled earlier by the Patrol Commander.

FOR FURTHER INFORMATION CONTACT: QMC D.K. LARSON, U.S. Coast Guard Marine Safety Office/Group Los Angeles/Long Beach, 165 N. Pico Avenue, Long Beach, California 90802; Tel: (310) 980–4442.

SUPPLEMENTARY INFORMATION: The California Cup is scheduled to occur on 23, 24 and 25 May 1997. These Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectator and participant vessels. In accordance with

the regulations in 33 CFR 100.1101, persons and vessels shall not anchor in or loiter in the regulated area, or impede the transit of participant or official patrol vessels, unless authorized by the Coast Guard Patrol Commander.

Dated: May 5, 1997.

R.T. Rufe, Jr.,

Vice Admiral, U.S. Coast Guard Commander, Eleventh Coast Guard District, Alameda, California.

[FR Doc. 97–12485 Filed 5–12–97; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

33 CFR Part 325

Processing of Department of the Army Permits

AGENCY: Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The Corps is making several minor editorial changes to its permit regulations to reflect a change in the title of a Division Office in the National Ocean Service (NOS), National Oceanic and Atmospheric Administration and the Agency's change of address. This amendment is necessary because Corps regulations require notification of the NOS by Corps Districts and permittees under certain circumstances.

EFFECTIVE DATE: May 13, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Eppard, HQUSACE, Regulatory Branch, CECW–OR at (202) 761–1783.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in sections 9 and 10 of the Rivers and Harbors Act of 1899 and section 404 of the Clean Water Act, the Corps issued regulations for the Regulatory Program in 33 CFR 320–330. In § 325.2(a)(9) (i) and (iii) and § 325.3(d)(2)(ii), and Appendix A–Permit Form and Special Conditions, a reference is made to the Charting and Geodetic Services, N/CG222, National Ocean Service, NOAA, Rockville, Maryland 20852. The correct identity and address for that Agency has changed and is now the National Ocean Service, Office of Coast Survey, N/CS261, 1315 East West Highway, Silver Spring, Maryland 20910–3282.

No other changes are being made to the permit regulations.

Procedural Requirements:

a. *Review Under Executive Order 12866*

The amendments contained in this rule are editorial and only reflect

another Federal Agency's internal reorganization and address change. There is no known impact on the public.

b. Review Under the Regulatory Flexibility Act

These rules have been reviewed under the Regulatory Flexibility Act (Pub. L. 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 businesses and small governments). The Corps expects that the economic impact of these changes to permit regulations will have no impact on the public, and accordingly, certifies that this proposal will have no significant economic impact on small entities.

c. Review Under the National Environmental Policy Act

An environmental assessment has been prepared for the Regulations in 33 CFR parts 320-330. We have concluded based on the minor nature of these editorial changes to the permit regulations that these amendments will not have significant impact to the human environment, and preparation of an environmental impact statement is not required.

d. Unfunded Mandates Act

This rule does not impose an enforceable duty among the private sector and therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small governments will not be significantly and uniquely affected by this rulemaking.

e. Submission to Congress and the GAO

Pursuant to Section 801(a)(1)(A) of the Administrative Procedure Act as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, the Corps has determined that submittal of this rule to the U.S. Senate, House of Representatives, and the Comptroller General of the General Accounting Office is not required. This rule reflects a change in agency organization and its relocation, corrects outdated materials in Department of the Army regulations. This is not a major rule within the meaning of Section 804(2) of the Administrative Procedure Act, as amended.

List of Subjects in 33 CFR Part 325

Administrative practice and procedure, Environmental protection,

Intergovernmental relations, Navigation, Water pollution control, Waterways.

For the reasons set out in the preamble, we are amending 33 CFR part 325, as follows:

PART 325—[AMENDED]

1. The authority citation for Part 325 continues to read as follows:

Authority: 33 U.S.C. 401 et seq.; 33 U.S.C. 1344; 33 U.S.C. 1413.

§§ 325.2 and 325.3 [Amended]

2. In 33 CFR 325.2(a)(9) (i) and (iii) and 325.3(d)(2)(ii) remove the words "Charting and Geodetic Services N/CG222, National Ocean Service, NOAA, Rockville, Maryland 20852" and add in their place the words "National Ocean Service, Office of Coast Survey, N/CS261, 1315 East West Highway, Silver Spring, Maryland 20910-3282".

Appendix A—Permit Form and Special Conditions [Amended]

3. In Appendix A—Permit Form and Special Conditions, under heading B. Special Conditions, special condition #5, remove the words "The Director, National Ocean Service (N/CG222, Rockville, Maryland 20852)" and add in their place the words "National Ocean Service, Office of Coast Survey, N/CS261, 1315 East West Highway, Silver Spring, Maryland 20910-3282".

Dated: May 1, 1997.

Approved.

For the Commander:

Charles M. Hess,

Chief, Operations, Construction and Readiness Division, Directorate of Civil Works.

[FR Doc. 97-12433 Filed 5-12-97; 8:45 am]

BILLING CODE 3710-92-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[MN41-01-7266a; FRL-5820-8]

Designation of Areas for Air Quality Planning Purposes; Minnesota

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is approving the St. Paul Park Area redesignation request submitted by the State of Minnesota on October 31, 1995. Minnesota requested that portions of Dakota and Washington Counties (the areas surrounding the Ashland Petroleum Company) be redesignated to

attainment for the National Ambient Air Quality Standard (NAAQS) for sulfur dioxide (SO₂). All future references to the areas surrounding the Ashland Petroleum Company will be made using St. Paul Park. Subsequent to this approval, Dakota and Washington Counties are each designated attainment in their entirety.

DATES: This "Direct final" is effective July 14, 1997 unless EPA receives adverse or critical comments by June 13, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of the revision request are available for inspection at the following address: Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone Todd Nettesheim at (312) 353-9153 before visiting the Region 5 Office.)

Written comments should be addressed to: Carlton Nash, Chief, Regulation Development Section, Air Programs Branch (AR-18J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Todd Nettesheim, Air Programs Branch, Regulation Development Section (AR-18J), United States Environmental Protection Agency, Region 5, 77 W. Jackson Boulevard, Chicago, Illinois 60604, (312) 353-9153.

SUPPLEMENTARY INFORMATION:

I. Background

The NAAQS for SO₂ consist of two standards: a primary standard for the protection of public health and a secondary standard for the protection of public welfare. The primary SO₂ standard consists of a 24-hour maximum of 0.14 particles per million (ppm) and an annual arithmetic mean ambient SO₂ concentration of 0.030 ppm. The secondary standard consists of a 3-hour maximum ambient SO₂ concentration of 0.5 ppm. (40 CFR 50.2-50.5)

Monitored violations of the primary SO₂ NAAQS from 1975 through 1977 led the Minnesota Pollution Control Agency (MPCA) to recommend EPA to designate Air Quality Control Region (AQCR) 131 as nonattainment for the SO₂ NAAQS. The AQCR 131 includes Anoka, Carver, Dakota, Hennepin, Ramsey, Scott, and Washington Counties in the State of Minnesota. On March 3, 1978, EPA published the designation of AQCR 131 as a primary nonattainment area for SO₂ based on these initial exceedences (43 FR 8962).