West Point, MS—McCharen Field, VOR/DME-B, Amdt. 4
Hannibal, MO—Hannibal Muni, NDB RWY 35, Amdt. 3
Hannibal, MO—Hannibal Muni, VOR/DME-A, Amdt. 2
Washington, NC—Warren Field, LOC RWY 5, Orig.
Columbus, OH—Rickenbacker ANGB, VOR RWY 23L, Amdt. 3
Columbus, OH—Rickenbacker ANGB, ILS-1, RWY 5R, Orig.
Findlay, OH—Findlay, VOR RWY 7, Amdt. 10
Findlay, OH—Findlay, VOR RWY 25, Amdt. 3
Findlay, OH—Findlay, VOR RWY 36, Amdt. 4
Findlay, OH—Findlay, NDB RWY 31, Amdt. 9
Houston, TX—Houston Gulf, VOR RWY 31, Amdt. 1

. . . *Effective November 16, 1989*

Fresno, CA—Fresno Air Terminal, VOR or TACAN RWY 11L, Amdt. 11
Fresno, CA—Fresno Air Terminal, LOC BC RWY 11L, Amdt. 8
Fresno, CA—Fresno Air Terminal, NDB RWY 29R, Amdt. 23
Fresno, CA—Fresno Air Terminal, ILS RWY 29R, Amdt. 31
Fresno, CA—Fresno-Chandler Downtown, VOR/DME-C, Amdt. 3
Fresno, CA—Fresno-Chandler Downtown, NDB-B, Amdt. 8
Hanford, CA—Hanford Muni, VOR-A, Amdt. 7
Madera, CA—Madera Muni, VOR RWY 30, Amdt. 7
Merced, CA—Merced Municipal/MacReady Field, VOR RWY 30, Amdt. 15
Merced, CA—Merced Municipal/MacReady Field, ILS RWY 30, Amdt. 11
Visalia, CA—Visalia Muni, VOR RWY 12, Amdt. 5
Visalia, CA—Visalia Muni, NDB RWY 30, Amdt. 3
Visalia, CA—Visalia Muni, ILS RWY 30, Amdt.5
Colorado Springs, CO—City of Colorado Springs Muni, ILS RWY 35, Amdt. 35
Detroit, MI—Detroit City, VOR RWY 33, Amdt. 27
Detroit, MI—Detroit City, ILS RWY 33, Amdt. 13
Guthrie, OK—Guthrie Muni, NDB RWY 16, Amdt. 3

. . *Effective October 24, 1989*

San Jose, CA—San Jose Intl, VOR RWY 12R, Amdt. 1
Charlotte, NC—Charlotte/Douglas Intl, ILS RWY 5, Amdt. 35

. . . *Effective October 20, 1989*

Fort Lauderdale, FL—Fort Lauderdale/Hollywood Intl, ILS RWY 9L, Amdt. 15
Note at end of § 97.23

The FAA published an Amendment in Docket No. 26028, Amdt. No. 1410 to Part 97 of the Federal Aviation Regulations (VOL 54 FR No. 195 Page 41591; dated 11 Oct 89) under Section 97.23 effective 22 SEP 89, which is hereby amended as follows:

Kalispell, MT—Glacier Park Intl, VOR RWY 30, Amdt. 8, change amendment number to Amdt. 9.

[FR Doc. 89-26537 Filed 11-9-89; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 111

Annual User Fee for Customs Broker's Permit

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of due date of broker's user fee.

SUMMARY: This document advises Customs brokers that for 1990 the annual user fee of $125 that is assessed for each permit held by an individual, partnership, association, or corporate broker is due by January 12, 1990. This announcement is being published to comply with the Tax Reform Act of 1986.

DATE: Due for fee: January 12, 1990.

FOR FURTHER INFORMATION CONTACT: Raymond R. Janiszewski, Chief, Broker Compliance and Evaluation Branch (202) 566-5307.

SUPPLEMENTARY INFORMATION:

Background

Section 13031 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99-272) established that an annual user fee of $125 is to be assessed for each Customs broker's permit held by an individual, partnership, association or corporate broker. This fee is set forth in the Customs Regulations in § 111.96 (19 CFR 111.96).

Section 111.96 Customs Regulations provides that the fee is payable for each calendar year in each district where a broker has a permit to do business by the due date which will be published in the **Federal Register** annually.

Section 1893 of the Tax Reform Act of 1985 (Pub. L. 99-514), provides that notice of the date on which payment is due of the user fee for each broker permit shall be published by the Secretary of the Treasury in the **Federal Register** by no later than 60 days before such due date.

This document notifies brokers that for 1990 the due date for payment of the user fee is January 12, 1990. It is expected that annual user fees for brokers for subsequent years will be due on or about the first of January each year.

Dated: November 8, 1989.

Carol B. Hallett,

Commissioner of Customs.

[FR Doc. 89-26637 Filed 11-9-89; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 430, 436, 440, 442, 446, and 455

[Docket No. 89N-0339]

Antibiotic Drugs; Updatings and Technical Changes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations by updating and making noncontroversial technical changes in accepted standards of antibiotic and antibiotic-containing drugs for human use. These changes will result in more accurate and usable regulations.

DATES: Effective December 13, 1989; comments, notices of participation, and requests for hearing by December 13, 1989; data, information, and analyses to justify a hearing by January 12, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA is amending the antibiotic drug regulations by updating and making noncontroversial technical changes in certain antibiotic drug regulations that provide for accepted standards of antibiotic and antibiotic-containing drugs intended for human use.

1. In 21 CFR 430.6(b)(34), the amount of cephalothin master standard that is equivalent to 1 microgram of cephalothin activity (potency) is revised from "1.066" to "1.056" micrograms to reflect the potency of a new lot of cephalothin master standard.

2. In 21 CFR 436.215, the second "of" in the footnote to the table in paragraph (b) is corrected to read "or", and the word "absorbence" in paragraph (c)

(10)(iii) is corrected to read "absorbance".

3. In 21 CFR 440.9a, paragraphs (a)(1) (vii) and (viii) are corrected by making the testing requirements for ampicillin content and concordance inapplicable when the high-performance liquid chromatographic (HPLC) assay procedure is used to determine the potency of sterile ampicillin sodium.

4. In 21 CFR 440.209b, the number of theoretical plates for sulbactam in paragraph (b)(1)(iii)(B) is revised from "5,000" to "3,500" and the resolution factor between the peaks for ampicillin and sulbactam alkaline degradation in paragraph (b)(1)(iii)(C) is revised from "4.0" to "1.2". These requirements were incorrectly stated in the **Federal Register** of November 4, 1987 (52 FR 42290).

5. In 21 CFR 442.15, the phrase "3-etheryl" in paragraph (a)(1) is corrected to read "3-ethenyl"; paragraphs (b)(1)(ii)(A) and (C) are corrected by revising the diluent used in the preparation of the working and sample solutions in the HPLC potency assay for cefixime trihydrate from "mobile phase" to "0.1 *M* phosphate buffer, pH 7.0"; and paragraph (b)(1)(iii)(E) is corrected by adding equal signs (=) to the first two formulas for calculating the capacity factor for cefixime.

6. In 21 CFR 446.60, the formula for calculating the capacity factor for minocycline in paragraph (b)(1)(iii)(*e*) is corrected, and the explanation of the term "C_u" in the formula for the calculation of the potency of the minocycline sample solution in paragraph (b)(1)(iv) is corrected.

7. In 21 CFR 446.260, paragraph (b)(1)(ii)(*a*) is corrected by adding the word "content" after "minocycline" in the first sentence.

8. In 21 CFR 455.82a, the number of theoretical plates for sulbactam in paragraph (b)(1)(iii)(B) is revised from "4,000" to "3,500". This requirement was incorrectly stated in the **Federal Register** of November 4, 1987 (52 FR 42290).

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

These amendments institute changes that are corrective, editorial, or of a minor technical nature. Because the amendments are not controversial, and because, when effective, they provide notice of accepted standards, FDA finds that notice, public procedure, and delayed effective date are unnecessary and not in the public interest. This final rule, therefore, becomes effective December 13, 1989. However, interested persons may, on or before December 13, 1989, submit comments on this regulation to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before December 13, 1989, a written notice of participation and request for hearing, and (2) on or before January 12, 1990, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order, and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR

Part 430: Administrative practice and procedure, Antibiotics.

Part 436: Antibiotics.

Part 440: Antibiotics.

Part 442: Antibiotics.

Part 446: Antibiotics.

Part 455: Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 430, 436, 440, 442, 446, and 455 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

§ 430.6 [Amended]

2. Section 430.6 *Definitions of the terms "unit" and "microgram" as applied to antibiotic substances* is amended in paragraph (b)(34) by removing "1.066" and replacing it with "1.056".

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

3. The authority citation for 21 CFR part 436 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

§ 436.215 [Amended]

4. Section 436.215 *Dissolution test* is amended in the footnote to the table in paragraph (b) by removing the second "of" and replacing it with "or", and in paragraph (c)(10)(iii) by removing "absorbence" and replacing it with "absorbance".

PART 440—PENICILLIN ANTIBIOTIC DRUGS

5. The authority citiation for 21 CFR part 440 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

6. Section 440.9a is amended by revising paragraphs (a)(1) (vii) and (viii) to read as follows:

§ 440.9a Sterile ampicillin sodium.

(a) * * *

(1) * * *

(vii) Its ampicillin content is not less than 84.5 percent, except if the high-performance liquid chromatographic

(HPLC) assay method is used, then the ampicillin content standard is not applicable.

(viii) The potency-base titration concordance is such that the difference between the potency value divided by 10 and the percent ampicillin content of the sample determined by the nonaqueous base titration is not more than 6, except if the HPLC assay method is used, then the concordance standard is not applicable.

* * * * *

§ 440.209b [Amended]

7. Section 440.209b *Sterile ampicillin sodium and sulbactam sodium* is amended in paragraph (b)(1)(iii)(B) by removing "5,000" and replacing it with "3,500", and in paragraph (b)(1)(iii)(C) by removing "4.0" and replacing it with "1.2".

PART 442—CEPHA ANTIBIOTIC DRUGS

8. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

9. Section 442.15 is amended in paragraph (a)(1) by removing "3-etheryl" and replacing it with "3-ethenyl", by revising the second sentence in paragraph (b)(1)(ii)(A) and the last sentence in paragraph (b)(1)(ii)(C), and in paragraph (b)(1)(iii)(E) by adding "=" after (k) in the first formula and after t_m in the second formula to read as follows:

§ 442.15 Cefixime trihydrate.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) * * * Further dilute quantitatively to a final concentration of 0.2 milligram of cefixime activity per milliliter in 0.1 *M* phosphate buffer, pH 7.0. * * *

* * * * *

(C) * * * Immediately prior to chromatography, further dilute 10 milliliters of stock solution to 100 milliliters with 0.1 *M* phosphate buffer, pH 7.0 to obtain a solution containing 0.2 milligram of cefixime activity per milliliter (estimated).

* * * * *

PART 446—TETRACYCLINE ANTIBIOTIC DRUGS

10. The authority citation for 21 CFR part 446 continues to read as follows:

Authority: Section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

11. Section 446.60 is amended in paragraph (b)(1)(iii)(*e*) by revising the first formula and in paragraph (b)(1)(iv) by revising the line beginning "C_u=" appearing under "where:" to read as follows:

§ 446.60 Minocycline hydrochloride.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(*e*) * * *

$$k' = \frac{t_r - t_o}{t_o}$$

* * * * *

(iv) * * *

where:

* * * * *

C_u = Milligrams of minocycline sample per milliliter of sample solution; and

* * * * *

12. Section 446.260 is amended by revising the first sentence in paragraph (b)(1)(ii)(*a*) to read as follows:

§ 446.260 Sterile minocycline hydrochloride.

* * * * *

(b) * * *

(1) * * *

(ii) * * * (*a*) Calculate the minocycline content of the single-dose vial as follows:

* * * * *

PART 455—CERTAIN OTHER ANTIBIOTIC DRUGS

13. The authority citation for 21 CFR part 455 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

§ 455.82a [Amended]

14. Section 455.82a *Sterile sulbactam sodium* is amended in paragraph (b)(1)(iii)(B) by removing "4,000" and replacing it with "3,500".

Dated: October 31, 1989.

Sammie R. Young,

Deputy Director, Office of Compliance Center for Drug Evaluation and Research.

[FR Doc. 89-26548 Filed 11-9-89; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 864 and 880

[Docket No. 87P-0336]

Medical Devices; Specimen Transport and Storage Container; Exemption From Most Current Good Manufacturing Practice Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting the generic type of device specimen transport and storage container from most of the current good manufacturing practice (CGMP) requirements for devices. FDA has determined that compliance with all of the CGMP requirements is unnecessary to assure that this device is safe and effective. This action is being taken in response to a citizen petition.

EFFECTIVE DATE: December 13, 1989.

FOR FURTHER INFORMATION CONTACT: Alicia B. Abbott, Center for Devices and Radiological Health (HFZ-332), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1128.

SUPPLEMENTARY INFORMATION: On September 28, 1987, Richard-Allan Medical Industries, Richland, MI 49083, submitted to FDA a petition (87P-0336) requesting that FDA exempt the petitioner's dry (empty) and prefilled specimen transport and storage containers from the CGMP regulations in 21 CFR part 820, with the exception of §§ 820.180 and 820.198. FDA requested additional information from the petitioner, and that information was submitted on February 4, 1988.

On May 10, 1989, FDA published in the **Federal Register** (54 FR 20147-20148) a proposed rule. Interested persons were invited to submit comments by July 10, 1989. One comment was received. The comment agreed with the proposal to exempt specimen transport and storage containers from premarket notification and most of the CGMP regulations. The comment, however, pointed out that if 21 CFR 880.6175 were removed, specimen containers used for the collection and transportation of body waste, body exudate, or tissue samples that are not to be used for diagnostic examination, would not be covered by any regulation. The comment suggested that the identification section of 21 CFR 864.3250 be revised to include these devices.

FDA agrees with the comment. The omission was inadvertent. FDA has revised the regulation accordingly. Pursuant to § 880.6175, the devices in question were already classified in class I and exempt from premarket notification procedures and the CGMP requirements with the exception of §§ 820.180 and 820.198.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Impact

FDA has carefully analyzed the economic effects of this rule and has determined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this rule has been carefully analyzed, and it has been determined that the rule does not constitute a major rule as defined in section 1(b) of the Executive Order. The effect of the rule will be only to relieve an unnecessary burden on the manufacturers of the devices subject to § 864.3250.

List of Subjects

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 864 and 880 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 864.3250 is revised to read as follows:

§ 864.3250 Specimen transport and storage container.

(a) *Identification.* A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the matter contained therein can be destroyed or used effectively for diagnostic examination. If prefilled, the device contains a fixative solution or other general purpose reagent to preserve the condition of a biological specimen added to the container.

(b) *Classification.* Class I (general controls). If the device is not intended for over-the-counter (OTC) distribution, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to the general requirements concerning records, and § 820.198, with respect to complaint files.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

3. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

§ 880.6175 [Removed]

4. Section 880.6175 *Specimen container* is removed from subpart G.

Dated: October 19, 1989.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-26498 Filed 11-9-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD11-89-20]

Regulated Navigation Area; San Francisco Bay

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a regulated navigation area in San Francisco Bay and implementing temporary mandatory participation in the existing Vessel Traffic Service system. This action is necessary due to the significant increase in vessel ferry traffic operating in the Bay. Increased ferry service is being used to provide alternate means of mass transportation since the normal traffic corridors in the Bay Area remain closed for repairs following structural damage resulting from the earthquake on October 17, 1989. Mandatory participation will be terminated and voluntary participation resumed as soon as the normal traffic corridors reopen and the need for increased vessel ferry service subsides.

EFFECTIVE DATE: This regulation becomes effective on 25 October, 1989 and will remain in effect until the normal traffic corridors in the Bay area are reopened. Local officials estimate that repairs to the landside bridges and highway approaches may take one to three months. This emergency will be terminated by publication of a document in the Federal Register.

ADDRESSES: Comments should be mailed to Commander (oan), Eleventh Coast Guard District, 400 Oceangate, Long Beach, CA 90822-5399. The comments will be available for inspection and copying at the Union Bank Building, 400 Oceangate, Room 701. Office hours are 7:00 a.m. to 4:00 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Van Houten, Eleventh Coast Guard District Aids to Navigation and Waterways Management Branch, Long Beach, California. Telephone number (213) 499-5414.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553 a Notice of Proposed Rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to facilitate the safety of navigation in San Francisco Bay.

Although this regulation is published as a final rule without prior notice, an opportunity for public comment is nevertheless desirable to ensure that the regulation is both reasonable and workable. Accordingly, persons wishing to comment may do so by submitting written comments to the office listed under "ADDRESS" in this preamble. Commenters should include their names and addresses, identify the docket number for the regulations, and give reasons for their comments. Based upon comments received, the regulation may be changed.

Drafting Information

The drafters of this regulation are Mr. Mike Van Houten, project officer for the Eleventh District Aids to Navigation and Waterways Management Branch, and Lieutenant Allen Lotz, project attorney for the Eleventh District Legal Office.

Discussion of Regulation

The circumstances requiring this regulation resulted from the disruption of normal landside traffic corridors (specifically the Oakland Bay Bridge and its highway approaches) due to structural damage sustained in the earthquake that struck the Bay Area on October 17, 1989. This has resulted in a significant increase in the volume of vessel ferry traffic operating in San Francisco Bay as an alternate means of mass transportation for commuters. Many of these vessels will be using new routes which cross existing vessel traffic lanes. Mandatory participation in the Vessel Traffic Service system is required to effectively monitor the increased commercial vessel traffic operating in the Bay, thereby facilitating the safety of navigation. This temporary regulation will be terminated as soon as the normal traffic corridors are reopened and the volume of ferry traffic decreases correspondingly. The intent of this regulation is to parallel the VTS procedures published in the "VTS San Francisco User's Manual" dated July 1984, with the one exception being that participation in the VTS will be mandatory rather than voluntary. Mariners holding this publication are encouraged to continue abiding by the procedures published therein.

This regulation is issued pursuant to 33 U.S.C. 1231 as set out in the authority citation for all of part 165.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Safety measures, Vessels, Waterways.

Regulation

In consideration of the foregoing, subpart D of part 165 of title 33, Code of Federal Regulations, is amended as follows:

PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5, 49 CFR 1.46.

2. A new § 165.T1193 is added to read as follows:

§ 165.T1193 San Francisco Bay—Regulated Navigation Area.

(a) *The following is a regulated navigation area.* The waters of San Francisco Bay from the San Francisco Approach Large Navigation Buoy in position 37–45.0 N and 122–41.5 W shoreward through the Bay and up the tributaries of the Bay as far inland as Stockton and Sacramento.

(b) *Purpose and applicability.* (1) This regulation is intended to facilitate orderly vessel traffic movement and enhance the safety of navigation during a period of increased ferry vessel service in San Francisco Bay following disruption of normal landside traffic corridors in the aftermath of the October 17 earthquake.

(2) This regulation is applicable to all commercial and public vessels, United States flag and foreign flag, transiting the area that are:

(i) 300 or more gross tons and propelled by machinery.

(ii) Carrying more than six passengers for hire while operating as a ferry or on an excursion.

(iii) 26 feet or over in length engaged in towing another vessel astern, alongside, or pushing ahead.

(iv) Likely by reason of size, special operation, intended route, cargo, or difficulty of maneuvering, to restrict or affect navigation of other vessels; or

(v) A hazard to navigation by reason of distress such as fire, collision, grounding, or mechanical, or personnel failure.

(c) *Effective dates.* This regulation becomes effective on October 25, 1989 and will be terminated as soon as the normal traffic corridors in the Bay area are reopened and the increased vessel ferry traffic subsides. Local officials estimate the repairs to landside bridges and highways may take one to three months.

(d) *Definition of terms.*

(1) *Vessel Traffic Service (VTS):* Vessel Traffic Service is a general term encompassing all elements of a system employed to manage vessel movements in a port or other congested area.

(2) *Vessel Traffic Center (VTC):* The facility operated by the Coast Guard on Yerba Buena Island, receives, evaluates, displays and disseminates verbal information concerning ship movements and other matters concerning safe navigation within the San Francisco Vessel Traffic Service Area.

(3) *Traffic Routing System (TRS):* A system of charted Traffic Separation Schemes (TSS), consisting of traffic lanes with separation lines, limited traffic areas, precautionary areas and recreation areas designed to coordinate the flow of vessel traffic into, within and out of a port or waterway.

(4) *Limited Traffic Area (LTA):* An area which should be traversed only after certain safety precautions have been observed.

(5) *Traffic Lane:* An area, specifically defined on charts by boundary lines and separation lines, intended for use by vessel traffic proceeding in approximately the same direction.

(6) *Separation Line:* A charted line separating traffic lanes for vessels proceeding in opposite or nearly opposite directions.

(7) *Boundary Line:* A charted line defining the lateral limits of traffic lanes. Special caution should be exercised when navigating near traffic lane boundary lines.

(8) *Precautionary Area:* An area at the convergence of two or more traffic separation schemes where special caution should be exercised.

(9) *Recreation Area:* An area intended primarily for use by recreational craft.

(10) *Deep-Draft Vessels:* Vessels which cannot safely adhere to the TSS because of insufficient water depths along the prescribed route.

(11) *Radar Area:* The portion of the regulated navigation area where the VTC has radar coverage and is defined as follows: The area from the San Francisco Approach Large Navigation Buoy to East Brothers Island to the North and San Mateo Bridge to the South.

(12) *Vessel Movement Reporting System Area (VMRS):* The portion of the regulated area in which there is no radar coverage. Vessel movements are tracked by radio telephone reports. This is the area North of East Brothers Island and South of the San Mateo Bridge.

(e) *Description.* The purpose of the San Francisco Vessel Traffic Service is accomplished through three basic elements: a traffic routing system, a communications network and a surveillance system. All three elements are coordinated from the Vessel Traffic Center (VTC) located on Yerba Buena Island. The VTC is manned by Coast Guard personnel trained in the collection, correlation, analysis and dissemination of vessel movement information.

(f) *Concept of operations.* (1) The normal and predominant role of the VTC is to INFORM. The VTC will inform a participant of other vessels in the vicinity, hazards to navigation, discrepancies in aids to navigation and other items of mutual concern. This will be done either at the participant's request or, when in the interest of safety, such information is considered beneficial. Operation at the *INFORMATIONAL* level constitutes the majority of VTC San Francisco's actions.

(2) In certain circumstances, the VTC will *RECOMMEND* action be taken by a participant to prevent a potentially dangerous situation. Such recommendations are designed to assist the participant in avoiding hazardous situations well before they would otherwise occur. For example, a modest change in speed now could prevent a potentially hazardous meeting situation later in a narrow channel.

(3) In an emergency, or when a dangerous situation is imminent, VTC San Francisco, acting for the Coast Guard Captain of the Port, will *DIRECT* the movement of participating vessels within the VTS area. Such direction will normally take place after either or both of the previous actions (*INFORMATION* and *RECOMMENDATION*) have failed to alleviate the potentially dangerous situation.

(g) *Communication Rules.* (1) San Francisco Vessel Traffic Service maintains a continuous radiotelephone watch on Channel 13 (156.65 MHz FM) and Channel 16 (156.80 MHz FM). The call sign is "San Francisco Vessel Traffic Service". After communications have been established, the abbreviated call sign "TRAFFIC" may be used. Participants should call and work "TRAFFIC" on Channel 13. Should communication on Channel 13 be lost, call "TRAFFIC" on Channel 16 and be prepared to shift to either channel 12 (156.60 MHz FM) or Channel 18A (156.90 MHz FM) for further communications with VTS. All communications with the VTC should be in the English language and use the 24 hour clock system.

(2) Nothing in these procedures contravenes or modifies the Vessel Bridge-to-Bridge Radiotelephone Regulations.

(i) Channel 13 is the frequency assigned by these regulations for operators of approaching vessels to communicate their intentions to each other.

(ii) The responsibility for complying with the Vessel Bridge-to-Bridge Radiotelephone Act, and making reports required of participants in the Vessel Traffic Service, remains with the master or person in charge of the vessel, or the person designated by the master or person in charge to pilot or direct the movement of the vessel. However, should the pilot be required to shift to another frequency the master must maintain the listening watch required on Channel 13 and make the required reports.

(iii) Since Channel 13 serves as both Bridge-to-Bridge and VTS frequency in the San Francisco VTS Area, VTS participants are not excused from the requirement, set forth in 47 CFR 83.2245, to monitor Channel 16 (156.80 MHz), the national distress, safety and calling frequency. The requirement to monitor Channel 16 does not apply to single channel stations installed in compliance with the Vessel Bridge-to-Bridge Radiotelephone Regulations.

(h) *Radar Coverage Area Rules*—(1) *Initial Report.* Active participants should make initial reports to the VTC upon entering the regulated navigation area from seaward or upon getting underway from within the RADAR AREA, giving the following information:

Vessel Name
Position or Location
Destination
Route (if not within the TRS)
Anticipated Pilot Change (if applicable)
Pilot Designation
Description of Tow (if applicable)
Deepest Draft (If Vessel Greater Than 300 Tons)

(2) *Additional Radar Area Reports.* (i) When passing under any bridge. (This allows reconfirmation of the identity of the radar contact. The bridges are merely convenient geographical check points.)

(ii) Upon completion of pilot change, departure of pilot or other change in person directing the movement of the vessel.

(iii) When previously reported conditions or intentions change.

(iv) When intending to deviate from the TRS.

(v) In emergency situations (after completing maneuvers necessary to protect the safety of life, property, or environment), giving all information pertinent to safety of navigation.

(vi) To report any condition (concentration of non-participants, weather, debris, vessel in distress, aid to navigation discrepancy, etc.) considered to be a hazard to navigation.

(3) *Radar Area Final Report.* Upon docking, anchoring, mooring or upon departing from the boundaries for the Radar Area the place and time should be reported to the VTC.

(4) *Loss of Radar Coverage.* In the event of loss of radar capability, the Radar Area will be declared a Vessel Movement Reporting System Area and vessels will be advised by the VTC what interim reports to make.

(i) *Vessel Movement Reporting System (VMRS) Rules.* The VMRS is in effect where there is no radar coverage in the VTS area. It is served solely by radiotelephone reports from participants. These reports are recorded and movements tracked by the VTC.

(1) *VMRS Area Initial Reports.* Participants should make initial reports to the VTC upon preparing to get underway from within the VMRS Area, giving applicable information from that prescribed for intial reports in the Radar Area.

(2) *VMRS Area Follow-up Reports.* Follow-up reports should be made:

(i) When actually underway.

(ii) When passing the following points in the northern VMRS:

POINT SAN PABLO, RIO VISTA BRIDGE, ANTIOCH BRIDGE, CARQUINEZ BRIDGE, LIGHT 51, PRISONERS POINT, S.P. RAILROAD BRIDGE, SACRAMENTO, STOCKTON, NEW YORK POINT

(iii) When entering or departing Petaluma River Entrance Channel or Mare Island Strait.

(iv) When passing the following points in the southern VMRS:

HUNTERS POINT, SAN MATEO BRIDGE

(v) When previously reported conditions or intentions change.

(vi) When intending to deviate from normally traveled routes.

(vii) In an emergency situation (after completing maneuvers necessary to protect the safety of life, property or environment), giving all information pertinent to safety of navigation.

(viii) To report any condition (concentration of nonparticipants, weather, debris, vessel in distress, aid to navigation discrepancy, etc.) considered to be a hazard to navigation.

(3) *VMRS Area Final Report.* (i) Upon docking, anchoring, mooring or departing the VMRS Area, the place and time should be reported to the VTC.

(ii) All reports should advise the time of the event being reported.

(4) *Read-back.* The VTC will acknowledge the receipt of reports by "reading back" the information received. The vessel can then confirm the accuracy of the information received at the VTC. If the VTC believes the report to be incomplete or in error, the vessel will be requested to repeat the report.

(j) *Traffic Routing System (TRS).* (1) A Traffic Routing System (TRS) is established in that portion of the VTS area seaward of the Golden Gate and, in the Bay, north of Hunters Point and south of Carquinez Strait. The TRS is composed of traffic lanes, precautionary areas, a limited traffic area, and recreation areas, and is shown on charts of the San Francisco area.

(2) The traffic lanes of the TRS are designed to separate the flow that a vessel traffic in such a way as to reduce the likelihood of a vessel moving in one direction will meet or cross the bow of another vessel bound in an opposite or nearly opposite direction. The lateral limits of the traffic lanes are defined by a separation line or boundary lines. Traffic proceeds within the lanes in the direction which holds the separation line on the port side of the vessel.

(3) Where traffic lanes converge or cross, precautionary areas are established. A circular area west of the Golden Gate and a circular area east of Alcatraz Island are designated precautionary areas. Potentially hazardous crossing encounters are limited by the traffic lanes to these relatively obstruction-free areas.

(4) All vessels should adhere to the TRS. The final decision to deviate from the TRS remains that of the master, pilot, or person in command. All intentions to proceed contrary to the TRS should be made known to the VTC

as far in advance as possible to permit evaluation and dissemination of necessary warnings to other participants.

(5) All vessels (including public vessels) should navigate within the vessel traffic lanes. Excepted are those vessels engaged in intra-harbor movements whose routes do not infringe on the traffic separation scheme.

(6) Vessels navigating within the traffic lanes should keep the separation line to the port side of the vessel and should maintain a course which conforms with the direction of the lane.

(7) Vessels should avoid crossing the TSS whenever possible. When it is necessary to cross a TSS, this should be done at as close to a right angle as practicable.

(8) Except when joining, leaving, crossing or navigating within a vessel traffic lane or precautionary area, vessels should stay clear of the lanes and precautionary areas by as wide a margin as practicable. Vessels choosing to operate outside of the lanes may do so, but should remain well outside.

(9) Vessels are encouraged to join and leave the traffic lanes at the precautionary areas or at the ends of the lanes. When it is necessary for a vessel to join or leave the traffic lane at some point other than the precautionary areas or a lane termination, the vessel should join or leave the traffic lane at as small an angle as practicable.

(10) Vessels within the traffic lanes who cannot comply with these traffic separation procedures because of an emergency should complete whatever maneuvers are required for safe navigation. Notify VTC of the circumstances as soon as possible.

(11) Vessels that for some reason other than an emergency, cannot comply with the traffic separation procedures should notify the VTC sufficiently in advance of each impending deviation to allow for evaluation and coordination with other vessels. This includes any vessel whose draft precludes it from following the traffic lanes. Even though similar deviations are made repeatedly, a vessel should inform VTC each and every time it proposes to deviate from the guidelines. The following are situations that may require a vessel to deviate from the TRS:

(i) Vessels inbound to ports in Oakland may desire to transit the D–E span of the Oakland Bay Bridge to facilitate safe entry into the Oakland Bar Channel. This is normally acceptable, provided there is no conflicting traffic for that span or the Limited Traffic Area south of Yerba Buena Island during the period of transit. The VTC should be notified of such intentions well in advance. In the event of conflicting traffic, the vessel will have the option of waiting until that route is clear, or using the TRS through A–B or B–C span.

(ii) Vessels whose draft precludes adherence to the TRS are considered "deep-draft vessels." Such vessels, when bound from sea to Anchorage 9 should use the "Deep-Draft Route" east of the Golden Gate Bridge. This route is eastbound in the westbound lane, north of Harding Rock and Alcatraz Island, east of Blossom Rock, then through the C–D or D–E span of the Oakland Bay Bridge to Anchorage 9. The Pilot or Master will determine the need to use this route and should report his decision to VTS. When such a vessel enters the Bay, the VTC informs other vessels in advance. During periods of traffic congestion, a Coast Guard escort may be provided to warn other vessels that the deep-draft vessel will be proceeding contrary to the TSS.

(12) The recreational boating public is generally aware of the TRS and has legitimate expectations that ships will adhere to it. It is normally not possible for the VTC to contact recreational vessels on the VTS radio frequencies and often they do not appear on radar. Therefore, particularly in the area north and south of Alcatraz Island (where many small boats are present both day and night), the hazards of deviation from the TRS are most pronounced. For these reasons, the VTS will recommend adherence whenever a proposal to deviate from the TRS is based only on convenience. In cases of known contrary movements, the VTC may make a Marine Safety Broadcast on channels 16 and 22A to warn the boating public of the impending deviation.

(13) Ferry vessels should notify VTC of their intended route upon departure and at any time during their transit when their progress is slowed or their route is changed. The VTC should again be notified upon completion of the movement. Ferry and tour boats are expected to comply with the TRS as closely as their routes will allow.

(14) Recreation areas should be avoided by vessels other than recreational craft. They should not be used by vessels of 300 gross tons or more for through passage or for any other purpose, except in case of emergency of special circumstances.

(15) The Pinole Shoal Channel in San Pablo Bay should be considered a ONE-WAY CHANNEL whenever an explosive or hazardous-material-laden vessel or a vessel with a draft of 30 feet or greater is transiting the channel.

(16) Explosive or hazardous-material-laden vessels should comply with the Captain of the Port guidelines for vessels with dangerous cargoes. All other vessels should proceed in such a manner as to limit meeting or passing situations with explosive or hazardous-material-laden vessels to those which are unavoidable.

(17) Any vessels that cannot enter port immediately upon arrival at the pilot station may proceed on various courses within the seaward portion of the VTS area in such a way as not to present a hazard to navigation. Alternatively they may seek safe anchorage in an area four miles due north of the charted position of the San Francisco large Navigation Buoy "SF". Ships so anchoring should inform the VTC.

(k) *Limited Traffic Area Procedures.* (1) In San Francisco Bay there is one area which, due to its location, is considered to present high risk of collision to vessels meeting within its boundaries. For this reason it has been designated a Limited Traffic Area (LTA). This area is located immediately south of Yerba Buena Island. It extends from the boundary lines of the vessel traffic lanes eastward to encompass the Oakland Bar Channel, Inner and Outer harbor Entrance Channels and Oakland Outer harbor. Within this area vessel movement is normally restricted to one-way traffic. The VTC will monitor and assist vessels in coordinating their movements through this area.

(2) The limited Traffic Area south of Yerba Buena Island should be used by only one vessel at a time or by vessels proceeding generally in the same direction.

(3) Vessels 300 gross tons or over intending to transit this area should notify the VTC of the intended period of transit. This should be done at least 15 minutes before entering the area and prior to committing the vessel to an unchangeable action. Such vessels should not enter the Limited Traffic Area when another vessel 300 gross tons or over is in the area proceeding in the opposite direction. However, under favorable conditions, and only after clear understanding has been reached on Channel 13 between vessels as to the point and manner of passing, two vessels may agree to pass within this area. The VTC will monitor and evaluate each such arrangement.

(4) In the event no safe passing arrangements are reached or the VTC does not consider the intended arrangement to be safe, the VTC will so inform the participants, recommending alternate action. If the situation is not resolved or the VTC is not convinced a safe passage can be made, the VTC may

direct action which will resolve the problem.

(5) The VTC will advise each vessel stating an intention to transit this area whenever its intended transit conflicts with the known intent of any other vessel. Vessels should notify the VTC immediately of any change in intended transit period to prevent unnecessary delays of other vessels.

(1) Regulated Navigation Area Check-in Locations—

(i) Transit from Pilot area to locations within San Francisco Bay:

(A) Participating vessels check-in upon picking up pilot.

(B) Check-in when passing under the Golden Gate Bridge.

(C) Check-in when passing Alcatraz Island.

(ii) South Bay Transit:

(A) Check-in when passing under the Oakland Bay Bridge.

(B) Check-in when passing Oakland Inner Harbor buoys 5 and 6 (Oakland Estuary transits).

(C) Check-in when passing under San Mateo Bridge (South Bay transits).

(D) Check-in when mooring.

(iii) Port of Sacramento/Stockton:

(A) Check-in when passing under the Richmond-San Rafael Bridge.

(B) Check-in when entering Pinole Shoals Channel (East Brothers area).

(C) Check-in when passing under the Carquinez Straits Bridge.

(D) Check-in when passing under the Southern Pacific Railroad Bridge.

(E) Check-in when passing New York Point.

(iv)Sacramento:

(A) Check-in when passing under the Rio Vista Bridge.

(B) Check-in when passing River marker 56 in the Sacramento Deep Water Ship Channel.

(C) Check-in when mooring at the Port of Sacramento.

(V) Stockton:

(A) Check-in when passing Antioch Point.

(B) Check-in when passing Prisoners Point.

(C) Check-in when mooring at the Port of Stockton. When proceeding outbound the same check-in locations apply.

Dated: October 25, 1989.

J.W. Kime,

Rear Admiral, U.S. Coast Guard Commander, Eleventh Coast Guard District.

[FR Doc. 89-26546 Filed 11-9-89; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3679-5; KY-062]

Approval and Promulgation of Implementation Plans KY: Approval of Revisions to Appendix N

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today approves a revision to Appendix N of the Kentucky State Implementation Plan (SIP). Appendix N consists of regulations developed by the Air Pollution Control District of Jefferson County (the District), and applies only in Jefferson County, Kentucky; they are implemented by the District. EPA approval of the regulations enables the District to retain authority for all subject activities in Jefferson County.

EFFECTIVE DATE: This action will be effective January 12, 1990, unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments should be addressed to Richard A. Schutt of EPA Region IV's Air Programs Branch (see EPA Region IV address below). Copies of the material submitted by Kentucky may be examined during normal business hours at the following location:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460

Region IV Air Programs Branch, Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365

Kentucky Department for Environmental Protection, Frankfort Office Park, 18 Reilly Road, Frankfort, Kentucky 40601

Air Pollution Control, District of Jefferson County, 914 East Broadway, Louisville, Kentucky 40204.

FOR FURTHER INFORMATION CONTACT: Richard A. Schutt of the EPA Region IV Air Programs Branch at 404-347-2864 (FTS-257-2864) and at the above address.

SUPPLEMENTARY INFORMATION: The Air Pollution Control District of Jefferson County (the district) develops and implements air quality regulations in Jefferson County, Kentucky. The District's regulations are at least as stringent as corresponding Kentucky regulations. The District's regulations are incorporated by the State as part of the Kentucky SIP; in this manner, the State has the authority to implement the regulations in Jefferson County if the District cannot.

The SIP revision affected by today's approval was adopted by the Air Pollution Control Board of Jefferson County on April 19, 1989, and submitted to EPA by Kentucky on August 2, 1989. The regulation being approved by this notice is 2.05 Prevention of Significant Deterioration of Air Quality. On September 1, 1989, at 54 FR 36307, EPA approved Kentucky's regulation 51:017 Prevention of Significant Deterioration of Air Quality. In the August 2, 1989, submittal letter, the secretary of the Kentucky Natural Resources and Environmental Protection Cabinet stated that "Regulation 2.05 has been reviewed by the Cabinet and has been found to be not less stringent than the corresponding state regulation" (that has recently been federally approved).

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective January 12, 1990 unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted.

If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective January 12, 1990.

Final Action: EPA is today finalizing approval of the addition of Regulation 2.05 contained in Appendix N of the Kentucky State Implementation Plan.

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225). On January 6, 1989, the Office of Management and Budget waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years.

Under Section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 12, 1990. This action may not be challenged later in proceedings to enforce its requirements (see 307(b)(2)).