

$n$  = Number of theoretical plates; and  
 $d_p$  = Average diameter of the particles in the analytical column packing in micrometers.

The absolute efficiency ( $h_p$ ) is satisfactory if it is not more than 15.

(C) *Resolution factor*. The resolution factor ( $R$ ) between the peak for clindamycin phosphate and the peak for clindamycin (hydrochloride) in the chromatogram of the resolution test solution is satisfactory if it is not less than 6.0.

(D) *Coefficient of variation (relative standard deviation)*. The coefficient of variation ( $S_R$  in percent) of 5 replicate injections of the working standard solution is satisfactory if it is not more than 2.5 percent. If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(iv) *Calculation*. Calculate the clindamycin content as follows:

$$\frac{\text{Milligrams of clindamycin per gram}}{\text{gram}} = \frac{A_u \times P_s \times d}{A_s \times 1,000}$$

where:

$A_u$  = Area of the clindamycin phosphate peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

$A_s$  = Area of the clindamycin phosphate peak in the chromatogram of the clindamycin phosphate working standard;

$P_s$  = Clindamycin activity in the clindamycin phosphate working standard solution in micrograms per milliliter; and

$d$  = Dilution factor of the sample.

(2) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted cream.

(3) *Identity*. The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the clindamycin phosphate working standard.

Dated: September 5, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95-23737 Filed 9-25-95; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Parts 126 and 127

[CGD 88-049]

RIN 2115-AD06

#### Waterfront Facilities Handling Liquefied Hazardous Gas

AGENCY: Coast Guard, DOT.

ACTION: Correcting Amendments.

**SUMMARY:** This document contains correcting amendments to the final rule in CGD 88-049, published on Thursday, August 3, 1995, at 60 FR 39788.

**EFFECTIVE DATE:** These amendments are effective on September 26, 1995.

**FOR FURTHER INFORMATION CONTACT:** CDR Dennis J. Haise, Operating and Environmental Standards Division (G-MOS-2), by telephone (202) 267-6451 or fax (202) 267-4570.

**SUPPLEMENTARY INFORMATION:** The final rule that is the subject of these amendments regulates transfers of liquefied hazardous gas, in bulk, to and from vessels and waterfront facilities.

#### Need for Correction

As published, the final rule contains errors that may prove to be misleading and that therefore need correction.

#### Substance of Correction

Accordingly, the final rule published on August 3, 1995 [CGD 88-049], is corrected as follows:

Discussion of the Comments on and Changes to the NPRM [Corrected]

1. Page 39789, in the second column, paragraph 9, in the last sentence the phrase "Section 127.110(c)" is corrected to read "Section 127.1101(c)".

2. Page 39790, in the first column, paragraph 18, in the last sentence the word "possible" is corrected to read "possibly".

3. Page 39790, in the third column, paragraph 22, in the first sentence the phrase "when a facility has fire or medical department of the facility" is corrected to read "when a facility has a fire or medical department on the facility".

4. Page 39791, in the first column, in the third full sentence from the top of the page the letters "LHG" are corrected to read "LNG".

Collection of Information [Corrected]

5. Page 39793, at the bottom of the second column, in the table noting "Section" and "Topic" the words "Decelaration of Inspection" are

corrected to read "Declaration of Inspection".

6. Page 39793, in the third column, under the heading DOT No: 2115, OMB Control No. "0052" is corrected to read "0552" and OMB Control No. "0013" is corrected to read "0054".

#### PART 127—WATERFRONT FACILITIES HANDLING LIQUEFIED NATURAL GAS AND LIQUEFIED HAZARDOUS GAS

§ 127.003 Incorporation by reference [Corrected]

7. Page 39794, in the second item under the title The American National Standards Institute (ANSI) the words "ANSI S12.13, Part 1" are corrected to read "ANSI S12.13, Part I".

§ 127.1203 Gas detection [Corrected]

8. Page 39797, in the third column, in paragraph (a) in the last sentence the words "ANSI S12.13, Part 1" are corrected to read "ANSI S12.13, Part I".

§ 127.1205 Emergency shutdown [Corrected]

9. Page 39798, in the first column, in paragraph (b)(4) the words "105°C (221°F)" are corrected to read "105°C (221°F)".

§ 127.1207 Warning alarms [Corrected]

10. Page 39798, also in the first column, in paragraph (b), in the first line the word "are" is corrected to read "area".

§ 127.1301 Persons in charge of transfers for the facility; Qualifications and Certification [Corrected]

11. Page 39798, in the second column, paragraph (a)(2) the word "Knowing" is corrected to read "Knows".

§ 127.1307 Emergency Manual [Corrected]

12. Page 39799, in the first column, in paragraph (b) the words "fire-prevention required" are corrected to read "fire-prevention plan required".

Dated: September 15, 1995.

G.N. Naccara,

Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 95-23799 Filed 9-25-95; 8:45 am]

BILLING CODE 4910-14-M

#### 33 CFR Part 165

[CGD01-95-147]

RIN 2115-AA97

#### Safety Zone: Deepavali Fireworks Festival, East River, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the Deepavali Fireworks Festival Program located in the East River, New York. The safety zone is in effect from 6:45 p.m. until 8:15 p.m. on Sunday, October 15, 1995, unless extended or terminated sooner by the Captain of the Port New York. The safety zone temporarily closes all waters of the East River, shore to shore, south of the Brooklyn Bridge and north of a line drawn from Pier 9, Manhattan to Pier 3, Brooklyn.

**EFFECTIVE DATE:** This rule is in effect from 6:45 p.m. until 8:15 p.m. on October 15, 1995, unless extended or terminated sooner by the Captain of the Port New York.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant (Junior Grade) K. Messenger, Maritime Planning Staff Chief, Coast Guard Group New York (212) 668-7934.

**SUPPLEMENTARY INFORMATION:**

**Drafting Information**

The drafters of this notice are LTJG K. Messenger, Project Manager, Coast Guard Group New York and CDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

**Regulatory History**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing an NPRM, and for making this regulation effective less than 30 days after Federal Register publication. Due to the date this application was received, there was insufficient time to draft and publish a notice of proposed rulemaking that allows for a reasonable comment period prior to the event. The delay encountered if normal rulemaking procedures were followed would effectively cancel this event. Cancellation of this event is contrary to the public interest.

Adequate measures are being taken to ensure mariners are aware of this regulation. Notification of this rule will be published locally in the First Coast Guard District's Local Notice to Mariners, and announced via Safety Marine Information Broadcasts.

**Background and Purpose**

On September 5, 1995, the Coast Guard received an Application for Approval of Marine Event from Garden State Fireworks to hold a fireworks program in the waters of the East River. The fireworks program is being sponsored by the Association of Indians in America Inc. This regulation establishes a temporary safety zone in

all waters of the East River, shore to shore, south of the Brooklyn Bridge and north of a line drawn from Pier 9, Manhattan to Pier 3, Brooklyn. The safety zone is in effect from 6:45 p.m. until 8:15 p.m. on October 15, 1995, unless extended or terminated sooner by the Captain of the Port New York. The safety zone prevents vessels from transiting this area of the East River, and is needed to protect mariners from the hazards associated with fireworks exploding in the area.

**Regulatory Evaluation**

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. This regulation closes a portion of the East River, to vessel traffic from 6:45 p.m. until 8:15 p.m. on October 15, 1995, unless extended or terminated sooner by the Captain of the Port New York. The East River is subjected to moderate commercial vessel traffic. Although this regulation prevents traffic from transiting the safety zone area, the effect of this regulation will not be significant for several reasons: the duration of the event is limited; the event is at a late hour; recreational traffic and some commercial traffic can take an alternate route via the Hudson and Harlem Rivers; the event has been held annually for the past several years without incident or complaint; and the extensive, advance advisories which will be made. Accordingly, the Coast Guard expects the economic impact of this regulation to be so minimal that a Regulatory Evaluation is unnecessary.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this regulation will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under Section 3 of the Small Business Act (15 U.S.C. 632).

For the reasons set forth in the Regulatory Evaluation, the Coast Guard expects the impact of this regulation to be minimal. The Coast Guard certifies under 5 U.S.C. 605(b) that this regulation will not have a significant economic impact on a substantial number of small entities.

**Collection of Information**

This regulation contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501).

**Federalism**

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this regulation does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**Environment**

The Coast Guard has considered the environmental impact of this regulation and concluded that under section 2.B.2.e. of Commandant Instruction M16475.1B, revised 59 FR 38654, July 29, 1994, the promulgation of this regulation is categorically excluded from further environmental documentation. A Categorical Exclusion Determination and Environmental Analysis Checklist are included in the docket. Under the National Environmental Policy Act, the approval of the permit for marine event for this event is a federal action which is categorically excluded in accordance with section 2.B.2.e(35)(h) of Commandant Instruction M16475.1B. This fireworks display lasts 30 minutes and is expected to involve less than 200 spectator craft.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

**Temporary Regulation**

For reasons set out in the preamble, the Coast Guard amends 33 CFR part 165 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, and 160.5; 49 CFR 1.46.

2. A temporary § 165.T01-147 is added to read as follows:

**§ 165.T01-147 Safety Zone; Deepavali Fireworks Festival, East River, New York.**

(a) *Location.* The safety zone includes all waters of the East River, shore to shore, south of the Brooklyn Bridge and north of a line drawn from Pier 9, Manhattan to Pier 3, Brooklyn.

(b) *Effective period.* This section is in effect from 6:45 p.m. until 8:15 p.m. on October 15, 1995, unless extended or terminated sooner by the Captain of the Port New York.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on scene patrol personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel via siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: September 15, 1995.

T.H. Gilmour,

*Captain, U.S. Coast Guard, Captain of the Port New York.*

[FR Doc. 95-23801 Filed 9-25-95; 8:45 am]

BILLING CODE 4910-14-M

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 52**

[CA 33-2-7095; FRL-5297-4]

**Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is finalizing the approval of a revision to the California State Implementation Plan (SIP) proposed in the Federal Register on June 9, 1992. The revision concerns a rule from the San Diego County Air Pollution Control District (SDCAPCD). This approval action will incorporate this rule into the federally approved SIP. The intended effect of approving this rule is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The revised rule controls VOC emissions from solvents used in the manufacturing of pharmaceuticals and cosmetics. Thus, EPA is finalizing the

approval of this revision into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

**EFFECTIVE DATE:** This action is effective on October 26, 1995.

**ADDRESSES:** Copies of the rule and EPA's evaluation report for the rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are available for inspection at the following locations:

Rulemaking Section (A-5-3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1219 "K" Street, Sacramento, CA 95814

San Diego County Air Pollution Control District, 9150 Chesapeake Drive, San Diego, CA 92123-1095

**FOR FURTHER INFORMATION CONTACT:**

Patricia A. Bowlin, Rulemaking Section, Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1188.

**SUPPLEMENTARY INFORMATION:****Background**

On June 9, 1992 in 57 FR 24447, EPA proposed to approve the following SDCAPCD rule into the California SIP: Rule 67.15, Pharmaceutical and Cosmetic Manufacturing. Rule 67.15 was adopted by SDCAPCD on December 18, 1990. The rule was submitted by the California Air Resources Board (CARB) to EPA on April 5, 1991 in response to EPA's 1988 SIP-Call and the CAA section 182(a)(2)(A) requirement that nonattainment areas fix their reasonably available control technology (RACT) rules for ozone in accordance with EPA guidance that interpreted the requirements of the pre-amendment Act. A detailed discussion of the background for the above rule and nonattainment area is provided in the NPRM cited above.

EPA has evaluated the above rule for consistency with the requirements of the CAA, EPA regulations, and EPA interpretation of these requirements as expressed in the various EPA policy guidance documents referenced in the NPRM cited above. EPA has found that

the rule meets the applicable EPA requirements. A detailed discussion of the rule provisions and evaluations has been provided in 57 FR 24447 and in technical support documents (TSDs) available at EPA's Region IX office.

**Response to Public Comments**

A 30-day public comment period was provided in 57 FR 24447. EPA received no comments regarding the NPRM.

**EPA Action**

EPA is finalizing action to approve the above rule for inclusion into the California SIP. EPA is approving the submittal under section 110(k)(3) as meeting the requirements of section 110(a) and Part D of the CAA. This approval action will incorporate this rule into the federally approved SIP. The intended effect of approving this rule is to regulate emissions of VOCs in accordance with the requirements of the CAA.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

**Unfunded Mandates**

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of \$100 million or more to the private sector or to State, local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under Part D of the Clean Air Act. These rules may bind State, local, and tribal governments to perform certain actions and also require the private sector to perform certain duties. The rules being approved by this action will impose no new requirements because affected sources are already subject to these regulations under State law. Therefore, no additional costs to State, local, or tribal governments or to the private sector result from this action. EPA has also determined that this final action does not include a mandate that may result in estimated costs of \$100 million or more to State, local, or tribal