

and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.

* * * * *

(4) * * * A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.

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6. Section 806.20 is amended by revising paragraphs (a) and (c) to read as follows:

§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.10 shall keep a record of such correction or removal.

* * * * *

(c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

7. Section 806.30 is revised to read as follows:

§ 806.30 FDA access to records.

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

Dated: July 9, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-21091 Filed 8-6-98; 8:45 am]

BILLING CODE 4160-01-F

ACTION: Statement of Policy.

SUMMARY: The Agency hereby announces its policy regarding requests for waiver of the two-year home country physical presence requirement set forth in Section 1182(e) of the Immigration and Nationality Act based upon the applicant's assertion that fulfillment of such requirement is not possible due to the loss of home country citizenship.

EFFECTIVE DATE: This policy statement is effective August 7, 1998.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Assistant General Counsel, United States Information Agency, 301 4th Street, SW, Washington, DC 20547; telephone, (202) 619-6531.

SUPPLEMENTARY INFORMATION: The Director of the United States Information Agency is required by Section 1182(e) of the Immigration and Nationality Act to make recommendations to the Attorney General regarding the grant or denial of the two-year home country physical presence requirement imposed upon certain aliens who have entered the United States on a J visa or subsequently acquired such nonimmigrant status. Aliens who have received government funds, pursued graduate medical education or training, or who have participated in an activity involving skills identified of interest to the government of his or her home country are subject to the two-year home country physical presence requirement, viz., "until it is established that such person has resided and been physically present in the country of his nationality or his last residence for an aggregate of at least two years following departure from the United States." If subject, an alien must fulfill this requirement or have it waived before he or she is eligible to adjust to H, L, or legal permanent resident status.

Recommendations regarding the grant or denial of a waiver request are based upon a review of the unique program, policy, and foreign relations aspects presented by each individual request. Recently, the Agency has been approached and requested to recognize a theory that certain aliens subject to the return home requirement should be granted a waiver because their home country has revoked, by operation of law, their citizenship due to the acquisition of citizenship or legal permanent residence in another country. This theory suggests that the section 1182(e) requirement should be waived because the loss of citizenship has made it impossible for the alien to fulfill this requirement. Having

reviewed this matter at length, the Agency cannot adopt this theory as a matter of policy and will not recommend the grant of a waiver based solely upon the loss of home country citizenship. In many cases, other means of fulfillment, such as the utilization of a nonimmigrant visa for entry into the home country are available.

The Agency will review, on a case by case basis, those extraordinarily few instances where fulfillment of the Section 1182(e) requirement is impossible due to facts totally beyond the control of the waiver applicant and which were not the predictable consequences of action on the part of the applicant. Compelling and probative evidence of such impossibility of performance, furnished by the alien, is necessarily a prerequisite to Agency review. Such evidence may be, for example, proof of denial of a request for a nonimmigrant visa from the home country or denial of a request to restore home country citizenship.

List of Subjects in 22 CFR Part 514

Cultural exchange programs.

Dated: July 30, 1998.

Les Jin,

General Counsel.

[FR Doc. 98-21137 Filed 8-6-98; 8:45 am]

BILLING CODE 8230-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-98-102]

RIN 2115-AA97

Safety Zone: Staten Island Fireworks, New York Harbor, Lower Bay

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Staten Island fireworks programs located in New York Harbor, Lower Bay. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of Lower Bay, New York Harbor.

DATES: This rule is effective July 21, 1998 through September 13, 1998. Compliance is required from 8:45 p.m. until 10:15 p.m. on the following dates: July 21, 1998; August 4, 1998; August 11, 1998; August 25, 1998; and September 12, 1998. If inclement weather causes cancellation of the fireworks display on September 12,

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program

AGENCY: United States Information Agency.

1998, then compliance is also required from 8:45 p.m. until 10:15 p.m. on September 13, 1998.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at Coast Guard Activities New York, 212 Coast Guard Drive, room 205, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (718) 354-4195.

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) A. Kenneally, Waterways Oversight Branch, Coast Guard Activities New York, at (718) 354-4195.

SUPPLEMENTARY INFORMATION:

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 an NPRM. Any delay encountered in this regulation's effective date would be contrary to public interest since immediate action is needed to close a portion of the waterway and protect the maritime public from the hazards associated with these fireworks displays.

Background and Purpose

The Borough of Staten Island has submitted an Application for Approval of Marine Event to hold five fireworks programs on the waters of New York Harbor, Lower Bay. This regulation establishes five safety zones in all waters of New York Harbor, Lower Bay within a 275 yards radius of a fireworks barge located in approximate position 40°35'11"N 074°03'42"W (NAD 1983), approximately 350 yards east of South Beach, Staten Island, New York. The safety zones will be enforced from 8:45 p.m. until 10:15 p.m. for the following five fireworks displays: Tuesday, July 21, 1998; Tuesday, August 4, 1998; Tuesday, August 11, 1998; Tuesday, August 25, 1998; and Saturday, September 12, 1998, with a rain date of Sunday, September 13, 1998, at the same time and place. The safety zones prevent vessels from transiting a portion of New York Harbor, Lower Bay and are needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Marine traffic will still be able to transit through New York Harbor, Lower Bay during the events. Public notifications

will be made prior to the events via the Local Notice to Mariners and marine information broadcasts.

Regulatory Evaluation

This final rule 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 not been reviewed 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 final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This finding is based on the limited marine traffic in the area, the zones will not interfere with any shipping channels in the Port of New York/New Jersey, recreational traffic will still be able to transit the area in the vicinity of the display, the minimal time that vessels will be restricted from the zones, and advance notifications which will be made.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For reasons discussed in the Regulatory Evaluation above, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This final rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612 and has determined that this final rule does not have sufficient implications for federalism to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impact of this final rule and concluded that under Figure 2-1, paragraph 34(g), of Commandant Instruction M16475.1C, this final rule is categorically excluded from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

Regulation

For the reasons discussed 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. Add temporary 165.T01-102 to read as follows:

Section 165.T01-102 Safety Zone: Staten Island Fireworks, New York Harbor, Lower Bay.

(a) *Location.* The following area is a safety zone: all waters of New York Harbor, Lower Bay within a 275 yard radius of the fireworks barge in approximate position 40°35'11"N 074°03'42"W (NAD 1983), approximately 350 yards east of South Beach, Staten Island, New York.

(b) *Effective period.* This safety zone is effective from July 21, 1998 through September 13, 1998. Compliance is required from 8:45 p.m. until 10:15 p.m. on the following dates: July 21, 1998; August 4, 1998; August 11, 1998; August 25, 1998; and September 12, 1998. If inclement weather causes cancellation of the fireworks display on September 12, 1998, then compliance is also required from 8:45 p.m. until 10:15 p.m. on September 13, 1998.

(c) *Regulations.*

(1) The general regulations contained in 33 C.F.R. 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: July 17, 1998.

R.E. Bennis,

Captain, U.S. Coast Guard,

Captain of the Port, New York.

[FR Doc. 98-21187 Filed 8-6-98; 8:45 am]

BILLING CODE 4910-15-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[OH116-1a; FRL-6134-5]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Ohio; Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (USEPA).

ACTION: Direct final rule.

SUMMARY: The USEPA is approving the Ohio State Plan submittal for implementing the Municipal Solid Waste (MSW) Landfill Emission Guidelines. The State's plan submittal was made pursuant to requirements found in the Clean Air Act (CAA). The State's plan was submitted to USEPA on March 30, 1998, in accordance with the requirements for adoption and submittal of State plans for designated facilities in 40 CFR part 60, subpart B. It establishes performance standards for existing MSW landfills and provides for the implementation and enforcement of those standards. The USEPA finds that Ohio's Plan for existing MSW landfills adequately addresses all of the Federal requirements applicable to such plans. In the proposed rules section of this **Federal Register**, the USEPA is proposing approval of, and soliciting comments on, this approval. If adverse comments are received on this action, the USEPA will withdraw this final rule and address the comments received in response to this action in a final rule on the related proposed rule, which is being published in the proposed rules section of this **Federal Register**. A second public comment period will not be held. Parties interested in commenting on this action should do so at this time. This approval makes the State's rule federally enforceable.

DATES: The "direct final" is effective on October 6, 1998, unless USEPA receives adverse or critical written comments by September 8, 1998. If adverse comment is received, USEPA will publish a timely withdrawal of the rule in the

Federal Register informing the public that the rule will not take effect.

ADDRESSES: Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the requested SIP revision and USEPA's analysis are available for inspection at the U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Randolph O. Cano at (312) 886-6036 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Randolph O. Cano, Environmental Protection Specialist, Regulation Development Section, Air Programs Branch (AR-18J), USEPA, Region 5, Chicago, Illinois 60604, (312) 886-6036.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 111(d) of the CAA, USEPA established procedures whereby States submit plans to control certain existing sources of "designated pollutants." Designated pollutants are defined as pollutants for which a standard of performance for new sources applies under section 111, but which are not "criteria pollutants" (i.e., pollutants for which National Ambient Air Quality Standards (NAAQS) are set pursuant to sections 108 and 109 of the CAA) or hazardous air pollutants (HAPs) regulated under section 112 of the CAA. As required by section 111(d) of the CAA, USEPA established a process, at 40 CFR part 60, subpart B, similar to the process required by section 110 of the CAA (regarding State Implementation Plan (SIP) approval) which States must follow in adopting and submitting a section 111(d) plan. Whenever USEPA promulgates a new source performance standard (NSPS) that controls a designated pollutant, USEPA establishes emissions guidelines in accordance with title 40 of the Code of Federal Regulations, § 60.22 (40 CFR 60.22) which contain information pertinent to the control of the designated pollutant from that NSPS source category (i.e., the "designated facility" as defined at 40 CFR 60.21(b)). Thus, a State's section 111(d) plan for a designated facility must comply with the emission guideline for that source category as well as 40 CFR part 60, subpart B.

On March 12, 1996, USEPA published emissions guidelines for existing MSW landfills (EG) at 40 CFR part 60, subpart

Cc (40 CFR 60.30c through 60.36c) and NSPS for new MSW Landfills at 40 CFR part 60, subpart WWW (40 CFR 60.750 through 60.759) (See 61 FR 9905-9929.). The NSPS and EG regulate MSW landfill emissions, which contain a mixture of volatile organic compounds (VOCs), other organic compounds, methane, and HAPs. VOC emissions can contribute to ozone formation which can result in adverse effects to human health and vegetation. The health effects of HAPs include cancer, respiratory irritation, and damage to the nervous system. Methane emissions contribute to global climate change and can result in fires or explosions when they accumulate in structures on or off the landfill site. To determine if control is required, nonmethane organic compounds (NMOCs) are measured as a surrogate for MSW landfill emissions. Thus, NMOC is considered the designated pollutant. The designated facility which is subject to the EG is each existing MSW landfill (as defined in 40 CFR 60.31c) for which construction, reconstruction or modification was commenced before May 30, 1991.

Pursuant to 40 CFR 60.23(a), States were required to submit a plan for the control of the designated pollutant to which the EG applies within nine months after publication of the EG (i.e. by December 12, 1996). If there were no designated facilities in the State, then the State was required to submit a negative declaration by December 12, 1996.

On March 30, 1998, the State of Ohio submitted its "Section 111(d) Plan for MSW Landfills" for implementing USEPA's MSW Landfill EG. The following provides a brief discussion of the requirements for an approvable State plan for existing MSW landfills and USEPA's review of Ohio's submittal with respect to those requirements. More detailed information on the requirements for an approvable plan and Ohio's submittal can be found in the Technical Support Document (TSD) accompanying this notice, which is available upon request.

II. Review of Ohio's MSW Landfill Plan

USEPA has reviewed Ohio's section 111(d) plan for existing MSW landfills against the requirements of 40 CFR part 60, subpart B and subpart Cc, as follows:

A. Identification of Enforceable State Mechanism for Implementing the EG

The regulation at 40 CFR 60.24(a) requires that the section 111(d) plan include emissions standards, defined in 40 CFR 60.21(f) as "a legally enforceable regulation setting forth an allowable rate